MINUTES OF 292ND MEETING OF REGISTRATION BOARD HELD ON 1ST – 2ND OCTOBER, 2019

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

292nd meeting of Registration Board was held on 1st & 2nd October, 2019 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was chaired by Dr. Obaidullah, Director, Pharmaceutical Evaluation & Registration Division, DRAP. The meeting started with recitation of the Holy Verses. The meeting was attended by following:-

1.	Dr. Rafeeq Alam Khan, Meritorious Professor & Dean Faculty of Pharmacy, Ziauddin University, Karachi.	Member
2.	Maj.Gen. Dr.Tahir Mukhtar Sayed, Director General Medicine, Pak Army, Rawalpindi	Member
3.	Prof.Dr.Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Women, Karachi	Member
4.	Mr.Aslam Shah, Senior Manager, Indus Hospital, Karachi	Member
5.	Dr. Amanullah Khan, Director, Drugs Testing Laboratory, Quetta. Government of Balochistan	Member
6.	Dr. Qurban Ali Ex-Director General, National Veterinary Laboratory, Islamabad	Member
7.	Mr. Muhammad Aslam, Deputy Draftsman, Representative of Ministry of Law & Justice, Islamabad	Member
8.	Mr. Ghulam Mujtaba, Deputy Director (Patent), Representative of Ministry of Law & Justice, Islamabad	Member
9.	Dr. Noor-us-Saba, Director, Biological Evaluation & Research Division, DRAP	Member
10.	Dr. Hafsa Karam Ellahi, Additional Director, Representative of QA&LT Division, DRAP	Member
11.	Mr. Abdullah, Additional Director (PE&R), DRAP.	Member
12.	Dr.Muhammad Akram, Represntative of Animal Husbandry Commissioner, M/o National Food Security & Research, Islamabad.	Co-opted Member

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

Mr. Tauqeer-ul-Haq, Mr. Hamid Raza, & Mr. Iftikhar Hussain (PPMA), Ms. Anila Sikandar and Mr. Nadeem Alamgir (Pharma Bureau) and Mr. Kamran Anwar (PCDA) attended the meeting as observers.

Item No. I: Confirmation of Minutes of 291st Meeting of Registration Board.

291st meeting of Registration Board was held on 2nd – 4th September 2019. The draft minutes of 291st meeting of Registration Board were circulated among the members of the meeting on 19th September 2019 for perusal/approval and comments (if any) within five days.

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

Decision: Registration Board confirmed the minutes of 291st meeting.

Item No. II Division of Pharmaceutical Evaluation & Registration

Pharmaceutical Evaluation Cell (PEC)

Case no. 01 Registration Applications for Local Manufacturing of (Human) Drugs.
a. New cases
b. Deferred cases

Case no. 02 Registration Applications of Newly Granted DML or New Section (Human)
a. New DML
b. New/Additional section(s)

Case no. 03 Registration Applications for Local Manufacturing of (Veterinary) Drugs.
a. New Cases
b. Deferred Cases

Case no. 04 Registration Applications of Newly Granted DML or New Section (Veterinary)
a. New DML /section
b. Deferred Cases

Case no. 05 Registration Applications of Categories to be Considered on Priority.
a. Local manufacturing applications of priority categories defined by Registration
Board in its 257th meeting
b. Export facilitation
c. Import applications of priority categories defined by Registration Board in its
257th meeting
i. Human
ii. Veterinary

Case no. 06 Registration Applications of Import Cases.
a. New Cases (Human)
b. New Cases (Veterinary)
c. Deferred Cases
i. Human
ii. Veterinary

Case no. 07 Registration Applications of Drugs for which Stability Study Data is Submitted.
a. New cases
b. Deferred cases
c. Verification of stability study data
d. Exemption from onsite verification of stability data

Case no. 08 Miscellaneous Cases.

Sr. No.	Name of Evaluator	Title
1	Mr. Ammar Ashraf Awan	**Evaluator PEC-II**
2	Mr. Muhammad Haseeb Tariq	**Evaluator PEC-III**
3	Mst. Farzana Raja	**Evaluator PEC-IV**
4	Mst. Iqra Aftab	**Evaluator PEC-V**
5	Mr. Muhammad Umar Latif	**Evaluator PEC-VI**
6	Mst. Haleema Sharif	**Evaluator PEC-VIII**
7	Mr. Haneef ullah	**Evaluator PEC-IX**
8	Mr. Muhammad Sarfaraz Nawaz	**Evaluator PEC-X**
9	Mst. Mehwish Javed Khan	**Evaluator PEC-XIII**
10	Mr. Muhammad Ahsan Hafiz	**Evaluator PEC-XIV**

Item No. I: Agenda of Evaluator PEC-II

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

a. New Cases.

1.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Linolid 600mg/300ml Infusion
	Composition	"Each 300ml Contains: Linezolid…..600mg"
	Diary No. Date of R& I & fee	Dy. No 28524 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Barizold infusion 600mg/300ml by M/s Getz Pharma (Reg#080288)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 17-01-2019 concluded as under: "Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division DRAP, Islamabad upon completion of the proposed changes for further processing."
	Remarks of the Evaluator[II]	• Finished product specification and testing method has not been submitted. • Manufacturing process outline has not been submitted.
	Decision: Deferred for following: • **Finished product specification and testing method has not been submitted.** • **Manufacturing process outline has not been submitted.**	
2.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Linolid 600mg Tablet
	Composition	"Each film coated tablet Contains: Linezolid……600mg"
	Diary No. Date of R& I & fee	Dy. No 28523 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Linexa Tablet 600mg by M/s. Cirin Pharma (Reg.# 073213)
	GMP status	As cited in above application.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
3.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Delves 50mg Tablet

	Composition	"Each Film Coated Tablet Contains: Diclofenac Potassium…..50mg"
	Diary No. Date of R& I & fee	Dy. No 28522 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Diclotim 50mg Tablet by M/s MBL Karachi (R.No.081019)
	GMP status	As cited in above application.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
4.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Alfazon 0.5mcg Tablet
	Composition	"Each Tablet Contains: Alfacalcidol…0.5mcg"
	Diary No. Date of R& I & fee	Dy. No 28518 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Vitamin D and analogues
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	One alpha tablet 0.5 µg by Teijin Pharma Corporation PMDA approved
	Me-too status (strength & dosage form)	Itoride Tablet by Lexicon Pharmaceutical. Reg No. 42040
	GMP status	As cited in above application.
	Remarks of the Evaluator[II]	• In contrary to reference product which is available as uncoated tablet firm has applied for film coated tablet. • Upon communication of above observations firm has submitted revised form 5 for uncoated tablets along with submission of fee of Rs.5,000/- vide deposit slip# 1924188 dated 26-09-2019.
	Decision: Approved.	
5.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Fexofin-D 60/120 mg Tablet
	Composition	"Each Tablet Contains: Fexofenadine HCl …….60mg Pseudoephedrine HCl …….120mg"
	Diary No. Date of R& I & fee	Dy. No 28519 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Uni-fexoderine Tablet by M/s Uni-Tiech Pharmaceuticals, Karachi. (Reg No. 061035)
	GMP status	As cited in above application.
	Remarks of the Evaluator[II]	• In contrary to reference product submitted by firm which is available as extended release tablet, no such details are mentioned in the submitted composition and master formulation. • Firm has submitted revised formulation for bilayer tablet with following composition:

		"Each bilayer Tablet Contains: Fexofenadine HCl……60mg Pseudoephedrine HCl…….120mg (as extended release layer)" • Firm has also submitted fee of Rs. 5,000- for revision of formulation.
	Decision: Deferred for evidence of availability of bilayer tablet compression machine.	
6.	Name and address of manufacturer / Applicant	"M/s Horizon Healthcare (Pvt) Ltd. Plot No. 33, Sundar Industrial Estate, Lahore"
	Brand Name +Dosage Form + Strength	Lancerid 30mg Capsule
	Composition	"Each Capsule Contains: Lansoprazole as Enteric Coated Pellets……30mg"
	Diary No. Date of R& I & fee	Dy. No 28520 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Proton pump inhibitor.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Leazole 30mg Capsules of M/s Leads Pharma (Pvt.) Ltd. (Reg.#035891)
	GMP status	As cited in above application.
	Remarks of the Evaluator[II]	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted. • Finished product specification has not been submitted.
	Decision: Deferred for following: • **Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.** • **Finished product specification has not been submitted.**	
7.	Name and address of manufacturer / Applicant	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Sartel 40mg Tablet
	Composition	"Each Tablet Contains: Telmisartan……40mg"
	Diary No. Date of R& I & fee	Dy. No 28545 dated 24-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Angiotensin II receptor antagonist
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Telday 40 Tablets of M/s. Novamed Pharmaceuticals, 28-Km, Ferozepur Road, Lahore (Reg.#077141)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 27-08-2018, 05-10-2018, 06-11-2018 concluding satisfactory level of GMP compliance
	Remarks of the Evaluator[II]	
	Decision: Approved.	
8.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Furiben 100mg Tablet
	Composition	"Each Tablet Contains: Flurbiprofen……100mg"
	Diary No. Date of R& I & fee	Dy. No 28460 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Strefen Tablets of Healers Pharmaceuticals (Reg.# 069733)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Remarks of the Evaluator[II]	• In contrary to reference product which is available as film coated tablet, you have applied for uncoated tablet.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for revision of formulation.	
9.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Cloxol 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Zuclopenthixol (as dihydrochloride)…25mg"
	Diary No. Date of R& I & fee	Dy. No 28466 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Neuroleptic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Lopix Tablet 25 mg of M/s Saydon Pharmaceuticals (Reg.#079400)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
10.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Valdox 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Agomelatine…….25mg
	Diary No. Date of R& I & fee	Dy. No 28471 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	VALDOXAN 25MG TABLET of M/S. SERVIER RESEARCH AND PHARMACEUTICALS (Reg.#079400)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
11.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Diacer 50mg Capsule
	Composition	"Each Capsule Contains: Diacerein……50mg"
	Diary No. Date of R& I & fee	Dy. No 28472 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, nonsteroids
	Type of Form	Form-5

	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diacerein 50 mg hard capsule by M/s BIOGARAN (ANSM France Approved)
	Me-too status (with strength and dosage form)	Dibro 50mg Capsules by M/s Winbrain Research Laboratories (Reg#071639)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
12.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Detrudine 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tolterodine Tartrate 1mg corresponding to Tolterodine …… 0.68mg"
	Diary No. Date of R& I & fee	Dy. No 28463 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Tolura Tablets 1mg of M/s Hilton Pharma (Reg.# 039220)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
13.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Detrudine 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tolterodine Tartrate 2mg corresponding to Tolterodine …… 1.37mg"
	Diary No. Date of R& I & fee	Dy. No 28464 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Tolura Tablets 2mg of M/s Hilton Pharma (R# 039221)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
14.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Bonic 150mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ibandronate Sodium Monohydrate eq. to Ibandronic Acid…150mg"
	Diary No. Date of R& I & fee	Dy. No 28462 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Bisphosphonate
	Type of Form	Form-5

	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Franjic 150mg Tablet of M/s Martin Dow Ltd. Karachi. (Reg.# 081130)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
15.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Detrudine SR 4mg Capsule
	Composition	"Each Modified Release Capsule Contains: Tolterodine Tartrate 4mg corresponding to Tolterodine…2.74mg"
	Diary No. Date of R& I & fee	Dy. No 28465 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Detrusitol SR 4mg, Prolonged-Release Capsules of M/s Parke-Davis & Company Limited, Karachi (Reg.# 053805)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Remarks of the Evaluator[II]	• Clarification of the applied formulation shall be submitted with reference to Innovator's product, regarding how formulation is made modified release.
	Decision: Deferred for clarification of the applied formulation with reference to Innovator's product, regarding how the formulation is made modified release.	
16.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals. Plot No.224, Sector 23, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Nimex 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nimesulide…100mg"
	Diary No. Date of R& I & fee	Dy. No 28459 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (strength & dosage form)	Nims tablet by M/s Sami
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Remarks of the Evaluator[II]	• In contrary to reference product which is available as uncoated tablet firm has applied for film coated tablet.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee for revision of formulation.	
17.	Name and address of manufacturer / Applicant	"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"
	Brand Name +Dosage Form + Strength	Levepsy 500mg Tablet

	Composition	"Each Film Coated Tablet Contains: Levetiracetam …… 500mg"
	Diary No. Date of R& I & fee	Dy. No 28447 dated 20-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status (strength & dosage form)	Elicia 500mg tablet of M/s Martin Dow Ltd.
	GMP status	Panel inspection conducted on 07-05-2019 concluded that the overall GMP compliance status of the firm is deemed satisfactory.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
18.	Name and address of manufacturer / Applicant	"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"
	Brand Name +Dosage Form + Strength	Levepsy 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levetiracetam…250mg"
	Diary No. Date of R& I & fee	Dy. No 28446 dated 20-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status (strength & dosage form)	Elicia 250mg tablet of M/s Martin Dow Ltd.
	GMP status	Panel inspection conducted on 07-05-2019 concluded that the overall GMP compliance status of the firm is deemed satisfactory.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
19.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Levetam 500mg Tablet
	Composition	"Each film CoatedTablet Contains: Levetiracetam…500mg"
	Diary No. Date of R& I & fee	Dy. No 30438 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status (with strength and dosage form)	Elicia 500mg tablet of M/s Martin Dow Ltd.
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
20.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Lamtro 2mg Tablet
	Composition	"Each dispersible Tablet Contains: Lamotrigine…2mg"

	Diary No. Date of R& I & fee	Dy.No 30450 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Health Canada
	Me-too status (strength & dosage form)	Lamictal Dispersible 2mg of M/s GSK (Reg.#039900)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
21.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Lamtro 5mg Tablet
	Composition	"Each dispersible Tablet Contains: Lamotrigine…5mg"
	Diary No. Date of R& I & fee	Dy. No 30451 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Health Canada
	Me-too status (with strength and dosage form)	LAMICTAL DISPERSIBLE 5MG of M/s Wellcome Foundation Ltd. UK. (Reg.#019532)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
22.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Tomate 25mg Tablet
	Composition	"Each film coated Tablet Contains: Topiramate……25mg"
	Diary No. Date of R& I & fee	Dy. No 30443 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Topamid 25mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 062310)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
23.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Tomate 50mg Tablet
	Composition	"Each film coated Tablet Contains: Topiramate……50mg"
	Diary No. Date of R& I & fee	Dy. No 30444 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Topamid 50mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 069778)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
24.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Venlaxin 50mg Tablet
	Composition	"Each Tablet Contains: Venlafaxine as HCl…50mg"
	Diary No. Date of R& I & fee	Dy. No 30446 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Faxon Tablets 50mg of M/s Himont Pharma (R# 049519)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
25.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Lamtro 50mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine…50mg"
	Diary No. Date of R& I & fee	Dy. No 30453 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sportin 50mg Tablets of M/s Fassgen Pharmaceuticals, (Reg.# 070345)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
26.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Serta 50mg Tablet
	Composition	"Each film coated Tablet Contains: Sertraline as HCl……50mg"
	Diary No. Date of R& I & fee	Dy. No 30426 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Yesme Tablet 50mg by M/s Metro Pharmaceuticals, Islamabad. (Reg.#081674)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
27.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Serta 100mg Tablet
	Composition	"Each film coated Tablet Contains: Sertraline as HCl…….100mg"
	Diary No. Date of R& I & fee	Dy. No 30427 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Ertalin 100 mg Tablets of M/s Genome Pharmaceuticals (Reg.# 076845)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
28.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Venlaxin 37.5mg Tablet
	Composition	"Each Tablet Contains: Venlafaxine as HCl……37.5mg"
	Diary No. Date of R& I & fee	Dy. No 30446 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-depressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nalfax Tablets 37.5mg.of M/s Dyson Research Laboratories (Reg.# 046945)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
29.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Levetam 250mg Tablet
	Composition	"Each film coated Tablet Contains: Levetiracetam……250mg"
	Diary No. Date of R& I & fee	Dy. No 30437 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (strength & dosage form)	Keppra Tablets 250mg by M/s AGP Ltd, (R# 045684)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
30.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Lamtro 25mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine…..25mg"
	Diary No. Date of R& I & fee	Dy. No 30452 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Lamogin Tablets 25mg of M/s Navegal Labs (Reg.# 043972)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
31.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Levetam 750mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levetiracetam……..750mg"
	Diary No. Date of R& I & fee	Dy. No 30439 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status (with strength and dosage form)	Elicia 750mg tablet of M/s Martin Dow Ltd.
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
32.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Venlaxin 75mg Tablet
	Composition	"Each Tablet Contains: Venlafaxine as HCl……75mg"
	Diary No. Date of R& I & fee	Dy. No 30448 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved
	Me-too status (with strength and dosage form)	Nodep 75mg tablet of M/s Shawan Pharmaceuticals, Islamabad (Reg.# 080388)

	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
33.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Lamtro 200mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine…….200mg"
	Diary No. Date of R& I & fee	Dy. No 30455 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Health Canada
	Me-too status (with strength and dosage form)	LAMICTAL 200mg of M/s Wellcome Karachi. (Reg.#014920)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
34.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Venlaxin 150mg Tablet
	Composition	"Each extended release tablet contains: Venlafaxine as HCl……150mg"
	Diary No. Date of R& I & fee	Dy. No 30449 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by Health Canada
	Me-too status (strength & dosage form)	Xaxine XR of M/s Airaaf Pharma. (Reg.#078872)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
35.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Lamtro 100mg Tablet
	Composition	"Each Tablet Contains: Lamotrigine…..100mg"
	Diary No. Date of R& I & fee	Dy. No 30454 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Epicta 100mg Tablets of M/s Alina Combine Pakistan, Karachi (Reg.# 039081)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.

	Remarks of the Evaluator[II]	
	Decision: Approved.	
36.	Name and address of manufacturer / Applicant	M/s Shaheen Pharmaceutical 3-Km Murghzar Road, Saidu Sharif, Swat.
	Brand Name +Dosage Form + Strength	Tomate 100mg Tablet
	Composition	"Each film coated Tablet Contains: Topiramate……100mg"
	Diary No. Date of R& I & fee	Dy. No 30445 dated 10-09-2018 Rs.20,000/- 10-09-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Engrax Tablets 100mg of M/s English Pharmaceuticals Industries. (Reg.# 040144)
	GMP status	Last inspection report dated 13-09-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
37.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arregesic 450/35 mg Tablets
	Composition	"Each Tablet Contains: Paracetamol……450mg Orphenadrine Citrate……35mg"
	Diary No. Date of R& I & fee	Dy. No 32438 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Norgesic of M/s iNova Pharmaceuticals Australia Pvt. Ltd. approved by TGA of Australia
	Me-too status (strength & dosage form)	Rid-All Forte by M/s Stanley Pharma (Reg.#069786)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
38.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrecam 15mg Tablet
	Composition	"Each Film Coated Tablet Contains: Meloxicam……15mg"
	Diary No. Date of R& I & fee	Dy. No 32446 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's & 20's; as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	MIWS Plus 15mg Tablets of M/s Weather folds (Reg.#078489)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	

39.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arecin 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin……500mg"
	Diary No. Date of R& I & fee	Dy. No 32434 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BIAXIN of M/s Abbvie approved by USFDA
	Me-too status (with strength and dosage form)	Klarinor 500 mg Tablets by M/s Nortech Pharmaceuticals (Pvt) Ltd (Reg#077970)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
40.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arretin 0.4mg Capsule
	Composition	"Each Capsule Contains: Tamsulosin HCl (as modified release pellets)…….0.4mg"
	Diary No. Date of R& I & fee	Dy. No 32452 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Alpha 1 adrenergic receptor blocker
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Uripro 0.4mg Capsule M/s Getz Pharma (Reg.#081040)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	Source of pellets: M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved.	
41.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arepride 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Itopride Hydrochloride……50mg"
	Diary No. Date of R& I & fee	Dy. No 32450 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Prokinetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved
	Me-too status (strength & dosage form)	ITP of M/s Sami Pharmaceuticals
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
42.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arestalo 10mg Tablet

	Composition	"Each Film Coated Tablet Contains: Escitalopram as Oxalate…10mg"
	Diary No. Date of R& I & fee	Dy. No 32444 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Zavesca tablet 10mg of Getz Pharma. (Reg.#045279)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
43.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrestat 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Febuxostat ……40mg"
	Diary No. Date of R& I & fee	Dy. No 32453 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Xanthine oxidase inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Febuxin by M/s AGP, Karachi (Reg. No. 081104)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
44.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrimax-Beta 20mg Tablet
	Composition	"Each Tablet Contains: Piroxicam as Beta Cyclodextrin…….20mg"
	Diary No. Date of R& I & fee	Dy. No 32432 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (strength & dosage form)	Achway Tablets of M/s Getz Pharma (Reg.#047355)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
45.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrser 50mg Tablet
	Composition	"Each Tablet Contains: Levosulpiride……50mg"
	Diary No. Date of R& I & fee	Dy. No 32428 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5

	Finished product Specifications	Manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Levidomed 50mg tablets of M/s Medochemie Ltd. approved by AIFA of Italy.
	Me-too status (strength & dosage form)	Sulvoric 50mg of M/s High-Q, Karachi (Reg.#070485)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
46.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrser 100mg Tablet
	Composition	"Each Tablet Contains: Levosulpiride……100mg"
	Diary No. Date of R& I & fee	Dy. No 32429 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AIFA of Italy
	Me-too status (strength & dosage form)	Scipride tablet 100mg M/s Getz Pharma
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
47.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrecam 7.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Meloxicam……7.5mg"
	Diary No. Date of R& I & fee	Dy. No 32430 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	MIWS 7.5 mg Tablets of M/s Weather folds (Reg.#078486)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
48.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Areco 500mcg Tablet
	Composition	"Each sugar Coated Tablet Contains: Mecobalamin…500mcg"
	Diary No. Date of R& I & fee	Dy. No 32436 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Coenzyme type/Vitamin B12
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA of Japan

	Me-too status (with strength and dosage form)	Mecovit 500mcg Tablet of M/s Zumars Pharma (Pvt) Ltd (Reg.# 057709)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	Firm had initially applied for film coated tablet, but upon communication of observations firm has submitted revised form 5 for sugar coated tablets along with submission of fee of Rs.5,000/- vide deposit slip# 1929604 dated 24-09-2019.
	Decision: Approved with JP specifications.	
49.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrenin 10mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains: Isotretinoin ……10mg"
	Diary No. Date of R& I & fee	Dy. No 32439 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Retinoids
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	• Stability data as per directions of 278th meeting of Registration Board shall be submitted.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board.	
50.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arecin 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Clarithromycin……250mg"
	Diary No. Date of R& I & fee	Dy. No 32443 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	BIAXIN of M/s Abbvie approved by USFDA
	Me-too status (with strength and dosage form)	Klarinor 250 mg Tablets by M/s Nortech Pharmaceuticals (Pvt) Ltd (Reg#077969)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
51.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arripcin 500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ciprofloxacin as Hydrochloride …… 500mg"
	Diary No. Date of R& I & fee	Dy. No 32445 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Ciprofloxacin tablets 500mg of M/s Special Concept Development (UK MHRA Approved)
	Me-too status (strength & dosage form)	Axcin Tablets 500mg of M/s Novartis Pharmaceuticals
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
52.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrenin 20mg Capsule
	Composition	Each Hard Gelatin Capsule Contains: Isotretinoin ……20mg"
	Diary No. Date of R& I & fee	Dy. No 32437 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Retinoids
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	• Stability data as per directions of 278th meeting of Registration Board shall be submitted.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board.	
53.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arripcin 250mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ciprofloxacin as Hydrochloride……250mg"
	Diary No. Date of R& I & fee	Dy. No 32433 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Fluoroquinolones, Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Axcin Tablets 250mg of M/s Novartis Pharmaceuticals
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
54.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arredol 500mg Tablets
	Composition	"Each Tablet Contains: Paracetamol……500mg"
	Diary No. Date of R& I & fee	Dy. No 32440 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Analgesic & Antipyretic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (strength & dosage form)	Paracetamol 500mg tablet of M/s Siza, (Reg# 008731)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
55.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrecox 60mg Tablets
	Composition	"Each Film Coated Tablet Contains: Etoricoxib……60mg"
	Diary No. Date of R& I & fee	Dy. No 32441 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Etoria 60mg Table of M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080818)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
56.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrenox 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lornoxicam……4mg"
	Diary No. Date of R& I & fee	Dy. No 32447 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg Filmtabletten by M/s Takeda Pharma AG, (Swiss Medic approved)
	Me-too status (with strength and dosage form)	Acabel 4mg Tablet by M/s Continental Pharma (Reg No:061603)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
57.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Aremeb MR Capsule
	Composition	"Each Modified Release Capsule Contains: Mebeverine HCl (as modified release pellets) eq. to Mebeverine …… 200mg"
	Diary No. Date of R& I & fee	Dy. No 32442 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Berrin 200 mg Capsules of M/s Focus &Rulz Pharmaceuticals, (Reg.#066660)

	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	Source of pellets: M/s Vision Pharmaceuticals, Islamabad.
	Decision: Approved with innovator's specification.	
58.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrser 25mg Tablet
	Composition	"Each Tablet Contains: Levosulpiride……25mg"
	Diary No. Date of R& I & fee	Dy. No 32427 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AIFA of Italy.
	Me-too status (strength & dosage form)	Sulvoric 25mg of M/s High-Q, Karachi (Reg.#070484)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
59.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arrenox 8mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lornoxicam……8mg"
	Diary No. Date of R& I & fee	Dy. No 32449 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (strength & dosage form)	Recam Tablet 8 mg by M/s Regal Pharma (Reg.#081952)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
60.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Arretil 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Domperidone Maleate Eq. to Domperidone ……10mg"
	Diary No. Date of R& I & fee	Dy. No 32448 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Peripheral dopamine receptor antagonist
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Kohidone 10mg Tablet of M/s Kohs Pharmaceuticals (Pvt) Ltd. (Reg.# 070705)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	

61.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Pooston Forte Tablet
	Composition	"Each Tablet Contains: Mefenamic Acid.....500mg"
	Diary No. Date of R& I & fee	Dy. No 32431 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Inflanil Forte Tablets of M/s Vision Pharma (R.# 033761)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
62.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Runnac SR 100mg Tablet
	Composition	"Each sustained release tablet contains: Diclofenac Sodium .....100mg"
	Diary No. Date of R& I & fee	Dy. No 32431 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Sintral SR Tablets 100mg of M/s Neomedix (R.# 081413)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	Firm had initially applied for enteric coated tablet, but upon communication of observations firm has submitted revised form 5 for sustained release tablets along with submission of fee of Rs.5,000/- vide deposit slip# 1929605 dated 24-9-2019
	Decision: Approved.	
63.	Name and address of manufacturer / Applicant	"M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, National Industrial Zone, Rawat, Rawalpindi"
	Brand Name +Dosage Form + Strength	Aremeb 135mg Tablet
	Composition	"Each Film coated Tablet Contains: Mebeverine HCl.....135mg"
	Diary No. Date of R& I & fee	Dy. No 32455 dated 28-09-2018 Rs.20,000/- 24-09-2018
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved b MHRA of UK
	Me-too status (strength & dosage form)	Colofac Tablets of M/s Abbott Labs. (Reg.# 006652)
	GMP status	Last inspection report dated 22-05-2018 concluded that the firm was found to be GMP compliant.
	Remarks of the Evaluator[II]	Firm had initially applied for enteric coated tablet, but upon communication of observations firm has submitted revised form 5 for film coated tablets along with submission of fee of Rs.5,000/- vide deposit slip# 1929603 dated 24-09-2019.
	Decision: Approved.	

64.	Name and address of manufacturer / Applicant	"M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Citramed 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levocetirizine dihydrochloride…5mg"
	Diary No. Date of R& I & fee	Dy. No 32336 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Antihistamine.
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's: Rs. 63.25/- 30's; Rs. 165.00/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Invocet tablet by M/s Aries Pharma (Reg.#078437)
	GMP status	Last inspection report dated 30-01-2018, concluding as under: "The management of the firm promised that they would continuous improvement in the light of observation at the time of inspection, documents reviewed and representatives of the firm commitment the firm may be considered to be operative in good level of cGMP compliance. However it was an old facility. Overall space is limited, workload is heavy due to heavy production for local and export purposes, the firm should plan for modification and or shifting to wide area in future. They were also advised to arrange more fire extinguishers and improve emergency exits in the building. They should also make a direct connection with fire brigade and install smoke detectors."
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP of the firm from QA & LT division.	
65.	Name and address of manufacturer / Applicant	"M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Medipride 2mg Tablet
	Composition	"Each Tablet Contains: Glimepiride……2mg"
	Diary No. Date of R& I & fee	Dy. No 32335 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Amarox 2mg Tablet of M/s Lisko Karachi (Reg.# 080338)
	GMP status	Same as above case
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP of the firm from QA & LT division.	
66.	Name and address of manufacturer / Applicant	"M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Deslort 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Desloratadine…..5mg"
	Diary No. Date of R& I & fee	Dy. No 32334 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength and dosage form)	Desdine 5mg Tablet of M/s M/s Hygeia Pharmaceuticals, Islamabad (Reg.# 080821)
	GMP status	Same as above case
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP of the firm from QA & LT division.	
67.	Name and address of manufacturer / Applicant	"M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Antifung 250mg Tablet
	Composition	"Each Tablet Contains: Terbinafine HCl…250mg"
	Diary No. Date of R& I & fee	Dy. No 32333 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Neoterbin Tablets 250mg by M/s Neomedix Pharmaceuticals, Islamabad. (Reg.# 081411)
	GMP status	Same as above case
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP of the firm from QA & LT division.	
68.	Name and address of manufacturer / Applicant	"M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Lornomed 8mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lornoxicam…8mg"
	Diary No. Date of R& I & fee	Dy. No 32332 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by EMA
	Me-too status (with strength and dosage form)	Recam Tablet 8 mg by M/s Regal Pharmaceuticals (Reg.#081952)
	GMP status	Same as above case.
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP of the firm from QA & LT division.	
69.	Name and address of manufacturer / Applicant	"M/s Medicraft Pharmaceuticals Pvt Ltd. 126-B, Indstrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Clopem 200mg/ml Injection
	Composition	"Each 1ml Ampoule Contains: Zuclopenthixol decanoate…200mg"
	Diary No. Date of R& I & fee	Dy. No 32331 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form 5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Zuphen Injection 200mg by M/s Standpharm Pakistan (Reg.#074299)
	GMP status	Same as above case.
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP of the firm from QA & LT division.	

70.	Name and address of manufacturer / Applicant	"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	V-Met 50mg/1000mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vidagliptin…..50mg Metformin HCl……1000mg"
	Diary No. Date of R& I & fee	Dy.No 28458 dated 20-08-2018 Rs.20,000/- 15-08-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (strength & dosage form)	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Remarks of the Evaluator[II]	Finished products specifications have not been submitted.
	Decision: Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.	
71.	Name and address of manufacturer / Applicant	"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	V-Met 50mg/850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vidagliptin…50mg Metformin HCl……850mg"
	Diary No. Date of R& I & fee	Dy. No 28457 dated 20-08-2018 Rs.20,000/- 15-08-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Galvus Met by Novartis Pharma, Pakistan
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Remarks of the Evaluator[II]	Finished products specifications have not been submitted.
	Decision: Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.	
72.	Name and address of manufacturer / Applicant	"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Newgaba 100mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…100mg"
	Diary No. Date of R& I & fee	Dy. No 28456 dated 20-08-2018 Rs.20,000/- 15-08-2018
	Pharmacological Group	Anti-epileptics

	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Remarks of the Evaluator[II]	Finished products specifications have not been submitted.
	Decision: Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.	
73.	Name and address of manufacturer / Applicant	"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Cef-B 90mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Ceftibuten as dihydrate…90mg"
	Diary No. Date of R& I & fee	Dy. No 28454 dated 20-08-2018 Rs.20,000/- 15-08-2018
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Zinir 90mg/5ml Suspension by M/s S.J&G Karachi (Reg.#080999)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019concluded as under: "Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Remarks of the Evaluator[II]	Finished products specifications have not been submitted.
	Decision: Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.	
74.	Name and address of manufacturer / Applicant	"M/s Bio Labs Pvt Ltd. Plot # 145, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Newgaba 50mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…50mg"
	Diary No. Date of R& I & fee	Dy. No 28455 dated 20-08-2018 Rs.20,000/- 15-08-2018
	Pharmacological Group	Anti-epileptics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Gabica 50mg Capsule by M/s Getz Pharma (Reg#048725)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 18 & 23-04-2019 concluded as under:

		"Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Bio Labs Pvt Ltd was considered to be operating at a reasonably acceptable compliance with GMP as of today as per the Drugs Act, 1976 and DRAP, Act, 2012 and rules framed there under."
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP of the firm from QA & LT division. Moreover Board directed the firm to submit Finished products specifications.	
75.	Name and address of manufacturer / Applicant	M/s City Pharmaceuticl Laboratories Plot no. 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Polymal 100mg Tablet
	Composition	Each tablet contains: Iron (III) hydroxide polymaltose complex equivalent to Elemental Iron ….. 100mg
	Diary No. Date of R& I & fee	Dy. No 30053 dated 06-09-2018 Rs.20,000/- 06-09-2018
	Pharmacological Group	Used in the treatment of iron deficiency/iron deficiency anaemia
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Chooz 100mg Tablets of M/s Weather Folds Pharmaceuticals, (Reg# 060135)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07-03-2019 concluding satisfactory level of GMP compliance"
	Remarks of the Evaluator[II]	
	Decision: **Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities**	
76.	Name and address of manufacturer / Applicant	M/s City Pharmaceuticl Laboratories Plot no. 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Flip IM 1gm Injection
	Composition	Each Vial Contains: Ceftriaxone as sodium…… 1gm
	Diary No. Date of R& I & fee	Dy.No 30049 dated 06-09-2018 Rs.20,000/- 06-09-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	Amcef Injection of M/s Linear Pharma (Reg.# 075343)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07-03-2019 concluding satisfactory level of GMP compliance"
	Remarks of the Evaluator[II]	
	Decision: Approved.	
77.	Name and address of manufacturer / Applicant	M/s City Pharmaceuticl Laboratories Plot no. 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Boxin 20mg Tablet
	Composition	Each Tablet Contains: Piroxicam as Piroxicam Beta Cyclodextrin…20mg
	Diary No. Date of R& I & fee	Dy. No 30047 dated 06-09-2018 Rs.20,000/- 06-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5

	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status (strength & dosage form)	Achway Tablets of M/s Getz Pharma (Reg.#047355)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07-03-2019 concluding satisfactory level of GMP compliance"
	Remarks of the Evaluator[II]	
	Decision: Approved.	
78.	Name and address of manufacturer / Applicant	M/s City Pharmaceuticl Laboratories Plot no. 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Telpram 10mg Tablet
	Composition	Each Tablet Contains: Escitalopram as Escitalopram Oxalate…10mg
	Diary No. Date of R& I & fee	Dy.No 30052 dated 06-09-2018 Rs.20,000/- 06-09-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (strength & dosage form)	Zavesca tablet 10mg of Getz Pharma. (Reg.#045279)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07-03-2019 concluding satisfactory level of GMP compliance"
	Remarks of the Evaluator[II]	
	Decision: Approved.	
79.	Name and address of manufacturer / Applicant	M/s City Pharmaceuticl Laboratories Plot no. 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Polymal-P 100/0.5 mg Tablet
	Composition	Each Tablet Contains: Iron (III)hydroxide polymaltose complex equivalent to Elemental Iron ….. 100mg Folic acid ….. 0.5mg
	Diary No. Date of R& I & fee	Dy. No 30054 dated 06-09-2018 Rs.20,000/- 06-09-2018
	Pharmacological Group	Haematinics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (strength & dosage form)	Haemotyl-F Tablets of Noa Hemis, Karachi. (R# 042284)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07-03-2019 concluding satisfactory level of GMP compliance"
	Remarks of the Evaluator[II]	
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities	
80.	Name and address of manufacturer / Applicant	M/s City Pharmaceuticl Laboratories Plot no. 12-A, I-5, Sector 5, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Taldin 175/25 mg Tablet
	Composition	Each Tablet Contains: Propyphenazone…..175mg Caffeine……25mg

	Diary No. Date of R& I & fee	Dy.No 30050 dated 06-09-2018 Rs.20,000/- 06-09-2018
	Pharmacological Group	Pyrazolone analgesic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (strength & dosage form)	Qutalidon Tablets of Genome Pharma. (Reg.# 064005)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07-03-2019 concluding satisfactory level of GMP compliance"
	Remarks of the Evaluator[II]	International availability in reference regulatory authorities of applied formulation could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

b. Deferred cases

81.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Valpine 5/160 tablet
	Composition	Each film coated tablet contains: Amlodipine (as besylate) …… 5mg Valsartan ….. 160mg
	Diary No. Date of R& I & fee	Dy. No. 2265; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's; Rs.126/-, 14's; Rs. 240/-, 28's; Rs. 450/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Amlodine Tablet 5/160 of M/s Jupiter Pharma (Reg.#081932)
	GMP status	Copy of cGMP panel inspection, dated 7-8-2018, 04-9-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Previous Remarks of the Evaluator.	• Master formulation includes "Valsartan as Potassium" whereas reference product approved by USFDA & MHRA contains Valsartan in pure form only. Clarification is required in this regard. • Upon communication of above observations firm has submitted revised master formulation containing Valsartan as base form only.
	Previous Decision	Registration board in its 288th meeting deferred for submission of fee for revision of formulation and for updated status of GMP of the firm from QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	Firm has submitted fee of Rs. 5,000/- for revision of formulation vide deposit slip# 0759250 dated 13-05-2019. Moreover firm has again referred to their inspection report dated 07-8-2018, 04-9-2018 & 22-11-2018, wherein fair level of compliance, was concluded and also the resumption of production in the Liquid Injectable section (general) was recommended.
	Decision: Approved.	

82.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Valpine tablet
	Composition	Each film coated tablet contains: Amlodipine (as besylate) …… 10mg Valsartan …….. 60mg
	Diary No. Date of R& I & fee	Dy. No. 2259; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's; Rs.140/-, 14's; Rs. 250/-, 28's; Rs. 500/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Amlodine Tablet 10/160 of M/s Jupiter Pharma (Reg.#081933)
	GMP status	Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Previous Remarks of the Evaluator.	• Master formulation includes "Valsartan as Potassium" whereas reference product approved by USFDA & MHRA contains Valsartan in pure form only. Clarification is required in this regard. • Upon communication of above observations firm has submitted revised master formulation containing Valsartan as base form only.
	Previous Decision	Registration board in its 288th meeting deferred for submission of fee for revision of formulation and for updated status of GMP of the firm from QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	Firm has submitted fee of Rs. 5,000/- for revision of formulation vide deposit slip# 0759249 dated 13-05-2019. Moreover firm has again referred to their inspection report dated 07-8-2018, 04-9-2018 & 22-11-2018, wherein fair level of compliance, was concluded and also the resumption of production in the Liquid Injectable section (general) was recommended
	Decision: Approved.	
83.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Valpine 5/80 tablet
	Composition	Each film coated tablet contains: Amlodipine (as besylate) …… 5mg Valsartan …….. 80mg
	Diary No. Date of R& I & fee	Dy. No. 2261; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's; Rs.98/-, 14's; Rs. 180/-, 28's; Rs. 340/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Amlodine Tablet 5/80 of M/s Jupiter Pharma (Reg.#081931)
	GMP status	Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under:

		"The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Previous Remarks of the Evaluator.	• Master formulation includes "Valsartan as Potassium" whereas reference product approved by USFDA & MHRA contains Valsartan in pure form only. Clarification is required in this regard. • Upon communication of above observations firm has submitted revised master formulation containing Valsartan as base form only.
	Previous Decision	Registration board in its 288th meeting deferred for submission of fee for revision of formulation and for updated status of GMP of the firm from QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC	Firm has submitted fee of Rs. 5,000/- for revision of formulation vide deposit slip# 0759255 dated 13-05-2019. Moreover firm has again referred to their inspection report dated 07-8-2018, 04-9-2018 & 22-11-2018, wherein fair level of compliance, was concluded and also the resumption of production in the Liquid Injectable section (general) was recommended
	Decision: Approved.	
Following case of M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore were presented in 288th meeting of Registration Board, wherein the Board deferred all the cases "**for updated status of GMP of the firm form QA & LT Division as inspection report submitted by firm does not conclude GMP compliant status."** Now the firm has again referred to their inspection report dated 07-8-2018, 04-9-2018 & 22-11-2018, wherein fair level of compliance, was concluded and also the resumption of production in the Liquid Injectable section (general) was recommended.		
84.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Stevia tablet 100mg
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate) …… 100mg
	Diary No. Date of R& I & fee	Dy. No. 2258; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-diabetic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; Rs.300/-, 20's; Rs. 600/-, 14's; Rs. 420/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Duvel 100mg Tablet of M/s Martin Dow Ltd. (Reg.#079616)
	GMP status	Copy of cGMP panel inspection dated 07-8-2018, 04-9-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Remarks of the Evaluator.	
	Decision: Approved.	
85.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Stevia-M tablet 50/500mg
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate) …… 50mg Metformin hydrochloride …… 500mg

	Diary No. Date of R& I & fee	Dy. No. 2257; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-diabetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's; Rs.150/-, 20's; Rs. 300/-, 14's; Rs. 210/-
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Treviamet 50mg/500mg Tablets by M/s GETZ Pharma Pakistan (Reg# 055443)
	GMP status	Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Remarks of the Evaluator.	• In contrary to approved by reference agencies/ authorities wherein the applied formulation is contains Metformin hydrochloride equal to 500mg, while you have applied for Metformin as hydrochloride equal to 500mg of Metformin. Clarification is required in this regard. • Upon communication of above observations firm has submitted revised master formulation containing Metformin hydrochloride equal to 500mg.
	Decision: Approved.	
86.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Stevia tablet 25mg
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate) …… 25mg
	Diary No. Date of R& I & fee	Dy. No. 2263; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-diabetic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; Rs.150/-, 20's; Rs. 300/-, 14's; Rs. 210/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Duvel 25mg Tablet by M/s Martin Dow Ltd. Karachi (Reg# 079614)
	GMP status	Copy of cGMP panel inspection, dated 7-8-2018, 4-9-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Remarks of the Evaluator.	
	Decision: Approved.	
87.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Stevia-M tablet 50/1000mg
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate) …… 50mg Metformin hydrochloride …… 1000mg
	Diary No. Date of R& I & fee	Dy. No. 2262; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-diabetic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's; Rs.180/-, 20's; Rs. 350/-, 14's; Rs. 240/-

	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Tagipmet 50/1000 Tablets by M//s. Highnoon Laboratories, (Reg.# 059787)
	GMP status	Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Remarks of the Evaluator.	• In contrary to approved by the reference agencies/authorities wherein the applied formulation is contains Metformin hydrochloride equal to 1000mg, while you have applied for Metformin as hydrochloride equal to 1000mg of Metformin. Clarification is required in this regard. • Upon communication of above observations firm has submitted revised master formulation containing Metformin hydrochloride equal to 1000mg.
	Decision: Approved with innovator's specification.	
88.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Stevia tablet 50mg
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate) …… 50mg
	Diary No. Date of R& I & fee	Dy. No. 2260; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Anti-diabetic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's; Rs.180/-, 20's; Rs. 360/-, 14's; Rs. 252/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Duvel 50mg Tablet by M/s Martin Dow Ltd. (Reg#079615)
	GMP status	Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Remarks of the Evaluator.	
	Decision: Approved.	
89.	Name and address of manufacturer / Applicant	M/s Pharmedic Lab., 15-16 Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Moflox tablet 400mg
	Composition	Each film coated tablet contains: Moxifloxacin (as hydrochloride) …… 400mg
	Diary No. Date of R& I & fee	Dy. No. 2264; 08-12-2016; Rs.20,000/- (08-12-2016)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	1 x 5's; Rs. 475/-
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Navelox Tablets 400mg by M/s Navegal Laboratories (R#068237)
	GMP status	Copy of cGMP panel inspection, dated 07-08-2018, 04-09-2018 & 22-11-2018 recommending as under: "The observations noted during the inspections were

		discussed at length with the firm's management and it was advised to rectify the shortcomings and submit compliance report."
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	
90.	Name and address of manufacturer / Applicant	M/s AGP Limited B-23-C S.I.T.E., Karachi ` ***Contract Manufactured by:*** M/s Seraph Pharmaceuticals Plot # 210, Industrial Triangle Kahuta, Road Islamabad
	Brand Name +Dosage Form + Strength	Neogene 2g IV Injection
	Composition	Each vial Contains: Ceftriaxone (as Sodium)...2gm
	Diary No. Date of R& I & fee	Dy. No. 18780: 23.05.2018 Rs. 50,000/-: 22.05.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's: as per PRC
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 2 g powder for solution for injection/infusion. MHRA approved
	Me-too status	Cefast 2g Injection I.V. Reg. No. 82281
	GMP status	AGP: GMP granted on the basis of inspection dated 16.10.2018. Seraph Pharma: GMP certificate issued on the basis of inspection dated 11.06.2018.
	Remarks of the Evaluator.	• The firm initially applied for contract manufacturing by UDL Pharmaceuticals. Later on, the firm updated Form 5 dated 10-06-2019, wherein the manufactured has been changed to Seraph Pharmaceuticals. • The firm M/s AGP Limited has submitted list of 09 products, out of which they have claimed 08 approved already product and 01 product applied for contact manufacturing by AGP Limited • The firm M/s AGP Limited submitted copy of contract manufacturing agreement between the applicant and manufacturer.
	Previous Decision	Registration Board in its 290th meeting deferred for submission of dossier on CTD format.
	Evaluation by PEC	The firm has requested as under: "Initial registration dossier was submitted on 22-05-2018 as contact manufacture from UDL Pharma Karachi but in 2018 UDL, stopped manufacturing & apply for the cancellation of their DML, in this situation we request to change the status of contract manufacturing from M/s UDL to M/s Seraph pharmaceuticals Islamabad. In the light of discussions regarding "Correction / revision in submitted applications on form 5 / 5A / 5D for registration of drugs" during the 291st Registration Board Meeting, it is requested to please consider our case on the base of submitted dossier on 22-05-2018." Moreover firm has also submitted fee of Rs. 5,000/- vide deposit slip# 0781952 dated 25-09-2019 for the change in manufacturer.
	Decision: Registration Board deliberated that the decision of 291st Board Meeting regarding "Correction / revision in submitted applications on Form 5 / 5A / 5D for registration of drugs", is not applicable for the cases wherein change of manufacturer is involved as variation. Hence Board deferred the case for submission of application on Form-5F as firm has submitted application after 7th March 2019.	

91.	Name and address of manufacturer / Applicant	M/s Crystolite Pharmaceuticals, Islamabad
	Brand Name +Dosage Form + Strength	Troximate 2.5mg tablet
	Composition	Each tablet contains: Methotrexate sodium eq. to 2.5mg of methotrexate
	Diary No. Date of R& I & fee	Dy. No.25482; 21-12-2017 ; Rs.20,000/- (21-12-2017)
	Pharmacological Group	Folic acid antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	100's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	METHOTREXATE TABLET 2.5M by PAK CHINA INTERNATIONAL KARACHI Reg# 066008
	GMP status	Last inspection report dated 12-11-2018 & 02-01-2019 recommends renewal of DML
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 278th meeting deferred the case for further deliberation regarding manufacturing facility for Cytotoxic drugs.
	Evaluation by PEC	The firm has referred to the Smpc of the reference product Maxtrex tablet approved by MHRA of UK wherein Pharmacotherapeutic group for the methotrexate 2.5mg tablets has been classified as Immunosuppressive agents with WHO ATC code as L04AX03. The Board has restricted the requirement for separate section for Cytotoxic drugs falling in the "L01" class of ATC code.
	Decision: Approved.	
92.	Name and address of manufacturer / Applicant	High-Q Pharmaceuticals, Karachi.
	Brand Name +Dosage Form + Strength	Vildomet 50mg+500mg Tablet
	Composition	Each film coated tablet contains: Vildagliptin ……50mg Metformin HCl ……. 500mg
	Diary No. Date of R& I & fee	Dy.No.447, 16-05-2013, Rs.60,000/-
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5D
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Galamet by M/s CCL Pharmaceuticsals
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding that firm is operating at an acceptable level of compliance.
	Remarks of the Evaluator.	
	Previous Decision	Registration Board in its 262nd meeting decided as under: "Registration Board deliberated that above mentioned formulation required submission of stability data as per guidelines approved by Registration Board in 251st meeting and product will remain deferred till submission of aforementioned data."
	Evaluation by PEC	Now the firm has submitted Registration Board in its subsequent meetings has approved the applied formulation without requiring stability data hence the firm may also be granted registration.
	Decision: Approved with innovator's specification	

Case No. 02: Registration Applications of Import Cases.

a. Deferred Cases.

i. Human

93.	Name and address of Applicant	M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan
	Detail of Drug Sale License	Address: M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, Manghopir Road, S.I.T.E., Karachi-75700, Pakistan Validity: 22-06-2019 Status: License to sell drugs by way of "Whole Sale"
	Name and address of manufacturer	M/s CENEXI, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France
	Name and address of marketing authorization holder	M/s Stragen Nordic A/S HelsingØrsgade 8C, HillerØd, Denmark
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 30408 Dated 10-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 10-09-2018
	Brand Name +Dosage Form + Strength	Urapidil Stragen I.V 50mg/10ml (Solution for Injection)
	Composition	Each 10ml contains: Urapidil ……. 50mg
	Finished Product Specification	USP
	Pharmacological Group	Alpha-adrenoceptor antagonist
	Shelf life	18 months
	Demanded Price	Rs. 8,000/- per 5's
	Pack size	5 ampoules
	International availability	Approved by ANSM of France
	Me-too status	N/A
	Detail of certificates attached	• Original Legalized CoPP Certificate No: 2286/1 Certifying Authority: District Government of Cologne, Deaprtment 24, Zeughausstrae 2-10, 50667 Cologne. (The name of issuing authority is included in the WHO list of "Competent authorities of countries participating in the WHO certification scheme on the quality of pharmaceutical products moving in international commerce" https://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/contacts/en/index1.html as accessed on 19-12-2018) Issue Date: 10-07-2018 Free sale in exporting country: Yes Applicant of certificate: M/s Stragen Pharma GmbH, Technologie Park Koln, eupener Strasse 135-137, 50933, Cologne, Germany. • GMP: No • Applicant of certificate: M/s Stragen Pharma GmbH, technologie Park Koln, Eupener Strasse 135-137, 50933, Cologne, Germany • Original legalized GMP Certificate Certificate no. HPF/FR/168/2017 valid upto 22-03-2020 Manufacturer Address: M/s CENEXI – Fontenay Sous Bois, 52, rue Marcel et Jacques Gaucher, 94120 Fontenay-sous-Bois, France Issued by French National Agency for Medicines and Health Products Safety.

	Remarks of the Evaluator: • Firm has submitted an Original legalized statement from M/s Stragen Pharma SA, Switzerland declaring M/s Stragen Nordic A/S Denmark (Product License Holder) an affiliate of M/s Stragen Pharma SA, Switzerland. The statement further grants the M/s Pharmatech Pakistan (Pvt.) Ltd, right to register and to commercialize, the finished product in Pakistan under Stragen Pharma's trademark. • Copy of "License and Supply Agreement" has been submitted between the applicant and M/s Stargen Pharma S.A., Switzerland. • Applicant for COPP is different from Product License Holder. • Only Long term stabilities data for three batches as per Zone IV-A conditions have been submitted by applying bracketing principle on 5ml & 20 ml ampoule
	Previous Decision: The above case was deferred in 289th meeting for evaluation of bracketing principle applied by the firm on "long term stabilities data" in view of applicable ICH guidelines and presentation of complete details before the Board.
	Evaluation by PEC: The firm has now submitted that due to out of specification results, for certain quality tests, accelerated stability studies (at 40ºC & 75%RH) were not completed for three batches. Now the firm has submitted long term stability studies data of three batches (at 30ºC & 65%RH) for 24 months. Long term stability studies of one of the batch has been performed upon following frequency: "Initial, 12th month, 18th month & 24 month." Upn seeking clarification of the above fact firm has referred to following section of ICH Q1A (R2) guidelines: ***"2.2.8. Stability Commitment*** When available long term stability data on primary batches do not cover the proposed shelf life granted at the time of approval, a commitment should be made to continue the stability studies post approval in order to firmly establish the shelf life. Where the submission includes long term stability data from three production batches covering the proposed shelf life, a post approval commitment is considered unnecessary. Otherwise, one of the following commitments should be made: 1. If the submission includes data from stability studies on at least three production batches, a commitment should be made to continue the long term studies through the proposed shelf life and the accelerated studies for 6 months. 2. If the submission includes data from stability studies on fewer than three production batches, a commitment should be made to continue the long term studies through the proposed shelf life and the accelerated studies for 6 months, and to place additional production batches, to a total of at least three, on long term stability studies through the proposed shelf life and on accelerated studies for 6 months. 3. If the submission does not include stability data on production batches, a commitment should be made to place the first three production batches on long term stability studies through the proposed shelf life and on accelerated studies for 6 months." Referring to above firm has now requested as under: "Out of 3 batches, only one of our submitted batch (F0046/141155) data is not covering the time points of 3, 6 & 9 months while initial 12, 18 & 24 months stability results are there. Real time Stability results are satisfactory till 18 months and we have requested for the shelf life of 18 months. With reference of ICH guideline Q1A (R2) under the heading of Stability Commitment for finished product, we request you to please consider our application for registration with a commitment to provide you real time stability data (covering all test point) for first commercial batch at Zone IVA, as soon as completed.**"**
	Decision: Registration Board after thorough deliberation decided that since firm has not submitted accelerated stability studies data, hence scientific justification shall be submitted to address the effect of short term excursions outside the label storage condition, e.g., during shipping or handling as required by ICH QI E (evaluation for Stability data) guidelines

Case No. 03: Registration Applications of Drugs for which Stability Study Data is Submitted.

a. Verification of Stability Study Data.

94.	Name and address of manufacturer / Applicant	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name +Dosage Form + Strength	Eflozin 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin……10mg"
	Diary No. Date of R& I & fee	Dy. No 37402 dated 12-11-2018 Rs.50,000/- 12-11-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	
	GMP status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA			
Drug	Eflozin 10mg Tablet		
Name of Manufacturer	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi		
Manufacturer of API	Empagliflozin: M/s Zhejiang Hongyuan Pharmaceutical Co., ltd. Linhai, Zheijiang, China.		
API Lot No.	20180401		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6,9,12,18,24 months		
Batch No.	121B18	122B18	123B18
Batch Size	4000 tablets	2000 tablets	2000 tablets
Manufacturing Date	04-07-2018	04-07-2018	04-07-2018
Date of Initiation	31-10-2018	31-10-2018	31-10-2018
No. of Batches	03		
Date of Submission	08-07-2019 (Dy. No. 11121)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate (Certificate#ZJ20180032) issued by China Food & Drug Administration for M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd. Valid Up to 14-03-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms,	Yes

laboratory reports, data sheets etc.	
Documents confirming import of API etc.	• Copy of invoice (Invoice No. 30180190) for 1 Kg of Empagliflozin has been submitted attested by Assistant Director DRAP, Karachi, dated 11-06-2018.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The frequency of testing for accelerated stability studies is not as per recommendations of 278th meeting of Registration Board i.e., 0,1,2,3,4 & 6 month.

95.	Name and address of manufacturer / Applicant	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name +Dosage Form + Strength	Eflozin 25mg Tablet
	Composition	"Each Film Coated Tablet Contains: Empagliflozin…25mg"
	Diary No. Date of R& I & fee	Dy. No 37403 dated 12-11-2018 Rs.50,000/- 12-11-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (strength & dosage form)	
	GMP status	Last GMP inspection report dated 24-04-2019 concluding acceptable level of good compliance with GMP guidelines
	Remarks of the Evaluator[II]	

STABILITY STUDY DATA

Drug	Eflozin 25mg Tablet		
Name of Manufacturer	M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi		
Manufacturer of API	Empagliflozin: M/s Zhejiang Hongyuan Pharmaceutical Co., ltd. Linhai, Zheijiang, China.		
API Lot No.	20180401		
Description of Pack (Container closure system)	Alu-Alu blister with unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6,9,12,18,24 months		
Batch No.	124B18	125B18	126B18
Batch Size	5000 tablets	2500 tablets	2500 tablets
Manufacturing Date	04-07-2018	04-07-2018	04-07-2018
Date of Initiation	31-10-2018	31-10-2018	31-10-2018
No. of Batches	03		

Date of Submission	08-07-2019 (Dy. No. 11122)

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has provided copy of GMP certificate (Certificate#ZJ20180032) issued by China Food & Drug Administration for M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd. Valid Up to 14-03-2023.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	• Copy of invoice (Invoice No. 30180190) for 1 Kg of Empagliflozin has been submitted attested by Assistant Director DRAP, Karachi, dated 11-06-2018.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The frequency of testing for accelerated stability studies is not as per recommendations of 278th meeting of Registration Board i.e., 0,1,2,3,4 & 6 month.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Eflozin 10mg & 25mg Tablets (Empagliflozin)) by M/s. Scilife Pharma (Pvt). Ltd., Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 23rd September, 2019.
Investigation Date and Time: 27th September, 2019 (Morning).
Investigation Site: Factory premises of M/s. Scilife Pharma (Pvt). Ltd., Korangi Creek, Industrial State, Karachi.

Background:
Chairman Registration Board considered the applications of M/s. Scilife Pharma (Pvt). Ltd., Korangi Creeck, Industrial State, Karachi for registration of Eflozin 10mg & 25mg Tablets (Empagliflozin) and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:
1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board).
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Ms. Sanam Kauser, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:
The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also

audited. The details of investigation may be summarized as under:

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API?	Firm has imported 1.0 kg Empagliflozin from M/s Zhejiang Hongyuan Pharmaceutical Co. Ltd, China having Invoice No 30180192 Dated: 29-05-2018, Batch number 20180401 and material is cleared by ADC dated 11-06-2018
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation form being implemented by the firm. The parameters included in this form are, DMF status, GMP certificate, Stability data, provision of reference standard of API and impurities standards etc. The firm has evaluated on this criteria and has been selected accordingly.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has documents confirming the import of reference standard and impurity standards (2 number).
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis of API, reference standard and impurities standards.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has valid GMP certificate of Zhejiang Hongyuan Pharmaceutical Co. Ltd, China issued by regulatory authority of their respective country of origin.
6.	Do you use API manufacturer method of testing?	Firm has used API manufacturer`s method of testing for testing of API.
7.	Do you have stability studies reports on API?	Firm has stability studies reports of API as provided by the manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed as per Stability Indicating Method (SIM) method and impurities/related substances/degradation products quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of API, reference standards of the API while impurities standards consumed.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients.
12.	Do you have documents confirming the import of the used excipients?	The firm has purchased all the excipients from the local market although they have certificate of analysis for all the excipients available with them.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of the product?	The firm has written and authorized protocol for the development of Eflozin (Empagliflozin) 10mg and 25mg tablets
15.	Have you performed Drug-excipients compatibility studies?	The firm has not performed Drug-excipients compatibility studies as their formulation is similar to that of the innovator formulation (Jardiance tablets of M/S. Boehringer Pharma Germany).

<table>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Jardiance 10mg and 25mg tablets M/S. Boehringer Pharma Germany. Jardiance 10mg tablets batch number 701430 and Jardiance 25mg tablets batch number 602702. The firm‘s product results are comparable to that of the Reference product which are given below,
<table>
<tr><td>Reference Product</td><td colspan="2">Jardiance Tablets</td></tr>
<tr><td>Strength</td><td>10mg</td><td>25mg</td></tr>
<tr><td>Batch number</td><td>701430</td><td>602702</td></tr>
<tr><td>CDP Results Obtained</td><td></td><td></td></tr>
<tr><td>Similarity Factor at pH 1.2</td><td>88.75</td><td>76.10</td></tr>
<tr><td>Similarity Factor at pH 4.5</td><td>69.63</td><td>98.03</td></tr>
<tr><td>Similarity Factor at pH 6.8</td><td>95.23</td><td>86.81</td></tr>
<tr><td>Limit</td><td>F2 ≥ 50</td><td>F2 ≥ 50</td></tr>
<tr><td>Remarks</td><td>Satisfactory</td><td>Satisfactory</td></tr>
</table></td></tr>
<tr><td>17.</td><td>Do yo have product developme t (R&D) section</td><td>The firm has dedicated area for product development (R&D) section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment’s available in product development section for development of the product?</td><td>The firm has dedicated manufacturing equipment’s in product development section for development of tablets dosage form.</td></tr>
<tr><td>19.</td><td>Are the equipments in product development section qualified?</td><td>The equipments in product development (PD) section are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has trained and qualified staff in product development section with proper knowledge and training in product development Including 03 Pharmacist, 04 Chemist and 01 Bio technologist.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of the product as required?</td><td>The firm has manufactured three stability batches for the stability studies of Eflozin 10mg tablets and 25mg tablets respectively. The details are given below, The tablets are packed in ALu-ALu blisters with pack size of 1 x 10s.
<table>
<tr><th>Sr.#</th><th colspan="2">Eflozin 10mg tablets</th><th colspan="2">Eflozin 25mg tablets</th></tr>
<tr><td>1</td><td>121B18</td><td>4,000 tabs</td><td>124B18</td><td>5,000 tabs</td></tr>
<tr><td>2</td><td>122B18</td><td>2,000 tabs</td><td>125B18</td><td>2,500 tabs</td></tr>
<tr><td>3</td><td>123B18</td><td>2,000 tabs</td><td>126B18</td><td>2,500 tabs</td></tr>
</table></td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tablets per testing frequency and number of testing frequencies / intervals) and minimum working
Capacity of the equipments.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>Firm has complete record of production of stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>Firm has detailed protocol for stability testing of stability batches.</td></tr>
</table>

26.	Do you have developed and validated the method for testing of stability batches?	The Firm has developed and performed detailed analytical method validation studies for testing of stability batches.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	The firm has not conducted method transfer studies, however, they have validated their method properly.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug.
29.	Do your method of analysis stability indicating?	Method of analysis is stability indicating as supported by force degradation stability studies.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record of the firm. Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available.
31.	Can you show Audit Trail reports on product testing?	Audit trail reports were available and randomly checked.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
33.	Do you have stability batches kept on stability testing?	Firm has completed the accelerated stability testing on the three stability batches of Eflozin 10mg tablets and Eflozin 25mg tablets respectively. However the real time stability testing is in progress on all the stability batches. Currently 9 months study has been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment's used in production and analysis?	Firm has valid calibration status for the equipment used in production and analysis of Eflozin (Empagliflozin) 10mg tablets & 25mg Tablets.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant.

Conclusion and Recommendations:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Eflozin 10mg & 25mg Tablets (Empagliflozin) is verifiable to satisfactory level.
2. Registration of the product "Eflozin 10mg & 25mg Tablets" is recommended in the name of the manufacturer.

Decision: Registration Board decided to approve registration of "Eflozin 10mg tablets (Empagliflozin 10mg) and Eflozin 25mg tablets (Empagliflozin 25mg) by M/s. Scilife Pharma (Pvt). Ltd., Korangi Creeck, Industrial State, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case No. 04: Miscellaneous Cases.

Following case was presented in 289th meeting of Registration Board.

96.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	SPIROX-10 Oral Powder
	Composition	Each 100gm contains: Spiramycin……10gm Doxycycline HCl……10gm Bromhexine HCl….2gm
	Diary No. Date of R& I & fee	Diary No:5138, 12-08-2015 , Rs: 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	Decontrolled/ 100gm, 500gm, 1kg, 2.5kg, 5kg, & 25 kg
	Me-too status (with strength and dosage form)	--
	GMP status	16-10-2018 Firm was operating at the fair level of GMP Compliance.
	Remarks of the Evaluator[II]	
	Previous Decision:	Registration Board in its 287th meeting deferred for confirmation of me-too status.
	Decision of 289th meeting: Approved with innovator's specifications.	

During the subsequent proceedings of the case it was identified that name of applicant was erroneously mentioned as "M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore" whereas actually the applicant was "M/s. Ras Pharmaceuticals (Pvt) Ltd., 25-Km Lahore Road, Multan" and case was initially deferred in 253rd meeting of Registration Board. Other details were same as presented above. The case is now submitted for information of the Board.

Decision: **Registration Board noted the information and approved the above case in the name of M/s. Ras Pharmaceuticals (Pvt.) Ltd., 25-Km Lahore Road, Multan**

Case No. 01 Registration applications of import cases

a. Deferred Cases.

i. Human

97.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP)
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP and Sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per sole agency agreement)
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CARBOPLATIN IV Injection 100mg Freeze dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Carboplatin…….100mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic
	Shelf life	2 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 392 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	Cannot be confirmed
	Me-too status	Carboplatin for injection 100mg/vial by M/s Mehran International. (Imported from China) (Reg # 052270) Carboplatin for injection 100mg/vial by PakChina International (Imported from China)(Reg # 066006)
	Detail of certificates attached	Original Legalized CoPP issued by Jining Food and Drug Administration valid till 14/12/2017 confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
	Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Approval status of the product with strength 100mg/vial cannot be confirmed. However product with 50mg/vial, 150mg/vial and 450mg/vial are approved by USFDA. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.
	Previous Decision(M-274): The Registration Board deferred the cases for; • Submission of clarification regarding since the data/assay values in the stability studies are	

unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true

- Evidence of approval status of the product in reference regulatory authorities in the applied strength.
- Detail of diluent to be used for reconstitution.

Evaluation by PEC:

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

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

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

Decision of 289th meeting of Registration Board	Deferred for following submissions: • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its

		275th meeting • Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.
	Evaluation by PEC	Firm has submitted following documents; • The firm has submitted real time stability study data according to zone IV-A of 03 batches for 02 years signed by QC Director with following details; Accelerated stability study data also submitted. • Batch number 170601 (Mfg. date: June 2017, Exp. Date: June, 2020) • Batch number 170603 (Mfg. date: June 2017, Exp. Date: June 2020) • Batch number 170602 (Mfg. Date: June 2017, Exp. Date: June 2020) • The firm has provided USFDA reference which could not be verified.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting.	
98.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP)
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China (As per CoPP and Sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per sole agency agreement)
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CARBOPLATIN IV Injection 200mg Freeze dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Carboplatin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antineoplastic agent, Platinum Containing cytotoxic
	Shelf life	3 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 3562Dated 6/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 03/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	Evidence of approval in Reference Regulatory Authority.
	Me-too status	Could not be confirmed
	Detail of certificates attached	Original Legalized CoPP issued by Jining Food and Drug Administration valid till 14/12/2017 confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
	Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Detail of diluent to be used for reconstitution. • Agreement does not include the carboplatin.

	• Evidence of approval in Reference Regulatory Authority. • Stability data sheets of atleast 3 batches according to Zone IVA. • Valid drug sale license. • Credentials are not signed . • Certificate no is not mentioned on COPP. • Clarification of pharmacological group. • Mention the type of container. • Product is present in USP while finished product specifications are not as per USP. Like pH in USP is 5-7 while you have provided 5.5-7.5. • URDU version label. • Site master file or signed credentials.

Evaluation by PEC:

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

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

Decision of 289th meeting of Registration Board	Deferred for following submissions: • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting • Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.
Evaluation by PEC	Firm has submitted following documents; • The firm has submitted real time and accelerated stability study data according to zone IV-A of 03 batches for 02 years signed by QC Director with following details; Accelerated stability study data

		also submitted. • Batch number 170604 (Mfg. date: June 2017, Exp. Date: June, 2020) • Batch number 170605 (Mfg. date: June 2017, Exp. Date: June 2020) • Batch number 170606 (Mfg. Date: June 2017, Exp. Date: June 2020) • The firm has provided USFDA reference which could not be verified.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting.	
99.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019
	Name and address of manufacturer	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China
	Name and address of marketing authorization holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CALCIUM FOLINATE injection 100mg Freeze dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Calcium folinate…. 100mg
	Finished Product Specification	BP
	Pharmacological Group	Anti dot to folic acid antagonist/Detoxifying agent for antineoplastic treatment
	Shelf life	2 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 385 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	Calcium folinate powder for solution 100mg/vial by M/s Mylan, ANSM France Approved
	Me-too status	Calcium flogen 100mg injection by M/s Genetech (IMPORTED from China) (Reg # 059269)
	Detail of certificates attached	Original Legalized CoPP (certificate No. 20150008) issued by Shanxi Food and Drug Administration valid till 31/08/2017 confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.
	Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274): The Registration Board deferred the cases for;

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

Evaluation by PEC:

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

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

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

Decision of 289th	Deferred for following submissions:

	meeting of Registration Board	• Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting • Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.
	Evaluation by PEC	Firm has submitted following documents; 1. The firm has submitted the evidience of approval of the product in Austria but it could not be verified. Leucoverin Injection by M/s Wyeth Lederle Pharma GMBH, Austria. 2. Real Time stability studies according to the conditions of zone IV-A for 2 years signed by Director QC of following batches; Accelerated stability study data also submitted. • 170501 (Mfg date; May, 2017 & Exp. Date: May, 2020) • 170502 (Mfg date; May, 2017 & Exp. Date: May, 2020) • 170503 (Mfg date; May, 2017 & Exp. Date: May, 2020)
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting.	
100.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019
	Name and address of manufacturer	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China
	Name and address of marketing authorization holder	M/s Shanxi PUDE Pharmaceutical Co., Ltd., First Pharmaceutical Zone, Economic & Development Zone of Datong, Shanxi, China Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	CALCIUM FOLINATE injection 300mg Freeze Dried cake for solution for IV injection (Lyophilized Powder)
	Composition	Each vial contains: Calcium folinate…. 300mg
	Finished Product Specification	BP
	Pharmacological Group	Anti dot to folic acid antagonist
	Shelf life	3 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 387 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	Could not be confirmed (Approved as lyophilized powder for injection 200mg/Vial & 350mg/Vial)
	Me-too status	Could not be confirmed
	Detail of certificates attached	Original Legalized CoPP (certificate No. 20150009) issued by Shanxi Food and Drug Administration valid till 15/09/2017 confirms the free of the product in exporting country. The facilities and operation conform to GMP as recommended by WHO.

Remarks of the Evaluator.	• The firm has applied for registration with generic name. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Decision: The Registration Board deferred the cases for;

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

Evaluation by PEC:

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

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

Shortcomings	Response by the firm
Clarifythe formulation whether Freeze dried cake or lyophilized powder	Lyophilized powder
The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Firm has submitted evidence of USFDA which could not be verified.
Variation in address mentioned on DSL and	Firm has submitted revised Form 5A

	Form 5A. Clarify	
	Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life

	Decision of 289th meeting of Registration Board	Deferred for following submissions: • Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting • Real time stability study data of 3 batches as per zone IV-A for the complete shelf life.
	Evaluation by PEC	Firm has submitted following documents; 1. The firm has submitted the evidence of approval of the product in Austria but it could not be verified. Leucoverin Injection by M/s Wyeth Lederle Pharma GMBH, Austria. 2. Real Time stability studies according to the conditions of zone IV-A for 2 years signed by Director QC of following batches; Accelerated stability study data also submitted. • 170504 (Mfg date; May, 2017 & Exp. Date: May, 2020) • 170505 (Mfg date; May, 2017 & Exp. Date: May, 2020) • 170506 (Mfg date; May, 2017 & Exp. Date: May, 2020)
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting.	

101.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co., Ltd., Tongji Tech Industry Garden, Jining High & New Technology Industries Development Zone, Jining, Shandong Province China Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	Docetaxel injection 20mg Freeze dried cake for solution for injection (Lyophilized powder)
	Composition	Each Vial (0.5ml) Contains: Docetaxel…….20mg
	Finished Product Specification	USP (Monograph is present for sterile solution)
	Pharmacological Group	Antineoplastic
	Shelf life	2 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 390 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	DOCEFREZ lyophilized powder for injection (20mg/vial of 1ml, 80mg/vial of 4ml) by Ms/ Sun Pharmaceutical Ind. Ltd,

	USFDA Approved.
Me-too status	Docet 20mg/0.5ml injection by M/s Helix Pharma (IMPORTED) (Reg # 072507)
Detail of certificates attached	Original legalized CoPP (certificate No. 151100B0/62248) issued by Jining Food and Drug Administration on 14/12/2015 confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has applied for registration with generic name. • The product is approved in USFDA as powder for injection in 1ml vial while the firm has applied with for powder for injection in 0.5ml vial. 1ml of the solvent is required for reconstitution. (Ref USFDA) and 2mg/0.5ml injection is approved in Health Canada as Solution for injection. • The firm has claimed USP specifications while the product is not present in USP/BP. • Firm has initially submitted real-time stability data conducted at 25 ± 2ºc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm has submitted stability data sheet specifying stability conditions as 30 ± 2ºc and 65 ± 5%RH with same results at each time point.

Previous Decision (M-274): The Registration Board deferred the cases for;

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

Evaluation by PEC:

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

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

Shortcomings	Response by the firm
The protocols of stability mentions conditions 30 ± 2oC and 65 ± 5%RH whereas the stability data mentions the condition 25 ± 2oC	Firm has submitted long term stability of 3 batches 1604051231, 1604051232, 1604051233. The batches were manufactured in April 2018 and the

	and 60 ± 5%RH. The data is same as submitted before	firm has submitted stability data till 36 months which should have been completed in April 2021 but the stability data sheets contains values for the time points which are yet to come.
	Clarifythe formulation whether lyophilized powder or concentrate	Concentrate
	The certifying authority for CoPP is Jinning Food and Drug Administration which is not a state or provincial certifying authority.	Firm has submitted that "as per the announcement of Shandong province food and drug administration, shandong province food and drug administration authorize the city level food and drug administration to issue CoPP. Since the manufacturer M/s Cisen Pharmaceutical Co. Ltd. is in Shandong province, therefore the city level Jinning food and drug administration is authorized to issue CoPP. Firm has also submitted following link but it could not be accessed http://www.sfda.gov.cn/art/2017/12/20/art_8045_782171.html
	Evidence of approval of applied formulation in reference regulatory authorities which were approved by Registration Board in its 275th meeting	Docetaxel Actavis 20mg/0.5ml concentrate and solvent for solution for infusionMHRA Approved.
	Firm has claimed USP specification but impurity and endotoxin specification of USP are more stringent than provided specification.	Firm has submitted that their docetaxel injection is according to CFDA standard, but the inner controlled parameter of impurity and endotoxin is more strict than USP standard. The firm has also compared USP standard limits with their inner controlled standards.
	Decision of 289th meeting of Registration Board	Registration Board deferred the case for following submission: • Clarification of the stability study data sheets which contains the results of 3 years stability study data for batches manufactured in April 2018. • Submission of original signed stability study data sheets along with complete results for long term stability of 3 batches 1604051231, 1604051232 and 1604051233 which were manufactured in April 2018.
	Evaluation by PEC	Firm has submitted following documents ➢ The firm has submitted that the stability of below mentioned batches was started from 11th April 2017, 13th April 2017 and 16th April 2017 of batch numbers 1604051231, 1604051232 and 164051233 respectively. 24 months study have been completed and submitted for consideration. Remaining 12 months study data will be provided after completion of period. ➢ The firm has submitted 24 months stability data signed by QC Director of following batches; Accelerated stability study data also submitted. ➢ Batch Number 1604051231 (Mfg. Date: 10th April 2017, Exp. Date: 10th April 2020) ➢ Batch Number 1604051232 (Mfg. Date: 12th April 2017, Exp. Date: 12th April 2020) ➢ Batch Number 1604051233 (Mfg. Date: 15th April 2017, Exp. Date: 15th April 2020)
	Decision: Registration Board approved the case as per policy for inspection of manufacturer abroad. Moroever the Board deliberated that as firm has submitted revised stability data thus it needs onsite verification and thus advised the inspection panel to verify and report the submitted stability data for applied product.	
102.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019

Name and address of manufacturer	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China.
Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. (as per CoPp and Sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per sole agency agreement)
Name of exporting country	China
Brand Name +Dosage Form + Strength	Oxaliplatin for injections 50mg Freeze dried cake for solution for IV injections (lyophilized)
Composition	Each Vial Contains: Oxaliplatin….. 50mg
Finished Product Specification	In House
Pharmacological Group	Antineoplastic
Shelf life	3 years
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No. 383 Dated 16/03/2017
Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
Demanded Price	As per SRO
Pack size	1×1's (7ml glass vial)
International availability	ELOXATIN for injection (50mg 100mg) by M/s SANOFI AVENTIS US, USFDA approved
Me-too status	Celdach 50 injection by Hakimsons (Reg # 72565) 64
Detail of certificates attached	Original Legalized CoPP (certificate No. 151100B0 /47076) issued by Jining Food and Drug Administration on 16/09/2015 is attached which confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO.
Remarks of the Evaluator.	• The firm has claimed In House manufacturing specifications while the product is available in USP. As per USP the product contains Oxaliplatin and Lactose monohydrate while according to formulation provided by the firm the product contains Oxaliplatin and Mannitol. • Firm has initially submitted real-time stability data conducted at 25 ± 2°c and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter, firm has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274): The Registration Board deferred the cases for;

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

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since	Firm has submitted stability study data sheets duly

the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	signed by the authorized personnel of manufacturer of 3 batches 170610, 170611, 170612 conducted as per the conditions of zone IV-A. The data submitted is only for 6 months. Additionally the impurities identified at various time points exceeds the limit identified in acceptance criteria i.e. NMT 0.2%. The firm has NOT submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Clarification regarding formulation since USP specifies the formulation containing Oxaliplatin with Lactose monohydrate while submitted formulation by you contains Oxaliplatin and Mannitol	Firm has submitted that their principle manufacturer has informed that China FDA does not approve lactose as excipient of lyophilized powder instead they accept mannitol because it provides more stability.

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

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

Decision of 289th meeting of Registration Board	Deferred for following submissions: • Real time stability study data of 3 batches as per zone IV-A for the complete shelf life. • Scientific justification for out of specification impurities (i.e. results greater than 0.2%) while the acceptance criteria was NLT 0.2%.
Evaluation by PEC	Firm has submitted following documents: Real Time and accelerated stability study data according to the conditions of zone IV-A for 2 years of following batches; Accelerated stability study data also submitted. • 12021800201

		(Mfg date; June, 2017 & Exp. Date: June, 2020) • 12021800202 (Mfg date; June, 2017 & Exp. Date: June, 2020) • 12021800203 (Mfg date; June, 2017 & Exp. Date: June, 2020) The data is of different batches than the previously submitted batches and the impurity results of these batches are within limits.
	Decision: Registration Board approved the case as per policy for inspection of manufacturer abroad. Moroever the Board deliberated that as firm has submitted revised stability data thus it needs onsite verification and thus advised the inspection panel to verify and report the submitted stability data for applied product.	
103.	Name and address of Applicant	M/s Mehran International , Pliva Avenue Hume Road Near World Map, Karachi, Pakistan
	Detail of DSL	Address: Mehran International, Plot No. JM 25/1 S.T. Homes shop No. 4/4-A, Jamshed quarter, Karachi. Validity: 16/01/2019
	Name and address of manufacturer	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China.
	Name and address of marketing authorization holder	M/s Cisen Pharmaceutical Co. Ltd., Tongji Tech-Industry Garden, Jining High & New Technology Ind. Development Zone, Jining, Shandong Province, China. (as per CoPP and Sole agency agreement) Exporting agent for Pakistan: M/s Ninhua Group Co., Ltd., 21 Jiangxia St. Ningbo, P.R. China (as per Sole Agency Agreement)
	Name of exporting country	China
	Brand Name +Dosage Form + Strength	OXALIPLATIN for injections 100mg Freeze dried cake for solution for IV injections (lyophilized)
	Composition	Each Vial Contains: Oxaliplatin….. 100mg
	Finished Product Specification	In House
	Pharmacological Group	Antineoplastic
	Shelf life	3 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 398 Dated 16/03/2017
	Fee including differential fee	Rs. 100,000/- Dated 15/03/2017
	Demanded Price	As per SRO
	Pack size	1×1's
	International availability	ELOXATIN for injection (50mg 100mg) by M/s SANOFI AVENTIS US, USFDA approved
	Me-too status	Celdach 50 injection by Hakimsons (Reg # 72564)
	Detail of certificates attached	Original Legalized CoPP (certificate No. 151100B0/47077) issued by Jining Food and Drug Administration on 16/09/2015 is attached which confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO.
	Remarks of the Evaluator.	• The firm has claimed In House manufacturing specifications while the product is available in USP. As per USP the product contains Oxaliplatin and Lactose monohydrate while according to formulation provided by the firm the product contains Oxaliplatin and Manitol. • Firm has initially submitted real-time stability data conducted at 25 ± 2ºc and 65 ± 5%RH, letter was issued to submit stability study data conducted according to the conditions of zone IV-A. In response to the letter firm

	has submitted stability data sheet specifying stability conditions as 30 ± 2°c and 65 ± 5%RH with same results at each time point.

Previous Decision(M-274): The Registration Board deferred the cases for;

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

Evaluation by PEC:

Shortcomings	Response by the firm
Submission of clarification regarding since the data/assay values in the stability studies are unjustifiable/irrational as there is no difference in assay values of initially submitted stability data (at 25 ± 2°c and 60 ± 5%RH) and the stability data submitted after issuance of letter (at 30 ± 2°c and 65 ± 5%RH). Since this ambiguity shows that the revised data (at 30 ± 2°c and 65 ± 5%RH) is not true.	Firm has submitted stability study data sheets duly signed by the authorized personnel of manufacturer of 3 batches 170613, 170614, 170615 conducted as per the conditions of zone IV-A. The data submitted is only for 6 months. Additionally the impurities identified at various time points exceeds the limit identified in acceptance criteria i.e. NMT 0.2%. The firm has NOT submitted any clarification regarding already submitted stability data sheets having same values at both conditions.
Detail of diluent to be used for reconstitution.	Firm has submitted details of preparation and administration of the applied formulation.
Clarification regarding formulation since USP specifies the formulation containing Oxaliplatin with Lactose monohydrate while submitted formulation by you contains Oxaliplatin and Mannitol	Firm has submitted that their principle manufacturer has informed that China FDA does not approve lactose as excipient of lyophilized powder instead they accept mannitol because it provides more stability.

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

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

	required.	criteria.
	Long term stability data of at least one year is required for grant of 2 years shelf life whereas you have provided data of 6 months with results of related substances out of specification.	Firm has submitted accelerated stability study stability data of 3 batches for one year instead of long term stability study data till claimed shelf life
	Decision of 289th meeting of Registration Board	Deferred for following submissions: • Real time stability study data of 3 batches as per zone IV-A for the complete shelf life. • Scientific justification for out of specification impurities (i.e. results greater than 0.2%) while the acceptance criteria was NLT 0.2%.
	Evaluation by PEC	Firm has submitted following documents: Real Time stability studies according to the conditions of zone IV-A for 2 years of following batches; Accelerated stability study data also submitted. • 12021800204 (Mfg date; June, 2017 & Exp. Date: June, 2020) • 12021800205 (Mfg date; June, 2017 & Exp. Date: June, 2020) • 12021800206 (Mfg date; June, 2017 & Exp. Date: June, 2020) The data is of different batches than the previously submitted batches and the impurity results of these batches are within limits.
	Decision: Registration Board approved the case as per policy for inspection of manufacturer abroad. Moroever the Board deliberated that as firm has submitted revised stability data thus it needs onsite verification and thus advised the inspection panel to verify and report the submitted stability data for applied product.	
104.	Name and address of manufacturer / Applicant	M/s Delta Pharma Pvt Ltd. Plot. No. 9, Nowshera Industrial Estate, Risalpur, Kpk, Pakistan
	Brand Name +Dosage Form +Strength	Excip 250mg/5ml Dry Powder Suspension
	Composition	Each 5ml Contains: Ciprofloxacin as Ciprofloxacin HCL…250mg
	Diary No. Date of R& I & fee	Dy. No 39937: 04-12-2018 PKR 20,000/- : 04-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ciproxin 250mg/5ml granules and solvent for oral suspension by Bayer (MHRA Approved)
	Me-too status	Novidat Dry Powder for Suspension by Sami Pharma
	GMP status	Firm is granted additional sections Oral liquid (general) and dry suspension (general) section on the basis of inspection dated 12-10-2018
	Remarks of the Evaluator.	• Justify the formulation containing ciprofloxacin as hydrochloride since the reference formulation approved by MHRA contains ciprofloxacin base. • Provide source of granules of ciprofloxacin since granulation process is not mentioned in method of manufacturing.
	Decision of 287th meeting of RB	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation
	Evaluation by PEC	• Source of pellets: Vision Pharmaceuticals • Firm has revised formulation as per reference product along with submission of 5,000 fee dated 07-02-2019. The revised formulation submitted by the firm is as: Each 5ml Contains: Ciprofloxacin …250mg

	Decision of 288th meeting of RB	Deferred for further deliberation upon the salt form of API, in view of reference product.
	Decision: Approved with following label claim: **Each 5ml after reconstitution Contains:** **Ciprofloxacin …….250mg**	
105.	Name and address of manufacturer / Applicant	M/s Delta Pharma Pvt Ltd. Plot. No. 9, Nowshera Industrial Estate, Risalpur, Kpk, Pakistan
	Brand Name +Dosage Form +Strength	Excip 125mg/5ml Dry Powder
	Composition	Each 5ml Contains: Ciprofloxacin as Ciprofloxacin HCL…125mg
	Diary No. Date of R& I & fee	Dy. No 39934: 04-12-2018 PKR 20,000/- : 04-12-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by Registration Board based on quantitative composition mentioned in SmPC of 250mg dry suspension
	Me-too status	Nafcin 125mg Suspension by Global Pharma
	GMP status	Firm is granted additional sections Oral liquid (general) and dry suspension (general) section on the basis of inspection dated 12-10-2018
	Remarks of the Evaluator.	• Justify the formulation containing ciprofloxacin as hydrochloride since the reference formulation approved by MHRA contains ciprofloxacin base. • Provide source of granules of ciprofloxacin since granulation process is not mentioned in method of manufacturing.
	Decision of 287th meeting of RB	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation
	Evaluation by PEC	• Source of pellets: Vision Pharmaceuticals • Firm has revised formulation as per reference product along with submission of 5,000 fee dated 07-02-2019. The revised formulation submitted by the firm is as: Each 5ml Contains: Ciprofloxacin …125mg
	Decision of 288th meeting of RB	Deferred for further deliberation upon the salt form of API, in view of reference product.
	Decision: Approved with following label claim **Each 5ml after reconstitution Contains:** **Ciprofloxacin …….250mg**	

Case No. 02 Registration Applications of Drugs for which Stability Study Data is Submitted

a. New Cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
106.	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area	Amlidy Tablet 25mg Each film coated tablet contains: Tenofovir alfenamide (as	Form 5D 03-09-2018 PKR 50,000/- (31-08-2018)	Vemlidy Tablet by Gilead Sciences (**USFDA** Approved)

	Karachi.	fumarate)……...25mg (Anti-viral)		29-01-2018. GMP rated as GOOD.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA			
Drug	Amlidy Tablet 25mg		
Name of Manufacturer	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area Karachi.		
Manufacturer of API	M/s. Shanghai Desano Chemical Pharmaceutical Co. Ltd. No. 417 Binhai Road, Laogang Town Pudong New Area Shanghai China.		
API Lot No.	DBH251-B15A-180702		
Description of Pack (Container closure system)	Yellow color round biconvex film coated tablet plain on both sides in Alu-Alu blister pack		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	NPD-T-374-P	NPD-T-359-L	NPD-T-388-P
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	23-10-2018	12-10-2018	25-10-2018
Date of Initiation	30-10-2018	30-10-2018	30-10-2018
No. of Batches	03		
Date of Submission	Dy.# 6507 dated 20-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Shanghai Food and Drug Administration
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice which is not clear
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcomings	Response by the firm
GMP certificate of the API manufacturer issued by relevant (i.e. provincial or federal) regulatory authority of China, since the submitted GMP has been issued by Shanghai Food and Drug Administration which is a district authority and does not have mandate to issue GMP certificate as per Chapter I General Provisions; Article 5 of Regulations for Implementation of the Drug Administration Law of the People's Republic of China.	Firm has submitted GMP certificate No. SH20170046 issued by China Food and Drug Administration which is valid till 03-12-2022.
Submit clear invoice attested by ADC in which the date of clearance along with signature / stamp is readable, since the submitted invoice is not clear.	Firm has submitted copy of commercial invoice which is cleared by ADC on 17-8-2018 specifying import of 0.47Kg tenofovir
Provide detailed method of testing / analysis of finished product.	Firm has submitted copy of testing method and analysis of finished drug.
Justify the acceptance criteria of dissolution test i.e. NLT 80% in 30 minutes without defining the time and value of "Q" since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. The FDA guidance "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" specifies under the heading DISSOLUTION ACCEPTANCE CRITERIA that *for immediate release solid oral drug products containing a high solubility drug substance, the dissolution criterion is Q=80% in 30 minutes*. Furthermore, USFDA chemistry review for the innovator product "Vemlidy Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in 15 minutes.	Firm has submitted commitment to revise the specification to NLT 80% (Q=75%) in 15 minutes. Firm has further submitted that they have tested the product at 9th month stability time point and the results are satisfactory in 15 minutes. • The dissolution results as per revised specification (i.e. NLT 80% in 15 minutes) at 9th month time point cannot be applied on 6 months real time and accelerated stability study data as per previous specifications i.e. NLT 80% in 30 minutes. • Firm has initiated stability studies on 10-2018 and the letter of shortcoming for difference in specifications was issued on 19-08-2019 (10 months after initiation of stability studies) and the firm has in its reply dated 28-08-2019 submitted that they have tested dissolution at 9th month time point.
Specify the exact storage conditions at which the API was kept after import in August 2018 till the manufacturing of batches in October 2018.	Firm has submitted that the storage condition recommended by its manufacturer is 2-8 degree and the firm has kept the material under the same conditions at MDL warehouse with continuous temperature monitoring.

Decision: Deferred for following:

- **Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 80% in 15 minutes] with values close to acceptance criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from innovator product [i.e. NLT 80% in 30 minutes].**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
107.	M/s S.J & G. Fazul Ellahie (Pvt) Ltd. E/46, S.I.T.E Karachi.	Berica Tablet 120mg Each film coated tablet contains: Etoricoxib ……120mg (Anti-viral)	Form 5D Dy No. 6671 19-6-2017 PKR 50,000/- (19-06-2017)	Acoxxel Tablet (**MHRA** Approved) GMP inspection report conducted on 20-04-2018

				& 24-04-2018, concluding satisfactory level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA			
Drug	Berica Tablet 120mg		
Name of Manufacturer	M/s S.J & G. Fazul Ellahie (Pvt) Ltd. E/46, S.I.T.E Karachi.		
Manufacturer of API	Glenmark Pharmaceutical Ltd, India.		
API Lot No.	ACE00616		
Description of Pack (Container closure system)	Single unit carton containing tablets in Alu-Alu blister pack		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	TR-065-17	TR-064-17	TR-063-17
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03-2017	03-2017	03-2017
Date of Initiation	15-4-2017	15-4-2017	15-4-2017
No. of Batches	03		
Date of Submission	Dy.# 7560 dated 29-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
#	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Administration Gujrat State India which is valid till 18-8-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 18-5-2016 specifying import of 100 Kg etoricoxib
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcomings	Response by the firm
Specify the manufacturer of API along with its address since the submitted GMP certificate is of Glenmark life sciences, while the COA and invoice specify Glenmark Pharmaceuticals. Further evidence is required for import of material from that particular source (along with address) since the submitted invoice do not contain address of API manufacturer.	Firm has submitted that the API was manufactured at the site Plot No. 141-143, 165-165, 170-172, Chandramouli Sahakari Audyogik Vashat Maryadit, Pune-Hydrerabad Highway, Mohol District Solapur. Firm has submitted a letter from Glenmark stating that Glenmark has re-organized itself by creating a wholly owned subsidiary for its API business to Glenmark Life Sciences. The agreement for this transfer was executed on 9th October 2018 and effective date for transfer was 1st December 2018. The wholy owned subsidiary for API business is now known as Glenmark Life Sciences Limited. Glenmark Life Sciences will be the API manufacturer of all API's from 1st December 2018 in place of Glenmark Pharmaceuticals. The API manufacturing sites at Ankleshwar, Dahej, Kurkumbh and Mhol will be transferred to Glenmark Life Sciences. The letter for re-organization of business was signed on 31st October 2018 and the re-organization was conducted from 1st December 2018. While the API was imported on 18-5-2016.
Provide scientific rational / justification for assay of finished product using UV method since the reference / innovator product has used HPLC method for assay of finished product.	Firm has submitted that "We used UV method for testing as it was already available for our registered product Berica Tablet 60mg. Although at 24 months' time point we have compared our results with HPLC method and found satisfactory results. This HPLC method will be validated and used before commercialization.
Justify the acceptance criteria of dissolution test i.e. NLT 75% without defining the time and value of "Q" since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. The FDA guidance "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" specifies under the heading **DISSOLUTION ACCEPTANCE CRITERIA** that for immediate release solid oral drug products containing a high solubility drug substance, the dissolution criterion is Q=80% in 30 minutes.	Firm has submitted that this molecule belongs to BCS class-II which have low solubility and high permeability therefore the limit of Q = 70% in 45 minutes was used (NLT 75%) which is Q+5. All our dissolution results are far higher than acceptance criteria.

Decision: Deferred for following:

- **Clarification for the address of API manufacturer since the submitted GMP certificate is of Glenmark life sciences, while the COA and invoice specify Glenmark Pharmaceuticals.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
108.	M/s S.J & G. Fazul Ellahie (Pvt) Ltd. E/46, S.I.T.E Karachi.	Berica Tablet 90mg Each film coated tablet contains: Etoricoxib ……90mg (Anti-viral)	Form 5D Dy No. 6672: 19-6-2017 PKR 50,000/- (19-06-2017)	Acoxxel Tablet (MHRA Approved) GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Berica Tablet 90mg		
Name of Manufacturer	M/s S.J & G. Fazul Ellahie (Pvt) Ltd. E/46, S.I.T.E Karachi.		
Manufacturer of API	Glenmark Pharmaceutical Ltd, India.		
API Lot No.	ACE00616		
Description of Pack (Container closure system)	Single unit carton containing tablets in Alu-Alu blister pack		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months	Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months)	Real Time: 0, 3, 6 (Months)	
Batch No.	TR-062-17	TR-061-17	TR-060-17
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	03-2017	03-2017	03-2017
Date of Initiation	15-4-2017	15-4-2017	15-4-2017
No. of Batches	03		
Date of Submission	Dy.# 7561 dated 29-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Food and Drug Administration Gujrat State India which is valid till 18-8-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 18-5-2016 specifying import of 100 Kg etoricoxib

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcomings	Response by the firm
Specify the manufacturer of API along with its address since the submitted GMP certificate is of Glenmark life sciences, while the COA and invoice specify Glenmark Pharmaceuticals. Further evidence is required for import of material from that particular source (along with address) since the submitted invoice do not contain address of API manufacturer.	Firm has submitted that the API was manufactured at the site Plot No. 141-143, 165-165, 170-172, Chandramouli Sahakari Audyogik Vashat Maryadit, Pune-Hydrerabad Highway, Mohol District Solapur. Firm has submitted a letter from Glenmark stating that Glenmark has re-organized itself by creating a wholly owned subsidiary for its API business to Glenmark Life Sciences. The agreement for this transfer was executed on 9th October 2018 and effective date for transfer was 1st December 2018. The wholy owned subsidiary for API business is now known as Glenmark Life Sciences Limited. Glenmark Life Sciences will be the API manufacturer of all API's from 1st December 2018 in place of Glenmark Pharmaceuticals. The API manufacturing sites at Ankleshwar, Dahej, Kurkumbh and Mhol will be transferred to Glenmark Life Sciences. The letter for re-organization of business was signed on 31st October 2018 and the re-organization was conducted from 1st December 2018. While the API was imported on 18-5-2016.
Provide scientific rational / justification for assay of finished product using UV method since the reference / innovator product has used HPLC method for assay of finished product.	Firm has submitted that "We used UV method for testing as it was already available for our registered product Berica Tablet 60mg. Although at 24 months' time point we have compared our results with HPLC method and found satisfactory results. This HPLC method will be validated and used before commercialization.
Justify the acceptance criteria of dissolution test i.e. NLT 75% without defining the time and value of "Q" since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. The FDA guidance "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" specifies under the heading **DISSOLUTION ACCEPTANCE CRITERIA** that for immediate release solid oral drug products containing a high solubility drug substance, the dissolution criterion is Q=80% in 30 minutes.	Firm has submitted that this molecule belongs to BCS class-II which have low solubility and high permeability therefore the limit of Q = 70% in 45 minutes was used (NLT 75%) which is Q+5. All our dissolution results are far higher than acceptance criteria.

Decision: Deferred for following:

- **Clarification for the address of API manufacturer since the submitted GMP certificate is of Glenmark life sciences, while the COA and invoice specify Glenmark Pharmaceuticals.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
109.	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.	Vemteno Tablet 25mg Each film coated tablet contains: Tenofovir alfenamide (as fumarate) ….25mg (Anti-viral)	Form 5 27-02-2019 PKR 20,000/- (27-02-2019)	Vemlidy Tablet by Gilead Sciences (**USFDA** Approved) GMP inspection report conducted on 20-04-2018 & 24-04-2018, concluding satisfactory level of GMP compliance.
	Evaluation by PEC: Firm has submitted accelerated and real time stability data of 6 months as per the requirement of Registration Board.			

STABILITY STUDY DATA

Drug	Vemteno Tablet 25mg		
Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt) Ltd. 62 Quaid-e-Azam Industrial Estate Kot Lakhpat Lahore.		
Manufacturer of API	Cipla Ltd. at plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune Mahrashtra India		
API Lot No.	LDP170006		
Description of Pack (Container closure system)	Pink round biconvex shape film coated tablet packed in Alu-Alu in bleach board with leaflet		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months	Accelerated: 6 months	
Frequency	Accelerated: 0, 3, 6 (Months)	Real Time: 0, 3, 6 (Months)	
Batch No.	T2/17	T3/17	T4/17
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	07-2017	08-2017	07-2017
Date of Initiation	08-2017	08-2017	08-2017
No. of Batches	03		
Date of Submission	Dy.# 7194 dated 25-05-2019		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Government of Karnataka, Drugs Control Department dated 21-02-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 24-02-2017 specifying import of 0.21Kg tenofovir alafenamide fumarate. The exact manufacturing site of the API manufacturer is not mentioned in the submitted invoice.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcomings	Response by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 70% Q after 30 minutes since the value of "Q" since the value of Q at level S1 is defined between 75 to 80 in various guidance documents of EDQM, FDA guidance documents and USP and the overall acceptance criteria for level S1 is set as Q+5. The FDA guidance "Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances" specifies under the heading **DISSOLUTION ACCEPTANCE CRITERIA** that *for immediate release solid oral drug products containing a high solubility drug substance (as defined herein), the dissolution criterion is Q=80% in 30 minutes.* Furthermore, USFDA chemistry review for the innovator product "Vemlidy Tablet" specifies that the acceptance criteria for dissolution test is NLT (Q+5) in **15** minutes.	Firm has submitted that as per CDP performed their results show more than 85% release in 15 minutes in Acetate Buffer pH 4.5. Initially we have used parameters taken from USFDA dissolution methods but after your good self highlighted the document of chemistry review, which suggests sampling time of 15 minutes. It is acknowledge & commit to revise product test method with revised sampling time and Q value which can be verified during on-site inspection. **Dissolution Specifications of the firm**: NLT 70% (Q) after 30 minutes **Dissolution Specifications of innovator product**: NLT 80%(Q) after 15 minutes Firm has performed complete stability studies as per the specification which is different from innovator product. Further the dissolution testing during CDP studies or at 9th month interval cannot be used to predict the product quality profile in terms of dissolution studies during 6 months accelerated study as well as during real time studies.
Specify the exact storage conditions at which the API was kept after ADC clearance in February 2017 till the manufacturing of batches in July and August 2017.	Firm has submitted that they have kept the material at 2-8 degree which is the recommended storage condition for this drug.
The submitted GMP certificate is of Cipla Limited Old Madras Road Virgonagar Post Bangalore (No. NB-110/78), while as per certificate of analysis the manufacturing site of API is Cipla Ltd. Plot D-22, MIDC Industrial Area, Kurkumbh Village, Taluka – Daund, District Pune, Mahrashtra. Clarify the exact manufacturing site and submit the GMP certificate.	Firm has submitted that the exact manufacturing site is Cipla Ltd. at plot D-22, MIDC Industrial Area Kurkumbh Village, Taluka Daund District Pune Mahrashtra India. The GMP certificate of said site can be verified during on-site inspection. **The firm has not submitted GMP certificate of the API manufacturer.**

Firm has performed 3rd month testing of batch T4-17 on 16-11-2017 which is 15 days earlier than 3 months period. Firm has submitted that as per their protocols they can test the product within 1 month of due date.

Decision: Deferred for following:

- **Scientific justification how the CDP studies or stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 80% (Q) in 15 minutes] with values close to acceptance**

criteria can be representative of whole 6 months stability conducted at accelerated and real time conditions with dissolution specifications different from innovator product [i.e. NLT 70% (Q) after 30 minutes].

- **Submission of valid GMP certificate from API manufacturer.**

Agenda of Evaluator PEC-IV

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

a. New cases

110.	Name and address of manufacturer / Applicant	M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Blucid-H Cream
	Composition	Each Gram Contains: Fusidic Acid……20mg Hydrocortisone Acetate…….10mg
	Diary No. Date of R& I & fee	Dy.No. 17088 dated 09-05-2018 Rs.20,000/- 09-05-2018
	Pharmacological Group	Antibiotic, Corticosteroid
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	5gram, 15grams; As per SRO
	Approval status of product in Reference Regulatory Authorities	Fucidin H Cream (UK MHRA Approved)
	Me-too status (with strength and dosage form)	Melas H Cream of M/s Atco Laboratories
	GMP status	"Cetificate of Good manufacturing practices based on inspection conducted on 19-07-2019"
	Remarks of the Evaluator	Strength on form 5 Fusidic Acid……20mg Hydrocortisone Acetate…….10mg while on covering letter and challan form Fusidic Acid……10mg Hydrocortisone Acetate…….05mg. Reply that strength on challan form & covering letter was due to clerical mistake. We undertake on stamp paper of Rs: 100/- that challan form Depositer Slip No. 0718283) will not be misused and will be used as registration fee of Blucid-H cream (Fusidic Acid……20mg , Hydrocortisone Acetate…….10mg) only
	Decision: Approved with innovator's specification.	
111.	Name and address of manufacturer / Applicant	M/s Farm Aid Group. Plot # 3/2, Phase I & II, Hattar Industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	Orlis 120mg Capsule
	Composition	Each Hard Gelatin Capsule Contains: Orilstat IR Pellets Eq. to Orlistat…..…120mg
	Diary No. Date of R& I & fee	Dy.No. 17069 dated 09-05-2018 Rs.20,000/- 08-05-2018
	Pharmacological Group	Lipase inhibitor
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Beacita 120mg Capsules of (MHRA approved)
	Me-too status	Orlisat 120mg Capsules by M/s Merck Sharp & Dhome,
	GMP status	Last GMP inspection conducted on 07-09-2017 and report concludes that Overall the firm was working under satisfactory level of GMP."
	Remarks of the Evaluator	Source of pellets: Vision
	Decision: The Registration Board deferred for further deliberation upon stability data requirement for orlistat pellets.	

112.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi Contract manufactured by: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Arfacobol 500mcg Injection
	Composition	Each ml Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy.No. 17056 dated 08-05-2018 Rs.50,000/- 08-05-2018
	Pharmacological Group	Co-enzyme-type vitamin B12
	Type of Form	Form 5
	Finished product Specification	Manufacture's specification
	Pack size & Demanded Price	5ml x 5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA approved
	Me-too status	Wycomin 500 mcg Injection by Wnsfeild Pharmaceutical,
	GMP status	Last GMP inspection M/s Adamjee Pharmaceuticals conducted on 20-08-2019 and report concludes that based on the stated observations their current compliance level is rated as Good." & Last GMP inspection of M/s Safe Pharmaceuticals conducted 31-07-2018.and report concludes that overall the firm was working under GOOD level of GMP compliance.
	Remarks of the Evaluator	• Contract manufacturing agreement attached • Number of sections of applicant approved by licensing Board: 08 • Number of products already registered/approved on contract manufacturing in the name of applicant:09
	Decision: Approved with innovator's specification.	
113.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi Contract manufactured by: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Ferobin 100mg/5ml Injection
	Composition	Each 5ml Contains: Iron as Iron (III)-hydroxide sucrose complex……..100mg
	Diary No. Date of R& I & fee	Dy.No. 17057 dated 08-05-2018 Rs.50,000/- 08-05-2018
	Pharmacological Group	Iron replacement product
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml x 5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Venofer 100mg/5ml Injection of MHRA approved
	Me-too status	Bisleri 100mg/5ml Injection of M/S Sami Pharma
	GMP status	Last GMP inspection M/s Adamjee Pharmaceuticals conducted on 20-08-2019 and report concludes that based on the stated observations their current compliance level is rated as Good." & Last GMP inspection of M/s Safe Pharmaceuticals conducted 31-07-2018.and report concludes that Overall the firm was working under GOOD level of GMP compliance.
	Remarks of the Evaluator	• Contract manufacturing agreement attached

		• Number of sections of applicant approved by licensing Board: 08 • Number of products already registered/approved on contract manufacturing in the name of applicant:09
	Decision: Approved.	
114.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi Contract manufactured by: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Water For Injection 5ml Ampoule
	Composition	Each 5ml Contains: Water for Injection…5ml
	Diary No. Date of R& I & fee	Dy.No. 17058 dated 08-05-2018 Rs.50,000/- 08-05-2018
	Pharmacological Group	Diluent/Vehicle
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Aqua-Nor Injection by M/s Nortech Pharmaceuticals,
	GMP status	Last GMP inspection M/s Adamjee Pharmaceuticals conducted on 20-08-2019 and report concludes that based on the stated observations their current compliance level is rated as Good." & Last GMP inspection of M/s Safe Pharmaceuticals conducted 31-07-2018.and report concludes that Overall the firm was working under GOOD level of GMP compliance.
	Remarks of the Evaluator	• Contract manufacturing agreement attached • Number of sections of applicant approved by licensing Board: 08 • Number of products already registered/approved on contract manufacturing in the name of applicant:09
	Decision: Approved.	
115.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi Contract manufactured by: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Smaz 40mg Injection
	Composition	Each Vial Contains: Esomeprazole Sodium Eq. to Esomeprazole……..40mg
	Diary No. Date of R& I & fee	Dy.No. 17053 dated 08-05-2018 Rs.50,000/- 08-05-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacture's specification
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Nexium IV injection of (USFDA approved)
	Me-too status	Esold Injection of M/s Weather Folds Pharmaceutical
	GMP status	Last GMP inspection M/s Adamjee Pharmaceuticals conducted on 20-08-2019 and report concludes that based on the stated observations their current compliance level is rated as Good." & Last GMP inspection of M/s Safe Pharmaceuticals

		conducted 31-07-2018.and report concludes that Overall the firm was working under GOOD level of GMP compliance.
	Remarks of the Evaluator	• Contract manufacturing agreement attached • Number of sections of applicant approved by licensing Board: 08 • Number of products already registered/approved on contract manufacturing in the name of applicant:09
	Decision: Approved with innovator's specification.	
116.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi Contract manufactured by: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Adazone 2g/Vial Injection IV
	Composition	Each Vial of Dry Subsatnce Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…2g
	Diary No. Date of R& I & fee	Dy.No. 17054 dated 08-05-2018 Rs.50,000/- 08-05-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone of MHRA approved
	Me-too status	Triax 2gm Injection of M/s. Wilshire Laboratories
	GMP status	Last GMP inspection M/s Adamjee Pharmaceuticals conducted on 20-08-2019 and report concludes that based on the stated observations their current compliance level is rated as Good." & Last GMP inspection of M/s Safe Pharmaceuticals conducted 31-07-2018.and report concludes that Overall the firm was working under GOOD level of GMP compliance.
	Remarks of the Evaluator	• Contract manufacturing agreement attached • Number of sections of applicant approved by licensing Board: 08 • Number of products already registered/approved on contract manufacturing in the name of applicant:09
	Decision: Approved.	
117.	Name and address of manufacturer / Applicant	M/s Adamjee Pharmaceuticals Pvt Ltd. Plot 39, Sector 15, Korangi Industrial Area, Karachi Contract manufactured by: M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Bonfit 5mg/ml Injection
	Composition	Each ml Contains: Cholecalciferol……5mg
	Diary No. Date of R& I & fee	Dy.No. 17055 dated 08-05-2018 Rs.50,000/- 08-05-2018
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished product Specification	BP Spec's
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too status	Calciferol Injection M/s Global Pharmaceuticals
	GMP status	Last GMP inspection M/s Adamjee Pharmaceuticals conducted on 20-08-2019 and report concludes that based on the stated observations their current compliance level is

		rated as Good." & Last GMP inspection of M/s Safe Pharmaceuticals conducted 31-07-2018.and report concludes that Overall the firm was working under GOOD level of GMP compliance.
	Remarks of the Evaluator	• Contract manufacturing agreement attached • Number of sections of applicant approved by licensing Board: 08 • Number of products already registered/approved on contract manufacturing in the name of applicant:09
	Decision: Approved.	
118.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aslav 160mg/5mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine (as Besylate)…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier; dated :30-12-2014
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Of (USFDA Approved)
	Me-too status	Co-Valzaar 5mg/160mg Tablet by M/s Vision Pharma
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
119.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aslav 160mg/10mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine (as Besylate)…10mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier; dated :30-12-2014
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Of (USFDA Approved)
	Me-too status	Co-Valzaar 10mg/160mg Tablet by M/s Vision Pharma
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
120.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Valarb-Diu 80mg/12.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…….80mg Hydrochlorothiazide ……12.5mg

	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier; dated :30-12-2014
	Pharmacological Group	Thiazide Diuretic /Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan Of (MHRA Approved)
	Me-too status	Co-Diovan Of M/S Novartis Pharma
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
121.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Valarb-Diu 160mg/25mg Tablet
	Composition	Each Film Coated Tablet Contains: Valsartan…….160mg Hydrochlorothiazide ……25mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier; dated :30-12-2014
	Pharmacological Group	Thiazide Diuretic /Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Co-Diovan Of (MHRA Approved)
	Me-too status	Co-Diovan Of M/S Novartis Pharma
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
122.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aslav-D 5mg/12.5mg/160 Tablet
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……5mg Hydrochlorothiazide(USP)……....12.5mg Valsartan(USP) ……...160mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :30-12-2014
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge HCT 10/160/12.5 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069548)
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	

123.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aslav-D 10mg/12.5mg/160 Tablet
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……10mg Hydrochlorothiazide(USP)……....12.5mg Valsartan(USP) ……...160mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :30-12-2014
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge HCT 10/160/12.5 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069548)
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
124.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aslav-D 10mg/25mg/160 Tablet
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……10mg Hydrochlorothiazide(USP)……....25mg Valsartan(USP) ……...160mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :30-12-2014
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge HCT 10/160/25 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069551)
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
125.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Aslav-D 10mg/25mg/320 Tablet
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……10mg Hydrochlorothiazide(USP)……....25mg Valsartan(USP) ……...320mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :30-12-2014
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge HCT 10/160/25 by Novartis (USFDA)

	Me-too status	Exforge HCT By Novartis (Reg. No. 069552)
	GMP status	Last GMP inspection conducted on 20-03-2018 and report concludes that considered to be operating at an acceptable level of compliance to the CGMP
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
126.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi..
	Brand Name +Dosage Form + Strength	Locame 4mg Tablet
	Composition	Each film coated tablet contains: Lornoxicam…4mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :24-05-2017
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's, 1 x 20's, 1 x 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg tablet (EMA approved)
	Me-too status	Lorfix 4mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
127.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi..
	Brand Name +Dosage Form + Strength	Locame 8mg Tablet
	Composition	Each film coated tablet contains: Lornoxicam……..8mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :24-05-2017
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's, 1 x 20's, 1 x 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too status	Lorfix 8mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
128.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi..
	Brand Name +Dosage Form + Strength	Amlove 5mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine (as Besylate)…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier; dated :08 -11-2017
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 7's & 2 x 14's: As per SRO
	Approval status of product in	Exforge Of (USFDA Approved)

	Reference Regulatory Authorities	
	Me-too status	Co-Valzaar 5mg/160mg Tablet by M/s Vision Pharma
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
129.	**Name and address of manufacturer / Applicant**	**M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi, Pakistan.**
	Brand Name +Dosage Form + Strength	Paxtan CR 25mg Tablet
	Composition	Each enteric , film coated Tablet Contains: Paroxetine HCl eq to Paroxetine……..…25mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :25-05-2017
	Pharmacological Group	Selective serotonin-reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's, : As per SRO
	Approval status of product in Reference Regulatory Authorities	PAXIL CR of (USFDA approved)
	Me-too status	Panox CR Tablet 25 mg M/s Regal Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
130.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi..
	Brand Name +Dosage Form + Strength	Tryit 50mg Tablet
	Composition	Each film coated Tablet Contains: Itopride as HCL…50mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated : 24-05-2017
	Pharmacological Group	Prokinetics
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's , 1 x 20's, 1 x 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved
	Me-too status	Itop 50mg Tablet by M/s Nexus.
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
131.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi..
	Brand Name +Dosage Form + Strength	Quiq XR 200mg Tablet
	Composition	Each Extended release Film Coated Tablet Contains: Quetiapine Fumarate eq. to Quetiapine…….200mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :12-06-2017
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's, 1 x 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	SEROQUEL XR (of USFDA approved)
	Me-too status	Pine XR Tablet of M/s. Werrick Pharmaceuticals
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
132.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi..
	Brand Name +Dosage Form + Strength	Linco 500mg Capsule
	Composition	Each Capsule contains: Lincomycin HCl eq to Lincomycin…….500mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :21-04-2016
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1 x 12's, 1 x100's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lincocine 500 mg Capsule by M/s Pfizer Holding France (ANSM approved)
	Me-too status	F-Linco 500mg capsule by M/s Fresh Pharmaceuticals
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
133.	Name and address of manufacturer / Applicant	M/s Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi..
	Brand Name +Dosage Form + Strength	Fosil 3gm Sachet
	Composition	Each Sachet contains: Fosfomycin Trometamol eq to Fosfomycin……3gm
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :13-07-2017
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	1 x 1's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Monuril Sachet (MHRA Approved)
	Me-too status	Fosib 3gm Sachet by M/s Ciba Pharma (Reg.#081515)
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
134.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medivorxin 2.5mg Tablet
	Composition	Each film coated Tablet Contains: Rivaroxaban……2.5mg
	Diary No. Date of R& I & fee	Dy.No. 32240 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Anticoagulant

	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 2.5mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 2.5mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
135.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medivorxin 10mg Tablet
	Composition	Each film coated Tablet Contains: Rivaroxaban……10mg
	Diary No. Date of R& I & fee	Dy.No. 32241 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 10mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 10mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
136.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medivorxin 15mg Tablet
	Composition	Each film coated Tablet Contains: Rivaroxaban……15mg
	Diary No. Date of R& I & fee	Dy.No. 32242 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 15mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 15mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
137.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Medivorxin 20mg Tablet
	Composition	Each film coated Tablet Contains: Rivaroxaban……20mg
	Diary No. Date of R& I & fee	Dy.No. 32243 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 20mg tablet Of (USFDA Approved)
	Me-too status	Xarelto 20mg Tablet Of M/S Bayer
	GMP status	Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
138.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Noxi-Med 4mg Tablet
	Composition	Each film coated Tablet Contains: Lornoxicam……4mg
	Diary No. Date of R& I & fee	Dy.No. 32235 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg tablet (EMA approved)
	Me-too status	Lorfix 4mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
139.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karchi, Pakistan
	Brand Name +Dosage Form + Strength	Noxi-Med 8mg Tablet
	Composition	Each film coated Tablet Contains: Lornoxicam……8mg
	Diary No. Date of R& I & fee	Dy.No. 32236 dated 27-09-2018 Rs.20,000/- 27-09-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg tablet (EMA approved)
	Me-too status	Lorfix 8mg Tablet of M/s AGP
	GMP status	Last GMP inspection conducted on 15-12-2017 and report concludes was considered to be operating at acceptable level of compliance with GMP guidelines
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
140.	Name and address of manufacturer / Applicant	M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi.
	Brand Name +Dosage Form + Strength	Xantra 500mg Injection
	Composition	Each 5ml Contains: Tranexamic Acid…500mg
	Diary No. Date of R& I & fee	Dy.No. 32067 dated 26-09-2018 Rs.20,000/- 26-09-2018
	Pharmacological Group	Antifibrinolytic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	5mlx 5's & 5ml x 10's :As per SRO
	Approval status of product in	TGA approved

	Reference Regulatory Authorities	
	Me-too status	Dravix 250mg/5ml Injection of Getz Pharma Karachi
	GMP status	Last GMP inspection conducted on 11/12/17 and report concludes at the time of inspection found at acceptable level
	Remarks of the Evaluator	
	Decision: Approved.	
141.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Atasart 4mg Tablet
	Composition	Each tablet Contains: Candesartan cilexetil…….4mg
	Diary No. Date of R& I & fee	Dy.No. 15717 dated 20-09-2017 Rs.20,000/- 20-09-2017
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, x 20's, 28's & 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND of USFDA approved
	Me-too status	Canex 4mg Tablets of Wellborne Pharmachem and Biologicals,
	GMP status	Last GMP inspection conducted on 10/04/18 and report concludes firm was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of the Evaluator	
	Decision: Approved.	
142.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Atasart 8mg Tablet
	Composition	Each tablet Contains: Candesartan cilexetil…8mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate dossier: Rs.20,000/- Dated 20-9-2017 (Duplicate dossier)
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, x 20's, 28's & 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND of USFDA approved
	Me-too status	Canex 8mg Tablets of Wellborne Pharmachem and Biologicals,
	GMP status	Last GMP inspection conducted on 10/04/18 and report concludes firm was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of the Evaluator	
	Decision: Approved.	
143.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Atasart Plus 16mg/12.5mg Tablet
	Composition	Each tablet Contains: Candesartan cilexetil…16mg Hydrochlorothiazide……..12.5mg
	Diary No. Date of R& I & fee	Dy.No. 15755 dated 20-09-2017 Rs.20,000/- 20-09-2017
	Pharmacological Group	Antihypertensive drug
	Type of Form	Form 5
	Finished product Specification	USP

	Pack size & Demanded Price	10's, 14's, x 20's, 28's & 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	ATACAND HCT of USFDA approved
	Me-too status	Prosartan-Du 16/12.5 of Helix Pharma
	GMP status	Last GMP inspection conducted on 10/04/18 and report concludes firm was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of the Evaluator	
	Decision: Approved.	
144.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Monti-F 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Montelukast as Sodium…10mg
	Diary No. Date of R& I & fee	Dy.No. 1069 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Singulair Of (MHRA Approved)
	Me-too status	Mecost 10mg Tablet M/s Sigma
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes firm was Overall the firm was GMP Compliant as per DRAP Guidelines."
	Remarks of the Evaluator	
	Decision: Approved.	
145.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Thiza 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin as Dihydrate…500mg
	Diary No. Date of R& I & fee	Dy.No. 1064 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Pharmacological Group	Antibiotic (Macrolide)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Azithromycin tablet of (MHRA approved)
	Me-too status	Azic 500mg Tablet by M/s NabiQasim
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes firm was Overall the firm was GMP Compliant as per DRAP Guidelines."
	Remarks of the Evaluator	
	Decision: Approved.	
146.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	W-Bast 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Ebastine…10mg
	Diary No. Date of R& I & fee	Dy.No. 1066 dated 08-01-2018 Rs. 20,000/- 08-01-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	EBASTINE ARROW 10 mg film-coated tablets

	Reference Regulatory Authorities	ANSM Approved
	Me-too status	Atmos Tablets 10mg of M/s Scotmann Pharmaceuticals
	GMP status	Last GMP inspection conducted on 15-09-2017 and report concludes firm was Overall the firm was GMP Compliant as per DRAP Guidelines."
	Remarks of the Evaluator	
	Decision: Approved.	
147.	Name and address of manufacturer / Applicant	M/S Sigma Pharma International (Pvt) Ltd. Plot # E-50 North Western Industrial Zone,Bin Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Erdes 225mg Sachet
	Composition	Each Sachet contains: Erdosteina….225mg
	Diary No. Date of R& I & fee	Dy.No. Duplicate Dossier: dated :24-05-2017
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	5's : As per SRO
	Approval status of product in Reference Regulatory Authorities	AIFA , Italy approved
	Me-too status	Dostin Sachets 225mg of M/s Brookes Pharmaceutical
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes On the basis of observation made by the panel it is concluded that firm has acceptable level of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
148.	Name and address of manufacturer / Applicant	M/s Hudson Pharma (Pvt.) Ltd. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Karachi
	Brand Name +Dosage Form + Strength	Xantra 250mg Injection
	Composition	Each 5ml Contains: Tranexamic Acid……250mg
	Diary No. Date of R& I & fee	Dy.No. 32066 dated 26-09-2018 Rs.20,000/- 26-09-2018
	Pharmacological Group	Antifibrinolytic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	5mlx 5's & 5ml x 10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	PMDA approved
	Me-too status	Dravix 250mg/5ml Injection of Getz Pharma Karachi
	GMP status	Last GMP inspection conducted on 11/12/17 and report concludes at the time of inspection found at acceptable level
	Remarks of the Evaluator	
	Decision: Approved.	

b. Deferred cases

149.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Neurosol Injection
	Composition	Each 3ml contains: Thiamine Hydrochloride(USP)..…100mg Pyridoxine Hydrochloride(USP)…..100mg Cyanocobalamin (USP)……1000mcg
	Diary No. Date of R& I & fee	Diary No: 23918 dated 11-07-2018 Rs.20,000/- Dated 10-07-2018
	Pharmacological Group	B-complex vitamin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	1's, 25's / As per SRO
	Approval status of product in Reference Regulatory Authorities	Neurobion Injection by M/s Merck (Germany) Merck KgaA,
	Me-too status (strength & dosage form)	Neurobion Injection by Merck (Reg. No. 001485)
	GMP status	Last GMP inspection conducted on 29-05-2017, 30-05-2017 & 13-07-2017, 03-04-2017 and report concludes that panel recommends the grant of drug manufacturing license.
	Previous remarks of the Evaluator.	Initially firm applied Thiamine Hydrochloride(USP)..…100mg Pyridoxine Hydrochloride(USP)…..100mg Cyanocobalamin (USP)……100mcg Now firm correct the formulation Thiamine Hydrochloride(USP)..…100mg Pyridoxine Hydrochloride(USP)…..100mg Cyanocobalamin (USP)……1000mcg With submission of fee Rs: 5000/- Challan No# 0778957 Dated: 28-08-2019
	Previous decision(s)	Deferred for following reasons: Deferred for submission of fee for revision of formulation.(M-291)
	Evaluation by PEC	Firm suibmitted Remaing fee of RS: 15000/- through Challan No: 0725177 dated: 23-09-2019
	Decision: Approved with innovator's specification.	

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

a. New DML

150.	Name and address of manufacturer / Applicant	M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Hi-Gyl 200mg/5ml Oral Suspension
	Composition	Each 5ml of Suspension Contains: Metronidazole Benzoate Eq. to Metronidazole…200mg
	Diary No. Date of R& I & fee	Dy.No. 8934 dated 28-02-2019 Rs.50,000/- 27-02-2019
	Pharmacological Group	Antiprotozoal/Antiinfective/Antiamebic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	60ml, 90ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Mogel 200mg Suspension of M/s Metro Pharmaceuticals
	GMP status	DML issued on 3-12-2018
	Remarks of the Evaluator	
	Decision: Approved.	
	Name and address of manufacturer / Applicant	**M/s Dew-Max Pharmaceutical Pvt Ltd. Plot No.6, Street # SS-4, National Industrial Zone, Rawat, Islamabad, Pakistan**
	Brand Name +Dosage Form + Strength	CO-Fylin Liquid Syrup
	Composition	Each 5ml of Liquid Syrup Contains: Acefylline Piperazine…45mg Diphenhydramine HCL…8mg
	Diary No. Date of R& I & fee	Dy.No 40558 dated 06-12-2018 Rs.20,000/- 05-12-2018
	Pharmacological Group	Antihistamine / xanthines
	Type of Form	Form 5
	Finished product Specification	Innovators Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed

	Me-too status	Acefyl cough Syrup by Nabiqasim
	GMP status	DML issued on 3-12-2018
	Remarks of the Evaluator	Evidence in RRA
	Previous Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting**(M-287)**	
	Response of firm: Ther firm has submitted for withdrawal of this application and in leiu of that has requested to consider the above preseneted application of "Hi-Gyl 200mg/5ml Oral Suspension" against the priority quota of new of DML	
	Decision: Registration Board acceded with firm's request and decided to reject the application of "CO-Fylin Liquid Syrup" and in leiu of that considered the application of "Hi-Gyl 200mg/5ml Oral Suspension"	

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

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

151.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Evrilus 5mg Tablet
	Composition	Eact tablet contains: Everolimus…..5mg
	Diary No. Date of R& I & fee	Dy.No. 41416 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Anti-neoplastic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	5 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Afinitor 5mg Tablets of (USFDA approved)
	Me-too status	Afinitor 5mg Tablets Of M/S Novartis Pharma
	GMP status	Last GMP inspection conducted on 11-03-2017 and report concludes that of GMPwas satisfactory
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
152.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Leluno 20mg Tablet
	Composition	Each film coated Tablet Contains: Leflunomide…20mg
	Diary No. Date of R& I & fee	Dy.No. 41958 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Immunosuppressant/ Sodium channel inactivator
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's :As per SRO
	Approval status of product in Reference Regulatory Authorities	Arava 20 mg of (MHRA approved)
	Me-too status	Opus Tablets 20mg by M/s Scotmann Pharmaceutical
	GMP status	Last GMP inspection conducted on 31-07-2018and report concludes that GOOD level of GMP compliance.
	Remarks of the Evaluator	The firm change formulation from "uncoated tablet" to "film coated" without submission of fee.
	Decision: Deferred for submission of fee for revision of formulation	
153.	Name and address of manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt Ltd. Plot No. C.I-20, Sector 6-B, Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Raiba 400mg Capsule

	Composition	Each Capsule Contains: Ribavirin…400mg
	Diary No. Date of R& I & fee	Dy.No. 41977 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Anti viral
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Ribuvir 400mg Capsule of M/s Martin Dow
	GMP status	Last GMP inspection conducted on 31-07-2018and report concludes that GOOD level of GMP compliance.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
154.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt Ltd, Plot #2, Street #4, National Industrial Zone, Rawat, islamabad
	Brand Name +Dosage Form + Strength	Rhomed 20mg Tablet
	Composition	Each film coated Tablet Contains: Leflunomide…20mg
	Diary No. Date of R& I & fee	Dy.No. 41444 dated 07-12-2018 Rs.20,000/- 07-12-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	3 x 10's : As per SRO
	Approval status of product in Reference Regulatory Authorities	Arava 20 mg of (MHRA approved)
	Me-too status	Opus Tablets 20mg by M/s Scotmann Pharmaceutical
	GMP status	Last GMP inspection conducted on 07-11-2018 and report concludes that overall GMP compliance is found Good of today.
	Remarks of the Evaluator	
	Decision: Registration Board approved registration of product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	

Case no. 04 Registration Applications of Import Cases.

a. Deferred Cases

i. Human

155.	Name and address of Applicant	M/s Al-Qasim Enterprises, Flat# 4, Minhas Plaza, Second floor, Munawar Colony, Adiala Road Rawalpindi, (Pakistan) Head office: 55 Block B, Faisal town Lahore, Pakistan
	Detail of Drug Sale License	Address Flat# 4, Minhas Plaza, Second floor, Munawar Colony, Adiala Road Rawalpindi, (Pakistan) **Validity :** 19/01/2019 **Status:** to stock, sale and distribute drugs
	Name and address of manufacturer	M/s ERIOCHEM, S.A. Ruta 12- Km 452 3107 Colonia Avellaneda- Entre Rios Argentina
	Name and address of marketing authorization holder	M/s TAARANG, S.A Balmes, 84- 4º – 2ª 08008 Barcelona Espana/Spain

	Name of exporting country	Argentina (Spain)
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 12534 Dated : 05/04/2018
	Fee including differential fee	Rs : 1,00,000 Dated : 04/05/2018
	Brand Name +Dosage Form + Strength	Pemetrexed 500mg Powder for Concentrate for infusion (Presentation of 50ml vial)
	Composition	Vial contains : Active Ingredients Pemetrexed (as disodium)……..500mg Other ingredients Mannitol……....500mg Hydochloric Acid Concentrated……..PH 7.2 (q.s.) Sodium Hydroxide (E-524)……. PH 7.2 (q.s.)
	Finished Product Specification	Inhouse Specifications
	Pharmacological Group	Anticance, Antifolate agent
	Shelf life	36 months
	Demanded Price	Rs; 69,000/- per Vial
	Pack size	1's (50ml)
	International availability	ALMITA of USFDA Approved
	Me-too status	Alimta 500mg Injectable Of Eli Lilly
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2017/03376 **Certified by:** AGNCIA ESPANOLA DEL MEDICAMENTO Y PRODUCTOS SANITARIOS C/ Campezo nº 1 – edif 8 28022 Madrid Espana/Spain **Issued on :** 21/12/2017 **Free sale:** Free sale of the product in exporting country.: **No** **GMP certificate** GMP inspection conducted by Spainish agency on 12-04-2016 GMP certificate No : ES/113HV/16 Signed dated: 27-07-2016 Valid for 3 years **Sole Contract Agreement** 11-10-2017
	Remarks of the Evaluator.	• COPP show no free sale in license holding country. • Firm reply: There is an existing usage patent that prevents Pemetrexed medicinal products from being marketed in EU countries, however after the expiry of the pateent the product may be launched in the market.
	Previous Decision. **(M-285)**	Deferred for evidence of free sale status.
	Remarks of the Evaluator.	Applicant submitted new COPP from Argentina (manufacturer of product). Name mentioned in COPP is MARTEXEL Lyophilized powder for Injection and also written product will be marketed in Pakistan under the name of Pemetrexed 500mg powder for concentrate for solution for infusion. At earlier COPP provided by spain shows license holder M/s TAARANG, S.A Balmes, 84- 4º – 2ª 08008 Barcelona Espana/Spain While now COPP from Argentina shows license holder M/s ERIOCHEM, S.A. Ruta 12- Km 452 (3107) Colonia Avellaneda- Departmento Parana Entre Rios Republic Argentina **COPP by Argentina (Manufacturer)**

		Certificate No: **Certified by:** INAME- Instituto Nacional de Medcamentos- National Institute of Drugs Avenida Caseros 2161 Ciudad autonoma de Buenos Aires- Republica Argentina **Issued on :** 31/01/2019 (Valid for 12 months) **Free sale:** Free sale of the product in Argentina.: **Yes**
	Previous Decision**(M-291)**	Deferr for further deliberation **(M-291)**
	Decision: Registration Board deferred the case for following: i. **Sole Agency agreement with marketing authorization holder.** ii. **Submission of Rs: 5000/- fee for change of marketing authorization holder.**	
156.	Name and address of Applicant	M/s Al-Qasim Enterprises, Flat# 4, Minhas Plaza, Second floor, Munawar Colony, Adiala Road Rawalpindi, (Pakistan) Head office: 55 Block B, Faisal town Lahore, Pakistan
	Detail of Drug Sale License	Address Flat# 4, Minhas Plaza, Second floor, Munawar Colony, Adiala Road Rawalpindi, (Pakistan) **Validity :** 19/01/2019 **Status:** to stock, sale and distribute drugs
	Name and address of manufacturer	M/s ERIOCHEM, S.A. Ruta 12- Km 452 3107 Colonia Avellaneda- Entre Rios Argentina
	Name and address of marketing authorization holder	M/s TAARANG, S.A Balmes, 84- 4º – 2ª 08008 Barcelona Espana/Spain
	Name of exporting country	Argentina (Spain)
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 12533 Dated : 05/04/2018
	Fee including differential fee	Rs : 1,00,000 Dated : 04/05/2018
	Brand Name +Dosage Form + Strength	Pemetrexed 100mg Powder for Concentrate for infusion (Presentation of 10ml vial)
	Composition	Vial contains : Active Ingredients Pemetrexed (as disodium)……..100mg Other ingredients Mannitol……....100mg Hydochloric Acid Concentrated……..PH 7.2 (q.s.) Sodium Hydroxide (E-524)……. PH 7.2 (q.s.)
	Finished Product Specification	Inhouse Specifications
	Pharmacological Group	Anticance, Antifolate agent
	Shelf life	36 months
	Demanded Price	Rs; 17,900/- per Vial
	Pack size	1's (10ml)
	International availability	ALMITA of USFDA Approved
	Me-too status	Alimta 100mg Injectable Of Eli Lilly
	Detail of certificates attached	**Valid and Legalized CoPP** **Certificate No**: 2017/03375 **Certified by:** AGNCIA ESPANOLA DEL MEDICAMENTO Y PRODUCTOS SANITARIOS C/ Campezo nº 1 – edif 8 28022 Madrid Espana/Spain **Issued on :** 21/12/2017 **Free sale:** Free sale of the product in exporting country.: No **GMP certificate** GMP inspection conducted by Spainish agency on 12-04-2016

		GMP certificate No : ES/113HV/16 Signed dated: 27-07-2016 Valid for 3 years **Sole Contract Agreement** 11-10-2017
	Remarks of the Evaluator.	• COPP shows no free sale in license holding country. • Firm reply: There is an existing usage patent that prevents Pemetrexed medicinal products from being marketed in EU countries, however after the expiry of the patent the product may be launched in the market.
	Previous Decision**.(M-285)**	Deferred for evidence of free sale status**.**
	Remarks of the Evaluator.	Applicant submitted new COPP from Argentina (manufacturer of product). Name mentioned in COPP is MARTEXEL Lyophilized powder for Injection and also written product will be marketed in Pakistan under the name of Pemetrexed 100mg powder for concentrate for solution for infusion. At earlier COPP provided by spain shows license holder M/s TAARANG, S.A Balmes, 84- 4º – 2ª 08008 Barcelona Espana/Spain While now COPP from Argentina shows license holder M/s ERIOCHEM, S.A. Ruta 12- Km 452 (3107) Colonia Avellaneda- Departmento Parana Entre Rios Republic Argentina **COPP by Argentina (Manufacturer)** **Certificate No**: **Certified by:** INAME- Instituto Nacional de Medcamentos- National Institute of Drugs Avenida Caseros 2161 Ciudad autonoma de Buenos Aires- Republica Argentina **Issued on :** 31/01/2019 (Valid for 12 months) **Free sale:** Free sale of the product in Argentina.: **No** M/s ERIOCHEM, S.A. Ruta 12- Km 452 3107 Colonia Avellaneda- Entre Rios Argentina: Informs that the reason why Pemetrexe 100mg is not commercialized in Argentina is because there is not medical prescription for this strength, only pemetrexed 500mg is used for treatment in the territory.
	Previous Decision**(M-291)**	Defer for further deliberation **(M-291)**
	Decision: Registration Board deferred the case for following: **i. Evidence of free sale status.** **ii. Sole Agency agreement with marketing authorization holder.** **iii. Submission of Rs: 5000/- fee for change of marketing authorization holder.**	

Case No. 05: Registration Applications of Drugs for which Stability Study Data is Submitted.

a. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
157.	M/s. Scilife Pharma Private Limited. Plot # FD – 57/58-2,Korangi Creek Industrial Park (KCIP) Karachi.	Umblica 7.1% Gel Each 10gm tube of gel contains: Chlorhexidine digluconate 7.1% w/w eq. to Chlorhexidine …4% w/w Antiseptics and disinfectants (USP specifications)	Form 5 Dy.No. Duplicate Doassier; Rs 20000/- (photocopy of challan) 5, 10, 15, & 20g Collapsible tube As per SRO	Not available in reference SRAs, However available in WHO Model List of Essential Medicines for Children and Nepal, Nigeria Last inspection conducted on 10-07-2018.and report concludes that GMP compliance level is rated as GOOD."	

STABILITY STUDY DATA

Drug	Umblica 7.1% Gel		
Name of Manufacturer	M/s. Scilife Pharma Private Limited. Plot # FD – 57/58- 2,Korangi Creek Industrial Park (KCIP) Karachi		
Manufacturer of API	Cadila pharmaceuticals Ltd Gujrat India		
API Lot No.	17CG020		
Description of Pack (Container closure system)	Aluminium Collasible tubes		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3,,6 (month) Real Time: 0,3 ,6, 9 (month)		
Batch No.	084B18	085B18	086B18
Batch Size	150 Tubes	150 Tubes	150 Tubes
Manufacturing Date	24-05-2018	24-05-2018	24-05-2018
Date of Initiation	28-05- 2018	28-05- 2018	28-05- 2018
No. of Batches	3		
Date of Submission	08-04-2019 (Dy. No. 2958)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status
1.	COA of API	Copy of COA by Cadila pharmaceuticals Ltd Gujrat India Limited is submitted.

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate No. 18101065 by Food & Drugs control Adminstration Gujrat state, India. Valid till 18-10-2021..
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of Commercial Invoice No CPL/BD/403/17-18 Dated: 13-11-2017 is submitted attested by ADC (Karachi) dated ;27-11-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- Initial testing of all 3 batches has been conducted as per BP specification while further testing on other time points has been done as per USP specifications
- The panel may be requested to verify initial testing of all three batches as per BP specification as claimed by the firm.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Umblica 7.1% Gel (Chlorhexidine digluconate) by M/s. Scilife Pharma (Pvt). Ltd., Karachi.

Reference No: F.3-11/2017-PEC (Pt) dated 28th August, 2019.
Investigation Date and Time: 19th September, 2019 (Morning).
Investigation Site: Factory premises of M/s. Scilife Pharma (Pvt). Ltd., Korangi Creek, Industrial State, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Scilife Pharma (Pvt). Ltd., Korangi Creeck, Industrial State, Karachi for registration of Umblica 7.1% Gel (Chlorhexidine digluconate) and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board).
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Ms. Sanam Kauser, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

UMBLICA 7.1% GEL

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API?	Firm imported Chlorhexidine gluconate solution 20% (W/V)2.0 Kg from M/s Cadila Pharmaceutical India, Taken approval 27-11-2017 Invoice No CPL/BD/403/17-18 having batch number "17CG020"
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation form being implemented by the firm. The parameters included in this form are, DMF status, GMP certificate, Stability data, provision of reference standard of API and impurities standards etc. The firm has evaluated on this criteria and has been selected accordingly.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has reference standard and impurity standard imported from the manufacturer.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis of API, reference standard and impurity standards.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has valid GMP certificate of chlorhexidine gluconate solution issued by regulatory authority of their respective country of origin.
6.	Do you use API manufacturer method of testing?	The Firm has used compendial method for API.
7.	Do you have stability studies reports on API?	Firm has stability studies reports on API provided by the manufacturer
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed as per SIM method and Related impurities have been quantified by the API manufacturer.
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of API, reference standards and impurities standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients.
12.	Do you have documents confirming the import of the used excipients?	The firm has purchased all the excipients from the local market although they have certificate of analysis for all the excipients available with them.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of the product?	The firm has written and authorized protocol for the development of the product Chlorhexidine gluconate gel 7.1% w/w
15.	Have you performed Drug-excipients compatibility studies?	The firm has not performed Drug-excipients compatibility studies as their formulation is similar to that of the reference product formulation (Kawach Gel, Lomus pharmaceutical Nepal) WHO approved product.
16.	Have you performed comparative studies?	Not performed
17.	Do you have product development (R&D) section	The firm has well equipped exclusive product development (R&D) section.
18.	Do you have necessary equipment's	The firm has used some equipment's of product development

	available in product development section for development of the product?	area and some of commercial area for the production of stability batches of Umblica 7.1% Gel.
19.	Are the equipments in product development section qualified?	The equipment in both area are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has a team of 3 pharmacists and 4 chemist, 1 biotechnologist with a machine operator in product development section with suitable knowledge and training in product development.
22.	Have you manufactured three stability batches for the stability studies of the product as required?	The firm has manufactured three stability batches of Chlorhexidine Gluconate 7.1% with batch numbers, 084B18, 085B18 and 086B18 each of 150 tubes. Product filled in aluminum collapsible tubes.
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tubes per testing frequency and number of testing frequencies / intervals) and minimum working Capacity of the equipment.
24.	Do you have complete record of production of stability batches?	Firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocol for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The Firm has verified the compendial method (USP method) which has been used for stability testing from third months and onward.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Verification of Pharmacopoeial method (USP) has been perfomed.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug.
29.	Do your method of analysis stability indicating?	The firm has used BP method for initial (zero time) testing while USP method for onward stability testing of the stability batches. Both the methods are stability indicating however, the firm has established stability indicating nature of the USP method (forced degradation studies) only. Proper spiking studies have also been used to support the verification of the method.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record of the firm. Audit trail was active on all HPLC systems used throughout stability study. Individual user log in and IDs were available.
31.	Can you show Audit Trail reports on product testing?	Audit trail reports were available and randomly checked.
32.	Do you have some remaining quantities of degradation products	The firm has remaining quantities of stability batches.

	and stability batches?	
33.	Do you have stability batches kept on stability testing?	The firm has completed the accelerated stability testing on the three stability batches however the real time stability testing is in progress on all the three stability batches. Currently 12 months study has been completed. First three commercial batches will be kept on stability.
34.	Do you have valid calibration status for the equipment's used in production and analysis?	The Firm has valid calibration status for the equipment used in production and analysis of the product.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant.
37.	**Any Remarks of PEC:** The panel may be requested to verify initial testing of all three batches has been conducted as per BP specification while further testing on another time points has been done as per USP specification.	The firm has used BP method for initial (zero time) testing while USP method for onward stability testing of the stability batches. Both the methods are stability indicating however, the firm has established stability indicating nature of the USP method (forced degradation studies) only. Proper spiking studies have also been used to support the verification of the method.

Conclusion and Recommendations:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Umblica 7.1% Gel (Chlorhexidine digluconate) is verifiable to satisfactory level.
2. Registration of the product "Umblica 7.1% Gel" is recommended in the name of the manufacturer.

Decision: Registration Board decided to approve registration of Umblica 7.1% Gel with change of brand name & with Innovator's specifications by M/s. Scilife Pharma Private Limited. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

b. Exemption from onsite verification of stability data

158.	Name and address of manufacturer / Applicant	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Agranil 60 mg
	Composition	Each film coated tablet contains: Ticagrelor… 60 mg
	Diary No. Date of R& I & fee	Dy.No 8185 dated 12-06-2098 Rs. 50,000/- Duplicate Dossier
	Pharmacological Group	Anti-coagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	BRILINTA of Astrazenica USFDA Approved.
	GMP status	Last inspection was conducted on 12-09-2018 for renewal / grant of GMP Certificate and the report concludes Good compliance of GMP.
	Remarks of the Evaluator[4]	

STABILITY STUDY DATA			
Drug	Agranil 60 mg tablet		
Name of Manufacturer	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area,Karachi		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Ro ad, Yangkou chemical industrial park, Rudong coastal economic developme nt zone, Nantong Jiangsu province 226407, PR china		
API Lot No.	RD-TG-201712111/RD-TG-201806261		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6,9 (month)		
Batch No.	PD01/18	PD02/18	PD03/18
Batch Size	2252 Tablets	2252 Tablets	2252 Tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	16-05-2018	16-05-2018	16-05-2018
No. of Batches	03		
Date of Submission	01-04-2019 (2311)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# RD-TG-201712111) from M/S Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued to M/s Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china. Issued by Nantong Food and drug administration. Valid up to 7-9-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes

7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

	Administrative Portion	
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Basovir 400 mg tablet and Vesoft 400/100mg Tablets in its 279 & 284 Meeting. • Date of Inspection: 16-02-2018 & 12-7-2018. • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 20-03-2018, Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
3.	Documents for the procurement of reference standard and impurity standards.	Firm have certificate of analysis of API, working standard, and Impurities, all provided by Nantong Chanyoo, China. The firm has clarified that the reference standard and impurity standards are provided free of cost along with the APIs' consignment and not separately by Nantong Chanyoo.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted GMP of M/s Nantong Chanyoo Pharmatech Co, Ltd China issued by Nantong food and Drug Adminstration**.** This certificate is valid until 07- 09, 2020.
5.	Mechanism for Vendor pre-qualification	The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.
6.	Certificate of analysis of the API, reference standards and impurity standards	The firm has submitted COA of API: Batch No. RD-TG-201712111 COA of Reference Standard: Batch No. WTG01-1409901 COA of Impurities: TGE: Batch No. WTG02-140901 TGD1: Batch No. WTG03-140901 TGD2: Batch No. WTG04-140901 TG-16: Batch No. WTG05-140901 De-ethoxyl of TG: Batch No. WTG06-1409901 Acetyl TG: Batch No. WTG07-1409901
7.	Documents for the procurement of excipients used in product development?	The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted photocopy of List of qualified staff involved in product development
	Production Data	
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted photocopy of Development Protocol for manufacturing

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record.
Details are as under:<table><tr><td colspan="3">Agranil 60 mg Tablet</td></tr><tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr><tr><td>PD01/18</td><td>2252 tablets</td><td>05-2018</td></tr><tr><td>PD02/18</td><td>2252 tablets</td><td>05-2018</td></tr><tr><td>PD03/18</td><td>2252 tablets</td><td>05-2018</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability
batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches.
The detail is as under:<table><tr><th>Batch No.</th><th>Batch yeild</th><th>Stability samples</th><th>Qty used</th><th>Remaining Qty in Chamber</th><th>Retain sample</th></tr><tr><td>PD01/ 18</td><td>2100 Tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>1400</td></tr><tr><td>PD02/ 18</td><td>2150 Tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>1450</td></tr><tr><td>PD03/ 18</td><td>2000 tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>1300</td></tr></table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 16-05-2018 to 16-11-2018 and for Real Time stability chamber starting from 16-05-2018 to 16-05-2018</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of method used for analysis of APIs along with COA.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Ticagrelor: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) & long term, 06 Months (30°C ± 2°C & 60±5%RH) stability study reports of 03 batches.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Drug-excipients compatibility studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Brilinta”.
The details are as follows:<table><tr><th>Feature</th><th>Reference product</th><th>Product of High-Q</th></tr><tr><td>Brand name</td><td>Brilinta 60mg tablet</td><td>Agranil 60mg tablet</td></tr><tr><td>Batch No.</td><td>PS06489</td><td>PD01/18</td></tr></table>Comparative dissolution studies have been performed in following mediums:
1. Ph 1.2 HCl buffer
2. Ph 4.5 Acetate buffer
3. Ph 6.8 Phosphate buffer</td></tr>
</table>

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted Audi trail could not be verified.

Remarks of Evaluator:

S. no	Deficiencies/Shortcomings	Reply by Firm
•	Which polymorphic form of ticagrelor is used in stability batches.	The product manufactured by us according to the synthetic route presented in the dossier is characterized as crystalline form II
•	Submitt Commercial invoices for excipients	Submitted
•	Authorized Protocols/SOP for the product development	Submitted
•	As per documents product developed from API batch no: RD-TG-201712111 having quanity of 1kg as per commercial invoice. However batch no: RD-TG-2018062 of API tested having quantity of 3 kg as per commercial invoice. Furthermore API testing have been performed after production of stability batches. Clarification is needed	COA of API by High Q batch no: RD-TG-201712111 submitted with testing date 18-04-2018.
•	Stability studies of API according to Zone –IV-A is required	6 month real time stability data submitted As per Stability studies of API according to Zone –IV-A submitted, initial testing done at july, 2018 while 3rd month testing done at Feb, 2019 **Stament from Nantong Chanyoo Pharmatec co., Ltd** **"**Since the stability study requires 3 batches of API , we did not arrange the stability study immediately after completion of the initial analysis of each batch. After 3 batches of API are collected and the stability study plan has been confirmed, the substances have been I into the stability study box. Before that, all the batches were stored in the warehouse in accordance with the storage conditions."
•	Evidence of procurement of reference product Briliant	Submitted
•	Submit complete auditrail for Assay, dissolution, comparative dissolution & method validation as submitted auditrail could not be verified	Submitted Audi trail could not be verified.
•	Value of Q in dissolution at 75 minute is NLT 70%. Please justify	Stability report mentioning correct specifications for dissolution as "NLT 80% (Q) in 75 minutes"

Decision: Registration Board deferred for clarification of following points:

- **Audit trail reports of the analysis performed on HPLC during stability studies.**
- **Valid GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority.**
- **Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements of USP for Q at 45 minutes and at 60 minutes.**

159.	Name and address of manufacturer / Applicant	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Agranil 90 mg
	Composition	Each film coated tablet contains: Ticagrelor… 90 mg

	Diary No. Date of R& I & fee	Dy.No 8184 dated 12-06-2098 Rs. 50,000/- Duplicate Dossier
	Pharmacological Group	Anti-coagulant
	Type of Form	Form 5
	Finished product Specifications	Manufacturers specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulator Authorities	BRILINTA of Astrazenica USFDA Approved.
	GMP status	Last inspection was conducted on 12-09-2018 for renewal / grant of GMP Certificate and the report concludes Good compliance of GMP.
	Remarks of the Evaluator[4]	

STABILITY STUDY DATA

Drug	Agranil 90 mg tablet		
Name of Manufacturer	M/s. High-Q Pharmaceuticals, Plot 224/23 Korangi Industrial Area,Karachi		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Ro ad, Yangkou chemical industrial park, Rudong coastal economic developme nt zone, Nantong Jiangsu province 226407, PR china		
API Lot No.	RD-TG-201712111		
Description of Pack (Container closure system)	Alu-PVC blister		
Stability Storage Condition	Real time : 30˚C ± 2˚ C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 9 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (month) Real Time: 0,3,6,9 (month)		
Batch No.	PD01/18	PD02/18	PD03/18
Batch Size	1408 Tablets	1408 Tablets	1408 Tablets
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	23-05-2018	23-05-2018	23-05-2018
No. of Batches	03		
Date of Submission	01-04-2019 (2312)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# RD-TG-201712111) from M/S Nantong Chanyoo Pharmatech Co., Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued to M/s Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province 226407, PR china. Issued by Nantong Food and drug administration. Valid up to 7-9-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

5.	Documents confirming import of API etc.	Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board approved Basovir 400 mg tablet and Vesoft 400/100mg Tablets in its 279 & 284 Meeting. • Date of Inspection: 16-02-2018 & 12-07-2018. • The HPLC is 21CFR Compliant. • Audit trail on the testing were available
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 20-03-2018, Copy of commercial invoice (invoice No. CY118070, dated: 08-03-2018) has been submitted, manufacturer is Nantong Chanyoo Pharmatech Co., Ltd, China, address: No.2, Tonghai Si Road, Yangkou chemical industrial park, Rudong coastal economic development zone, Nantong Jiangsu province china attested by ADC DRAP Karachi dated 20-03-2018.
3.	Documents for the procurement of reference standard and impurity standards.	Firm have certificate of analysis of API, working standard, and Impurities, all provided by Nantong Chanyoo, China. The firm has clarified that the reference standard and impurity standards are provided free of cost along with the APIs' consignment and not separately by Nantong Chanyoo.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted GMP of M/s Nantong Chanyoo Pharmatech Co, Ltd China issued by Nantong food and Drug Adminstration**.** This certificate is valid until 07- 09, 2020.
5.	Mechanism for Vendor pre-qualification	The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.
6.	Certificate of analysis of the API, reference standards and impurity standards	The firm has submitted COA of API: Batch No. RD-TG-201712111 COA of Reference Standard: Batch No. WTG01-1409901 COA of Impurities: TGE: Batch No. WTG02-140901 TGD1: Batch No. WTG03-140901 TGD2: Batch No. WTG04-140901 TG-16: Batch No. WTG05-140901 De-ethoxyl of TG: Batch No. WTG06-1409901 Acetyl TG: Batch No. WTG07-1409901

<table>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted copy of vender evaluation questionnaire for vender pre-qualification along with filled questionnaire from both APIs manufacturers.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for manufacturing`</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><td colspan="3">Agranil 60 mg Tablet</td></tr>
<tr><td>Batch No.</td><td>Bach size</td><td>Mfg. Started</td></tr>
<tr><td>PD01/18</td><td>1408 tablets</td><td>05-2018</td></tr>
<tr><td>PD02/18</td><td>1408 tablets</td><td>05-2018</td></tr>
<tr><td>PD03/18</td><td>1408 tablets</td><td>05-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning remaining quantity of three trial batches.
The detail is as under:
<table>
<tr><th>Batch No.</th><th>Batch yeild</th><th>Stability samples</th><th>Qty used</th><th>Remaining Qty in Chamber</th><th>Retain sample</th></tr>
<tr><td>PD01/ 18</td><td>1295 Tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>595</td></tr>
<tr><td>PD02/ 18</td><td>1267 Tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>567</td></tr>
<tr><td>PD03/ 18</td><td>1338 tablets</td><td>40×14’s (560)</td><td>290</td><td>29×14’s (406)</td><td>638</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for Accelerated stability chamber from 16-05-2018 to 16-11-2018 and for Real Time stability chamber starting from 16-05-2018 to 16-05-2018</td></tr>
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<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Specifications and Testing Method of Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 & 09 months stability data Accelerated & Real Time respectively.</td></tr>
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<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies</td><td>The firm has submitted Drug-excipients compatibility studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted Comparative dissolution study of their product with Innovator’s Brand “Brilinta”.
The details are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of High-Q</th></tr>
<tr><td>Brand name</td><td>Brilinta 90mg tablet</td><td>Agranil 60mg tablet</td></tr>
<tr><td>Batch No.</td><td>PS01092</td><td>PD01/18</td></tr>
</table></td></tr>
</table>

		Comparative dissolution studies have been performed in following mediums: 1. Ph 1.2 HCl buffer 2. Ph 4.5 Acetate buffer 3. Ph 6.8 Phosphate buffer
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Submitted Audi trail could not be verified.

Remarks of Evaluator:

S.no	Deficiencies/Shortcomings	Reply by Firm
1.	Which polymorphic form of ticagrelor is used in stability batches.	The product manufactured by us according to the synthetic route presented in the dossier is characterized as crystalline form II
2.	Submitt Commercial invoices for excipients	Submitted
3.	Authorized Protocols/SOP for the product development	Submitted.
4.	As per documents product developed from API batch no: RD-TG-201712111 having quanity of 1kg as per commercial invoice. However batch no: RD-TG-2018062 of API tested having quantity of 3 kg as per commercial invoice. Furthermore API testing have been performed after production of stability batches. Clarification is needed	COA of API by High Q batch no: RD-TG-201712111 submitted with testing date 18-04-2018.
5.	Stability studies of API according to Zone –IV-A is required	6 month real time stability data submitted As per Stability studies of API according to Zone –IV-A submitted, initial testing done at july, 2018 while 3rd month testing done at Feb, 2019 **Stament from Nantong Chanyoo Pharmatec co., Ltd** **"**Since the stability study requires 3 batches of API , we did not arrange the stability study immediately after completion of the initial analysis of each batch. After 3 batches of API are collected and the stability study plan has been confirmed, the substances have been I into the stability study box. Before that, all the batches were stored in the warehouse in accordance with the storage conditions."
6.	Evidence of procurement of reference product Briliant	Submitted
7.	Submit complete auditrail for Assay, dissolution, comparative dissolution & method validation as submitted auditrail could not be verified	Submitted auditrail could not be verified.
8.	Value of Q in dissolution at 75 minute is NLT 70% . Please justify	Stability report mentioning correct specifications for dissolution as "NLT 80% (Q) in 75 minutes"

Decision: Registration Board deferred for clarification of following points:

- **Audit trail reports of the analysis performed on HPLC during stability studies.**
- **Valid GMP certificate of the API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co, Ltd. China, issued by relevant provincial or state regulatory authority.**
- **Clarification of applied dissolution limits, since reference product specify the acceptance criteria of dissolution test as "Shall comply with requirements of USP for Q at 45 minutes and at 60 minutes.**

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

a. New Cases.

160.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22205 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name +Dosage Form + Strength	Vascoval 5mg/160mg Tablet
	Composition	"Each film coated tablet contains: Amlodipine as Besilate…5mg Valsartan…160mg"
	Pharmacological Group	C09DB01 Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, Propose pack size as per PRC.
	Approval status of product in Reference Regulatory Authorities.	Exforge USFDA Approved.
	Me-too status	081932; Amlodine Tablet 5/160 M/s Jupiter Pharma, Rawat Islamabad
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	• The master formulation mentions Amlodipine as besilate 6.95mg/Tablet whereas, the label claim is Amlodipine (as Besilate)…5mg.
	Decision: Deferred for revision of master formulation as per label claim i.e. Amlodipine (as Besilate)…5mg.	
161.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22206 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name+Dosage Form+ Strength	Vascoval 10mg/160mg Tablet
	Composition	"Each film coated tablet contains: Amlodipine as Besilate…10mg Valsartan…160mg"
	Pharmacological Group	C09DB01 Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, Propose pack size as per PRC.
	Approval status of product in Reference Regulatory Authorities.	Exforge USFDA Approved.
	Me-too status	081933; Amlodine Tablet 10/160 M/s Jupiter Pharma, Rawat Islamabad
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	The master formulation mentions Amlodipine as besilate 13.90 mg/Tablet whereas, the label claim is Amlodipine (as Besilate)…10 mg.
	Decision: Deferred for revision of master formulation as per label claim i.e. Amlodipine (as Besilate)…10mg.	

162.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22204 dated 26-06-2018 Rs.20,000/- 26-6-2018
	Brand Name+Dosage Form+ Strength	Vascoval 5mg/80mg Tablet AMV Baffle Trammel
	Composition	"Each film coated tablet contains: Amlodipine as Besilate…5mg Valsartan…80mg"
	Pharmacological Group	C09DB01 Angiotensin II receptor blockers (ARBs) and calcium channel blockers
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Exforge MHRA Approved.
	Me-too status	081931; Amlodine Tablet M/s Jupiter Pharma, Rawat Islamabad
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	• The master formulation mentions Amlodipine as besilate 6.95mg/Tablet whereas, the label claim is Amlodipine (as Besilate)…5mg.
	Decision: Deferred for revision of master formulation as per label claim i.e. Amlodipine (as Besilate)…5mg.	
163.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22200 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name+Dosage Form+ Strength	Maxzid 4mg Tablet
	Composition	"Each film coated tablet contains: Tizanidine HCl eq to Tizanidine…4mg"
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents M03BX02
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Zanaflex® USFDA Approved.
	Me-too status	080865; "Zinzan 4mg Tablet "Wellborne Pharmachem and Biologicals, Hattar."
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or revision of formulation from film coated tablet to uncoated tablet	

	with submission of requisite fee.	
164.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22199 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name+Dosage Form+ Strength	Maxzid 2mg Tablet
	Composition	"Each film coated tablet contains: Tizanidine HCl eq to Tizanidine…2mg"
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents M03BX02
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Zanaflex® USFDA Approved.
	Me-too status	078514 ; Xinasia Tablets Med Asia Pharmaceuticals (Pvt) Ltd., Risalpur
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee.	
165.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22195 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name+Dosage Form+ Strength	Maxizole 2% topical cream w/w
	Composition	"Each g contains: Miconazole Nitrate…2%w/w"
	Pharmacological Group	Antifungals For Topical Use D01AC02 Imidazole and triazole derivatives
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10g, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Miconazole 7 USFDA Approved
	Me-too status	078895; "Bicrole Cream 2% "M/s Searle IV Solutions (Pvt.) Ltd, Lahore
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	
	Decision: Approved.	
166.	Name and address of manufacturer / Applicant	"M/s Maxitech Pharma Pvt Ltd.Plot No. E-178, S.I.T.E. Super Highway, Phase II, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22194 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name+Dosage Form+ Strength	Piro 2% Cream w/w

	Composition	"Each g of cream contains: Mupirocin calcium eq. to mupirocin….20mg"
	Pharmacological Group	Antibiotics For Topical Use D06AX09
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	5g, 15g, as per PRC.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	076451; Mupream 20mg Cream M/s Sante Pvt. Karachi.
	GMP status	21-02-2019 Conclusion: Based on above observations and keeping in view the attitude of the management of the firm towards constant improvement their current GMP compliance level is rated as Good.
	Remarks of the Evaluator.	
	Decision: Approved.	
167.	Name and address of manufacturer / Applicant	"M/s Searle IV Solutions Pvt Ltd. 1.5 km, Manga Raiwind Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 24439 dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name+Dosage Form+ Strength	Nolopred 0.5%) Eye Drops
	Composition	"Each 5ml ophthalmic solution contains: Loteprednol Etabonate…0.5%"
	Pharmacological Group	Anti-inflammatory Agents S01BA14 Corticosteroids, plain
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	5mlx1's, in plastic bottle, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lotemax Ophthalmic Suspension TGA Approved.
	Me-too status	081636; Lotemax 0.5% eye drops M/s Innvotek Pharmaceuticals (Pvt) Ltd, Islamabad
	GMP status	27-02-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	• Firm has eye drops section. • Evidence of approval of applied formulation as ophthalmic solution in reference regulatory authorities/ agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) as ophthalmic solution along with registration number, brand name and name of firm.
	Decision: Deferred for the following reasons: **Evidence of approval of applied formulation as ophthalmic solution in reference regulatory authorities / agencies which were declared/approved by the Registration Board in its 275th meeting.** **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) as ophthalmic solution along with registration number, brand name and name of firm.**	
168.	Name and address of manufacturer / Applicant	"M/s Sante Pvt Ltd. 245/2-Z, Block 6, PECHS, Karachi 75400"
	Diary No. Date of R& I & fee	Dy.No 22189 dated 26-06-2018 Rs.20,000/- 26-06-2018 Duplicate
	Brand Name+Dosage Form+ Strength	Brinza Ophthalmic Suspension "Brinzolamide 1% Brimonidine Tartrate 0.2%
	Composition	"Each ml contains:

		Brinzolamide…10mg Brimonidine Tartrate …2mg"
	Pharmacological Group	Anti-glaucoma Preparations and Miotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs.
	Pack size & Demanded Price	As per PRC.
	Approval status of product in Reference Regulatory Authorities.	SIMBRINZA™ (brinzolamide/brimonidine tartrate ophthalmic suspension) 1%/0.2% USFDA Approved.
	Me-too status	091907; Simbrinza by Novartis
	GMP status	02-07-2019 Conclusion: Based on the current practices and keeping in view the attitude of the management towards better compliance of GMP their overall compliance level for the said dosage form is rated as Good.
	Remarks of the Evaluator.	Firm has ophthalmic section. • The provided Me too couldnot be confirmed.
	Decision: Registration Board deliberated that since the referred me-too product "Simbrinza" was first approved in 268th meeting of Registration Board and Board in 240th meeting has already decided that stability studies data will be required for new formulation and its subsequent generic, hence Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board as it's a subsequent generic.	
169.	Name and address of manufacturer / Applicant	"M/s Sante Pvt Ltd. 245/2-Z, Block 6, PECHS, Karachi 75400"
	Diary No. Date of R& I & fee	Dy.No 2218 dated 26-06-2018 Rs.20,000/- 26-06-2018 Duplicate
	Brand Name +Dosage Form + Strength	Xepat-OD 0.7% Opthalmic Solution
	Composition	"Each ml contains: Olopatadine as Hydrochloride eq to Olopatadine…7mg"
	Pharmacological Group	Decongestants And Antiallergics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	PAZEO (olopatadine hydrochloride ophthalmic solution) 0.7%For topical ophthalmic administration. USFDA Approved.
	Me-too status	Could not be confirmed in applied strength.
	GMP status	02-07-2019 Conclusion: Based on the current practices and keeping in view the attitude of the management towards better compliance of GMP their overall compliance level for the said dosage form is rated as Good.
	Remarks of the Evaluator.	Firm has ophthalmic section. Firm has submitted that stability is under process.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
170.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals Pvt. LTD. 538-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Clarient Drops 125mg/5ml
	Composition	Each 5ml contains: Clarithromycin taste masked pellets …125mg
	Diary No. Date of R& I & fee	Dy. No.17967; 12-10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Amber Glass bottle, Dropper, 25 ml , As per SRO

	Approval status of product in Reference Regulatory Authorities	MHRA Approved AS granules for oral suspension.
	Me-too status (with strength and dosage form)	Registration Number: 026262 Brand Name: Clara Drops Each 5ml Contains:- Manufacturer Name: Saydon Pharmaceutical Industries.
	GMP status	24-05-2019 Conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has the relevant section. <u>Shortcomings:</u> • Evidence of approval of applied formulation as drops in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Clarify whether drops are oral suspension or solution. • Clarify the composition whether enteric coated pellets or immediate release. Internationally it is approved as granules whereas, firm have applied for pellets.
	Decision: Deferred for submission of justification of master formulation as it does not mention all the requisite excipients for formulation of suspension as mentioned by innovator or revision of master formulation.	
171.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals Pvt. LTD. 538-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Bril DS Suspension 200mg
	Composition	Each 5ml contains: Ibuprofen…200mg
	Diary No. Date of R& I & fee	Dy. No.17966; 12-10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Glass bottle,120 ml , As per SRO
	Approval status of product in Reference Regulatory Authorities	Pinofen Seven Plus 200 mg/5 ml Oral Suspension MHRA Approved
	Me-too status (with strength and dosage form)	Registration Number: 070851 Brand Name: Brufen Suspension DS Manufacturer Name: Abbott Laboratories, Karachi
	GMP status	24-05-2019 Conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has the relevant section..
	Decision: Approved.	
172.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals Pvt. LTD. 538-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cvox Dry Powder Suspension 125mg
	Composition	Each 5ml contains: Ciprofloxacin as HCl…125mg
	Diary No. Date of R& I & fee	Dy. No.17972; 12-10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	Quinolones
	Type of Form	Form-5
	Finished product Specifications	Innovator
	Pack size & Demanded Price	Glass bottle, 60ml , As per SRO

	Approval status of product in Reference Regulatory Authorities	Not available.
	Me-too status (with strength and dosage form)	077456 ; "Ciproking 125 mg Dry powder Suspension "M/s Medicraft Pharmaceuticals (Pvt) Ltd., Peshawar
	GMP status	24-05-2019 Conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Firm has the relevant section. • Taste masked micropellets obtained from Vision Pharmaceuticals.(in-house specifications). • Box Warning for Quinolones. <u>Shortcomings:</u> • Clarification regarding brand name whether CVOX or CIVOX. • The innovator product is marketed with a solvent containing following ingredients o Soya lecithin, o Medium chain triglycerides, o Strawberry flavour, o Sucrose, o Purified water. • .Registration Board Decision (M-269). Keeping in view the following statement written in Qualitative and quantitative composition "2.5 mL suspension after reconstitution (1/2 measuring spoon) contains 125 mg ciprofloxacin" and domestic conditions for difficulties in dispensing 250mg/5ml suspension for children under 2 years of age, Registration Board decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA.
	Decision: Deferred the following reasons: • **Clarification regarding brand name whether CVOX or CIVOX.** • **Revision of formulation as per innovator product i.e. "Ciprofloxacin", as the applied formulation is "Ciprofloxacin as hydrochloride".** • **Submission of details of solvent for oral suspension as per reference product as approved by USFDA and MHRA.**	
173.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals Pvt. LTD. 538-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Cvox Dry Powder Suspension 250mg
	Composition	Each 5ml contains: Ciprofloxacin as HCl…250mg
	Diary No. Date of R& I & fee	Dy. No.17973; 12-10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	Quinolones
	Type of Form	Form-5
	Finished product Specifications	Innovator
	Pack size & Demanded Price	Glass bottle, 60ml , As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved Ciprofloxacin Microcapsules
	Me-too status (with strength and dosage form)	077457 ; "Ciproking 250 mg Dry powder Suspension "M/s Medicraft Pharmaceuticals (Pvt) Ltd., Peshawar."
	GMP status	24-05-2019 Conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations.

		The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has the relevant section. Taste masked micropellets obtained from Vision Pharmaceuticals.(in-house specifications). Box Warning for Quinolones. Shortcomings:. • Clarification regarding brand name whether CVOX or CIVOX. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Internationally the approved formulation is Ciprofloxacin whereas, the firm has applied for ciprofloxacin as hydrochloride.
	Decision: Deferred the following reasons: • **Clarification regarding brand name whether CVOX or CIVOX.** • **Revision of formulation as per innovator product i.e. "Ciprofloxacin", as the applied formulation is "Ciprofloxacin as hydrochloride".** • **Submission of details of solvent for oral suspension as per reference product as approved by USFDA and MHRA.**	
174.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals Pvt. LTD. 538-C, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Clarient XL Tablet 500mg
	Composition	Each film coated extended release tablet contains: Clarithromycin …500mg
	Diary No. Date of R& I & fee	Dy. No.17968; 12-10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Alu-Alu, Alu-PVC, As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status (with strength and dosage form)	Registration Number: 061884 Brand Name: Rithmo XL 500mg Tablet Manufacturer Name: Sami Pharmaceuticals (Pvt) Ltd
	GMP status	24-05-2019 Conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Firm has the relevant section.
	Decision: Approved.	
175.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad
	Brand Name+Dosage Form + Strength	Fenolip Tablets 48mg
	Composition	Each film coated tablet contains: Fenofibrate…..48mg
	Diary No. Date of R& I & fee	Dy.No 6392 dated 21-02-2018 Rs. 20,000/- Dated 19-02-2018, 2018 & Rs. 5,000/- Dated 19-02-2018 (15-4-2019-revision of formulation from uncoated to film coated)
	Pharmacological Group	Fibrates
	Type of Form	Form-5
	Finished product Specification	USP Specifications

	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	TRICOR film coated tablets USFDA Approved
	Me-too status	058479 Fenoget 48mg Tablet M/s Getz Pharma (Pvt.) Ltd, Karachi
	GMP status	Last inspection report dated 25-10-2018 with following recommendations: "As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
176.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fenolip Tablets 54mg
	Composition	Each film coated tablet contains: Fenofibrate…..54mg
	Diary No. Date of R& I & fee	Dy.No 6393 dated 21-02-2018 Rs. 20,000/- Dated 19-02-2018, Dated 19-02-2018 (15-04-2019-revision of formulation from uncoated to film coated)
	Pharmacological Group	Fibrates
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved.
	Me-too status	058696; Atcofibrate 54mg Tablet Each film coated tablet contains:- Fenofibrate (Micronized)….54 mg By Atco Laboratories Limited, Karachi
	GMP status	Last inspection report dated 25-10-2018 with following recommendations: "As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however,keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
177.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fenolip Tablets 145mg
	Composition	Each tablet contains: Fenofibrate…..145mg
	Diary No. Date of R& I & fee	Dy.No 6394 dated 21-02-2018 Rs. 20,000/- Dated 19-02-2018
	Pharmacological Group	Fibrates
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in	FENOFIBRATE BIOGARAN

	Reference Regulatory Authorities	Uncoated Tablet (ANSM Approved)
	Me-too status	058480; Fenoget 145mg Tablet M/s Getz Pharma (Pvt.) Ltd, Karachi
	GMP status	Last inspection report dated 25-10-2018 with following recommendations: "As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however,keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals.
	Remarks of the Evaluator	FENOFIBRATE BIOGARAN contains 145 mg fenofibrate nanoparticles, whereas the firm has not applied the formulation as nanoparticles.
	Decision: Deferred for clarification of applied formulation as the innovator product mentions fenofibrate nanoparticles.	
178.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fenolip Tablets 160mg
	Composition	Each tablet contains: Fenofibrate…..160mg
	Diary No. Date of R& I & fee	Dy.No 6395 dated 21-02-2018 Rs. 20,000/- 19-02-2018
	Pharmacological Group	Fibrates
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved Uncoated tablets
	Me-too status	058697 ; Atcofibrate 160mg Tablet Each film coated tablet contains:- Fenofibrate (Micronized)…160 mg M/s Atco Laboratories Limited, Karachi
	GMP status	Last inspection report dated 25-10-2018 with following recommendations: "As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however,keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
179.	Name and address of manufacturer / Applicant	M/s Evolution Pharmaceuticals (Pvt.) Ltd. Plot #: 25 & 26, Street No. S-3, RCCI, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Elisor Tablets 40mg
	Composition	"Each tablet contains: Pravastatin Sodium…40mg"
	Diary No. Date of R& I & fee	Dy.No 6384 dated 21-02-2018 Rs. 20,000/- 19-02-2018
	Pharmacological Group	Statin / HMG-CoA Reductase Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA approved.
	Me-too status	032049; Pralip –40 Tablets Pravastatin Sodium…40mg M/s Hilton Pharma (Pvt) Ltd,

	GMP status	Last inspection report dated 25-10-2018 with following recommendations: "As the operations have not started as of yet at M/s Evolution Pharmaceuticals, Rawat the GMP status can only be ascertained upon the start of active pharmaceutical; however, keeping in view the facility inspected the firm has requisite manufacturing facility for manufacturing of Pharmaceuticals.
	Remarks of the Evaluator	
	Decision: Approved.	
180.	Name and address of manufacturer / Applicant	M/s Wellborne Pharmachem and Biologicals, Plot no. 51/1, 52/2, Phase I and II Industrial Estate, Hattar.
	Diary No. Date of R& I & fee	Diary No:3056, 23/01/2018, Rs: 20,000/- 22/01/2018
	Brand Name +Dosage Form + Strength	Nebron Tablet 2.5mg
	Composition	Each film coated tablet contains: Nebivolol as HCl….2.5mg
	Pharmacological Group	Beta blocking agents, selective (C07AB12)
	Type of Form	Form 5
	Finished product Specification	Manufacturer Spec.
	Pack size & Demanded Price	2x7's , Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bystolic USFDA Approved
	Me-too status	061344; Nebil 2.5mg Tablet of M/s Getz Karachi
	GMP status	07-11-2018 Conclusion: As per available manufacturing, quality control and environmental facilities provided, documentation reviewed, technical/qualified personnel employed and observations made during inspection, the firm Wellborne Hattar is considered to be operating under satisfactory level of Cgmp compliance and hence recommend for the grant of Cgmp certificate.
	Remarks of the Evaluator.	Evidence of international availability as film coated tablet. The Master formulation mentions the quantity of API as 2.888mg.
	Decision: Deferred for the following reasons: **Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee.** **Revision of master formulation as per label claim i.e. "Nebivolol as HCl….2.5mg" as the master formulation mentions the quantity of API as 2.888mg.**	
181.	Name and address of manufacturer / Applicant	M/s Wellborne Pharmachem and Biologicals,, Plot no. 51/1, 52/2, Phase I and II Industrial Estate, Hattar.
	Diary No. Date of R& I & fee	Diary No:3057, 23/01/2018, Rs: 20,000/- 22/01/2018
	Brand Name +Dosage Form + Strength	Nebron Tablet 5mg
	Composition	Each film coated tablet contains: Nebivolol as HCl….5mg
	Pharmacological Group	Beta blocking agents, selective (C07AB12)
	Type of Form	Form 5
	Finished product Specification	Manufacturer Spec.
	Pack size & Demanded Price	2x7's , Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bystolic USFDA Approved
	Me-too status	061345; Nebil 5mg Tablet of M/s Getz Karachi
	GMP status	07-11-2018 Conclusion: As per available manufacturing, quality control and environmental facilities provided, documentation

		reviewed, technical/qualified personnel employed and observations made during inspection, the firm Wellborne Hattar is considered to be operating under satisfactory level of Cgmp compliance and hence recommend for the grant of Cgmp certificate.
	Remarks of the Evaluator.	Evidence of international availability as film coated tablet. The Master formulation mentions the quantity of API as 5.722mg.
	Decision: Deferred for the following reasons: **Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee.** **Revision of master formulation as per label claim i.e. "Nebivolol as HCl….5mg" as the master formulation mentions the quantity of API as 5.722mg.**	
182.	Name and address of manufacturer / Applicant	M/s Wellborne Pharmachem and Biologicals,Plot no. 51/1, 52/2, Phase I and II Industrial Estate, Hattar.
	Diary No. Date of R& I & fee	Diary No:3058, 23/01/2018, Rs: 20,000/- 22/01/2018
	Brand Name +Dosage Form + Strength	Nebron Tablet 10mg
	Composition	Each film coated tablet contains: Nebivolol as HCl….10mg
	Pharmacological Group	Beta blocking agents, selective (C07AB12)
	Type of Form	Form 5
	Finished product Specification	Manufacturer Spec.
	Pack size & Demanded Price	2x7's , Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bystolic USFDA Approved
	Me-too status	061345; Nebil 5mg Tablet of M/s Getz Karachi
	GMP status	07-11-2018 Conclusion: As per available manufacturing, quality control and environmental facilities provided, documentation reviewed, technical/qualified personnel employed and observations made during inspection, the firm Wellborne Hattar is considered to be operating under satisfactory level of Cgmp compliance and hence recommend for the grant of Cgmp certificate.
	Remarks of the Evaluator.	Evidence of international availability as film coated tablet. The Master formulation mentions the quantity of API as 11.44mg.
	Decision: Deferred for the following reasons: **Evidence of approval of applied formulation as film coated tablet in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee.** **Revision of master formulation as per label claim i.e. "Nebivolol as HCl….10mg" as the master formulation mentions the quantity of API as 11.44mg.**	
183.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-I dated 03-08-2018 Rs.20,000/- 03-8-2018
	Brand Name +Dosage Form + Strength	Vidamet 50mg+1000mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vidagliptin…50mg Metformin as HCl…1000mg"
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD08
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs.

	Pack size & Demanded Price	3x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.
	Me-too status	081907; Galmet 50mg/1000mg Tablet M/s Vision Pharmaceuticals, Kahuta Road, Islamabad.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	• The applied formulation is Metformin as HCl…1000mg whereas, internationally it is approved as Metformin HCl.
	Decision: Registration Board approved the formulation as "Each Film Coated Tablet Contains: Vidagliptin…50mg, Metformin HCl…1000mg".	
184.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-I dated 03-08-2018 Rs.20,000/- 03-8-2018
	Brand Name +Dosage Form + Strength	Vidamet 50mg+850mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vidagliptin…50mg Metformin as HCl…850mg"
	Pharmacological Group	Combinations of oral blood glucose lowering drugs A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	3x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	GALVUMET\ TGA Approved
	Me-too status	081906; Galmet 50mg/850mg Tablet M/s Vision Pharmaceuticals, Kahuta Road, Islamabad.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	The applied formulation is Metformin as HCl…850mg whereas, internationally it is approved as Metformin HCl.
	Decision: Registration Board approved the formulation as "Each Film Coated Tablet Contains: Vidagliptin…50mg, Metformin HCl…850mg".	
185.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-B dated 03-08-2018 Rs.20,000/- 03-8-2018
	Brand Name +Dosage Form + Strength	Terbimed 125mg Tablet
	Composition	"Each Film Coated Tablet Contains: Terbinafine HCl eq. to Terbinafine…125mg"
	Pharmacological Group	Antifungals for systemic use D01BA02
	Type of Form	Form 5
	Finished product Specification	USP/BP
	Pack size & Demanded Price	10's, as per PRC
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 125mg (uncoated tablets) TGA Approved.
	Me-too status	070118; "Terbizine Tablet of M/s Candid Pharma
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	Firm has applied for film coated tablet whereas; internationally it is available as uncoated tablet.
	Decision: Deferred for revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee.	

186.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-C dated 03-08-2018 Rs.20,000/- 03-8-2018
	Brand Name +Dosage Form + Strength	Terbimed 250mg Tablet
	Composition	"Each film coated tablet Contains: Terbinafine as HCL…250mg"
	Pharmacological Group	Antifungals for systemic use D01BA02
	Type of Form	Form 5
	Finished product Specification	USP/BP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 250mg TGA Approved.
	Me-too status	081184; Cutis 250mg Tablet Tabros Pharma Karachi.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	Firm has applied for film coated tablet whereas, internationally it is available as uncoated tablet.
	Decision: Deferred for revision of formulation from film coated tablet to uncoated tablet with submission of requisite fee.	
187.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-J dated 03-08-2018 Rs.20,000/- 3-08-2018
	Brand Name +Dosage Form + Strength	Ondasave 8mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ondansetron HCl Dihydrate eq. to Ondansetron…8mg"
	Pharmacological Group	Antiemetics And Antinauseants A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP.
	Pack size & Demanded Price	1x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZOFRAN Tablets, 8 mg (ondansetron HCl dihydrate equivalent to 8 mg of ondansetron), USFDA Approved.
	Me-too status	081451; Ondonx Tablet of M/s Genix Pharma Karachi.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	• The master formulation mentions Ondansetron HCl Dihydrate …8mg whereas, label claim mentions Ondansetron HCl Dihydrate eq. to ondansetron…8mg"
	Decision: Approved.	
188.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-G dated 03-08-2018 Rs.20,000/- 3-08-2018
	Brand Name +Dosage Form + Strength	Ondasave 8mg/4ml Injection
	Composition	"Each 4ml Contains: Ondansteron HCl Dihydrate…8mg"
	Pharmacological Group	Antiemetics And Antinauseants A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	USP/BP
	Pack size & Demanded Price	4 ml glass ampoule, As per SRO.

	Approval status of product in Reference Regulatory Authorities.	Firm has submitted Germany approved.
	Me-too status	081892; Doston 8mg Injection Each ampoule of 4ml contains:-Ondansetron hydrochloride equivalent to Ondansetron……..8mg M/s Vision Pharmaceuticals, Kahuta Road, Islamabad.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	Liquid Injectable section is present. • Internationally it is approved as Each ampoule of 4ml contains:-Ondansetron hydrochloride equivalent to Ondansetron whereas, you have applied for Ondansteron HCl Dihydrate.
	Decision:Registration board approved the applied formulation as follow "Each ampoule of 4ml contains:-Ondansetron hydrochloride equivalent to Ondansetron…8mg.	
189.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-E dated 03-08-2018 Rs.20,000/- 3-08-2018
	Brand Name +Dosage Form + Strength	Ondasave 4mg/5ml Syrup
	Composition	"Each 5ml of Syrup Contains: Ondansetron HCl eq. to Ondansetron…4mg"
	Pharmacological Group	Antiemetics And Antinauseants A04AA01 Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished product Specification	Not provided.
	Pack size & Demanded Price	60ml, 120ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Not provided.
	Me-too status	Couldnot be confirmed
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	• Oral Liquid section is present. • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.
	Decision: Deferred for the following reasons: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
190.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-A dated 03-08-2018 Rs.20,000/- 3-08-2018
	Brand Name +Dosage Form + Strength	Amisave 100mg/2ml Injection (IM/IV)
	Composition	"Each 2ml Contains: Amikacin Sulphate…100mg"
	Pharmacological Group	J01GB06 Other aminoglycosides
	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	2ml type I glass ampoule, As per SRO.

	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	081056; Ekasin 100mg Injection of M/s Epharm Karachi.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	• International availability of applied formulation couldn't be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.	
191.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-H dated 03-08-2018 Rs.20,000/- 03-8-2018
	Brand Name +Dosage Form + Strength	Dingo 0.5mg/ml Syrup
	Composition	"Each 5ml of syrup contains: Desloratadine…2.5mg
	Pharmacological Group	R06AX27 Other antihistamines for systemic use
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs.
	Pack size & Demanded Price	120ml, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved Oral Solution.
	Me-too status	081671; Mdisin 2.5mg Syrup M/s Metro Pharmaceuticals, Islamabad
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	Firm has oral liquid section.
	Decision: Deferred for the clarification of applied formulation as internationally it is approved as oral solution whereas, the applied formulation is syrup.	
192.	Name and address of manufacturer / Applicant	"M/s Medisave Pharmaceuticals.,Plot 578-579, Sundar Industrial Estate, Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26712-D dated 03-08-2018 Rs.20,000/- 03-8-2018
	Brand Name +Dosage Form + Strength	Medistil 10ml Injection
	Composition	"Each Ampoule Contains: Water for Injection…10ml"
	Pharmacological Group	Diluent
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	100s, 500s, 10cc glass ampoule.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	076482; Water for Injection 10ml By Healthtek Kar.
	GMP status	11-12-2017 & 10-01-2018. GMP Certificate issued on 15-03-2018.
	Remarks of the Evaluator.	Firm has SVP infusion section.
	Decision: Approved with innovator's specification.	
193.	Name and address of manufacturer / Applicant	"M/s AGP Limited.B-23, S.I.T.E. Karachi"
	Diary No. Date of R& I & fee	Dy.No 26444 dated 01-08-2018 Rs.20,000/- 31-7-2018
	Brand Name +Dosage Form + Strength	Vilzamet 50/850 mg Tablet
	Composition	"Each film coated tablet Contains: Vildagliptin…50mg Metformin Hydrochloride…850mg"
	Pharmacological Group	Drugs Used In Diabetes A10BD08

	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	Rs. 1082.66 for 14's.
	Approval status of product in Reference Regulatory Authorities.	GALVUMET\ TGA Approved
	Me-too status	081906; Galmet 50mg/850mg Tablet M/s Vision Pharmaceuticals, Islamabad.
	GMP status	13-05-2019 Conclusion: Keeping in view the overall GMP standards in the firm, based on the fact of above observations their overall compliance level was noted good.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
194.	Name and address of manufacturer / Applicant	"M/s AGP Limited.B-23, S.I.T.E. Karachi"
	Diary No. Date of R& I & fee	Dy.No 26443 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Brand Name +Dosage Form + Strength	Vilzamet 50/500 mg Tablet
	Composition	"Each film coated Tablet Contains: Vildagliptin…50mg Metformin Hydrochloride…500mg"
	Pharmacological Group	Drugs Used In Diabetes A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	Rs. 1077/- for 14's.
	Approval status of product in Reference Regulatory Authorities.	GALVUMET\ TGA Approved
	Me-too status	081905; Galmet 50mg/500mg Tablet M/s Vision Pharmaceuticals, Islamabad.
	GMP status	13-05-2019 Conclusion: Keeping in view the overall GMP standards in the firm, based on the fact of above observations their overall compliance level was noted good.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
195.	Name and address of manufacturer / Applicant	"M/s AGP Limited.B-23, S.I.T.E. Karachi"
	Diary No. Date of R& I & fee	Dy.No 26604 dated 02-08-2018 Rs.20,000/- 02-08-2018
	Brand Name +Dosage Form + Strength	Delirep 500µg Tablet
	Composition	"Each Tablet Contains: Roflumilast…500 µg "
	Pharmacological Group	R03DX07 Other systemic drugs for obstructive airway diseases
	Type of Form	Form 5
	Finished product Specification	Manufacture Specs.
	Pack size & Demanded Price	10's for Rs. 174.00/-.
	Approval status of product in Reference Regulatory Authorities.	Daliresp Tablets USFDA Approved.
	Me-too status	NA
	GMP status	13-05-2019 Conclusion: Keeping in view the overall GMP standards in the firm, based on the fact of above observations their overall compliance level was noted good.
	Remarks of the Evaluator.	Submission of stability studies data as per Requirements of Registration Board decision of 251st meeting and 278th meeting.

	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
196.	Name and address of manufacturer / Applicant	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"
	Diary No. Date of R& I & fee	Dy.No 26607 dated 02-08-2018 Rs.20,000/- 31-07-2018
	Brand Name +Dosage Form + Strength	Lurasid 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lurasidone HCl…60mg"
	Pharmacological Group	Antipsychotics N05AE05 Indole derivatives
	Type of Form	Form 5
	Finished product Specification	Innovator Specs.
	Pack size & Demanded Price	10's, 20's, 30's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Latuda USFDA Approved
	Me-too status	NA
	GMP status	02-07-2019 Conclusion: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remarks of the Evaluator.	• Submission of stability studies data and related documents as per Decision of 278th meeting of Registration board as the applied formulation is subsequent new drug generic version.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
197.	Name and address of manufacturer / Applicant	"M/s Kaizen Pharmaceuticals Pvt Ltd. E-127-129, North Western Industrial Zone, Bin Qasim, Karachi"
	Diary No. Date of R& I & fee	Dy.No 26606 dated 02-08-2018 Rs.20,000/- 31-07-2018
	Brand Name +Dosage Form + Strength	Lurasid 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lurasidone HCl…20mg"
	Pharmacological Group	Antipsychotics N05AE05 Indole derivatives
	Type of Form	Form 5
	Finished product Specification	Innovator Specs.
	Pack size & Demanded Price	10's, 20's, 30's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Latuda USFDA Approved
	Me-too status	NA
	GMP status	02-07-2019 Conclusion: The building, facilities and procedures demonstrated at the time of inspection found at satisfactory level of GMP compliance. Moreover, firm should focus on above mentioned observations and comply with them on priority basis.
	Remarks of the Evaluator.	• Submission of stability studies data and related documents as per Decision of 278th meeting of Registration board as the applied formulation is subsequent new drug generic version.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	

198.	Name and address of manufacturer / Applicant	"M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi"
	Diary No. Date of R& I & fee	Dy.No 26700 dated 03-08-2018 Rs.20,000/- 03-08-2018
	Brand Name +Dosage Form + Strength	Peroxa CR 12.5 mg Tablet
	Composition	"Each enteric, film coated, controlled release tablet Contains: Paroxetine Hydrochloride Eq. to Paroxetine…12.5mg"
	Pharmacological Group	Anti-depressants N06AB05 Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 28's, 30's, 42's, 50's, 60's, 70's, 80's, 90's, 100's Rs. 500/tablet.
	Approval status of product in Reference Regulatory Authorities.	Paxil CR USFDA Approved. Warning: Suicidal Thoughts And Behaviors
	Me-too status	081953; Panox CR Tablet 12.5 mg M/s Regal Pharmaceuticals, Islamabad
	GMP status	24-04-2018 Conclusion: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remarks of the Evaluator.	
	Decision: Approved.	
199.	Name and address of manufacturer / Applicant	"M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi"
	Diary No. Date of R& I & fee	Dy.No 26701 dated 03-08-2018 Rs.20,000/- 03-08-2018
	Brand Name +Dosage Form + Strength	Peroxa CR 25 mg Tablet
	Composition	"Each enteric, film coated, controlled release tablet Contains: Paroxetine Hydrochloride Eq. to Paroxetine…25mg"
	Pharmacological Group	Anti-depressants N06AB05 Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 28's, 30's, 42's, 50's, 60's, 70's, 80's, 90's, 100's Rs. 1000/tablet.
	Approval status of product in Reference Regulatory Authorities.	Paxil CR USFDA Approved with boxwarning. Warning: Suicidal Thoughts And Behaviors
	Me-too status	081955; Panox CR Tablet 25 mg M/s Regal Pharmaceuticals, Islamabad
	GMP status	24-04-2018 Conclusion: "Based on current inspection, documents reviewed it was noted that firm is currently working under satisfactory level of cGMP compliance. (Show cause notice revoked on 27-04-2018)"
	Remarks of the Evaluator.	
	Decision: Approved.	
200.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26820 dated 06-08-2018 Rs.20,000/- 06-08-2018
	Brand Name +Dosage Form + Strength	Ebak 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ebastine…20mg"

	Pharmacological Group	R06AX22 Other antihistamines for systemic use
	Type of Form	Form 5
	Finished product Specification	JP Specs.
	Pack size & Demanded Price	10s, 14's, As per SRO.As per leader price
	Approval status of product in Reference Regulatory Authorities.	Kestine Netherland Approved.
	Me-too status	080844; "Lobastin Tablet 20mg "M/s Lowitt Pharmaceutical (Pvt) Ltd, Peshawar."
	GMP status	High-Q Pharmaceuticals Karachi. 10/04/18 Conclusion: "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of the Evaluator.	
	Decision: Approved.	
201.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26819 dated 06-08-2018 Rs.20,000/- 06-08-2018
	Brand Name +Dosage Form + Strength	Dayline 2g IV Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…2g"
	Pharmacological Group	J01DD04 Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Rocephin 2 g powder for solution for infusion EMA Approved.
	Me-too status	041429; "SPORCEF-2gm Injection "M/s Lowit Pharma (Pvt) Ltd., Peshawar,"
	GMP status	High-Q Pharmaceuticals Karachi. 10/04/18 Conclusion: "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of the Evaluator.	
	Decision: Approved.	
202.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 26821 dated 06-08-2018 Rs.50,000/- 06-08-2018
	Brand Name +Dosage Form + Strength	Dayfort 2g IM/IV Injection
	Composition	"Each Vial Contains: Ceftazidime as Pentahydrate…2g"
	Pharmacological Group	J01DD02 Third-generation cephalosporin
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	1'S, As per PRC
	Approval status of product in Reference Regulatory Authorities.	Fortum® 2 g powder for solution for injection or infusion IV (MHRA Approved)
	Me-too status	Could not be confirmed.
	GMP status	10/04/18 Conclusion: "Based on the areas inspected, the people met and the documents reviewed, and considering the finding of inspection, including the observations & advises made, M/s High-Q Pharma is located at plot no.224, sector 23, Karachi was considered to be operating at an acceptable level of compliance with good manufacturing practices for Pharma products."
	Remarks of the Evaluator.	• IM could not be confirmed in the applied strength. • Me too in applied strength could not be confirmed.
	Deferred for following reasons: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
203.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd., 28 KM, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Fortexone Injection 250mg IM Cefomed Cefnome
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	Diary No. Date of R& I & fee	Dy.No 26707 dated 03-08-2018 Rs.20,000/- 03-08-2018
	Pharmacological Group	J01DD04 Third-generation cephalosporins
	Type of Form	Form-5
	Finished product Specification	USP Specs.
	Pack size & Demanded Price	1's / As per SRO.
	Approval status of product in Reference Regulatory Authorities.	EMA Approved.
	Me-too status	073207; "Trize Injection 250mg IM. M/s Lawari International, , Swat (contract manufacturing from M/s. Fassgen Pharmaceuticals)"
	GMP status	22-01-2019 Conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Nova-Med Lahore. is considered to be operating at Good level of compliance of GMP requirements.
	Remarks of the Evaluator.	
	Decision: Approved.	
204.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd., 28 KM, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Fortexone Injection 500mg IM Cefomed Cefnome
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	Diary No. Date of R& I & fee	Dy.No 26708 dated 03-08-2018 Rs.20,000/- 03-08-2018
	Pharmacological Group	J01DD04 Third-generation cephalosporins
	Type of Form	Form-5

	Finished product Specification	USP Specs.
	Pack size & Demanded Price	1's / As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Rocephin IM 500 mg Powder and Solvent for Solution for Injection MHRA Approved.
	Me-too status	073208 ; "Trize Injection 500mg IM. M/s Lawari International, Saidu Sharif Swat (contract manufacturing from M/s. Fassgen Pharmaceuticals)"
	GMP status	22-01-2019 Conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Nova-Med Lahore. is considered to be operating at Good level of compliance of GMP requirements.
	Remarks of the Evaluator.	
	Decision: Approved.	
205.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd., 28 KM, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Fortexone Injection 1g IM Cefomed Cefnome
	Composition	Each Vial Contains: Sterile Ceftriaxone Sodium Eq. to Ceftriaxone……..1g
	Diary No. Date of R& I & fee	Dy.No 26709 dated 03-08-2018 Rs.20,000/- 03-08-2018
	Pharmacological Group	3rd Generation Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specs.
	Pack size & Demanded Price	1's / As per SRO.
	Approval status of product in Reference Regulatory Authorities.	EMA Approved.
	Me-too status	073209 ; Trize Injection 1g IM. "M/s Lawari International, ,Saidu Sharif Swat (contract manufacturing from M/s. Fassgen Pharmaceuticals)"
	GMP status	22-01-2019 Conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Nova-Med Lahore. is considered to be operating at Good level of compliance of GMP requirements.
	Remarks of the Evaluator.	
	Decision: Approved.	
206.	Name and address of manufacturer / Applicant	"M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi." \
	Diary No. Date of R& I & fee	Dy.No 26702 dated 03-08-2018 Rs.20,000/- 03-08-2018
	Brand Name +Dosage Form + Strength	Lisino-H 20mg + 12.5mg Tablet
	Composition	"Each Tablet Contains: Lisinopril Dihydrate eq. to Lisinopril…20mg Hydrochlorothiazide…12.5mg"
	Pharmacological Group	C09BA03 ACE inhibitors and diuretics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Zestoretic uncoated tablets. USFDA Approved with box warning.
	Me-too status	081496; Co-Zairl 20mg Tablet of M/s PPP Karachi.

	GMP status	01-07-2019 Conclusion: Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection M/s Getz Pharma Karachi is considered to be operating at an acceptable level of compliance of GMP requirements.
	Remarks of the Evaluator.	
	Decision: Approved.	
207.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:41155, 06/12/2018, Rs: 20,000/- 06/12/2018
	Brand Name +Dosage Form + Strength	Rivas 6mg Capsule
	Composition	Each Capsule Contains: Rivastigmine as Hydrogen Tartrate Eq. to Rivastigmine…6mg
	Pharmacological Group	Anti-Dementia Drugs Anticholinesterases (N06DA03)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 28's, 60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Rivastigmine Mylan 6mg hard capsules MHRA Approved
	Me-too status	079954; Riveme 6mg Capsule of M/s Genix Karachi.
	GMP status	19-09-2018, Grant of additional sections.
	Remarks of the Evaluator.	
	Decision: Approved.	

b. Deferred cases

208.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:41508, 07/12/2018, Rs: 20,000/- Dated 07/12/2018
	Brand Name +Dosage Form + Strength	Volden Forte 50mg Capsule
	Composition	Each Capsule Contains: Diclofenac Sodium as Enteric Coated Pellets……..... 50mg"
	Pharmacological Group	Acetic acid derivatives and related substances M01AB05
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	20's, 30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	DIFENE Ireland Approved.
	Me-too status	071688; Hegen-50 Capsules M/s Healers Pharma, Peshawar.
	GMP status	19-09-2018, Grant of additional sections.
	Remarks of the Evaluator.	• Source of pellets: Vision Pharma • Signature of applicant missing on Form 5.
	Previous Decision (M-287): Deferred for signatures of of applicant on Form-5.	
	Evaluation by PEC: Firm has submitted signed Form 5.	
	Decision: Approved.	
209.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:41509, 07/12/2018, Rs: 20,000/- Dated 07/12/2018
	Brand Name +Dosage Form + Strength	Volden Forte SR 100mg Capsule
	Composition	Each Capsule Contains: Diclofenac Sodium as Sustained Release Pellets 32%...100mg"

	Pharmacological Group	Acetic acid derivatives and related substances M01AB05
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	20's, 30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Rhumalgan XL100 mg Modified-Release Capsules MHRA Approved
	Me-too status	069771 Med-Diclo Capsules Meditech Pharmaceuticals 15-D Industrial Estate, Jamrud Road, Peshawar
	GMP status	19-09-2018, Grant of additional sections.
	Remarks of the Evaluator.	• Source of pellets: Vision Pharma • Signature of applicant missing on Form 5.
	Previous Decision (M-287): Deferred for signatures of of applicant on Form-5.	
	Evaluation by PEC: Firm has submitted signed Form 5.	
	Decision: Approved.	
210.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd.,Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Diary No. Date of R& I & fee	Diary No:41538, 07/12/2018, Rs: 20,000/- Dated 07/12/2018
	Brand Name +Dosage Form + Strength	Mebetex SR Capsule 200mg
	Composition	Each Capsule Contains: Mebeverine HCL(SR Pellets 50%)…200mg
	Pharmacological Group	Synthetic anticholinergic, esters with tertiary amino group A03AA04
	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	10's, 20's, 30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Colofac MR MHRA Approved.
	Me-too status	080547; Mebrest-200 Capsule M/s Aurik Pharmaceuticals, Islamabad
	GMP status	19-09-2018, Grant of additional sections.
	Remarks of the Evaluator.	• Source : Vision Pharma. • Signature of applicant missing on form 5.
	Previous Decision (M-287): Deferred for signatures of of applicant on Form-5.	
	Evaluation by PEC: **Firm has submitted signed Form 5.**	
	Decision: Approved.	
211.	Name and address of manufacturer / Applicant	M/s. Lisko Pakistan (Pvt.) Ltd.L-10-D, Block# 21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Voltrex Plus tablet 75mg+200mcg
	Composition	Each enteric coated tablet contains: Diclofenac sodium….75 mg Misoprostol……0.2mg
	Diary No. Date of R& I & fee	Dy. No. 7982, 07-07-2017 , Rs.20,000/- (07-07-2017)
	Pharmacological Group	NSAID/Prostaglandin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's, Alu Alu; Rs 60/Tablet
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Registration Number: 024014 Brand Name: Cytopan-75 Tablets Manufacturer Name: M/s Getz Pharma (Pvt) Ltd, Karachi
	GMP status	

	Remarks of the Evaluator.	Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Recommendations)
	Decision	• Approved in USFDA with Box Warning. • The formulation contains misoprostol 1% HPMC dispersion and contains inner enteric coated layer surrounded by misoprostol dispersion coating and the method of manufacturing submitted is in line with the innovator product. • Evidence of availability of requisite manufacturing equipment by area FID not provided by the firm. • Availability of Misoprostol as 1 % HPMC could not be verified from Form 5.
	Previous Decision(M-283): Deferred for the following reasons: • Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm. • Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. • Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID.	
	Evaluation by PEC: • Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm. Firm has not provided evidence of availability of requisite manufacturing equipment by area FID. • Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. Firm has submitted revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. • Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID. FID-V Karachi, vide his letter no. F.SAA.02-06/2018- FID-V (K)dated 30-08-2018, has confirmed that firm has purchased two stability chambers with capacity of 250L (Accelerated) and 800L (Real time), placed in their QC department.	
	Decision: Registration Board deferred the case for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submits DQ (Design Qualification), IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	
212.	Name and address of manufacturer / Applicant	M/s. Lisko Pakistan (Pvt.) Ltd.L-10-D, Block# 21, Shaheed Rashid Minhas Road, Federal "B" Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Voltrex Plus tablet 50mg+200mcg
	Composition	Each enteric coated tablet contains: Diclofenac sodium….50mg Misoprostol……0.2mg
	Diary No. Date of R& I & fee	Dy. No. 7975, 07-07-2017 , Rs.20,000/- (07-07-2017)
	Pharmacological Group	NSAID/Prostaglandin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's, Alu Alu; Rs 50/Tablet
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA
	Me-too status	Registration Number: 026839 Brand Name: Prostol Tablets Manufacturer Name: Flow Pharmaceutical (Pvt) Ltd, 17-KM Sheikhupura Road, Lahore
	GMP status	Latest GMP inspection conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Recommendations)
	Remarks of the Evaluator.	• Approved in USFDA with box warning. • The formulation contains misoprostol 1% HPMC dispersion and contains inner enteric coated layer

		surrounded by misoprostol dispersion coating and the method of manufacturing submitted is in line with the innovator product. • Evidence of availability of requisite manufacturing equipment by area FID not provided by the firm. • Availability of Misoprostol as 1 % HPMC couldnot be verified from Form 5.
	Decision: Deferred for the following reasons: • Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm. • Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. • Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID.	
	Evaluation by PEC: • Evidence of availability of requisite manufacturing equipment by area FID to be provided by the firm. Firm has not provided evidence of availability of requisite manufacturing equipment by area FID. • Submission of revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. Firm has submitted revised Form 5 mentioning misoprostol as 1 % HPMC dispersion. • Un-availability of stability chamber for conducting real time stability analysis as per observations mentioned in inspection report of area FID. FID-V Karachi, vide his letter no. F.SAA.02-06/2018- FID-V (K)dated 30-08-2018, has confirmed that firm has purchased two stability chambers with capacity of 250L (Accelerated) and 800L (Real time), placed in their QC department.	
	Decision: Deferred for evidence of availability of bilayer compression machine, acknowledged in any panel inspection report or else submit DQ (Design Qualification),IQ (Installation Qualification Reports) & OQ (Operation Qualification) reports for the bilayer compression machine.	

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

a. New Cases

213.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Vetapine Injection (50ml)
	Composition0	Each ml Contains: Atropine Sulphate…1mg
	Diary No. Date of R&I & fee	Dy No. 26845; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Antispasmodic
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	50ml / De-controlled
	Me-too status	049677; Atropine Injection By M/s. Alina
	GMP status	26 & 27-7-2019 Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved.	
214.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Vetamec Plus Injection 10ml
	Composition	Each ml Contains: Ivermectin…10mg Vitamin A…250,000 IU Vitamin D3…37500 IU Vitamin E…25mg
	Diary No. Date of R&I & fee	Dy No. 26848; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Anthelmintic + Vitamin

	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	10ml/ De-Controlled
	Me-too status	046563 (10ml) of Bovimec Injection By Leads Pharma
	GMP status	26 & 27-7-2019 Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	• The Me-too provided for applied formulation has different strength.
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
215.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Vetfos-B12 Injection 100ml
	Composition	Each ml Contains: Toldimfos Sodium…200mg Vitamin B12…50µg
	Diary No. Date of R&I & fee	Dy No. 26847; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Phosphorus Metabolism + Vitamin
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	100ml / De-Controlled
	Me-too status	033253 Tonovit Injection By Selmore
	GMP status	26 & 27-7-2019 Conclusion:Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved.	
216.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Marbo-Vetz 10% Injection (100ml)
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R&I & fee	Dy No. 26854; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	100ml / De-Controlled
	Me-too status	074054 Marbostar 10% Injection By M/s. Huzaifa
	GMP status	26 & 27-7-2019 Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved.	
217.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Marbo-Vetz 10% Injection (50ml)
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R&I & fee	Dy No. 26853; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	50ml / De-Controlled
	Me-too status	074054 Marbostar 10% Injection By M/s. Huzaifa "10ML,20ML,50ML,100ML,250ML"

	GMP status	26 & 27-7-2019 Conclusion:Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	----
	Decision: Approved.	
218.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Vetamec Plus Injection 50ml
	Composition	Each ml Contains: Ivermectin…10mg Vitamin A…250,000 IU Vitamin D3…37500 IU Vitamin E…25mg
	Diary No. Date of R&I & fee	Dy No. 26849; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Anthelmintic + Vitamin
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	50ml / De-Controlled
	Me-too status	046563 Bovimec Injection By Leads Pharma
	GMP status	26 & 27-7-2019 Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	• The Me too provided for applied formulation has different strength.
	Decision: Deferred for the Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
219.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Butamin Injection (20ml)
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin…0.05mg
	Diary No. Date of R&I & fee	Dy No. 26850; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Phosphorus/Vitamin Supplement
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	20ml / De-Controlled
	Me-too status	074046 Carosil Injection By M/s. Huzaifa (100ml)
	GMP status	26 & 27-7-2019 Conclusion:Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	Me too in 20 ml fill volume could not be confirmed.
	Decision: Approved.	
220.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Butamin Injection (100ml)
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin…0.05mg
	Diary No. Date of R&I & fee	Dy No. 26851; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Phosphorus/Vitamin Supplement
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	100ml / De-Controlled
	Me-too status	074046 Carosil Injection By M/s. Huzaifa
	GMP status	26 & 27-7-2019 Conclusion: Based on the above observations their current

		GMP compliance level is rated as good.
	Remarks of Evaluator	----
	Decision: Approved.	
221.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Marbo-Vetz 10% Injection (20ml)
	Composition	Each ml Contains: Marbofloxacin…100mg
	Diary No. Date of R&I & fee	Dy No. 26852; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	20ml / De-Controlled
	Me-too status	074054 Marbostar 10% Injection By M/s. Huzaifa
	GMP status	26 & 27-7-2019 Conclusion:Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	----
	Decision: Approved.	
222.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Vetfos-B12 Injection 50ml
	Composition	Each ml Contains: Toldimfos Sodium…200mg Vitamin B12…50µg
	Diary No. Date of R&I & fee	Dy No. 26846; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Phosphorus Metabolism + Vitamin
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	50ml / De-Controlled
	Me-too status	033253 Tonovit Injection By Selmore
	GMP status	26 & 27-7-2019 Conclusion:Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved.	

b. Deferred Cases

223.	Name and address of Manufacturer / Applicant	D-Maarson Pharmaceuticals Plot # 17, Street SS-2, National Industrial Zone, Rawat
	Brand Name, Dosage Form, Strength	Tyco-Maars Oral w/s Powder
	Composition	Each g contains:- Tylosin tartrate ……..……980 mg
	Diary No., Date of R & I & Fee	Dy.6444, 21/02/2018, Rs.20,000
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Approval Status of Product In Reference Regulatory Authorities	N/A
	Me-Too Status	081736 Tylotar-98 Oral Powder "Each g Contains:- Tylosin Tartrate ……...0.98 Kg "M/S. Evergreen Pharmaceuticals, Lahore.
	GMP Status	3-11-2018. Recommendations: GMP is a continual process and keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded

		that M/s D-Maarson Pharma Rawat has basic facilities for Minutes of 288th Meeting of Registration Board (14-15th February, 2019), DRAP | 1019manufacturing and testing of pharmaceuticals (Vet). At the time of inspection the firm was operating in accordance with GMP however the areas of improvement have been discussed and agreed by the representatives of the firm.
	Remarks of Evaluator	Me too is available in different strength.
	Decision of 288th Meeting: Deferred for evidence of applied formulation/drug already approved by DRAP (generic /me-too status) along with registration number, brand name and name of firm.	
	Evaluation by PEC: Firm has submitted the following Me Too: 081736 Tylotar-98 Oral Powder "Each Kg Contains:- Tylosin Tartrate ……...0.98 Kg "M/S. Evergreen Pharmaceuticals, Lahore.	
	Previous Decision (M-290): Deferred for evidence of applied formulation/drug already approved by DRAP (generic /me-too status) along with registration number, brand name and name of firm as the provided me too couldn't be verified.	
	Evaluation by PEC: Firm has submitted following Me- too which has been verified: Reg. No.: 088629, Tylo-Forte water Soluble Powder by M/s Breeze Pharma.	
	Decision: Approved.	

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

b. Export facilitation

Export Facilitation: Applications was received through letter No.F.-1-6/2019-PR.1 (EFD) "M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan" have achieved benchmark of USD 290,656.636 as defined in the Board's decision during fiscal year 2017-2018. In this regard, please find the following applications submitted by the firm.		
224.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 16132 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Brand Name +Dosage Form + Strength	Oxaban Tablet 2.5mg
	Composition	Each film coated tablet contains: Rivaroxaban …….2.5mg
	Pharmacological Group	Anti-thrombotic Agents Direct factor Xa inhibitors B01AF01
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs.
	Pack size & Demanded Price	14's, 28's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Xeralto; USFDA Approved with box warning. (A) PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA
	Me-too status	074794; Xarelto 2.5mg Tablets M/s Bayer Pakistan (Private) Limited, Karachi.
	GMP status	M/s Nabi Qasim Pvt Ltd Karachi 02-08-2018 Conclusion: Based on the area inspected, people met, and documents reviewed and considering the finding of the inspection, M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of the Evaluator.	1. **Innovator Product Shelf life (USFDA)** The approved expiry is 30 months in the HDPE

		bottles and 18 months in the blisters when stored at USP controlled room temperature. (USFDA). **2. <u>Polymorphic form I</u>** **Drug substance (EMA)** Rivaroxaban has been tested for polymorphism and pseudo-polymorphism according to the ICH Q6A guideline (decision tree 4). Rivaroxaban crystallizes in three polymorphs. Polymorph I is the thermodynamically stable one and has been used in all tablet formulations during clinical development and will be used in the commercial product. The identity of polymorph I is routinely controlled by Raman spectroscopy at release. **Drug substance (AusPAR)** Three polymorphic crystalline forms are known, Form I is the form used (in all tablet strengths). **Drug substance (Germany)** Rivaroxaban manufactured by this manufacturer has been sufficiently characterized. Rivaroxaban contains one stereogenic center. The enantiomer produced is the (S)-configuration. Rivaroxaban exhibits polymorphism. The manufacturing process consistently leads to Form 1 of rivaroxaban. **3. <u>Micronized Rivaroxaban</u>** **Micronized Rivaroxaban (USFDA)** Rivaroxaban belongs to BCS Class II so in order to increase bioavailability, the drug substance is micronized. **Micronized Rivaroxaban (EMA)** Three key intermediates must be synthesised, which are then used in the reaction to form the active substance. After re-crystallization of rivaroxaban crude, the material is micronised.
	Decision: The Registration Board approved the applied formulation with drug substance having polymorphic form 1, use of micronized rivaroxaban, shelf life of 18 months and innovators' specification.	
225.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 27719 dated 13-08-2018 Rs.20,000/- 13-08-2018
	Brand Name +Dosage Form + Strength	Bronchirol 150µg Rotacaps
	Composition	Each rotacap contains: Indacaterol maleate eq. to indacaterol 150 µg
	Pharmacological Group	Adrenergics, Inhalants R03AC18 Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	30's, as per PRC.
	Approval status of product in Reference Regulatory Authorities.	Hirobriz Breezhaler (EMA Approved)
	Me-too status	069586; "Onbrez breezhaler 150 mcg Inhalation powder hard capsules 150 mcg. Novartis pharma (pakistan) limited, karachi
	GMP status	M/s Nabi Qasim Pvt Ltd Karachi 02-08-2018 Conclusion: Based on the area inspected, people met, and documents reviewed and considering the finding of the inspection, M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of cGMP Requirements at the time of inspection.

	Remarks of the Evaluator.	**Polymorphic Form (EMA)** It contains one chiral centre and the drug substance is the R-isomer. Polymorphic form A has been defined as crystal form of indacaterol maleate. **M-290 Decision** Registration Board discussed the case in detail. It was deliberated that the dosage form of "Dry Powder Inhaler Capsule" necessitates particle size of formulation blend in micron range, in order for the active pharmaceuticalingredient (API) to reach and be absorbed at site of action (lungs). This requires specialized manufacturing and testing equipment like high shear mixer, spiral jet mills, Marple-miller impactor, Andersen Impactor, Multistage Liquid Impinger, Next Generation Impinger etc. Hence, considering the manufacturing, testing and labeling requirements for Dry Powder Inhaler Capsules, the Board decided as under: • Manufacturers shall have separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend. • In case the applied formulation only involves the Drug of general category, it may be manufactured in the capsule general section but if the applied formulation includes a steroidal drug then firm shall require separate section for "Dry Powder Inhaler Capsule" to avoid chances of cross contamination. • Manufacturer shall include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" in the Finished Product Specifications,as per Pharmacopoeia recommendations. Availability of necessary apparatus for the performance of these two tests shall also be ensured. • The applicants shall use the Drug Delivery Device, which is compatible with the intended product for delivering the required "Target Delivery Dose". The applicant shall submit the label claim for "Target Delivery Dose" based upon the studies with the intended delivery system under defined test conditions (i.e., flow rate, duration). • The Board further advised the P.E&R division to include following information on the registration letter of Dry Powder Inhaler Capsules: - Label claim for the "Target Delivered Dose" - Description of the delivery device (inhaler) intended to be marketed along with the applied formulation • The Board further decided that manufacturers of already registered drug products of DPI shall be advised to follow above guidelines.
	Decision: Deferred for the following reasons: • **Manufacturers shall have separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend.** • **Manufacturer shall include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" in the Finished Product Specifications, as per Pharmacopoeia recommendations. Availability of necessary apparatus for the performance of these two tests shall also be ensured.**	

	• **The applicants shall use the Drug Delivery Device, which is compatible with the intended product for delivering the required "Target Delivery Dose". The applicant shall submit the label claim for "Target Delivery Dose" based upon the studies with the intended delivery system under defined test conditions (i.e., flow rate, duration).**	
226.	Name and address of manufacturer / Applicant	"M/s Nabiqasim Industries Pvt Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 27720 dated 13-08-2018 Rs.20,000/- 13-08-2018
	Brand Name +Dosage Form + Strength	Bronchirol 300µg Rotacaps
	Composition	Each rotacap contains: Indacaterol maleate eq. to indacaterol 300 µg
	Pharmacological Group	Adrenergics, Inhalants R03AC18 Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	30's, as per PRC.
	Approval status of product in Reference Regulatory Authorities.	Hirobriz Breezhaler (EMA Approved)
	Me-too status	069587; "Onbrez breezhaler 150 mcg Inhalation powder hard capsules 150 mcg. Novartis pharma (pakistan) limited, karachi
	GMP status	M/s Nabi Qasim Pvt Ltd Karachi 02-08-2018 Conclusion: Based on the area inspected, people met, and documents reviewed and considering the finding of the inspection, M/s Nabi Qasim Karachi is considered to be operating at an acceptable level of compliance of cGMP Requirements at the time of inspection.
	Remarks of the Evaluator.	**Polymorphic Form (EMA)** It contains one chiral centre and the drug substance is the R-isomer. Polymorphic form A has been defined as crystal form of indacaterol maleate.
	Decision: Deferred for the following reasons: • **Manufacturers shall have separate manufacturing facility/section for manufacturing of DPIs including specialized mixing facility to ensure the required particle size of the formulation blend.** • **Manufacturer shall include the test of "Uniformity of Delivered Dose" and "Aerodynamic Particle Size Distribution" in the Finished Product Specifications, as per Pharmacopoeia recommendations. Availability of necessary apparatus for the performance of these two tests shall also be ensured.** • **The applicants shall use the Drug Delivery Device, which is compatible with the intended product for delivering the required "Target Delivery Dose". The applicant shall submit the label claim for "Target Delivery Dose" based upon the studies with the intended delivery system under defined test conditions (i.e., flow rate, duration).**	
Export Facilitation: Applications was received through letter No.F.-1-6/2019-PR.1 (EFD) ""M/s Sante Pvt Ltd .245/2-Z, Block 6, PECHS, Karachi 75400", Pakistan" have achieved benchmark of USD 1,508,674.45 as defined in the Board's decision during fiscal year 2017-2018. In this regard, please find the following applications submitted by the firm.		
227.	Name and address of manufacturer / Applicant	"M/s Sante Pvt Ltd . 245/2-Z, Block 6, PECHS, Karachi 75400"
	Diary No. Date of R& I & fee	Dy.No 16946 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Brand Name +Dosage Form + Strength	Santhine Cream 13.9% Sanflo, Florisan
	Composition	Each g contains: Eflornithine HCl…13.9%
	Pharmacological Group	Other dermatologicals D11AX16
	Type of Form	Form 5

	Finished product Specification	Manufacturer Spec.
	Pack size & Demanded Price	Rs. 980.00/- per 15 g tube.
	Approval status of product in Reference Regulatory Authorities.	Vaniqa 13.9% USFDA Approved.
	Me-too status	073869; Depilus Cream of M/s Atco Lab. Karachi.
	GMP status	02-07-2019 Conclusion: Based on the current practices and keeping in view the attitude of the management towards better compliance of GMP their overall compliance level for the said dosage form is rated as Good.
	Remarks of the Evaluator.	Evidence of section approval.
	Decision: Approved with innovator's specification.	
228.	Name and address of manufacturer / Applicant	"M/s Sante Pvt Ltd. 245/2-Z, Block 6, PECHS, Karachi 75400"
	Diary No. Date of R& I & fee	Dy.No 1676 dated 14-01-2019 Rs.20,000/- 14-01-2019
	Brand Name +Dosage Form + Strength	Santogan tartrate Opthalmic Solution 0.2% Bromo-T, Glaucoma
	Composition	Each ml contains: Brimonidine Tartrate… 2mg
	Pharmacological Group	Sympathomimetics in glaucoma therapy S01EA05
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs.
	Pack size & Demanded Price	Rs. 350/- pack of 5ml.
	Approval status of product in Reference Regulatory Authorities.	ALPHAGAN BRIMONIDINE TARTRATE that product was not discontinued or withdrawn for safety or efficacy reasons** Discontinued
	Me-too status	044835; "Brimonidine Tartrate Ophthalmic Solution Alcon Laboratories, Inc, USA. Ali Gohar & Company (Pvt) Ltd., Karachi
	GMP status	02-07-2019 Conclusion: Based on the current practices and keeping in view the attitude of the management towards better compliance of GMP their overall compliance level for the said dosage form is rated as Good.
	Remarks of the Evaluator.	Evidence of section approval.
	Decision: Approved with innovator's specification.	

Agenda of Evaluator PEC-VI

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

b. Deferred cases

229.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories, Karachi
	Brand Name +Dosage Form + Strength	Spaswin Injection
	Composition	Each 3ml ampoule contains: Hydrated Phloroglucinol……40mg
	Diary No. Date of R& I & fee	Dy. No.15969; 30-4-2018; Rs.20,000/- (30-4-2018)
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	3ml ampoule ,As per Drap Policy
	Approval status of product in Reference Regulatory Authorities.	Could not be Confirmed
	Me-too status	Europas Injection Each 3ml contains:- Phloroglucinol……..40mg Reg # 039247

	GMP status	CLB granted additional section of Liquid Injectable (General) section on 259th meeting held on 29& 30th March 2018.
	Remarks of the Evaluator.	Approval in RRA could not be confirmed
	Decision of 282nd meeting:	• Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Evaluation by PEC:	Firm has requested to withdraw this product and applied a new product as under: Spaswin Injection Each 4ml ampoule contains: Hydrated Phloroglucinol…….40mg Trimethyl Phloroglucinol…..0.04mg DY # 1335, Rs.20,000 19-07-2018 Musclotropic Antispasmodic Pack size and Price are as per SRO International Availability and me-too status could not be confirmed
	Decision of 285th meeting of RB:	Deferred for following: □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.
	Evaluation by PEC:	The firm has provided following reference; • Spasfon , solution for injection in ampoule by M/s Teva Health, ANSM France Approved • Spasfon Injection 4ml by M/s Himont Both the references are verified. The firm has submitted requiste fee of Rs. 20,000/- vide challan No.0733515 dated 18/01/2019 for correction in the composition of the applied formulation. The correct formulation is given below: Each 4ml ampoule contains: Hydrated Phloroglucinol…….40mg Trimethyl Phloroglucinol…..0.04mg
	Decision: Approved as per Innovator's specifications with following composition: **Each 4ml ampoule contains:** **Hydrated Phloroglucinol…….40mg** **Trimethyl Phloroglucinol…..0.04mg**	
230.	Name and address of manufacturer / Applicant	M/s Faas Pharmaceuticals, Karachi
	Brand Name +Dosage Form + Strength	Methofaas tablets
	Composition	Dy. No.1439; 23-8-2017; Rs.20,000/- (22-8-2017)
	Diary No. Date of R& I & fee	Each film coated tablet contains: Methocarbamol….400mg Paracetamol….500mg
	Pharmacological Group	Analgesic skeletal muscle relexant matase Inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	3x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed

	Me-too status	Could not be confirmed
	GMP status	Routine GMP inspection conducted on 14-07-2017 concluded that the current level of compliance is rated satisfactory L issue date 21-2-2018
	Remarks of the Evaluator.	Evidence of approval in reference regulatory authorities and me-too status could not be confirmed
	Previous Decision and replies:	Decision of 283rd : Deferred for following: □ Evidence of applied formulation/drug already approved by DRAP (generic status) alongwith registration number, brand name and name of firm □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board. .
	Evaluation by PEC: Firm has submitted that me-too status as "Baxamin tablet by Schazoo Pharma reg no. 064558". And International availability as "Extra Strength back Pain Manufactured by M/s Pharmetics , Canada." Film coating in above reference products could not be confirmed.	
	Decision: Deferred for following: □ **Evidence of applied formulation/drug already approved by DRAP (generic status) alongwith registration number, brand name and name of firm** □ **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board.** .	
231.	**Name and address of manufacturer / Applicant**	**M/s Hi-Med Pharmaceuticals, 208c Sunder Industrial Estate, Lahore**
	Brand Name +Dosage Form + Strength	Hicip 250mg/5ml Oral Dry Powder for Suspension
	Composition	Dy. No.9894; 9-7-2018; Rs.20,000/- (26-6-2018)
	Diary No. Date of R& I & fee	Each 5ml contains: Ciprofloxacin as HCl (Taste mask micro-pellets 35%)…..250mg
	Pharmacological Group	Quinlones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ciproxin 250 mg/5 ml granules and solvent for oral Suspension by M/s Bayer Healthcare, MHRA approved.
	Me-too status	Ciprin 250mg/5ml suspension of M/s Werrick pharmaceuticals
	GMP status	Grant of New DML Approved dated 13-06-2018
	Remarks of the Evaluator.	Pellets are obtained from Vision Pharma, Islamabad.
	Previous Decision and replies:	Decision: Deferred for following: □ Justification of formulation containing ciprofloxacin as HCl, while the reference product contains ciprofloxacin base. Confirmation from Licensing Division whether M/s Vision Pharmaceuticals, Islamabad is licensed to manufacture Ciprofloxacin as taste masked pellets/granules and whether the granules manufactured contains ciprofloxacin as HCl or base.
	Evaluation by PEC: Firm has submitted that they will prepare granules by themselves. Firm has also revised formulation as per RRAi.e. (Each 5ml contains: Ciprofloxacin (Taste mask micro-pellets 35%)…..250mg) product with fee of Rs.5,000/- Deposit slip no: 1959059	
	Decsion: Approved.	

232.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals, 208c Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Hicip 125mg/5ml Oral Dry Powder for Suspension
	Composition	Dy. No.9894; 9-7-2018; Rs.20,000/- (26-6-2018)
	Diary No. Date of R& I & fee	Each 5ml contains: Ciprofloxacin as HCl (Taste mask micro-pellets 35%).....125mg
	Pharmacological Group	Quinlones
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ciprfloxacin for suspension by M/s Lupin ltd USFDA approved.
	Me-too status	Ciprin 125mg/5ml suspension of M/s Werrick pharmaceuticals
	GMP status	Grant of New DML Approved dated 13-06-2018
	Remarks of the Evaluator.	Pellets are obtained from Vision Pharma, Islamabad.
	Previous Decision and replies:	Decision: Deferred for following: Justification of formulation containing ciprofloxacin as HCl, while the reference product contains ciprofloxacin base. Confirmation from Licensing Division whether M/s Vision Pharmaceuticals, Islamabad is licensed to manufacture Ciprofloxacin as taste masked pellets/granules and whether the granules manufactured contains ciprofloxacin as HCl or base.
	<u>Evaluation by PEC:</u> Firm has submitted that they will prepare granules by themselves. Firm has also revised formulation as per RRAi.e. (Each 5ml contains: Ciprofloxacin (Taste mask micro-pellets 35%).....125mg) product with fee of Rs.5,000/- Deposit slip no: 1959063	
	Decsion: Approved.	

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

a. New DML

M/s. IQRA Pharmaceuticals, Islamabad (New License)

Following registration dossiers have been received vide letter No.F.1-2/2015-Lic dated 05/03/2019 stating that the firm has been granted approval of new DML by way of formulation by Central Licensing Board in its 269th meeting for following thirteen (13)sections

1. Tablet section (General)
2. Capsule section (General)
3. Cream/Ointment/Gel section
4. Oral liquid syrup section (General)
5. Dry powder oral suspension section (General)
6. Liquid Sterile Ampoule section (General)
7. Liquid Sterile Ampoule section (psychotropic)
8. Tablet section (psychotropic)
9. Sterile Ampoule section (steroid)
10. Sterile infusion/small volume vial section (General)
11. *Dry Powder for Injection (*Cephalosporin*)*
12. Capsule section (Cephalosporin)
13. Dry powder oral suspension section (Cephalosporin)

The following applications have been evaluated and presented before the Board

Sr.#	Section	No. of products	No. of molecules
1.	Tablet section (General)		
2.	Capsule section (General)		
3.	Cream /Ointment/Gel Section		
4.	**Oral liquid syrup section (General)**	**8**	**07**
5.	Dry powder oral suspension section (General)		
6.	Liquid Sterile Ampoule section (General)		
7.	Liquid Sterile Ampoule section (psychotropic)		
8.	Tablet section (psychotropic)		
9.	Sterile Ampoule section (steroid)		
10.	Sterile infusion/small volume vial section (General)		
11.	*Dry Powder for Solution for Injection (*Cephalosporin*)*		
12.	Capsule section (Cephalosporin)		
13.	Dry powder oral suspension section (Cephalosporin)		

Oral liquid syrup section (General) 8 products/ 7 molecules

235.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	IPILIUM 5mg/5ml Liquid Oral suspension
	Diary No. Date of R& I & fee	Diary No:15560, Dated 07/03/2019, Rs: 20,000/-
	Composition	Each 5ml of liquid suspension contains: Domperidone ……..5mg
	Pharmacological Group	Peripheral Dopamine Receptor Antagonist/ Antiemetic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	60ml,90ml ,120ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Domperidone 1mg/ml Oral Suspension by M/s Wockhardt UK Ltd, MHRA approved
	Me-too status	Dome-one oral suspension 5mg/5ml by M/s Shrooq pharma Reg No.40316
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved with innovator's specifications.	

236.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	LEQIM 2.5mg/5ml Liquid syrup
	Diary No. Date of R& I & fee	Diary No:15523, Dated 07/03/2019, Rs: 20,000/-
	Composition	Each 5ml of liquid syrup contains: Levocetirizine Dihydrochloride ……2.5mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	30ml,60ml ,90ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xyzal 0.5mg/ml oral solution of M/s UCB Pharma Limited (MHRA Approved)
	Me-too status	Ocitra Syrup of M/s Searle Pakistan (Pvt.) Ltd (R.#054519)
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved with innovator's specifications.	
237.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	ONSET 4mg/5ml Liquid syrup
	Diary No. Date of R& I & fee	Diary No:15512, Dated 07/03/2019, Rs: 20,000/-
	Composition	Each 5ml of liquid syrup contains: Ondansetron (as hydrochloride 146roduct146146)…..4mg
	Pharmacological Group	Selective Serotonin 5-HT3 antagonist
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	30ml,60ml ,90ml,120ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zofran Oral solution by Novartis Pharms (USFDA Approved)
	Me-too status	Dantron 4mg/5ml syrup by M/s Shrooq Pharmaceuticals.(Reg# 77076)
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved	
238.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	LEPIQ 100mg/ml Liquid Oral Syrup
	Diary No. Date of R& I & fee	Diary No:15561, Dated 07/03/2019, Rs: 20,000/-
	Composition	Each ml of liquid syrup contains: Levetiracetam ……..…100 mg
	Pharmacological Group	Anti-epileptic
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	30ml,60ml ,90ml,120ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Keppra 100mg/ml oral solution by M/s UCB INC(USFDA Approved)
	Me-too status	Elicia Oral Solution 100mg/ml by M/s Martindow ltd Reg No.81154
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved.	
239.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	ADCOS 100mg/5ml Liquid Oral Suspension

	Diary No. Date of R& I & fee	Diary No:15562, Dated 07/03/2019, Rs: 20,000/-
	Composition	Each 5ml of liquid suspension contains: Ibuprofen ……..…100 mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	60ml ,90ml,120ml,450ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Proven oral suspension ibuprofen 20mg/Ml oral liquid bottle. TGA Australia approved
	Me-too status	Ibo-Z Suspension 100mg. by M/s Z-Jans Pharmaceuticals (Pvt) Ltd, Peshawar. Reg No. 054571
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved.	
240.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	ADCOS-DS 200mg/5ml Liquid Oral Suspension
	Diary No. Date of R& I & fee	Diary No:15563, Dated 07/03/2019, Rs: 20,000/-
	Composition	Each 5ml of liquid suspension contains: Ibuprofen ……..…200 mg
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	60ml ,90ml,120ml,450ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ibuprofen 200 mg/ 5ml oral suspension by M/s Aspire Pharma Ltd, MHRA approved
	Me-too status	Brufen DS 200mg/5ml Suspension by M/s Abbott (Reg#070851)
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved.	
241.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	Rofer Liquid Oral Syrup 40mg
	Diary No. Date of R& I & fee	Diary No:15564, Dated 07/03/2019, Rs: 20,000/-
	Composition	Each 15ml Contain: Elemental iron (as iron protein succinylate)…40mg (Iron protein succinylate…..800mg)
	Pharmacological Group	Antianemic preparations
	Type of Form	Form 5
	Finished Product Specification	Innovator's specsifications
	Pack size & Demanded Price	60ml ,90ml,120ml,/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ferplex 40mg oral solution by M/s Italfarmaco Spain Ferrocur Effik, CIMA Spain Approved
	Me-too status	Fero-slim Syrup by M/s Fynk Pharmaceuticals (Reg#062725)
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved.	
242.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	NORIM 5mg/5ml Liquid Oral Syrup
	Diary No. Date of R& I & fee	Diary No:15579, Dated 07/03/2019, Rs: 20,000/-

	Composition	Each 5 ml of liquid syrup contains: Cetirizine dihydrochloride……5mg
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	30ml ,60ml,90ml,/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Benadryl Allergy Children's 1mg/ml Oral solution of McNeil Products, UK (MHRA approved)
	Me-too status	Selzine 5mg/5ml Syrup M/s. Pharmasol Private Limited, Lahore Reg#055301
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decsion: Approved.	

M/s Greater Pharma Rawat Rawalpindi was granted Drug Manufacturing License by way of formulation in 269th meeting of CLB, accordingly the firm had applied several products for registration in 289th meeting of Drug Registration Board with the following details:

Sr. No.	Section	No. of molecules	No. of Products
1	Cream/Ointment Section (General)	09	10
2	Topical Lotion Section (General)	08	08
3	Capsule section (General)	10	13
4	**Cream/Ointment Section (Steroid)**	**07**	**07**
5	Topical Lotion section (Steroid)	02	02

The firm has applied for registration of another product in **Cream/Ointment Section (Steroid),** After inclusion of the below mentioned product, status of the product will become as;
No. of Products= 08
No. of Molecules= 08

243.	Name and address of manufacturer / Applicant	M/s Greater Pharma Plot no. 35. Street no. SS-3 National Industrial Zone RCCI RAWat Islamabad.
	Brand Name +Dosage Form + Strength	Topica Cream, 0.1%
	Composition	Each gram contains: Prednicabate…….. 1mg (0.1% w/w)
	Diary No. Date of R& I & fee	Dy. No. 16781; 07/03/2019; Rs.20,000/-
	Pharmacological Group	Topical corticosteroids
	Type of Form	From 5
	Finished product Specification	USP
	Pack size & Demanded Price	10g, 15g, 30g/ price as per SRO
	Approval status of product in Reference Regulatory Authorities.	Dermatop ointment 0.1% by M/s valent pharms north, USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	New License
	Remarks of the Evaluator.	Me too status of the product could not be confirmed. The available strength is 0.25% w/w in Pakistan.
	Decision of 284th meeting of RB	
	Decsion: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

b. New/Additional Sections

CLB in its 266th meeting held on 24th October, 2018 and 269th meeting held on 26th February, 2019 has considered the case of M/s Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan and approved the regularization of building layout for following sections along with quality control laboratory and warehouse on the recommendation of panel of inspection.

The firm has said that none our product against these sections have discussed in any meeting. AD Reg-I has confirmed that M/s Medimarker has not been issued any registration/ approval. However a number of approvals have been granted for contract manufacturing.

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

New Approved Sections

S. No	Section	No. of products	No. of molecules
1	Dry Powder Injection (Cephalosporin) Section	10	04
2	Dry Powder Suspension (Cephalosporin) Section	10	06
3	Sterile Liquid Ampoule Section	10	08
4	Sterile Liquid Vial Section	08	06
5	Sterile Ear & Eye Drops Section	10	10
6	Ointment & Cream Section	09	09
7	Sachet Section	10	07

Cream & Ointment Section
11 Molecules 11 Products

244.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Medesone Cream 0.1%
	Composition	Each Gram of cream contains: Betamethasone as velerate….0.1% (w/w)
	Diary No. Date of R&I &fee	Dy. No.12256 07/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Corticosteroids
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1×5gm/tube and 1×15gm/tube Price as per SRO
	Approval status of product in Reference regulatory authority	Valnac 0.1% cream by M/s Actavis Mid atlantic, USFDA Approved
	Me-too status	Betacin 0.1% cream, by M/s Geofman Pharmaceuticals Reg # 9316
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and cGMP certificate
	Remarks of the Evaluator	
	Decsion: Approved.	
245.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Medesone-N Cream 0.1% & 0.5%
	Composition	Each Gram of cream contains: Betamethasone as velerate……0.1% Neomycin Sulphate……...0.5%
	Diary No. Date of R&I &fee	Dy. No.12255 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Corticosteroids/antibiotic
	Type of Form	Form 05
	Finished product Specification	
	Pack size & Demanded Price	1×5gm/tube and 1×15gm/tube price as per SRO
	Approval status of product in Reference	Cannot be confirmed.

	regulatory authority	
	Me-too status	Betaderm-N Cream By M/s Atco Laboratories. Reg # 8564
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	Evidence of approval of applied product in reference regulatory authorities/agencies cannot be confirmed. The product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
246.	**Name and address of Manufacturer / Applicant**	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Markrash Cream 0.1% & 8.5%
	Composition	Each Gram of cream contains: Benzalkonium Chloride ……..0.1% Zinc Oxide ……..8.5%
	Diary No. Date of R&I &fee	Dy. No.17173 07/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	antiseptic
	Type of Form	Form 05
	Finished product Specification	
	Pack size & Demanded Price	1×20gm/tube Price as per SRO
	Approval status of product in Reference regulatory authority	Cannot be confirmed
	Me-too status	Rashnil Cream by M/s Abbott Lab, reg # 6356
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	The product is not present in available pharmacopoeia (USP, BP,JP). Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
247.	**Name and address of Manufacturer / Applicant**	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Clodesone Cream 1%
	Composition	Each Gram of cream contains: Clotrimazole…….. 1%
	Diary No. Date of R&I &fee	Dy. No.17138 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	antifungal
	Type of Form	Form 05
	Finished product Specification	USP
	Pack size & Demanded Price	1×10gm/tube and 1×A15gm/tube Price as per SRO
	Approval status of product in Reference regulatory authority	Clotrimazole 1% cream by M/s Taro, USFDA Approved
	Me-too status	Imazole cream (10mg/gm) by M/s Himont Pharma, Reg # 27135
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp

		certificate
	Remarks of the Evaluator	
	Decision: Approved.	
248.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Terbi-Mark Cream 1%
	Composition	Each Gram of cream contains: Terbinafine as Hcl ……..1%
	Diary No. Date of R&I &fee	Dy. No.147178, 07/03/2019, PKR 20,000/= 06/03/201
	Pharmacological Group	Antifungal
	Type of Form	Form 05
	Finished product Specification	JP
	Pack size & Demanded Price	1×10gm/tube Price as per SRO
	Approval status of product in Reference regulatory authority	Terbinafine HCl 1% cream by M/s Taro, USFDA Approved
	Me-too status	Terbisan caream 1% by M/s Elko organization (PvT) ltd. Reg # 27076
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	
	Decision: Approved.	
249.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Markonza Cream 2%
	Composition	Each Gram of cream contains: Miconazole Nitrate ……..2%
	Diary No. Date of R&I &fee	Dy. No.17148 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1×20gm/tube Price as per SRO
	Approval status of product in Reference regulatory authority	Daktacort hydrocortisone cream (2%w/w / 1%w/w) by McNeil Products (MHRAApproved)
	Me-too status	Tinearin tube (2gm/100gm) by M/s Global pharma, Reg # 26981
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	
	Decision: Approved.	
250.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Markdiaz Cream 1%
	Composition	Each Gram of cream contains: Silver Sulfadiazine……. 1%
	Diary No. Date of R&I &fee	Dy. No.17147, 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Antibiotic (Sulfonamides)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×20gm/tube Price as per SRO
	Approval status of product in Reference	Silvazine cream 1% by M/s Kings Pharms LLc ,

	regulatory authority	USFDA Approved
	Me-too status	SILZIN cream 1% by M/s COMBAT EURASIAN PHARMA (imported) (Reg#21193)
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	
	Decision: Approved.	
251.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Neodicin Ointment 0.5%
	Composition	Each Gram of Ointment contains: Neomycin as Sulphate……0.5%
	Diary No. Date of R&I &fee	Dy. No.17166 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 05
	Finished product Specification	USP
	Pack size & Demanded Price	1×15gm/tube Price as per SRO
	Approval status of product in Reference regulatory authority	Cannot be confirmed
	Me-too status	Neomycin skin ointment by M/s Eros pharma, Reg # 31261
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	Evidence of approval of the product in reference regulatory authorities cannot be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
252.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt) Ltd A-104,S.I.T.E. Area, Hyderabad
	Brand Name +Dosage Form + Strength	Medesone-CL Cream 0.05% & 1%
	Composition	Each Gram of cream contains: Betamethasone Dipropionate……..0.05% Clotrimazole……..1%
	Diary No. Date of R&I &fee	Dy. No.17141 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Corticosteroids/Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5gm/tube and 1×10gm/tubeAs per SRO
	Approval status of product in Reference regulatory authority	Lotriderm Cream by M/S MSD ltd (MHRA Approved)
	Me-too status	Lotriderm-B Cream by M/s Hoover (R# 064534)
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	The approved product in reference country contains bethamethasone propionate equivalent to bethamethasone 0.05% while the applied formulation contains betamethasone propionate 0.05%. The formulation required to be revised.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	

CLB in its 266th meeting held on 24th October, 2018 and 269th meeting held on 26th February 2019 has considered the case of M/s Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan and approved the regularization of building layout for following sections along with quality control laboratory and warehouse on the recommendation of panel of inspection.

The firm has said that none our product against these sections have discussed in any meeting. AD Reg-I has confirmed that M/s Medimarker has not been issued any registration/ approval. However a number of approvals have been granted for contract manufacturing.

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

New Approved Sections

S. No	Section	No. of products	No. of molecules
1	Dry Powder Injection (Cephalosporin) Section	10	04
2	Dry Powder Suspension (Cephalosporin) Section	10	06
3	Sterile Liquid Ampoule Section	10	08
4	Sterile Liquid Vial Section	08	06
5	Sterile Ear & Eye Drops Section	10	10
6	Ointment & Cream Section	10	08
7	Sachet Section	10	07

Sterile Ear & Eye Drops Section
10 Molecules 10 Products

253.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Cin-Mark Drops 0.3% (Opthalmic solution / eye drops)
	Composition	Each ml contains: Ciprofloxacin as HCl……0.3% (w/v)
	Diary No. Date of R&I &fee	Dy. No.1223 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Fluoroquinolone Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5ml Price As per SRO
	Approval status of product in Reference regulatory authority	Ciloxan eye drops 0.3% (solution) by M/s Novarits Pharms Copps, USFDA Approved
	Me-too status	Alciprox 0.3% Eye Drops by M/s al-Shifa Pharma, Reg. No. 026389
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	
	Decision: Approved.	
254.	**Name and address of Manufacturer / Applicant**	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Megenta Drops
	Composition	Gentamycin sulphate……0.3%
	Diary No. Date of R&I &fee	Dy. No. _____ 26/02/2019, PKR 20,000/=
	Pharmacological Group	Aminoglycosides Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	AMDIPHARM UK Limited Capital House, 85 King William Street, London EC4N 7BL, United Kingdom MHRA Approved
	Me-too status	OCUGENT 0.3% 5ml Drops FARMIGEA Pharmaceuticals (Pvt) Ltd, Pakistan

	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and cGMP certificate
	Remarks of the Evaluator	
	Decision: Approved.	
255.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Moximed Drops 0.5% (Opthalmic solution/Eye drops)
	Composition	Each ml contains: Moxifloxacin as HCl……0.5% (w/v)
	Diary No. Date of R&I &fee	Dy. No.12242; 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Fluoroquinolones Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	(1×10ml) Price As per SRO
	Approval status of product in Reference regulatory authority	MOXIFLOXACIN HCL 0.5% 10 ml Drops (Solution) by M/s SANDOZ Pharmaceuticals Ltd 145 Jules Leger Boucherville QC, J4B 7K8 Health Canada Approved
	Me-too status	Moxicin 0.5% Drops M/s Schazoo Labs, Reg # 50297
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	
	Decision: Approved.	
256.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Natam Drops 0.5% (Opthalmic solution / Eye-Ear drops)
	Composition	Each ml contains: Natamycin……. 5%
	Diary No. Date of R&I &fee	Dy. No.12245 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Aminoglycosides Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5ml, 1×10ml Price As per SRO
	Approval status of product in Reference regulatory authority	NATACYN 5% eye suspension by M/s NOVARTIS PHARMS COPPs, USFDA Approved
	Me-too status	NATACIN 5% 5ml Drops SCHAZOO Pharmaceuticals (Pvt) Ltd, Pakistan
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	The formulation approved in reference country is Suspension while the applied formulation is Solution.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
257.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Nicimarbot Drops (154roduct154154154 solution Eye/Ear drops)
	Composition	Each ml contains: Tobramycin Sulphate……0.3% (w/v)
	Diary No. Date of R&I &fee	Dy. No.12248 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Aminoglycosides Antibiotics

	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5ml Price As per SRO
	Approval status of product in Reference regulatory authority	TOBREX 0.3% Eye Drops NOVARTIS PHARMACEUTICALS Ltd, USFDA Approved
	Me-too status	ORBACIN 0.3% eye drops by M/s Zafa Pharma, Reg # 20200
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	The intended use of reference product is for Ocular administration while the firm has applied for Ocular as well as Otic route of administration. Label claim of the applied formulation is not as per the reference formulation. The applied formulation contains Tobramycin Sulphate while product approved in reference country+Me-too contain Tobramycin.
	Decision: Deferred for the following: • **Revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.**	
258.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Norosin Drops 0.3% (Opthalmic Solution/Eye drops)
	Composition	Each ml contaions: Norfloxacin……0.3% (w/v)
	Diary No. Date of R&I &fee	Dy. No.12244; 06/03/2019, PKR 20,000/= 05/03/2019
	Pharmacological Group	Fluoroquinolone Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	(1×5ml)As per SRO
	Approval status of product in Reference regulatory authority	Zoroxin eye drops (Solution) by M/s Laboratoires THEA, AGES Austria Approved
	Me-too status	FLONOX 0.3% w/v 5ml Drops INNVOTEK Pharmaceuticals (Pvt) Ltd, Pakistan, Reg # 26959
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	
	Decision: Approved.	
259.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Oflomark drops 0.3% (Opthalmic Solution/Eye drops)
	Composition	Each ml contains: Ofloxacin as HCl……0.3% (w/v)
	Diary No. Date of R&I &fee	Dy. No.12248; 06/03/2019, PKR 20,000/=, 05/03/2019
	Pharmacological Group	Fluoroquinolone Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5ml, Price As per SRO
	Approval status of product in Reference regulatory authority	Ofloxacin 0.3% Opthalmic Solution by M/s Akorn, USFDA approved
	Me-too status	Flobacin 0.3% Eye Drops Reg. No. 031208 M/s Alza Pharmaceuticals,
	GMP status	The firm last inspected on 18-10-2018 for Grant of

		Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	The firm has applied for Ofloxacin As HCl, while the product approved in reference country and me-too contain Ofloxacin base. Revision of formulation is required.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
260.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Ramphen Drops (ophthalmic solution/ Eye-Ear Drops)
	Composition	Each ml contains: Chloramphenicol……0.5% (w/v)
	Diary No. Date of R&I &fee	Dy. No. 17167 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Dichloroacetic Acid Derivatives/antibiotic
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5ml price As per SRO
	Approval status of product in Reference regulatory authority	Chloramphenicol 0.5% Eye Drops (solution), by M/s Martindale Pharmaceuticals Limited, MHRA approved
	Me-too status	Op-chlor eye drops 0.5% by M/s E.pharm lab Karachi, Reg # 85676
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	The applied formulation is approved for Ocular administration while the firm has applied the product for Ocular and Otic administration.
	Decision: Deferred for revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.	
261.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Nepaf 0.1% Eye Drops (Opthalmic solution/ Eye-Ear drops)
	Composition	Each ml contains: Nepafenac……0.1% (w/v)
	Diary No. Date of R&I &fee	Dy. No. 17168 07/03/2019, PKR 20,000/=
	Pharmacological Group	NSAIDs
	Type of Form	Form – 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1×5ml, price As per SRO
	Approval status of product in Reference regulatory authority	Nevanac 0.1% Eye Drops (suspension) by M/s NOVARTIS, USFDA Approved
	Me-too status	Cannot be confirmed
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and cGMP certificate
	Remarks of the Evaluator	Me-too status of the applied formulation cannot be confirmed. The proposed applied formulation is in Solution form while the product approved in reference country is suspension. Moreover, the approved formulation is reference country is intended to be applied on Eyes while the

		applied formulation is intended to be administered to the eyes as well as Ears.
	Decision: Deferred for the following: • **Deferred for evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm.** • **Revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.**	
262.	Name and address of Manufacturer / Applicant	Medimarker's Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Zoltim Eye Drops Opthalmic solution/ Eye-Ear drops)
	Composition	Each ml contains: Dorzolamide HCl……2% Timolol Maleate……0.5%
	Diary No. Date of R&I &fee	Dy. No. 17146 07/03/2019, PKR 20,000/= 06/03/2019
	Pharmacological Group	Carbonic Anhydrase Inhibitors with Beta Blockers
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5ml, price As per SRO
	Approval status of product in Reference regulatory authority	Cosopt ophthalmic solution by M/s OakPharms INC, USFDA approved
	Me-too status	COSOPT 2% 5ml Drops OBS Pharmaceuticals (Pvt) Ltd, Pakistan Reg # 25294
	GMP status	The firm last inspected on 18-10-2018 for Grant of Additional sections and Cgmp certificate Panel recommends Grant of Additional sections and Cgmp certificate
	Remarks of the Evaluator	The label claim is not as per reference formulation (Dorzolamide HCl and Timolol as Maleate) and is required to be revised. The approved formulation is reference country is intended to be applied on Eyes while the applied formulation is intended to be administered to the eyes as well as Ears.
	Decision: Deferred for the following: • **Revision of formulation and label claim intended for use as per reference product along with submission of requisite fee.**	

Miscellaneous cases:

Following Duplicate application dossier was received from R-I section vide letter No. F.1-2/209-Reg-I dated 20th August, 2019 along with the extract from record of R-I section regarding verification of receipt of the said application.

263.	Name and address of manufacturer / Applicant	M/s Searle company limited, 1st floor NICL building Abbasi Shaheed Road off: Shahrah e Faisal Karachi Factory: The Searle company limited F-39 Site Karachi Pakistan.
	Brand Name +Dosage Form + Strength	Jentinment 50/850mg Tablet
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…..50mg Metformin HCl……...850mg
	Diary No. Date of R& I & fee	Dy. No. 18660; 23/10/2017; Rs.20,000/- (20-10-2017)
	Pharmacological Group	Anti Diabetic
	Type of Form	Form 5 (Duplicate Dosier)
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10's, 14's, 28's/ Price as per DPC

	Approval status of product in Reference Regulatory Authorities.	Janumet 50/850 mg film coated Tablet by Merck Sharp & Dohme (Australia) Pty Ltd (TGA Approved)
	Me-too status	Inosita Plus tablet 50/850 by M/s Pharmeve Reg No. 83004
	GMP status	The firm was inspected on 27.06.2018, wherein the GMP of the firm was rated good.
	Remarks of the Evaluator.	
	Decision of 284th meeting of RB	
	Decision: Approved. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	

Agenda of Evaluator PEC-IX

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

a. New cases

264.	Name and address of manufacturer / Applicant	M/s Himont Pharmaceuticals Pvt Ltd. 17-km, Ferozepur Road, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Azomont 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin…500mg
	Diary No. Date of R& I & fee	Dy No. 27714: 13.08.2018 PKR 20,000/-: 10.08.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	6's; as per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX (azithromycin) 250 mg and 500 mg film-coated tablets, for oral use. USFDA
	Me-too status	Arsomycin 500mg Tablets. Reg. No. 85508
	GMP status	The firm was inspected on 04.10.2018 to 04.10.2018, wherein the firm was reported to be at statisfactory elvel of GMP compliance. Some advises were given in report to the firm for future upgradation.
	Remarks of the Evaluator.	•
	Decision: Approved	
265.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Telmisin 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R& I & fee	Dy No. 28183: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmark 20mg film-coated tablets. MHRA approved Telmisartan 20mg tablets. MHRA approved
	Me-too status	Telsan 20mg Tablets. Reg. No. 47221
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• Brand name may be changed to avoid confusion with tamsulosin. • You have mentioned coating in the manufacturing outlines. Justify.
	Decision: Deferred for clarification of mentioning coating in the manufacturing outlines	
266.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Ceretam 800mg Tablet

	Composition	Each Film Coated Tablet Contains: Piracetam…800mg
	Diary No. Date of R& I & fee	Dy No. 28182: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's, 3x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Piracetam 800mg film-coated tablet. MHRA approved
	Me-too status	Nootropil Tablet 800mg. Reg. No. 82277
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
267.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Rivas 1.5mg Capsule
	Composition	Each Capsule Contains: Rivastigmine as Hydrogen Tartrate…1.5mg
	Diary No. Date of R& I & fee	Dy No. 28179: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	KERSTIPON 1.5 MG CAPSULE HARD. MHRA approved
	Me-too status	Rivsaff Capsule 1.5mg. Reg. No. 81394
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
268.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Rivas 3mg Capsule
	Composition	Each Capsule Contains: Rivastigmine as Hydrogen Tartrate…3mg
	Diary No. Date of R& I & fee	Dy No. 28180: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Anticholinesterases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	KERSTIPON 3 MG CAPSULE HARD. MHRA approved
	Me-too status	Rivsaff Capsule 3mg. Reg. No. 81395
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
269.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Adomet 250mg Tablet
	Composition	Each Film Coated Tablet Contains: Methyldopa BP eq. to Anhydrous Methyldopa…250mg
	Diary No. Date of R& I & fee	Dy No. 25422: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Antifungal

	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	100's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ALDOMET® (METHYLDOPA) film-coated. MHRA approved
	Me-too status	Dopamat 250mg Tablet. Reg. No. 56148
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Deferred for correction of pharmacological group	
270.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Adecaine 20mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Lidocaine Hydrochloride…….20mg
	Diary No. Date of R& I & fee	Dy No. 30567: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	ANESTHETICS, LOCAL
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2mlx50's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	LIDOCAINE ACCORD 10 mg / ml (2ml) solution for injection. ANSM approved.
	Me-too status	Lignox Injection. Reg. No. 76968
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention to improve further."
	Remarks of the Evaluator.	Stamped signatures of qualified persons are placed on file.
	Decision: Approved	
271.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Amadol 50mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Tramadol HCL…50mg
	Diary No. Date of R& I & fee	Dy No. 30565: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Other opioids
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRAMAL tramadol hydrochloride 50mg/1mL injection ampoule. TGA approved
	Me-too status	Palmadol Injection 50mg. Reg. No. 82969 (does not depict vial or ampule)
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention to improve further."
	Remarks of the Evaluator.	Stamped signatures of qualified persons are placed on the file.
	Decision: Approved	

272.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Amcam 20mg Injection
	Composition	Each 1ml Ampoule Contains: Piroxicam…20mg
	Diary No. Date of R& I & fee	Dy No. 30565: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	1mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FELDENE 20 mg / 1 ml solution for injection for intramuscular use **(vial)**. AIFA approved
	Me-too status	Piroxinor 20mg Injection. Reg. No. 80001
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention to improve further."
	Remarks of the Evaluator.	• Stamped signatures of qualified persons are placed on the file.
	Decision: Approved	
273.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Densten 8mg/4ml Injection
	Composition	Each 4ml Ampoule Contains: Ondansetron as Hydrochloride Dihydrate….8mg
	Diary No. Date of R& I & fee	Dy No. 30563: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	4mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZOFRAN ondansetron 8mg/4mL (as hydrochloride dihydrate) injection ampoule. TGA approved
	Me-too status	ZOFRAN INJECTION 8MG / 4ML. Reg. No. 20669
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention to improve further."
	Remarks of the Evaluator.	• Stamped signatures of qualified persons are placed on the file.
	Decision: Approved with USP specifications.	
274.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Kamivil 50mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Promethazine HCL…50mg
	Diary No. Date of R& I & fee	Dy No. 30568: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Phenothiazine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2mlx5's; As per SRO

	Approval status of product in Reference Regulatory Authorities.	DBL PROMETHAZINE HYDROCHLORIDE 50mg/2mL injection BP ampoule. TGA approved
	Me-too status	Prom Injection (2ml). Reg. No. 44008 (does not reveal ampule or vial)
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention to improve further."
	Remarks of the Evaluator.	Stamped signatures of qualified persons are placed on the file.
	Decision: Approved.	
275.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	K-Hepta 5g/10ml Infusion Concentrate
	Composition	Each 10ml Ampoule Contains: L-Ornithine L-Asparate…5g
	Diary No. Date of R& I & fee	Dy No. 30562: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Liver therapy
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10mlx1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Hepa-Merz 5 g / 10 ml infusion solution concentrate (ampule). AGES approved
	Me-too status	Enervin Infusion (10ml). Reg. No. 81547 (does not reveal ampule or vial)
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention to improve further."
	Remarks of the Evaluator.	• Stamped signatures of qualified persons are placed on the file.
	Decision: Approved	
276.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Mucoline 250mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Citicoline as sodium…250mg
	Diary No. Date of R& I & fee	Dy No. 30561: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2mlx1's, 2mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CITICOLINE PANPHARMA 250 mg/ 2 ml, solution injectable (IM,IV) ampoule. ANSM approved
	Me-too status	Citograin Injection (2ml). Reg. No. 50042
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention

		to improve further."
	Remarks of the Evaluator.	• Stamped signatures of qualified persons are placed on the file.
	Decision: Approved	
277.	Name and address of manufacturer / Applicant	M/s Amaan Pharma. 30 km, Sheikhupura Road, Lahore
	Brand Name +Dosage Form + Strength	Thiomax 4mg/2ml Injection
	Composition	Each 2ml Ampoule Contains: Thiocolchicoside…4mg
	Diary No. Date of R& I & fee	Dy No. 30557: 11.09.2018 PKR 20,000/-: 11.09.2018
	Pharmacological Group	MUSCLE RELAXANTS, Centrally Acting AGENTS
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	2mlx1's, 2mlx5's, 2mlx6's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	THIOCOLCHICOSIDE PHARMY II 4 mg/2 ml, solution injectable ampule. ANSM approved
	Me-too status	Myolax Injection. Reg. No. Reg. No. 69277
	GMP status	The firm was inspected on 11.05.2018, with the following conclusion: "Overall manufacturing facility, equipment/ instruments and hygienic condition of the firm was good. However they are needed improvements in documentation related to production and quality control. Firm showed good intention to improve further."
	Remarks of the Evaluator.	• Stamped signatures of qualified persons are placed on the file.
	Decision: Approved	
278.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Dapox 30mg Tablet
	Composition	Each Film Coated Tablet Contains: Dapoxetine Hydrochloride Eq. to Dapoxetine…30mg
	Diary No. Date of R& I & fee	Dy No. 30216: 07.09.2018 PKR 20,000/-: 06.09.2018
	Pharmacological Group	Other urologicals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	6's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	PRILIGY dapoxetine 30 mg (as hydrochloride) film-coated tablet blister pack. TGA approved
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Undertaking at the end of Form 5 has not been submitted. • You have applied for film-coated tablet. However, coating material has not been submitted. • Evidence of me-too product (name and registration number) approved by DRAP is required. • Stamped signatures of qualified persons are placed on the file. • Form 5 has been signed by the Chief Operating Officer, not CEO of the firm.
	Decision: Deferred for the following: • **Undertaking at the end of Form 5 has not been submitted.** • **The firm applied for film-coated tablet. However, coating material has not been submitted.** • **Evidence of me-too product (name and registration number) approved by DRAP is required.**	

279.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Delite 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Sildenafil Citrate Eq. to Sildenafil…50mg
	Diary No. Date of R& I & fee	Dy No. 30218: 07.09.2018 PKR 20,000/-: 06.09.2018
	Pharmacological Group	Drugs used in erectile dysfunction
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	4's, 8's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	VIAGRA sildenafil (as citrate) 25mg, 50mg and 100mg film-coated tablet. TGA approved
	Me-too status	Could not be confirmed
	GMP status	GMP Certificate issued on 08.05.2018.
	Remarks of the Evaluator.	• Undertaking at the end of Form 5 has not been submitted. • You have applied for film-coated tablet. However, coating material has not been submitted. • Evidence of me-too product (name and registration number) approved by DRAP is required. • Stamped signatures of qualified persons are placed on the file.
	Decision: Deferred for the following: • **Undertaking at the end of Form 5 has not been submitted.** • **The firm applied for film-coated tablet. However, coating material has not been submitted.** • **Evidence of me-too product (name and registration number) approved by DRAP is required.**	
280.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	Clodip Tablet 75mg
	Composition	Each film-coated tablet contains: Clopidogrel as bisulfate….75mg.
	Dairy No. Date of R & I fee	Dy.No.7198: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Platelet aggregation inhibitors excl. heparin
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x10's Pack of Blister: As per SRO
	Approval status of product in Reference Regulatory Authorities	PLAVIX® (clopidogrel bisulfate) tablets film-coated (75mg and 300mg), for oral use. Approved by USFDA
	Me-too status	Plavix Tablet film-coated 75mg. Reg. No. 75977
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	
	Decision : Approved	
281.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd., Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	Tenilol Tablet 100mg
	Composition	Each Tablet contains: Atenolol …. 100mg
	Dairy No. Date of R & I fee	Dy No. 7204: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack Size & Demanded Price	2x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Atenolol 100mg Tablets Approved by MHRA (both film-coated and plain)
	Me-too status	Atenosap -100 Tablets. Reg. No. 77097 Dysonol Tablet 100mg, film-coated. Reg. No. 67870
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	
	Decision : Approved	
282.	Name and address of manufacturer/Applicant	A. J. Mirza Pharma (Pvt.) Ltd.,Plot No.44, Sector No. 27 Korangi Industrial Area Karachi, Pakistan.
	Brand Name+ Dosage Form+ Strength	Tenilol Tablet 50mg
	Composition	Each Tablet contains: Atenolol …. 50mg
	Dairy No. Date of R & I fee	Dy No. 7203: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	2x10's Blister pack , As per SRO
	Approval status of product in Reference Regulatory Authorities	Atenolol 50mg Tablets Approved by MHRA (both film-coated and plain)
	Me-too status	Atenosap -100 Tablets. Reg. No. 77094 Hetolol Tablets 50mg film-coated. Reg. No. 69749
	GMP status	The firm provided inspection report dated 13.03.2019, wherein the renewal of DML for the following sections has been recommended. Tablet (G), Capsule (G), Liquid syrup (G).
	Remarks of the Evaluator	
	Decision : Approved	
283.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	Sofocin 250mg/5ml Suspension
	Composition	Each 5ml Suspension Contains: Fosfomycin as Calcium…250mg
	Diary No. Date of R& I & fee	Dy No. 27968: 15.08.2018 PKR 20,000/-: 15.08.2018
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Fosfocina Suspensión 250mg/5ml (as calcium salt). CIMA approved
	Me-too status	Fosfosyn Dry Suspension. Reg. No. 76924
	GMP status	The firm was inspected on 29.03.2019, wherein the panel concluded that the firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved	
284.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK
	Brand Name +Dosage Form + Strength	Losapine 5mg/50mg Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg Amlodipine as Camsylate…5mg
	Diary No. Date of R& I & fee	Dy No. 28139: 17.08.2018 PKR 20,000/-: 17.08.2018

	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 29.03.2019, wherein the panel concluded that the firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	• Provide proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board, and direct weblink thereof. • Evidence of approval of me-too product by DRAP is required.
	Decision: Deferred for the following: • **Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board, and direct weblink thereof.** • **Evidence of approval of me-too product by DRAP is required.**	
285.	Name and address of manufacturer / Applicant	Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi
	Brand Name +Dosage Form + Strength	Stazz Injection 250mg IV
	Composition	Each vial contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IV) by Lupin Pharmaceuticals Inc. US-FDA approved
	Me-too status	Ceftirains 250mg (ceftriaxone Sodium) I.V Injection by Sunrise Pharma (Pvt) Ltd. Reg. No. 78655
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator.	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Decision: Deferred for the following: • **Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.** • **Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.**	

	• **Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.**	
286.	Name and address of manufacturer / Applicant	Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi
	Brand Name +Dosage Form + Strength	Stazz Injection 500mg IV
	Composition	Each vial contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IV). US-FDA approved
	Me-too status	Wincef 500 mg (Ceftriaxone sodium) IV. Reg. No. 78097
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator.	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Decision: Deferred for the following: • **Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker..** • **Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.**	
287.	Name and address of manufacturer / Applicant	Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi
	Brand Name +Dosage Form + Strength	Stazz Injection 1g IV
	Composition	Each vial contains: Ceftriaxone Sodium Eq. to Ceftriaxone…1g
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 1 g (IV). US-FDA approved
	Me-too status	Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection. Reg. No. 70663
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator.	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and

		which one is contract taker. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Decision: Deferred for the following: • **Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker..** • **Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.**	
288.	Name and address of manufacturer / Applicant	Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi
	Brand Name +Dosage Form + Strength	Getfix 100mg/5ml dry suspension
	Composition	Each 5ml contain: Cefixime as trihydrate……100mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Cefixime 100 mg/5 ml Powder for Oral Suspension. MHRA approved
	Me-too status	Elixime Dry Suspension 100mg. Reg. No. 53729
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator.	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Decision: Deferred for the following: • **Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker..** • **Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.**	
289.	Name and address of manufacturer / Applicant	Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi
	Brand Name +Dosage Form + Strength	Getfix 200mg/5ml dry suspension
	Composition	Each 5ml contain: Cefixime as trihydrate……200mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier)

		PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) for oral suspension. **USFDA** approved
	Me-too status	Elixime Dry Suspension 200mg. Reg. No. 53730
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator.	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.
	Decision: Deferred for the following: • **Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker..** • **Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.**	
290.	Name and address of manufacturer / Applicant	Espoir Pharmaceuticals (Pvt) Ltd. PCSIR, TBIC II Pvt. Ltd Karachi
	Brand Name +Dosage Form + Strength	Getfix Capsule 400mg
	Composition	Each capsule contain: Cefixime as trihydrate……400mg
	Diary No. Date of R& I & fee	Dy No. NIL: 11.06.2013 (duplicate dossier) PKR 20,000/-: 11.06.2013 PKR 30,000/-: 16.06.2016
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SUPRAX® (cefixime) capsules, for oral use by Lupin Ltd for Lupin Pharma. Approved by US-FDA
	Me-too status	Nowcef 400mg Capsule by Nawan Lab. Karachi. Reg. No. 82219
	GMP status	The firm was inspected on 02.04.2019, wherein acceptable level of GMP was reported.
	Remarks of the Evaluator.	• Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker.. • Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma. • Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.

	Decision: Deferred for the following: • **Submit complete contract manufacturing agreement between the applicant and manufacturer (as per SRO) mentioning that which firm is contract giver and which one is contract taker..** • **Provide list of all approved products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all applied products for contract manufacturing by your firm, i.e., M/s Espoir Pharma.** • **Provide list of all approved sections of you firm, i.e., M/s Espoir Pharma.**	
291.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Canwim 16mg Tablet
	Composition	Each Tablet Contains: Candesartan Cilexetil…16mg
	Diary No. Date of R& I & fee	Dy No. 28178: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Angiotensin II antagonists, plain
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 20's, 28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ATACAND® (candesartan cilexetil) 16 mg non-film-coated tablets, for oral use. **US-FDA** approved
	Me-too status	Cansart Tablets by CCL Pharma. Reg. No. 33953
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
292.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Canwim 8mg Tablet
	Composition	Each Tablet Contains: Candesartan Cilexetil…8mg
	Diary No. Date of R& I & fee	Dy No. 28177: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Angiotensin II antagonists, plain
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 20's, 28's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ATACAND® (candesartan cilexetil) 8 mg non-film-coated tablets, for oral use by ANI Pharms Inc. **US-FDA** approved
	Me-too status	Cansart 8mg Tablets by CCL Pharma. Reg. No. 82665
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
293.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Paradrine tablet 450/35mg
	Composition	Each Tablet Contains: Paracetamol…450mg Orphenadrine Citrate…35mg
	Diary No. Date of R& I & fee	Dy No. 28170: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Orphenadrine, combinations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 30's, 100's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	NORGESIC paracetamol orphenadrine citrate blister pack (uncoated). **TGA** approved

	Me-too status	Barfim Tablets. Reg. No. 78572
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
294.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Telmisin 20mg Tablet
	Composition	Each Tablet Contains: Telmisartan…20mg
	Diary No. Date of R& I & fee	Dy No. 28183: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Telmark 20mg film-coated tablets. **MHRA** approved Telmisartan 20mg tablets. MHRA approved
	Me-too status	Telsan 20mg Tablets. Reg. No. 47221
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• Brand name may be changed to avoid confusion with tamsulosin.
	Decision: Approved with change of brand name	
295.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tiowim 18mcg Capsule
	Composition	Each Capsule Contains: Tiotropium as Bromide monohydrate…18mcg
	Diary No. Date of R& I & fee	Dy No. 28169: 17.08.2018 PKR 20,000/-: 17.08.2018
	Pharmacological Group	Anticholinergics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	6's, 15's, 20's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Spiriva® 18 microgram Capsules for Inhalation. **MHRA** approved
	Me-too status	Tyo Rotacaps 18mcg. Reg. No. 82188
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The firm was asked to provide proof of availability of manufacturing facility for rota caps, as per decision of 290th meeting of RB. The firm did not respond to the query.
	Decision: Deferred for proof of availability of manufacturing facility for Dry powder inhaler capsules, as per decision of 290th meeting of RB	
296.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Nilstin Oral drops
	Composition	Each ml contains: Nystatin……100,000IU
	Diary No. Date of R& I & fee	Dy No. 28167: 17.08.2018 PKR 20,000/-: 07.08.2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	NILSTAT ORAL DROPS nystatin 100000 IU/mL suspension bottle. **TGA** approved
	Me-too status	Nimstat Oral drops. Reg. No. 68504

	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
297.	Name and address of manufacturer / Applicant	Eros Pharmaceuticals (Pvt) Limited, Plot # 94-95 Sector 23, Korangi Industrial Area, Karachi 74900, Sindh, Pakistan
	Brand Name +Dosage Form + Strength	Erogent 0.1% Cream
	Composition	Each gram contains: Gentamicin as sulphate……1mg
	Diary No. Date of R& I & fee	Dy No. NIL: 03.11.2010 (duplicate dossier, Form 5 freshly signed) PKR 8,000/-: 03.11.2010 PKR 60,000/-: 18.05.2015 (for 05 dossier)
	Pharmacological Group	Other antibiotics for topical use
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GARAMYCIN 0.1% Cream topical. Discontinued not for safety or efficacay reasons USFDA.
	Me-too status	Mafgent 0.1% Cream. Reg No. 79881
	GMP status	The firm was inspected on 11.12.2018 with the following conclusion: Keeping in view the request of the firm, the competent Authority is pleased to constitute the panel for through cGMP inspection of the Ophthalmic section of the firm and for the verification of improvements before resumption of production.
	Remarks of the Evaluator.	
	Decision: Approved	
298.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Getprazole 20mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Rabeprazole Sodium…20mg
	Diary No. Date of R& I & fee	Dy No. 25784: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; Rs. 400/-
	Approval status of product in Reference Regulatory Authorities.	PARIET™ 20mg gastro-resistant tablet. MHRA approved
	Me-too status	Rabekan Tablet, 20mg enteric coated. Reg. No. 83829
	GMP status	The firm was inspected on 26.06.2018 with the following conclusion: "Based on the area inspected, the people met and the documents reviewed, the considering the findings of the inspection, including the observations listed in the inspection report, M/s Getz pharma, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today."
	Remarks of the Evaluator.	• Form has been signed by Sr. Manager Reulatory affairs. • The firm has mentioned methylene chloride (dichloromethane) in the manufacturing outlines. The firm did not clarify the same.
	Decision: Deferred for the justification of using methylene chloride as coating solvent since it has been declared as banned excipient.	

299.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd. 29-30/27, Korangi Industrial Area, Karachi."
	Brand Name +Dosage Form + Strength	Getprazole 10mg Tablet
	Composition	Each Enteric Coated Tablet Contains: Rabeprazole Sodium…10mg
	Diary No. Date of R& I & fee	Dy No. 25783: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's; Rs. 200/-
	Approval status of product in Reference Regulatory Authorities.	PARIET™ 10mg gastro-resistant tablet. MHRA approved
	Me-too status	Raprazole Tablet, 10mg enteric coated. Reg. No. 83279
	GMP status	The firm was inspected on 26.06.2018 with the following conclusion: "Based on the area inspected, the people met and the documents reviewed, the considering the findings of the inspection, including the observations listed in the inspection report, M/s Getz pharma, Karachi was considered to be operating at an acceptable level of compliance with GMP guidelines as of today."
	Remarks of the Evaluator.	• Form has been signed by Sr. Manager Reulatory affairs. • The firm has mentioned methylene chloride (dichloromethane) in the manufacturing outlines. The firm did not clarify the same
	Decision: Deferred for the justification of using methylene chloride as coating solvent since it has been declared as banned excipient.	
300.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131- Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	Olsar HCT Tablet 40/12.5mg
	Composition	Each film-coated tablet contains: Olmesartan medoxomil….40mg Hydrochlorthiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy No. 27981: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	BENICAR HCT (olmesartan medoxomil and hydrochlorothiazide) tablets, for oral use, film-coated. USFDA approved.
	Me-too status	Olmietec Tablet 40/12.5, film-coated. Reg. No. 50719
	GMP status	The firm was inspected on 26.07.2017, wherein the firm was rated at satisfactory level of cGMP.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
301.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131- Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	Olsar HCT Tablet 20/12.5mg
	Composition	Each film-coated tablet contains: Olmesartan medoxomil….20mg Hydrochlorthiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy No. 27980: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications

	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	BENICAR HCT (olmesartan medoxomil and hydrochlorothiazide) tablets, for oral use, film-coated. USFDA approved.
	Me-too status	Olmietec Tablet 40/12.5, film-coated. Reg. No. 50719
	GMP status	The firm was inspected on 26.07.2017, wherein the firm was rated at satisfactory level of cGMP.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
302.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131- Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	Olsar-AM Tablet 40/10mg
	Composition	Each film-coated tablet contains: Olmesartan medoxomil……40mg Amlodipine as besilate…….10mg
	Diary No. Date of R& I & fee	Dy No. 27979: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	AZOR 10/40 mg (amlodipine and olmesartan medoxomil) film-coated. **USFDA** approved
	Me-too status	Olmis-A 10mg/40mg Tablet. Reg. No. 83259
	GMP status	The firm was inspected on 26.07.2017, wherein the firm was rated at satisfactory level of cGMP.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
303.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131- Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	Olsar-AM Tablet 40/5mg
	Composition	Each film-coated tablet contains: Olmesartan medoxomil……40mg Amlodipine as besilate…….5mg
	Diary No. Date of R& I & fee	Dy No. 27978: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	AZOR 5/40 mg (amlodipine and olmesartan medoxomil) film-coated. **USFDA** approved
	Me-too status	Olmis-A 5mg/40mg Tablet. Reg. No. 83257
	GMP status	The firm was inspected on 26.07.2017, wherein the firm was rated at satisfactory level of cGMP.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
304.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131- Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	Olsar-AM Tablet 20/10mg
	Composition	Each film-coated tablet contains: Olmesartan medoxomil……20mg Amlodipine as besilate…….10mg
	Diary No. Date of R& I & fee	Dy No. 27977: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's; as per SRO

	Approval status of product in Reference Regulatory Authorities.	AZOR 10/20 mg (amlodipine and olmesartan medoxomil) film-coated. **USFDA** approved
	Me-too status	Olmis-A 10mg/20mg Tablet. Reg. No. 83258
	GMP status	The firm was inspected on 26.07.2017, wherein the firm was rated at satisfactory level of cGMP.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
305.	Name and address of manufacturer / Applicant	Hicon Pharmaceuticals, 131- Industrial Estate, Hayatabad
	Brand Name +Dosage Form + Strength	Olsar-AM Tablet 20/5mg
	Composition	Each film-coated tablet contains: Olmesartan medoxomil……20mg Amlodipine as besilate…….5mg
	Diary No. Date of R& I & fee	Dy No. 27976: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Antihypertensives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 20's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	AZOR 5/20 mg (amlodipine and olmesartan medoxomil) film-coated. **USFDA** approved
	Me-too status	Olmis-A 5mg/20mg Tablet. Reg. No. 83256
	GMP status	The firm was inspected on 26.07.2017, wherein the firm was rated at satisfactory level of cGMP.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
306.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Nalgesic Injection 10mg/ml
	Composition	Each ml contains: Nalbuphine hydrochloride….10mg
	Diary No. Date of R& I & fee	Dy No. 27716 13.08.2018 PKR 20,000/-: 13.08.2018
	Pharmacological Group	Morphinan derivatives
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufactuer's specifications.
	Pack size & Demanded Price	1ml; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	NUBAIN (Nalbuphine Hydrochloride) Injection, 10 mg/mL (1ml ampule). Health Canada approved.
	Me-too status	Nalburax Injection. Reg. No. 28830 (deos not show ampule or vial)
	GMP status	The firm was inspected on 16th-28th August, 2018 Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator.	• Form 5 has been signed by person from medical and regulatory department of the firm.
	Decision: Deferred for signatures of respective personnels.	
307.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Nalgesic Injection 20mg/ml
	Composition	Each ml contains: Nalbuphine hydrochloride….20mg
	Diary No. Date of R& I & fee	Dy No. 27717 13.08.2018 PKR 20,000/-: 13.08.2018
	Pharmacological Group	Morphinan derivatives
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufactuer's specifications.

	Pack size & Demanded Price	1ml; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	NUBAIN® (Nalbuphine Hydrochloride) 20 mg/mL, 1 mL ampuls. Not discontinued or withdrawn for safety or efficacy reasons in USFDA
	Me-too status	Nalfoline 20mg/ml IM/IV Injection. Reg. No. 83906 (deos not show ampule or vial)
	GMP status	The firm was inspected on 16th-28th August, 2018 Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator.	• Form 5 has been signed by person from medical and regulatory department of the firm.
	Decision: Deferred for signatures of respective personnels.	
308.	Name and address of manufacturer / Applicant	M/s Barrett Hodgson Pakistan (Private) Ltd. F/423, SITE, Karachi
	Brand Name +Dosage Form + Strength	Lincostar Capsule 500mg
	Composition	Each capsule contains: Lincomycin as HCl….20mg
	Diary No. Date of R& I & fee	Dy No. 27715: 13.08.2018 PKR 20,000/-: 13.08.2018
	Pharmacological Group	Lincosamides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	12's; Rs. 180/-
	Approval status of product in Reference Regulatory Authorities.	Lincocine 500 mg capsule (Lincomycin as HCl hydrate) by Pfizer Holding France. Approved by ANSM France
	Me-too status	Linnco 500mg Capsule (Lincomycin as HCl) by Mafins Pharmaceuticals (Pvt) Ltd., Karachi. Reg. No. 79898
	GMP status	The firm was inspected on 16th-28th August, 2018 Conclusion: The firm has complied and addressed all the observations as advised in the last inspection. Overall found satisfactory and progressive towards good level of GMP compliance.
	Remarks of the Evaluator.	• Form 5 has been signed by person from medical and regulatory department of the firm. • The USP has specified Raman spectroscopy for dissolution study of Lincomycin capsules. The firm was asked to provide proof of provision of Raman spectrophotometer. The firm replied that they will arrange the same. • The firm was asked to revise the API to Lincomycin as HCl monohydrate in label claim. The firm replied that they will revise the same.
	Decision: Deferred for the following: • **Proof of provision of Raman spectrophotometer.** • **Revision of the API to Lincomycin as HCl monohydrate in label claim** • **Signatures of respective personnels.**	
309.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Jectofer 50mg/ml injection
	Composition	Each ml contains: Ferric carboxymaltose eq. to elemental iron…..50mg
	Diary No. Date of R& I & fee	Dy No. 6181: 23.09.2014 (Duplicate dossier) PKR 20,000/-: 23.09.2014
	Pharmacological Group	Iron preparations
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications

	Pack size & Demanded Price	1x10ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	INJECTAFER® (ferric carboxymaltose injection), for intravenous use (750mg/15ml). USFDA approved. Ferinject 50 mg iron/mL solution for injection/infusion (2ml, 10ml, 20ml). MHRA approved FERINJECT 50 mg/ml, solution injectable/pour perfusion (infusion) (10ml). ANSM approved
	Me-too status	Ferinject Injectable (500mg/10ml). Reg No. 72548
	GMP status	The firm was inspected on 5-6.12.2017, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	• Provide complete step-wise manufacturing outlines, mentioning sterilization/sterile filling process and packing.
	Decision: Deferred for submission of complete step-wise manufacturing outlines, mentioning sterilization/sterile filling process and packing.	

b. Deferred cases

310.	Name and address of manufacturer / Applicant	M/s Alen Pharmaceuticals Pvt Ltd. 138-Nowshera Industrial, Risalpur, KPK. Contract manufacturing by: M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK
	Brand Name +Dosage Form + Strength	Alenpra 40mg Infusion
	Composition	Each vial contains: Omeprazole…..40mg
	Diary No. Date of R& I & fee	Dy No. 15206: 25404.2018 PKR 50,000/-: 20.04.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg Powder for Solution for Injection. MHRA approved
	Me-too status	RISEK 40MG INJECTION. Reg. No. 45617
	GMP status	Inspection of M/s Welwrd Pharmaceuticals was conducted on 12.11.2018, wherein the following sections of the firm were considered to be operating at satisfactory level of GMP. i) Tablet Section (General/antibiotics) ii) Liquid injectable section (General/antibiotics) iii) Dry injectable section (General/antibiotics) iv) Dry powder injectable (cephalosporins) While the remaining sections viz Capsule general, dry powder suspension general and Sachet sections were observed with certain shortcomings that need to be rectified. The firm M/s Alen Pharma was inspected on 31.05.2018, where no conclusion has been made thereof.
	Remarks of the Evaluator.	• The firm was asked to revise "Esomeprazole sodium" to "Esomeprazole as sodium" in Form 5 and adjust its quantity as per salt factor in master Formula. The firm revised the salt to omeprazole sodium in Master formula without submission of any fee. Furthermore the label claim is omeprazole base. • Clarification is required whether lyophilized powder is filled or lyophilization is conducted after filling. • The firm submitted list of 16 already approved product for contract manufacturing of M/s Alen Pharmaceuticals Pvt Ltd. • The firm submitted that one other product has been

		applied applied for contract manufacturing by M/s Alen Pharmaceuticals Pvt Ltd. • The firm submitted List of 08 approved sections and 02 additional sections.
	Pervious decision	The Board in its 290th meeting deferred the case for the following: • Submission of fee for revision of salt and correction of label claim. • Clarification is required whether lyophilized powder is filled or lyophilization is conducted after filling.
	Evaluation by PEC	The Firm has changed the molecule rather than salt form. It has been identified that the firm has also submitted Form 5 from another manufacturing site/unit, i.e., M/s Alen Pharmaceuticals (Pvt) Ltd. 36-A, Industrial Estate, Hayatabad, Peshawar.
	Decision: Regsitration Board did nopt accede with firm's request	
311.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Vildamed 50/850 mg Tablet
	Composition	Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin HCl…850mg
	Diary No. Date of R& I & fee	Dy No. 19150: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed Manufacturer's specifications
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/850 vildagliptin 50 mg/metformin hydrochloride 850 mg film coated tablet. TGA approved
	Me-too status	GALVUS MET 50MG/850MG TABLETS. Reg. No. 66106
	GMP status	The firm was inspected on 15.02.2017 wherein the firm was considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator.	• The shelf-life of reference product in TGA is 18 months. • The name of signatory is not present on the form 5.
	Pervious decision	The Board in its 291st meeting deferred the case for revision of salt form in line with the reference product along with submission of applicable fee.
	Evaluation by PEC	• The firm has revised metformin to Metformin HCl along with submission of Rs. 5000/- fee. • Revision of Form5 and Master Formula is still required.
	Decision: Deffered for salt form in Form5 and Master Formula.	
312.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bambut 10mg Tablet
	Composition	Each tablet contains: Bambuterol HCl…….10mg
	Diary No. Date of R& I & fee	Dy No. 19164: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished Product Specification	The firm did not provide the reference.
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Bambac 10mg tablet (plain). **USFDA** approved
	Me-too status	Ordain Tablet 10mg. Reg No. 55186
	GMP status	The firm was inspected on 15.02.2017 wherein the firm was

		considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator.	• The name of signatory is not present on the form 5. • The firm has claimed BP specifications. Upon clarification, the form did not provide proof of availability of the finished product in BP. • The firm applied for tablet. However, coating material and process has been mentioned. Upon clarification, the firm removed coating compostion and coating process. The reference product is film-coated. • The firm has mentioned 11mg/tab of API in Master Formula.
	Pervious decision	The Board in its 291st meeting deferred the case for the following: • Clarification of 11mg/tab of API in Master Formula.
	Evaluation by PEC	• The firm has revised 11mg of API to 10 mg per tab. • The product in Reference Regulatory Authoritiy is plain tablet
	Decision: Approved with innovator's specifications	
313.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bambut 20mg Tablet
	Composition	Each tablet contains: Bambuterol HCl…….20mg
	Diary No. Date of R& I & fee	Dy No. 19158: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished Product Specification	The firm did not provide the reference.
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Bambac 20mg tablet (plain). USFDA approved
	Me-too status	Ordain Tablet 10mg. Reg No. 55187
	GMP status	The firm was inspected on 15.02.2017 wherein the firm was considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator.	• The name of signatory is not present on the form 5. • The firm has claimed BP specifications. Upon clarification, the form did not provide proof of availability of the finished product in BP. • The firm applied for tablet. However, coating material and process has been mentioned. Upon clarification, the firm removed coating compostion. • The firm has mentioned 22mg/tab of API in Master Formula.
	Pervious decision	The Board in its 291st meeting deferred the case for the following: • Clarification of 22mg/tab of API in Master Formula. • Revision of formulation in line with the reference product along with submission of applicable fee.
	Evaluation by PEC	• The firm has revised 22mg of API to 20 mg per tab. • The product in Reference Regulatory Authoritiy is plain tablet.
	Decision: Approved with innovator's specifications.	
314.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	STRA-M 50mg Tablet

	Composition	Each film-coated tablet contains: Sertraline as HCl…….50mg
	Diary No. Date of R& I & fee	Dy No. 19163: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	ZOLOFT (sertraline hydrochloride) tablets, for oral use film-coated. **USFDA** approved with box warning
	Me-too status	Seralin 50mg Tablet film coated. Reg No. 83323
	GMP status	The firm was inspected on 15.02.2017 wherein the firm was considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator.	• The firm has mentioned enteric film-coated tablet. Upon clarification, the firm did not reply.
	Pervious decision	The Board in its 291st meeting deferred the case for clarification of mentioning enteric film-coated tablet
	Evaluation by PEC	• The firm submitted that it was a typo mistake
	Decision: Approved	
315.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Megrital 400mg Tablet
	Composition	Each tablet contains: Carbamazepine…..400mg
	Diary No. Date of R& I & fee	Dy No. 15536: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Tegral 400mg Tablet. Reg. No. 79918 (does not depict coating)
	GMP status	The firm was inspected on 15.02.2017 wherein the firm was considered to be operating at acceptable level of compliance with GMP guidelines.
	Remarks of the Evaluator.	• Clarification is required about solvent-E. • The firm revised the formulation from coated tablet to un-coated tablet with submission of Rs. 5000/- fee.
	Previous decision	The Board in its 289th meeting deferred the case for clarification about solvent-E.
	Evaluation by PEC	• The firm submitted that the solvent is not used, as the tablet is now uncoated. • Proof of international availability could not be confirmed.
	Previous decision	The Board in its 291st meeting deferred the case for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting.
	Evaluation by PEC	The firm submitted the following international availability: Carbagen 400 mg tablets (available at medicines.org.uk). It has been mentioned on the website that: *The electronic medicines compendium (emc) contains up to date, easily accessible information about medicines licensed for use in the UK. emc has more than 14,000 documents, all of which have been checked and approved by either the UK or European government agencies which license medicines.*

		These agencies are the UK Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA).
	Decision: Approved	
316.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Fedsert Tablet 50mg
	Composition	Each film-coated tablet contains: Sertraline as HCl……50mg
	Diary No. Date of R& I & fee	Dy No. 9505: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	ZOLOFT (sertraline hydrochloride) 50mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Lowtral 50mg Tablets. Reg. No. 51000
	GMP status	The firm was inspected 30.01.2019 with the following conclusion and recommendations: Conclusion: The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance. Recommendations: They are advised to:- 1- Further increase no of Pharmacist in production section. 2- Purchase another HPLC for tests and analysis. 3- Provide room for retention samples.
	Remarks of the Evaluator.	• The firm revised 'sertraline as HCl' to 'sertraline HCl' in Master formula only.
	Previous decision	The Board in its 289th meeting deferred the case for fee.
	Evaluation by PEC	The firm submitted that they have already submitted the fee since correction of equivalency of salt form in label claim does not require additional fee.
	Decision: Approved	
317.	Name and address of manufacturer / Applicant	Fedro Pharmaceuticals (Pvt.) Ltd., 149-Industrial Estate, Hayatabad, Peshawar, Khyber Pakhtunkhwa, Pakistan
	Brand Name +Dosage Form + Strength	Fedsert Tablet 100mg
	Composition	Each film-coated tablet contains: Sertraline as HCl……100mg
	Diary No. Date of R& I & fee	Dy No. 9508: 14.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	ZOLOFT (sertraline hydrochloride) 100mg film-coated tablets, for oral use. USFDA approved
	Me-too status	Lowtral 100mg Tablets. Reg. No. 50993
	GMP status	The firm was inspected 30.01.2019 with the following conclusion and recommendations: Conclusion: The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance.

		Recommendations: They are advised to:- 1- Further increase no of Pharmacist in production section. 2- Purchase another HPLC for tests and analysis. 3- Provide room for retention samples.
	Remarks of the Evaluator.	• The firm revised 'sertraline as HCl' to 'sertraline HCl' in Master formula only.
	Previous decision	The Board in its 289th meeting deferred the case for fee.
	Evaluation by PEC	The firm submitted that they have already submitted the fee since correction of equivalency of salt form in label claim does not require additional fee.
	Decision: Approved	
318.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mucotin 225mg Sachet
	Composition	Each sachet contains: Erdosteine…225mg
	Diary No. Date of R& I & fee	Dy No. 15546: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Mucolytics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ERDOTIN 225 MG GRANULATO PER SOSPENSIONE ORALE. **AIFA** approved
	Me-too status	Mucolec 225 mg Sachet. Reg. No. 78593
	GMP status	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• Form 5 is different in some points from the approved one. • The reference product is in the form of granule for suspension. The firm has not mentioned any granulation process or granulating agent. Upon clarification, the firm submitted that the API is already in granular form. It is just passed through sieve.
	Previous decision	The Board in its 289th meeting deferred the case for submission of applicable Form 5.
	Evaluation by PEC	The firm submitted applicable enclosure of Form 5.
	Decision: Approved with innovator's specifications.	
319.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Mensodol Tablet 500/25mg
	Composition	Each film-coated tablet contains: Paracetamol…500mg Pamabrom…25mg
	Diary No. Date of R& I & fee	Dy No. 15549: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Anilides + Pamabrom (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	30's, 100's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Women's Tylol Caplets. Reg. No. 62787
	GMP status	The firm was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• Form 5 is different in some points from the approved one. • Justification is required about 3% excess.

		• Provide proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board. • The label claim in Form 5 is "Each tablet contains". However, coating composition have been mentioned in Master Formula. Justify/clarify.
	Previous decision	The Board in its 289th meeting deferred the case the following: • Justification is required about 3% excess. • Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board. • The label claim in Form 5 is "Each tablet contains". However, coating composition have been mentioned in Master Formula. Justify/clarify.
	Evaluation by PEC	• The firm submitted that the overage was mentioned mistakenly. • The firm submitted that the label claim is film-coated tablet. • Proof of International availability of same formulation with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting.	
320.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Fortexone IV Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…2g
	Diary No. Date of R& I & fee	Dy No. 18879: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CEFTRIAXONE ACT ceftriaxone (as sodium) 2g powder for injection vial (IV). TGA approved
	Me-too status	Cytozon Injection 2gm I.V. Reg. No. 84896
	GMP status	The firm was inspected on 5-6.12.2017, wherein the firm was reported to be GMP compliant.
	Remarks of the Evaluator.	• There is no name of signatory on first page of Form 5. • In the revised outlines, there is no sterilization process for the vials. • Revision of "Ceftriaxone Sodium Eq. to Ceftriaxone" to "Ceftriaxone Sodium" is required in Master Formula only. • The firm has applied for vials. However, in the revised outlines, ampules has been mentioned.
	Previous decision	The Board in its 290th meeting deferred the case for the following: • Name of signatory on first page of Form 5 is required. • In the revised outlines, there is no sterilization process for the vials. • Revision of "Ceftriaxone Sodium Eq. to Ceftriaxone" to "Ceftriaxone Sodium" is required in Master Formula only. • The firm has applied for vials. However, in the revised

		outlines, ampules have been mentioned. Clarification is required.
	Evaluation by PEC	• The firm submitted revised Form 5. • The firm submitted revised manufacturing outlines. Revision of "Ceftriaxone Sodium Eq. to Ceftriaxone" to "Ceftriaxone Sodium" is required in Master Formula only.
	Decision: Deferred for revision of "Ceftriaxone Sodium Eq. to Ceftriaxone" to "Ceftriaxone Sodium" in Master Formula only.	

Case no. 02 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

321.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Amantasan-10 (Oral w/s powder)
	Composition	Each 100 gm contains:- Amantadine HCl…..……10g
	Diary No. Date of R& I & fee	Dy No. 17241: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Adamantane derivatives (under DOPAMINERGIC AGENTS)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 25kg; Decontrolled
	Me-too status	Metadine Powder. Reg # 88040
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications and with pack sizes of 100g, 500g, 1kg, 2.5kg, 5kg.	
322.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Amantasan-20 (Oral w/s powder)
	Composition	Each 100 gm contains:- Amantadine HCl…..……20g
	Diary No. Date of R& I & fee	Dy No. 17242: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Adamantane derivatives (under DOPAMINERGIC AGENTS)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 25kg; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
323.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Hydox-50 (Oral w/s powder)
	Composition	Each 100 gm contains: Doxycycline hyclate…..……50g
	Diary No. Date of R& I & fee	Dy No. 17239: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Tetracycline
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 25kg; Decontrolled

	Me-too status	Seldox oral powder. Reg # 058717
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Remarks of the Evaluator.	•
	• **Decision: Approved with innovator's specifications and with pack sizes of 100g, 500g, 1kg, 2.5kg, 5kg.**	
324.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Hydox-70 (Oral w/s powder)
	Composition	Each 100 gm contains: Doxycycline hyclate…..……70g
	Diary No. Date of R& I & fee	Dy No. 17240: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Tetracycline
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 25kg; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
325.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Lincosan-4.4 (Oral w/s powder)
	Composition	Each 100 gm contains: Lincomycin HCl…..……4.4g
	Diary No. Date of R& I & fee	Dy No. 17235: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Lincosamides
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 10kg, 25kg; Decontrolled
	Me-too status	Lincos-P oral powder. Reg # 049667
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications and with pack sizes of 100g, 500g, 1kg, 2.5kg, 5kg.	
326.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Lincosan-11 (Oral w/s powder)
	Composition	Each 100 gm contains: Lincomycin HCl…..……11g
	Diary No. Date of R& I & fee	Dy No. 17236: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Lincosamides
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 10kg, 25kg; Decontrolled
	Me-too status	I-link powder (110mg/g). Reg. No. 62065
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications and with pack sizes of 100g, 500g, 1kg, 2.5kg, 5kg.	

327.	Name and address of manufacturer / Applicant	M/s Sanna Laboratories, 1019-B. Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Neosan-72 (Oral w/s powder)
	Composition	Each 1000 gm contains: Neomycin sulphate…..……720g
	Diary No. Date of R& I & fee	Dy No. 17237: 10.05.2018 PKR 20,000/-: 09.05.2018
	Pharmacological Group	Other aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 25kg; Decontrolled
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 04.07.2017, wherein FAIR level of GMP compliance was reported.
	Remarks of the Evaluator.	•
	Decision: Deferred for the evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

b. Deferred Cases

328.	Name and address of manufacturer / Applicant	Selmore Pharmaceuticals (Pvt.) Ltd., 36 Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Bosol Injection 5ml
	Composition	Each ml contains: Buserelin as acetate……...0.004mg
	Diary No. Date of R& I & fee	Dy No. 10005: 16.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	Gonadotropin releasing hormone analogues
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	5ml; Decontrolled
	Me-too status	Conceptal Injection. Reg. No. 058939
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator.	• The firm was asked to justify 5% overage. The firm submitted that this is a hormones, so during manufacturing process some loss in potency may occur. To maintain its potency throughout shelf-life, 5% overage is added.
	Previous decision	• The Board in its 290th meeting deferred the case for further delibration on firm's response
	Evaluation by PEC	• The submitted photocopy of master formulation, wherein they have removed 5% overage of API.
	Decision: Approved with innovator's specifications.	
329.	Name and address of manufacturer / Applicant	Selmore Pharmaceuticals (Pvt.) Ltd., 36 Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Tycostrep Injection
	Composition	Each ml contain: Tylosin Tartrate……...50mg Colistin sulphate…….10mg Streptomycin as sulphate…….100mg
	Diary No. Date of R& I & fee	Dy No. 10006: 16.03.2018 PKR 20,000/-: 14.03.2018
	Pharmacological Group	colistin, combinations with macrolides and sterptomycins (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications

	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	TARGET CRD INJECTION. Reg. No. 046577
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator.	• The me-too product contains streptomycin base.
	Previous decision	The Board in its 290th meeting deferred the case for further delibration on firm's response
	Evaluation by PEC	The firm has submitted that: • The me-too product contains streptomycin base. • The USP monograph has streptomycin base with salfate. • In the British pharmacopeia, streptomycin injection contains streptomycin salfate.
	Decision: Approved with innovator's specifications.	
330.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Carovit - E Injection
	Composition	Each ml contains: ß-Carotene…15mg dl-α-Tocopherol Acetate (20mg) eq. to α-Tocopherol…18.22mg
	Diary No. Date of R& I & fee	Dy No. 22519: 28.06.2018 PKR 20,000/-: 28.06.2018 PKR 20,000/-: 23.09.2019
	Pharmacological Group	Vitamin A + vitamin E (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Me-too status	DALMAVITAL SOLUTION FOR INJECTION. Reg. No. 48130
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended.
	Remarks of the Evaluator.	• The firm submitted revised dl-α-Tocopherol Acetate (20mg) to dl-α-Tocopherol Acetate (21.96mg) eq. to α-Tocopherol…20mg. The firm again provided, wherein they again revised it to dl-α-Tocopherol Acetate has been revised to dl-α-Tocopherol Acetate (20mg) eq. to α-Tocopherol 18.22mg.
	Previous decision	The Board in its 291st meeting deferred the case for submission of fee for revision of strength of API.
	Evaluation by PEC	The firm submitted Rs. 20,000/- fee.
	Decision: Approved with innovator's specifications.	
331.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Tydoxin Forte Powder
	Composition	Each 100gm Contains: Tylosin Tartrate…20g Doxycycline hyclate…40g
	Diary No. Date of R& I & fee	Dy No. 15745: 27.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Antibiotics (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	100g, 500g, 1000g; Decontrolled
	Me-too status	DOXITYL WATER SOLUBLE POWDER. Reg. No. 59115
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator.	The me-too product contains Doxycycline as base.

	Previous decision	The Board in its 290th meeting deferred the case for confirmation of me-too product.
	Evaluation by PEC	The firm revised the API from Doxycycline as hyclate to Doxycycline hyclate and provided the following me-too product: BAX TYLO 60 POWDER. Reg. No. 72640
	Decision: Approved with innovator's specifications.	
332.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Provit-M Granules
	Composition	Each kg Contains: Vitamin A…0.8g Vitamin D3…0.16g Vitamin E…0.38g Vitamin B1…1g Vitamin B2…1.25g Vitamin B6…4g Vitamin B12…0.001g Nicotinamide…6.25g Copper Sulphate…0.25g Magnesium Sulphate…25g Calcium Chloride…0.023g Zinc Sulphate…2.17g Maganese Sulphate…10g Potassium Iodide…0.5g Sodium Selenite…0.01g Dicalcium phosphate (Phosphorous)…150g Sodium Chloride…120g
	Diary No. Date of R& I & fee	Dy No. 15746: 27.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Vitamins with minerals
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	500g, 1kg, 2.5kg; Decontrolled
	Me-too status	WHITE GOLD **POWDER**. Reg. No. 58842
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended
	Remarks of the Evaluator.	• The provided me-too product contains Vitamin B1 and Vitamin B6 in addition to other compositions. The firm added the same to composition with submission of Rs. 5000/-fee. • The firm had applied for granules, but the manufacturing outlines did not depict granulation process. Moreover, the me-too product is in the form of Powder. The firm revised the manufacturing outlines meant for granules. The firm further provided pictures of label and packing of me-too product White Gold Granules by Leads Pharma (Reg. No. 58842), which is registered in the me-too data as powder.
	Previous decision	The Board in its 290th meeting deferred the case for the following: • Submission of differential fee for revision of composition. • Revision of label claim and manufacturing outlines in line with the reference product.
	Evaluation by PEC	• The firm submitted Rs. 15,000/- fee. • The firm has applied for granules, but the me-too

		product is in the form of Powder. • The firm provided another me-too Product (granule), wherein phosphorus has been mentioned instead of diclacium phosphate.
	Decision: Approved with innovator's specifications.	
333.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	PULMOTIN-D LIQUID
	Composition	Each 1000 ml contain: Tylosin Tartrate……..100g Doxycycline HCl…….200g Bromhexine HCl……2.5g Colistin Sulphate……450 MIU
	Diary No. Date of R & I & Fee	Dy No. 11708: 06.03.2019 Rs. 20,000/-: 01.03.2019 Rs. 20,000/-: 24.09.2019
	Pharmacological Group	Antibiotic with Expectorant
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100 ml, 500 ml, 1 Litre, 2.5 Litre, 5 Litre : As per Policy of MoH
	Me-too Status	BIO-UNIBIOTIC LIQUID. Reg No. 074006
	GMP Status	New License (Inspection Date: 04.10.2018 & 05.11.2018)
	Remarks of the Evaluator	• The firm revised bromohexine HCl….25g per 1000ml to 2.5g per 1000ml along with submission of Rs. 5000/- fee.
	Previous decision	The Board in its 290th meeting deferred the case for submission of differential fee for revision of strength.
	Evaluation by PEC	The firm submitted Rs. 15,000/- fee. Rs. 5000 already submitted.
	Decision: Approved with innovator's specifications.	
334.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	CINA FORTE LIQUID ORAL
	Composition	Each ml contain: Enrofloxacin……75mg Sulphamethoxy Pyridazine …. 75mg Sulphamethazine……..…..... 50mg Trimethoprim …….. 25mg
	Diary No. Date of R & I & Fee	Dy No. 11650: 06.03.2019 Rs. 20,000/-: 01.03.2019
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100 ml, 500 ml, 1 Litre, 2.5 Litre, 5 Litre : As per Policy of MoH
	Me-too Status	CINA T.S Oral Suspension. Reg No. 031456 (enroflodacine instead of enrofloxacin in me-too) EACH ML CONTAINS:- TRIMETHORPIM 25MG. SULPHAMETHAZINE 50MG. SULPHAMETHOXYPARADAZINE 75MG. ENROFLODACINE (CENOXINE) 75MG.
	GMP Status	New License (Inspection Date: 04.10.2018 & 05.11.2018)
	Remarks of the Evaluator	• The firm was asked to adjust the strength of APIs as per me-too products along with submission of applicable fee. The firm submitted Rs. 5000/- fee, but did not revise the compositions in Form 5 and master formula.
	Previous decision	The Board in its 290th meeting deferred the case for the following:

		• Submission of differential fee for revision of strength. • Revision of compositions in Form 5 and master formula.
	Evaluation by PEC	• The firm adjusted the strength of APIs compositions in Form 5 and master formula as per me-too products (CENATIN ORAL LIQUID. Reg. No. 78379) along with submission of Rs. 15,000/- fee.
	Decision: Approved with innovator's specifications.	
335.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Klavimox WSP
	Composition	Each 100 grams contain: Amoxicillin as trihydrate…….16g clavulanic acid as potassium salt ……..4g
	Diary No. Date of R& I & fee	Dy No. 2021: 16.01.2018 PKR 20,000/-: 15.01.2018
	Pharmacological Group	Amoxicillin and beta-lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	100g, 500g, 1 kg, 10kg, 25kg,; As per SRO (10% less than the brand leader)
	Me-too status	PRIMOX-PLUS WATER SOLUBLE POWDER. Reg. No. 074026
	GMP status	The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018.
	Remarks of the Evaluator.	• The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm did not reply. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management. • The product is intended for oral use. In the proposed dosage, the firm has mentioned 1ml/20kg body weight, which is submitted for Clavimox Injection. Clarification is was asked from the firm. The firm did not reply. • Correction of 'clavulanic acid as potassium' to 'potassium clavulanate' is required in Master Formula. • The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee. • Available in USP, wherein the monograph is for "for oral suspension'.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Correction of amoxicillin as trihydrate to amoxicillin

		trihydrate in Master Formula is required. • Details of environmental control processing including waste disposal management is needed. • The product is intended for oral use. In the proposed dosage, the firm has mentioned 1ml/20kg body weight, which is submitted for Clavimox Injection. Clarification is required from the firm. • Correction of 'clavulanic acid as potassium' to 'potassium clavulanate' is required in Master Formula. • The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee.
	Evaluation by PEC	• The firm removed overage. • Updated Form 5 submitted. • The firm has claimed innovator's specifications • The firm changed clavulanic acid to clavulanic acid as potassium salt without submission of fee. • The product is intended for oral use. In the proposed dosage, the firm has mentioned 1ml/20kg body weight, which is submitted for Clavimox Injection. • Available in USP, wherein the monograph is for "for oral suspension'.
	Previous decision	The Board in its 289th meeting deferred the case for the following: • Submission of fee for revision of salt form. • Submission of correct dosage • Clairifaction about the dosage form.
	Evaluation by PEC	• The firm submitted Rs. 5,000/- fee. • **Submission of correct dosage is required** • **Clairifaction about the dosage form is required.**
	Decision: Deferred for the following: • **Submission of correct dosage is required** • **Clairifaction about the dosage form is required.**	
336.	Name and address of manufacturer / Applicant	Mylab Pvt. Ltd Khankah Shareef Bahawalpur
	Brand Name +Dosage Form + Strength	Avipen 325 WSP
	Composition	Each gram contains: phenoxymethylpenicillin (293mg) eq. to potassium phenoxymethylpenicillin…….325mg
	Diary No. Date of R& I & fee	Dy No. 2020: 16.01.2018 PKR 20,000/-: 16.01.2018
	Pharmacological Group	Beta-lactamase sensitive penicillins
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacture's specifications
	Pack size & Demanded Price	100g, 500g; 1 kg, 10kg, 25kg; As per SRO (10% less than the brand leader)
	Me-too status	PHENOXYPEN WATER SOLUBLE POWDER. Reg. No. 081303
	GMP status	The firm has been granted additional section Oral powder (penicillin) on the basis of inspection dated 13-14.09.2018.
	Remarks of the Evaluator.	• The firm has mentioned in master Formula that "appropriate overage is added to compensate the potency loss on storage". The firm was asked for clarification. However, the firm did not reply. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product

		specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management are missing. • The me-too product contains phenoxymethylpenicillin (293mg/g) eq. to potassium phenoxymethylpenicillin (325mg/g). The firm was asked for correction is required in label claim (Form 5 only) along with submission of applicable fee. The firm neither changed the label claim in Form 5 nor submitted the applicable fee.
	Previous decision	The Board in its 288th meeting deferred the case for the following: • Justification on scientific basis for addition of overage in master formulation. • The firm was asked to submit complete updated Form 5 duly signed by all concerned persons. However, the firm submitted incomplete Form 5. • The firm was asked to submit complete finished product specifications and testing method. However, the firm did not submit the same. • Details of environmental control processing including waste disposal management are missing. • The me-too product contains phenoxymethylpenicillin (293mg/g) eq. to potassium phenoxymethylpenicillin (325mg/g). The firm was asked for correction is required in label claim (Form 5 only) along with submission of applicable fee. The firm neither changed the label claim in Form 5 nor submitted the applicable fee.
	Evaluation by PEC	• The firm removed overage. • Updated Form 5 submitted. • The firm has claimed innovator's specifications • The me-too product contains phenoxymethylpenicillin (293mg/g) eq. to potassium phenoxymethylpenicillin (325mg/g). The firm was asked for correction in label claim (Form 5 only) along with submission of applicable fee. The firm submitted Rs. 5000/- fee but revision of label claim is required.
	Previous decision	• The Board in its 289th meeting deferred the case for revision of label claim
	Evaluation by PEC	• The firm revised the label claim
	Decision: Approved with innovator's specifications.	

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

a. New cases

336.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceutical Pvt. Ltd., 538- C Sundar Industrial Estate Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Monti tablet 10mg
	Composition	Each film- coated tablet contains: Montelukast as Sodium ….10mg
	Diary No. Date of R& I & fee	Dy.No.27781; 13-08-2018; Rs.20,000 (10-08-2018)
	Pharmacological Group	Anti- Asthmatic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Jukast -10 tablet of M/s Jupiter Pharma (Reg. # 081919)
	GMP status	Last GMP inspection was conducted on 24-05-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	Firm has General tablet section as mentioned in the submitted section approval letter.
	Decision: Approved	
337.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceutical Pvt. Ltd., 538- C Sundar Industrial Estate Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Doxair 100mg/5ml Syrup
	Composition	Each 5ml contains: Doxofylline……...100mg
	Diary No. Date of R& I & fee	Dy.No.27782; 13-08-2018; Rs.20,000 (10-08-2018)
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	60ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	Doxofillina ABC 200 mg / 10 ml Syrup by M/s ABC Farmaceutici SpA – Corso Vittorio (Italian Medicine Agency (AIFA) Italy Approved)
	Me-too status	Unifyline Syrup 100mg/ 5ml by M/s Platinum Pharmaceuticals (Reg.# 047180)
	GMP status	Last GMP inspection was conducted on 24-05-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	Firm has General Oral Liquid section as mentioned in the submitted section approval letter.
	Decision: Approved	
338.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt. Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name + Dosage Form+ Strength	Abegron tablet 25mg
	Composition	Each extended- release tablet contains: Mirabegron…….25mg
	Diary No. Date of R& I & fee	Dy.No.27399; 09-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Urinary Anti- spasmodics
	Type of Form	Form- 5
	Finished product Specification	As per innovators' specifications
	Pack size & Demanded Price	10's, 20's, 30's & as per PRC
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was 02-08-18 and the report concludes satisfactory level of GMP compliance. Moreover, firm should focus on mentioned observations and comply with

		them on priority basis.
	Remarks of the Evaluator XIII	• The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version. • General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board. Further, Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
339.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt. Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name+ Dosage Form + Strength	Abegron tablet 50mg
	Composition	Each extended- release tablet contains: Mirabegron…….50mg
	Diary No. Date of R& I & fee	Dy.No.27400; 09-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Urinary Anti- spasmodics
	Type of Form	Form- 5
	Finished product Specification	As per innovators' specifications
	Pack size & Demanded Price	10's, 20's, 30's & as per PRC
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was 02-08-18 and the report concludes satisfactory level of GMP compliance. Moreover, firm should focus on mentioned observations and comply with them on priority basis.
	Remarks of the Evaluator XIII	The applied formulation needs submission of six months accelerated and real time stability studies data as the applied formulation is subsequent drug generic version. General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board. Further, Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
340.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt. Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name+ Dosage Form + Strength	Eltrom tablet 25mg
	Composition	Each film- coated tablet contains: Eltrombopag as Olamine …25mg
	Diary No. Date of R& I & fee	Dy.No.27054; 07-08-2018; Rs.20,000 (03-08-2018)
	Pharmacological Group	Thrombopoietin receptor agonists
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	10's, 20's, 30's & as per PRC
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Revolade Tablets 25mg of M/s GSK (Reg.No. 069584)
	GMP status	Last GMP inspection was 02-08-18 and the report concludes satisfactory level of GMP compliance. Moreover, firm should focus on mentioned observations and comply with them on priority basis.
	Remarks of the Evaluator XIII	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	

341.	Name and address of manufacturer / Applicant	M/s Kaizen Pharmaceuticals Pvt. Ltd., E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.
	Brand Name+ Dosage Form + Strength	Eltrom tablet 50mg
	Composition	Each film- coated tablet contains: Eltrombopag as Olamine …50mg
	Diary No. Date of R& I & fee	Dy.No.27055; 07-08-2018; Rs.20,000 (03-08-2018)
	Pharmacological Group	Thrombopoietin receptor agonists
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	10's, 20's, 30's & as per PRC
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Revolade Tablets 50mg of M/s GSK (Reg. No. 069585)
	GMP status	Last GMP inspection was 02-08-18 and the report concludes satisfactory level of GMP compliance. Moreover, firm should focus on mentioned **observations** and comply with them on priority basis.
	Remarks of the Evaluator XIII	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
342.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial State, Raiwind, Lahore.
	Brand Name+ Dosage Form + Strength	Lepsi XR Tablet 500mg
	Composition	Each film- coated extended release tablet contains: Levetiracetam……...…500mg
	Diary No. Date of R& I & fee	Dy.No.27084; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 60's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Leveticam 500mg tablets of M/s WnsFeild Pharma (Reg. # 084221)
	GMP status	Last GMP inspection was conducted on 29-03-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	General tablet section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved	
343.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals (Pvt.) Ltd., Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name+ Dosage Form + Strength	Thiolax tablet 4mg
	Composition	Each uncoated tablet contains: Thiocolchicoside……..4mg
	Diary No. Date of R& I & fee	Dy.No.27070; 07-08-2018;Rs.20,000 (07-08-2018)
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM (France)
	Me-too status	Wodnik 4mg tablet of M/s Martin Dow (Reg. # 081138)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Remarks of the Evaluator XIII	Firm has General tablet section as mentioned in the GMP

		inspection report. No USP or BP monograph is available for applied formulation.
	Decision: Approved with innovator's specifications.	
344.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Plot No. 8, Street No. S-8, Industrial Estate, Rawat, Islamabad.
	Brand Name+ Dosage Form + Strength	Relidap tablet 60mg
	Composition	Each film- coated tablet contains: Dapoxetine HCl……60mg
	Diary No. Date of R& I & fee	Dy.No.27407;09-08-2018; Rs.20,000 (09-08-2018)
	Pharmacological Group	Urological
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 27-12-2018 and the report concludes that the firm is working in compliance with the GMP standards as of today; points of improvement have been discussed and agreed by the management.
	Remarks of the Evaluator XIII	• Firm has General tablet section as mentioned in the GMP inspection report. • Me-too status could **not** be confirmed.
	Decision: Deferred for evidence of applied formulation/ drug already approved by DRAP (generic /me-too status) along with registration number, brand name and name of firm.	
345.	Name and address of manufacturer / Applicant	M/s Reliance Pharma, Plot No. 8, Street No. S-8, Industrial Estate, Rawat, Islamabad.
	Brand Name+ Dosage Form + Strength	Viagra Sild tablet 100mg
	Composition	Each film- coated tablet contains: Sildenafil as Citrate……..…100mg
	Diary No. Date of R& I & fee	Dy.No.27406; 09-08-2018; Rs.20,000(09-08-2018)
	Pharmacological Group	Urological
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 6's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	**Could not be confirmed**
	GMP status	Last GMP inspection was conducted on 27-12-2018 and the report concludes that the firm is working in compliance with the GMP standards as of today; points of improvement have been discussed and agreed by the management.
	Remarks of the Evaluator XIII	• No official monograph is available for the applied formulation in USP, BP, IP or JP. • Firm has General tablet section as mentioned in the GMP inspection report. • Me- too status could **not** be confirmed.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
346.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, Plot # 22, 23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+ Dosage Form + Strength	Spasmax tablet 80mg/ 80 mg
	Composition	Each film- coated tablet contains: Hydrated Phloroglucinol 80mg eq. anhydrous Phloroglucinol……62.233mg Trimethylphloroglucinol……...…….80mg

	Diary No. Date of R& I & fee	Dy.No.27550; 10-08-2018; Rs.20,000(10-08-2018)
	Pharmacological Group	Drugs for functional Gastrointestinal disorders
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM; France Approved as sugar- coated
	Me-too status	Spasrid tablet 80mg/ 80 mg of M/s Barrett Hodgson (Reg. # 034743)
	GMP status	Last GMP inspection was conducted on 11-02-2019 and the report concludes issuance of GMP certificate to M/s Vision Pharma Islamabad as the firm is found at a good level of GMP.
	Remarks of the Evaluator XIII	• Firm has General tablet section as mentioned in the GMP inspection report. • ANSM; France Approved as sugar- coated while applied as film- coated tablet. • No official monograph is available for the applied formulation in USP, BP, IP or JP.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
347.	Name and address of manufacturer / Applicant	M/s Ophth Pharma (Pvt.) Ltd, Plot No. 241, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+ Dosage Form + Strength	T- Limus Ointment 0.1%
	Composition	Each ml contains: Tacrolimus……1mg
	Diary No. Date of R& I & fee	Dy.No.27395; 09-08-2018;Rs.20,000 (09-08-2018)
	Pharmacological Group	Immuno- suppressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10g & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Eczemus 0.1% Ointment of M/s Brookes Pharma (Reg. # 045493)
	GMP status	Last GMP inspection was conducted on 10-05-2018 and the report concludes issuance of GMP certificate on 10-5-2018.
	Remarks of the Evaluator XIII	Sterile cream section is available in the firm as mentioned in the submitted GMP inspection report. No official monograph is available for the applied formulation.
	Decision: Registration Board approved registration of product with innovator's specification and with protective measures in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
348.	Name and address of manufacturer / Applicant	M/s Ophth Pharma (Pvt.) Ltd, Plot No. 241, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name+ Dosage Form + Strength	T- Limus Ointment 0.3%
	Composition	Each ml contains: Tacrolimus……3mg
	Diary No. Date of R& I & fee	Dy.No.27396; 09-08-2018;Rs.20,000 (09-08-2018)
	Pharmacological Group	Immuno- suppressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10g & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved

	Me-too status	Eczemus 0.3% Ointment of M/s Brookes Pharma (Reg. # 045494)
	GMP status	Last GMP inspection was conducted on 10-05-2018 and the report concludes issuance of GMP certificate on 10-05-2018.
	Remarks of the Evaluator XIII	• Sterile cream section is available in the firm as mentioned in the submitted GMP inspection report. • The applied formulation is non- pharmacopoeial.
	Decision: Registration Board approved registration of product with innovator's specification and with protective measures in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
349.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name+ Dosage Form + Strength	Ketosaid 0.5% Eye Drops 5ml
	Composition	Each ml contains: Ketorolac Tromethamine……..…5mg
	Diary No. Date of R& I & fee	Dy.No.27414; 09-08-2018; Rs.20,000(09-08-2018)
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5ml & As per PCA
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Ketrosan 0.5% Sterile Ophthalmic Solution of M/s Elko Organisation (Reg. # 026391)
	GMP status	Last GMP inspection was conducted on 1-10-2018 and the report concludes good level of GMP compliance. Continuous improvement for procedures shall be followed.
	Remarks of the Evaluator XIII	• The applied formulation is non- pharmacopoeial. • General Eye Drops Section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved with innovator's specifications.	
350.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name+ Dosage Form + Strength	Katifen Eye Drops 0.025%
	Composition	Each ml contains: Ketotifen as fumarate…….0.25mg
	Diary No. Date of R& I & fee	Dy.No.27412; 09-08-2018; Rs.20,000(09-08-2018)
	Pharmacological Group	Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	5ml & As per PCA
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Kartilerg Eye Drops 0.025% of M/s Vega Pharma (Reg.#054031)
	GMP status	Last GMP inspection was conducted on 1-10-2018 and the report concludes good level of GMP compliance. Continuous improvement for procedures shall be followed.
	Remarks of the Evaluator XIII	• The applied formulation is non- pharmacopoeial. • General Eye Drops Section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved with innovator's specifications.	
351.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name+ Dosage Form + Strength	Timodor Eye Drops 20mg/ 5mg

	Composition	Each ml contains: Dorzolamide as Hydrochloride……...20mg Timolol as Maleate……...5mg
	Diary No. Date of R& I & fee	Dy.No.27413;09-08-2018; Rs.20,000 (09-08-2018)
	Pharmacological Group	Carbonic Anhydrous Inhibitor/ Beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	5ml & As per PCA
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Dorlol Eye Drops of M/s Genix Pharma (Reg. # 073468)
	GMP status	Last GMP inspection was conducted on 1-10-2018 and the report concludes good level of GMP compliance. Continuous improvement for procedures shall be followed.
	Remarks of the Evaluator XIII	General Eye Drops Section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved	
352.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products Pvt. Ltd. D-122, Sindh Industrial Trading Estate, Karachi
	Brand Name+ Dosage Form + Strength	Lonube Ophthalmic Solution 5mg/ ml
	Composition	Each ml contains: Levobunolol HCl……..…5mg
	Diary No. Date of R& I & fee	Dy.No.27410; 09-08-2018;Rs.20,000 (09-08-2018)
	Pharmacological Group	Anti- glaucoma preparation
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml & As per PCA
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Leubonol Sterile Ophthalmic Solution of M/s Sami Pharma (Reg. # 026621)
	GMP status	Last GMP inspection was conducted on 1-10-2018 and the report concludes good level of GMP compliance. Continuous improvement for procedures shall be followed.
	Remarks of the Evaluator XIII	General Eye Drops Section is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved	
353.	Name and address of manufacturer / Applicant	M/s Vision Pharmaceuticals, Plot # 22, 23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name+ Dosage Form + Strength	Calador sachet 600mg
	Composition	Each sachet contains: Ibuprofen (effervescent granules)……..…600mg
	Diary No. Date of R& I & fee	Dy.No.27551; 10-08-2018;Rs.20,000 (10-08-2018)
	Pharmacological Group	Anti- inflammatory/ Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Brufen Granules 600mg of M/s BGP Products Ltd. (MHRA Approved)
	Me-too status	Hibufen 600mg Sachet of M/s Hirani's Kar (Reg. # 081554)
	GMP status	Last GMP inspection was conducted on 11-2-2019 & report concludes issuance of GMP certificate to M/s Vision Pharma Islamabad as firm is found at a good level of GMP.
	Remarks of the Evaluator XIII	General Sachet (Powder) section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovator's specifications.	

354.	Name and address of manufacturer / Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot No.33, Sunder Industrial Estate, Lahore.
	Brand Name+ Dosage Form + Strength	Liptin- M XR tablet 50mg/ 1000 mg
	Composition	Each extended- release tablet contains: Sitagliptin as Phosphate……..50mg Metformin HCl……....1000mg
	Diary No. Date of R& I & fee	Dy.No.27557; 10-08-2018; Rs.20,000(10-08-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	14's, 28's & 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 50/1000 mg tablet of M/s Highnoon Labs (Reg.# 084650)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes: "The firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division DRAP, Islamabad upon completion of the proposed changes for further processing."
	Remarks of the Evaluator XIII	Firm has not submitted stability studies data.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
355.	Name and address of manufacturer / Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot No.33, Sunder Industrial Estate, Lahore.
	Brand Name+ Dosage Form + Strength	Liptin- M XR tablet 100mg/ 1000 mg
	Composition	Each extended- release tablet contains: Sitagliptin as Phosphate…….....100mg Metformin HCl…….....1000mg
	Diary No. Date of R& I & fee	Dy.No.27558; 10-08-2018; Rs.20,000(10-08-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	14's, 28's & 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tagipmet XR 50/1000mg tablet of M/s Highnoon (R# 084651)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes: "The firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division DRAP, Islamabad upon completion of the proposed changes for further processing."

	Remarks of the Evaluator XIII	Firm has not submitted stability studies data.
	Decision: Registration Board deferred the case for submission of stability study data as per the guidelines provided in 278th meeting of Registration Board.	
356.	Name and address of manufacturer / Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot No.33, Sunder Industrial Estate, Lahore.
	Brand Name+ Dosage Form + Strength	Recid tablet 20mg
	Composition	Each film- coated tablet contains: Famotidine……..20mg
	Diary No. Date of R& I & fee	Dy.No.27555; 10-08-2018; Rs.20,000(10-08-2018)
	Pharmacological Group	H2 receptor Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Famotric 20mg Tablet of M/s Klifton Pharma, (Reg. # 058312)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes: "The firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division DRAP, Islamabad upon completion of the proposed changes for further processing."
	Remarks of the Evaluator XIII	
	Decision: Approved	
357.	Name and address of manufacturer / Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot No.33, Sunder Industrial Estate, Lahore.
	Brand Name+ Dosage Form + Strength	Recid tablet 40mg
	Composition	Each film- coated tablet contains: Famotidine……..40mg
	Diary No. Date of R& I & fee	Dy.No.27556; 10-08-2018; Rs.20,000(10-08-2018)
	Pharmacological Group	H2 receptor Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 30's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Famotric 40mg Tablet of M/s Klifton Pharma (R# 058313)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes: "The firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division DRAP, Islamabad upon completion of the proposed changes for further processing."
	Remarks of the Evaluator XIII	
	Decision: Approved	

358.	Name and address of manufacturer / Applicant	M/s Horizon Healthcare (Pvt.) Ltd, Plot No.33, Sunder Industrial Estate, Lahore.
	Brand Name+ Dosage Form + Strength	Ramacin tablet 500mg
	Composition	Each film- coated tablet contains Azithromycin as Dihydrate…….500mg
	Diary No. Date of R& I & fee	Dy.No.27554; 10-08-2018; Rs.20,000(10-08-2018)
	Pharmacological Group	Macrolide
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	3's, 6's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Azithrolide tablets of M/s Heal Pharma (Reg. # 084234)
	GMP status	Last GMP inspection was conducted on 17-01-2019 and the report concludes: "The firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division DRAP, Islamabad upon completion of the proposed changes for further processing."
	Remarks of the Evaluator XIII	
	Decision: Approved	

359.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Lab Pvt. Ltd, 149-Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Tranz capsule 250mg
	Composition	Each capsule contains: Tranexamic Acid……...250mg
	Diary No. Date of R& I & fee	Dy.No.27231; 08-08-2018;Rs.20,000 (08-08-2018)
	Pharmacological Group	Anti- fibrinolytic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30's, 100's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in Italy (AIFA)
	Me-too status	Aneptil 250mg capsules of M/s Alina Combine Pakistan (Reg. # 020510)
	GMP status	Last GMP inspection was conducted on 30-01-2019 and the report concludes: The firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance.
	Remarks of the Evaluator XIII	The official monograph for the applied formulation is available in JP. General capsule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with JP specifications.	
360.	Name and address of manufacturer / Applicant	M/s Fedro Pharmaceuticals Lab Pvt. Ltd, 149-Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Tranz capsule 500mg

	Composition	Each capsule contains: Tranexamic Acid……...500mg
	Diary No. Date of R& I & fee	Dy.No.27232; 08-08-2018;Rs.20,000 (08-08-2018)
	Pharmacological Group	Anti- fibrinolytic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30's, 100's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in Italy (AIFA)
	Me-too status	Aneptil 500mg capsules of M/s Alina Combine Pakistan (Reg. # 020511)
	GMP status	Last GMP inspection was conducted on 30-01-2019 and the report concludes: The firm rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance.
	Remarks of the Evaluator XIII	The official monograph for the applied formulation is available in JP. General capsule section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with JP specifications.	
361.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt. Ltd, Plot No. 03, Street No S- 5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Lurbi tablet 100mg
	Composition	Each **film- coated** tablet contains: Flurbiprofen……..100mg
	Diary No. Date of R& I & fee	Dy.No.27233; 08-08-2018; Rs.20,000 (08-08-2018)
	Pharmacological Group	Analgesic/ NSAID
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's, 2x 10's, 6x 5's & As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA as sugar- coated
	Me-too status	Biofen 100mg tablet of M/s Mission Pharma Kar (Reg. # 081600)
	GMP status	Last GMP inspection was conducted on 12-06-18 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • Film- coated tablet is applied while it is available in RRA as sugar- coated.
	Decision: Deferred for revision of formulation as per reference product along with submission of requisite fee.	
362.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt. Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Canzol 1% Cream
	Composition	Each gram of cream contains: Clotrimazole…….10mg
	Diary No. Date of R& I & fee	Dy.No.27234; 08-08-2018; Rs.20,000 (08-08-2018)
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	USFDA Approved

	Me-too status	Clotra Cream of M/s Hisun Pharma (Reg. # 051061)
	GMP status	Last GMP inspection was conducted on 12-06-18 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator XIII	General Semi Solid section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved	
363.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt. Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Bento 1mg Cream (0.1%)
	Composition	Each gram of cream contains: Betamethasone as Valerate……..1mg
	Diary No. Date of R& I & fee	Dy.No.27236; 08-08-2018; Rs.20,000 (08-08-2018)
	Pharmacological Group	Corticosteroid
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Betamethasone Valerate Cream of M/s Pioneer (R# 011692)
	GMP status	Last GMP inspection was conducted on 12-06-18 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator XIII	General Semi Solid section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved	
364.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt. Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Bento- N Cream
	Composition	Each gram of cream contains: Betamethasone as Valerate……1mg Neomycin Sulphate……5mg
	Diary No. Date of R& I & fee	Dy.No.27237; 08-08-2018; Rs.20,000 (08-08-2018)
	Pharmacological Group	Corticosteroid/ Antibacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Betameth-N of M/s Shaigan Pharma(Reg.#038364)
	GMP status	Last GMP inspection was conducted on 12-06-18 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator XIII	General Semi Solid section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovator's specifications.	
365.	Name and address of manufacturer / Applicant	M/s Linta Pharmaceuticals Pvt. Ltd, Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Bento- G Cream
	Composition	Each gram of cream contains: Betamethasone as Dipropionate……0.5mg Gentamycin as Sulphate……1mg
	Diary No. Date of R& I & fee	Dy.No.27238; 08-08-2018; Rs.20,000 (08-08-2018)
	Pharmacological Group	Corticosteroid/ Antibacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diprogenta cream by MSD (Germany Approved)
	Me-too status	Mysoderm Cream of M/s Ali Gohar (Reg. # 024121)

	GMP status	Last GMP inspection was conducted on 12-06-18 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator XIII	• The applied formulation is non- pharmacopoeial. • General Semi Solid section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved with innovator's specifications.	
366.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name +Dosage Form + Strength	Longaceph 250mg I/V Injection
	Composition	Each vial contains: Ceftriaxone as Sodium …….. 250mg
	Diary No. Date of R& I & fee	Dy.No.26971; 06-08-2018; Rs.50,000 (06-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rocephin Roche I/V Inj of M/s Roche (Reg. # 008433)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-01-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Decision: Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.	
367.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name +Dosage Form + Strength	Longaceph 500mg I/V Injection
	Composition	Each vial contains: Ceftriaxone as Sodium …… 500mg
	Diary No. Date of R& I & fee	Dy.No.26969; 06-08-2018; Rs.50,000 (06-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Rocephin Roche I/ V Inj of M/s Roche (Reg. # 008435)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-1-2019 and the report concludes good level of GMP compliance.

	Remarks of the Evaluator XIII	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Decision: Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.	
368.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name +Dosage Form + Strength	Longaceph 250mg I/M Injection
	Composition	Each vial contains: Ceftriaxone as Sodium …….. 250mg
	Diary No. Date of R& I & fee	Dy.No.26971; 06-08-2018; Rs.50,000 (06-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 vial + Ampoule of 2ml solvent & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Topcef 250mg Injection IV/IM of M/s Pride (R # 025876)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-1-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Decision: Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.	
369.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name +Dosage Form + Strength	Longaceph 500mg I/M Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……. 500mg
	Diary No. Date of R& I & fee	Dy.No.26710; 03-08-2018; Rs.50,000 (03-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 vial+ Ampoule of 2ml solvent & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Topcef 500mg Injection IV/IM of M/s Pride Pharma (Reg. # 025877)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-01-2019 and the report concludes good level of GMP compliance.

	Remarks of the Evaluator XIII	No. of approved sections of applicant firm are 06. No. of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Decision: Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.	
370.	Name and address of manufacturer / Applicant	M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot # A-248 & A-256 to A-259 H.I.T.E. Lasbela Balochistan, Pakistan. Contract Manufacturer: M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore.
	Brand Name +Dosage Form + Strength	Longaceph 1g I/V Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……..……. 1g
	Diary No. Date of R& I & fee	Dy.No.26711; 03-08-2018; Rs.50,000 (03-08-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 1's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Topcef 500mg Injection IV/IM of M/s Pride Pharma (Reg. # 025878)
	GMP status	M/s NovaMed: Last GMP inspection was conducted on 27-12-2017 as a result of which GMP Certificate was issued on 03-01-2018. M/s Akhai: Last GMP inspection was conducted on 03-1-2019 & report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	No.of approved sections of applicant firm are 06. No.of approved drugs on contract basis of applicant firm is 01. Manufacturer has Dry powder injection Cephalosporin section.
	Decision: Registration Board decided to defer for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km,Ferozepur Road, Lahore.	
371.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt. Ltd K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi.
	Brand Name +Dosage Form + Strength	Dronate 2mg/ml Eye Drops
	Composition	Each ml of solution contains: Sodium Hyaluronate…..2mg
	Diary No. Date of R& I & fee	Dy.No.20327; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Lubricant
	Type of Form	Form- 5
	Finished product Specification	Innovators specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Hylo 2mg/ ml Eye Drops of M/s Helix (Reg. # 067031)
	GMP status	Last GMP inspection was conducted on 09-10-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	• Eye Drops (General) section is available in the firm as mentioned in the submitted section approval letter. • The official monograph is available in JP.
	Decision: Approved with JP specifications	
372.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt. Ltd K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi.
	Brand Name +Dosage Form + Strength	Winbrex Eye Drops 15mg/ml

	Composition	Each ml of solution contains: Tobramycin……....15mg
	Diary No. Date of R& I & fee	Dy.No.20326; 05-06-2018;Rs.20,000 (05-06-2018)
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	**Could not be confirmed in the applied strength (Available strength is 0.3%)**
	Me-too status	Obrex Forte 1.5% Eye Drops of M/s Vega Pharma (Reg. # 071502)
	GMP status	Last GMP inspection was conducted on 09-10-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	• Eye Drops (General) section is available in the firm as mentioned in the submitted section approval letter. • Internationally, could not be confirmed in the applied strength (available strength is 0.3%).
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
373.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Razole tablet 20mg
	Composition	Each enteric- coated tablet contains: Rabeprazole as Sodium……...20mg
	Diary No. Date of R& I & fee	Dy.No.27062; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form- 5
	Finished product Specification	Innovators
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Ranzot 20mg Tablet of M/s Hygeia (Reg. # 081197)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved	
374.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Lornox Tablet 4mg
	Composition	Each film- coated tablet contains: Lornoxicam……..4mg
	Diary No. Date of R& I & fee	Dy.No.27064; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- inflammatory and Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 4 mg Film tabletten by M/s Takeda Pharma AG,(Swiss Medic Approved)
	Me-too status	Lornox 4mg tablet of M/s Ray Pharma (Reg. # 066713)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	• No USP or BP monograph is available for the applied formulation. • General tablet section is available in the firm as

		mentioned in the submitted DML. • Applied brand name may be changed as it resembles with an already approved brand name of another firm.
	Decision: Approved with innovator's specifications and change of brand name.	
375.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Lornox Tablet 8mg
	Composition	Each film- coated contains: Lornoxicam……..8mg
	Diary No. Date of R& I & fee	Dy.No.27065; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- inflammatory and Anti- rheumatic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8 mg Film tabletten by M/s Takeda Pharma AG,(Swiss Medic Approved)
	Me-too status	Lornox 8mg tablet of M/s Ray Pharma (Reg. # 061083)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	• No USP or BP monograph is available for the applied formulation. • Applied brand name may be changed as it resembles with an already approved brand name of another firm. • General tablet section is available in the firm as mentioned in the submitted DML. • Initially, 4mg was written throughout the dossier instead of 8mg while fee challan is of 8mg. • Now, firm has revised all the documents as 8mg tablet.
	Decision: Deferred for submission of fees for revision of strength of applied formulation.	
376.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Avantra tablet 10mg
	Composition	Each film- coated tablet contains: Memantine as HCl……..10mg
	Diary No. Date of R& I & fee	Dy.No.27058; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- dementia
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Namentec 10mg Tablet of M/s Pharmatec (R # 075937)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	General tablet section is available in the firm as mentioned in the submitted DML.
	Decision: Approved	
377.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Meverine SR capsule 200mg
	Composition	Each modified- release capsule contains: Mebeverine as HCl as Extended Release Pellets Eq. to Mebeverine HCl……200mg
	Diary No. Date of R& I & fee	Dy.No.27060; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Drugs for functional Gastro-intestinal disorder
	Type of Form	Form- 5

	Finished product Specification	In- house
	Pack size & Demanded Price	As per SRO & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Mebesid capsule of M/s N.S Pharma(Reg.# 086467)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator XIII	• General capsule section is available in the firm as mentioned in the submitted GMP inspection report. • Source of pellets is M/s Vision Pharma. • All the data related to pellets has been submitted. • The applied formulation s non- pharmacopoeial.
	Decision: Approved with innovators' specifications.	
378.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot 119, Street # 8, I- 10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Benglip Tablet 50/500mg
	Composition	Each film- coated tablet contains:- Metformin HCl …….....500mg Sitagliptin as Phosphate Monohydrate …...50mg
	Diary No. Date of R& I & fee	Dy.No.20332; 05-06-2018;Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Silmax- M 50mg/ 500mg Tablet of M/s High-Q Pharma (Reg. # 076399)
	GMP status	Last GMP inspection was conducted on 08-11-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as is mentioned in the submitted GMP inspection report. • Firm's previous address was M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad. • Now, the address has been changed as M/s Benson Pharmaceuticals, Plot # 3, Main Road, National Industrial Zone, RCCI, Rawat which is verified by submitted DML issued by CLB. • No official monograph is available for the applied formulation. • Fees for new DML needs to be submitted.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
379.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot 119, Street # 8, I- 10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Benglip Tablet 50/ 1000mg
	Composition	Each film- coated tablet contains:- Metformin HCl ……..….....1000mg Sitagliptin as Phosphate Monohydrate…...50mg
	Diary No. Date of R& I & fee	Dy.No.20333;05-06-2018;Rs.20,000(05-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's, 28's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved

	Me-too status	Silmax- M 50mg/ 1000mg Tablet of M/s High-Q Pharma (Reg. # 076400)
	GMP status	Last GMP inspection was conducted on 08-11-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as is mentioned in the submitted GMP inspection report. • Firm's previous address was M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad. • Now, the address has been changed as M/s Benson Pharmaceuticals, Plot # 3, Main Road, National Industrial Zone, RCCI, Rawat which is verified by submitted DML issued by CLB. • No official monograph is available for the applied formulation. • Fees for new DML needs to be submitted.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
380.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot 119, Street # 8, I- 10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Benparo Tablet 20mg
	Composition	Each film- coated tablet contains:- Paroxetine as Hydrochloride……..20mg
	Diary No. Date of R& I & fee	Dy.No.20581;07-06-2018;Rs.20,000 (07-06-2018)
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor (SSRI)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Neoxetine Tablets 20mg of M/s Neomedix (Reg. # 081407)
	GMP status	Last GMP inspection was conducted on 08-11-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as is mentioned in the submitted GMP inspection report. • Firm's previous address was M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad. • Now, the address has been changed as M/s Benson Pharmaceuticals, Plot # 3, Main Road, National Industrial Zone, RCCI, Rawat which is verified by submitted DML issued by CLB. • Fees for new DML needs to be submitted.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
381.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot 119, Street # 8, I- 10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Benparo CR Tablet 12.5mg
	Composition	Each film- coated controlled release tablet contains: Paroxetine as Hydrochloride……12.5mg
	Diary No. Date of R& I & fee	Dy.No.20582;07-06-2018;Rs.20,000 (07-06-2018)
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor (SSRI)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as enteric, film-coated, bilayer, controlled- release tablet

	Me-too status	Pext- CR 12.5mg tablet of M/s Aurik Pharma (Reg. # 080545)
	GMP status	Last GMP inspection was conducted on 08-11-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as is mentioned in the submitted GMP inspection report. • Firm's previous address was M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad. • Now, the address has been changed as M/s Benson Pharmaceuticals, Plot # 3, Main Road, National Industrial Zone, RCCI, Rawat which is verified by submitted DML issued by CLB. • USFDA Approved as enteric, film-coated, bilayer, controlled- release tablet. • Fees for new DML needs to be submitted.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
382.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot 119, Street # 8, I- 10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Benparo CR Tablet 25mg
	Composition	Each film- coated, controlled release tablet contains: Paroxetine as Hydrochloride……...25mg
	Diary No. Date of R& I & fee	Dy.No.20580; 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Selective Serotonin Reuptake Inhibitor (SSRI)
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as enteric, film-coated, bilayer, controlled- release tablet
	Me-too status	Myroxit CR 25 mg Tablets of M/s Welmark (Reg.# 078598)
	GMP status	Last GMP inspection was conducted on 08-11-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as is mentioned in the submitted GMP inspection report. • Firm's previous address was M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad. • Now, the address has been changed as M/s Benson Pharmaceuticals, Plot # 3, Main Road, National Industrial Zone, RCCI, Rawat which is verified by submitted DML issued by CLB. • USFDA Approved as enteric, film-coated, bilayer, controlled- release tablet. • Fees for new DML needs to be submitted.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
383.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot 119, Street # 8, I- 10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Vildamet Tablets 50/ 1000mg
	Composition	Each film- coated tablet contains:- Vildagliptin ……..…..…….…….....50mg Metformin HCl……..……....1000mg
	Diary No. Date of R & I & fee	Dy.No.20585;07-06-2018;Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	In- house

	Pack size & Demanded Price	30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Galvus-Met 50mg/1000mg of M/s Novartis Pharma (Reg. # 066107)
	GMP status	Last GMP inspection was conducted on 08-11-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• Firm's previous address was M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad. • Now, the address has been changed as M/s Benson Pharmaceuticals, Plot # 3, Main Road, National Industrial Zone, RCCI, Rawat which is verified by submitted DML issued by CLB. • General tablet section is available in the firm as is mentioned in the submitted GMP inspection report. • Fees for new DML needs to be submitted.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
384.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Zitamet tablet 50mg/ 500mg
	Composition	Each film- coated tablet contains: Sitagliptin as Phosphate Monohydrate ….50mg Metformin HCl…….500mg
	Diary No. Date of R& I & fee	Dy.No.26262; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- hyperglycemic Agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Sita Plus 50/ 500mg tablet of M/s PharmEvo (Reg.#055477)
	GMP status	Last GMP inspection was conducted on 07-12-2017 with good GMP compliance. The management expressed very firm commitment for earlier compliance to the suggestions.
	Remarks of the Evaluator XIII	No official monograph is available for the applied formulation. Tablet General Section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
385.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Zitamet tablet 50mg/ 1000mg
	Composition	Each film- coated tablet contains: Sitagliptin as Phosphate Monohydrate ….50mg Metformin HCl……...1000mg
	Diary No. Date of R& I & fee	Dy.No.26263; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- hyperglycemic Agent
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	14's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Sita Plus 50/1000 Tablet of M/s PharmEvo (Reg. # 055486)
	GMP status	Last GMP inspection was conducted on 07-12-2017 with good GMP compliance. The management expressed very

		firm commitment for earlier compliance to the suggestions.
	Remarks of the Evaluator XIII	No official monograph is available for the applied formulation. Tablet General Section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved with innovators' specifications.	
386.	Name and address of manufacturer / Applicant	M/s Scilife Pharma Pvt. Ltd. Plot # FD- 57/ 58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name+ Dosage Form + Strength	Lowsartan HCT tablet 50mg/ 12.5 mg
	Composition	Each film- coated tablet contains: Losartan Potassium…….…….50mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy.No.27403; 09-08-2018; Rs.20,000 (09-08-2018)
	Pharmacological Group	Angiotensin- II Antagonist and Diuretic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 14's, 28's & as per DPC
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Co- Eziday tablet of M/s Werrick Pharma (Reg. # 027042)
	GMP status	Last GMP inspection was conducted on 24-04-2019 and the report concludes that the firm is operating at an acceptable level of good compliance with GMP guidelines.
	Remarks of the Evaluator XIII	General tablet section is available in firm as mentioned in the submitted copy of DML.
	Decision: Approved	
387.	Name and address of manufacturer / Applicant	M/s Scilife Pharma Pvt. Ltd. Plot # FD- 57/ 58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name+ Dosage Form + Strength	Lowsartan HCT tablet 100mg/ 12.5 mg
	Composition	Each film- coated tablet contains: Losartan Potassium……..…….…….100mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy.No.27404; 09-08-2018; Rs.20,000 (09-08-2018)
	Pharmacological Group	Angiotensin- II Antagonist and Diuretic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	7's, 14's, 28's & as per DPC
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Hyzaar 100mg/ 12.5mg tablets of M/s Mova Pharma (Reg. # 047647)
	GMP status	Last GMP inspection was conducted on 24-04-2019 and the report concludes that the firm is operating at an acceptable level of good compliance with GMP guidelines.
	Remarks of the Evaluator XIII	General tablet section is available in firm as mentioned in the submitted copy of DML.
	Decision: Approved	
388.	Name and address of manufacturer / Applicant	M/s Scilife Pharma Pvt. Ltd. Plot # FD- 57/ 58-A2, Korangi Creek Industrial Park, Karachi
	Brand Name+ Dosage Form + Strength	Lowsartan HCT tablet 100mg/ 25 mg
	Composition	Each film- coated tablet contains: Losartan Potassium…….…….100mg Hydrochlorothiazide……25mg
	Diary No. Date of R& I & fee	Dy.No.27405; 09-08-2018; Rs.20,000 (09-08-2018)
	Pharmacological Group	Angiotensin- II Antagonist and Diuretic
	Type of Form	Form- 5
	Finished product Specification	USP

	Pack size & Demanded Price	7's, 14's, 28's & as per DPC
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Lotass Plus 100mg/25mg Tablet of M/s Getz (Reg. # 076788)
	GMP status	Last GMP inspection was conducted on 24-04-2019 and the report concludes that the firm is operating at an acceptable level of good compliance with GMP guidelines.
	Remarks of the Evaluator XIII	General tablet section is available in firm as mentioned in the submitted copy of DML.
	Decision: Approved	
389.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zandan tablet 2mg
	Composition	Each tablet contains: Tizanidine as HCl……2mg
	Diary No. Date of R& I & fee	Dy.No.30048; 06-09-2018; Rs.20,000 (06-09-2018)
	Pharmacological Group	A central a2-adrenergic agonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's & Rs. 85/-
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status	Tizodine 2mg of M/s Batala Pharma (Reg. # 043718)
	GMP status	Last GMP inspection was conducted on 06-03-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	General tablet section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved	
390.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Bisacodyl 5mg Tablet
	Composition	Each sugar and enteric- coated tablet contains: Bisacodyl……..…5mg
	Diary No. Date of R& I & fee	Dy.No.30046; 06-09-2018; Rs.20,000 (06-09-2018)
	Pharmacological Group	Stimulant / Laxative
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10x 10's & Rs. 32/-
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Bisacodyl 5mg tablet of M/s SAMI (Reg. # 002981)
	GMP status	Last GMP inspection was conducted on 06-03-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	General tablet section is available in the firm as mentioned in the submitted GMP inspection report. The official monograph for the applied formulation is available in BP.
	Decision: Approved with BP specifications	
391.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Trancid 500mg Capsule
	Composition	Each capsule contains: Tranexamic Acid……500mg
	Diary No. Date of R& I & fee	Dy.No.30056; 06-09-2018; Rs.20,000 (06-09-2018)
	Pharmacological Group	Antihemorrhagics, Antifibrinolytics agent
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2x 10's & Rs. 230/-
	Approval status of product in Reference Regulatory Authorities	Approved in Italy (AIFA)
	Me-too status	Aneptil 500mg capsules of M/s Alina Combine Pakistan (Reg. # 020511)
	GMP status	Last GMP inspection was conducted on 06-03-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• General capsule section is available in the firm as mentioned in the submitted GMP inspection report. • The official monograph for the applied formulation is available in JP.
	Decision: Approved with JP specifications.	
392.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form Strength	Cefol- CF 500/30/2 mg Tablet
	Composition	Each tablet contains: Paracetamol……..500mg Caffeine……..30mg Chlorpheniramine Maleate……...2mg
	Diary No. Date of R& I & fee	Dy.No.30045; 06-09-2018; Rs.20,000 (06-09-2018)
	Pharmacological Group	Analgesic/ Antipyretic/ Psycho-stimulant/ Anti- histamine
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10x 10's & Rs. 160/-
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Rumadol CF Tablets of M/s Rasco Pharma (Reg. # 074416)
	GMP status	Last GMP inspection was conducted on 06-03-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • International reference could not be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
393.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form Strength	Tramadol 50mg capsule
	Composition	Each capsule contains: Tramadol HCl……..…50mg
	Diary No. Date of R& I & fee	Dy.No.30051; 06-09-2018; Rs.20,000 (06-09-2018)
	Pharmacological Group	Opoid Analgesic
	Type of Form	Form- 5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	1x 10's & Rs. 145/-
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Tramal Capsule 50mg of M/s Impex Plus (Reg. # 010170)
	GMP status	Last GMP inspection was conducted on 06-03-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	General capsule section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved.	
394.	Name and address of manufacturer / Applicant	M/s City Pharmaceutical Laboratories, Plot No. 12A, Sector 5, I-5 New Serveyno-276, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Trancid 250mg capsule

	Composition	Each capsule contains: Tranexamic Acid……...250mg
	Diary No. Date of R& I & fee	Dy.No 30055;06-09-2018; Rs.20,000 (06-09-2018)
	Pharmacological Group	Anti- fibrinolytic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3 x 10's & Rs. 200/-
	Approval status of product in Reference Regulatory Authorities	Approved in Italy (AIFA)
	Me-too status	Aneptil 250mg capsules of M/s Alina Combine Pakistan (Reg. # 020510)
	GMP status	Last GMP inspection was conducted on 06-03-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator XIII	General capsule section is available in the firm as mentioned in the submitted GMP inspection report. The official monograph for the applied formulation is available in JP.
	Decision: Approved with JP specifications.	

b. Deferred cases

395.	Name and address of manufacturer / Applicant	M/s Remington Pharmaceutical Industries Pvt. Limited, 18 km, Multan Road.
	Brand Name +Dosage Form + Strength	Divilda tablet 50mg
	Composition	Each film- coated tablet contains: Vildagliptin ……...…….50mg
	Diary No. Date of R& I & fee	Dy.No.18959;24-05-2018; Rs.20,000 (24-05-2018)
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Galvus uncoated tablet of Novartis (MHRA Approved)
	Me-too status	Galvus of M/s Novartis (Reg. # 059038)
	GMP status	Last GMP inspection was conducted on 16-01-2018 and GMP certificate was granted.
	Previous remarks of the Evaluator	• The applied formulation is non- pharmacopoeial. • The formulation was applied as film- coated tablet while it is approved in reference as uncoated tablet. • Now, the firm has revised its master formulation according to the reference but requisite fees still needs to be submitted for revision of formulation.
	Previous decision	• Deferred in 291st DRB meeting as the requisite fees i.e. Rs. 5000/- still needs to be submitted for revision of formulation.
	Evaluation by PEC	• Firm has submitted the requisite fees i.e. Rs. 5000/- for revision of formulation.
	Decision: Approved with innovators' specifications.	

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

b. Deferred Cases.

396.	Name and address of manufacturer / Applicant	M/s Candid Pharmaceuticals Opposite pusrur sugar mills Sialkot Road, Pasrur
	Brand Name +Dosage Form + Strength	KALFEN TABLET 50mg
	Composition	Each film coated tablet contains: Diclofenac potassium……50mg
	Diary No. Date of R& I & fee	1904, 08-05-2017, 20,000/-, 24-04-2017
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2 × 10's; Rs. 98.00/-
	Approval status of product in Reference Regulatory Authorities.	Diclofenac Potassium 50 mg Tablets (film-coated) by Accord Healthcare Limited Dexcel®-Pharma Ltd. (MHRA approved)
	Me-too status	Arnil-P 50mg Tablet by Brookes Pharma, (Reg # 82129)
	GMP status	Inspection Report dated 15-12-2016 which concludes that firm was found to be operating at a satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for updated status of GMP of the firm form QA & LT division (M-288).
	Evaluation by PEC	Copy of GMP inspection report dated 31-01-2019 concluded that overall condition of premises regarding to production area /machinery/ equipment was satisfactory. However, they need more improvements regarding to above observations.
	Decision: Approved.	
397.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Pot # 03, Main Road, National Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	ORS Powder
	Composition	Each sachet contains: Potassium chloride…….1.50g Sodium chloride…….....2.69g Dextrose anhydrous……9.91g Tri-sodium citrate……..2.90g
	Diary No. Date of R& I & fee	310, 02-01-2019, 20,000/-, 02-01-2019
	Pharmacological Group	Oral Rehydration Therapy
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO approved formulation
	Me-too status	Peditral Low Sachet of Searle Pakistan Each Sachet contains: Anhydrous Glucose……..13.5g Tri sodium citrate dihydrate……..2.9g Sodium chloride…….2.6g Potassium chloride…….1.5g Me-too is different in quantity of Dextrose anhydrous.
	GMP status	Last GMP inspection was conducted on 12-06-2017 and the report concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	• The firm has been granted new Sachet section under re-grant of DML at new manufacturing site. • The firm has submitted duplicate dossier and record retrieved from R & I section via receiving register.

	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-288). Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation (M-289).
	Evaluation by PEC	The firm has revised the formulation as per me-too reference as below: Each Sachet contains: Anhydrous Glucose……..13.5g Tri sodium citrate dihydrate……..2.9g Sodium chloride…….2.6g Potassium chloride…….1.5g Fee challan of Rs. 5000/-, (Deposit slip # 0770332) dated 27-05-2019 has been deposited for revision of formulation. The firm was granted GMP certificate based on inspection conducted on 13-11-2018. The firm has deposited remaining fee of Rs. 15000/- (deposit slip # 0827112) dated 16-09-2019.
	Decision: Approved with IP specifications.	
398.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Pot # 03, Main Road, National Zone, Rawat, Rawalpindi contract manufactured by M/s Bio-Labs (Pvt.) Ltd, Plot No.145, Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Viteben 5mg/ml Injection
	Composition	Each ml ampoule contains: Cholecalciferol……..5mg eq to 200,000IU of Vitamin D
	Diary No. Date of R& I & fee	Dy. No.283; 24-11-2017; Rs.50,000/- (23-11-2017)
	Pharmacological Group	Analogue of Vitamin D
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1ml, 1's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 BON of Bouchara, ANSM Approved
	Me-too status	GET-D of GETZ Pharma Pakistan
	GMP status	(M/s Bio Labs)Last GMP inspection dated 05-12-2017 and 06-12-2017; fair compliance to GMP level.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products (M-285). Registration Board directed the firm to submit revised application and fee with new address (M-290).
	Evaluation by PEC	The firm has submitted copy of new DML, showing new address along with new GMP is attached for your ready reference. The fee of Rs. 5000/- (Deposit slip # 827114) dated 16-09-2019 has been deposited. M/s Bio-Labs was granted GMP certificate based on inspection dated 23-04-2019.
	Decision: Registration Baord referred the case to QA & LT division for updated GMP status of M/s Bio-Labs. Moreover, the Board also directed the applicant to submit remaining fee Rs. 15,000/- for revised Form 5, submitted on behalf of new DML.	
399.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Limited, 13km, Multan road, Lahore
	Brand Name +Dosage Form + Strength	Irofol Tablets

	Composition	Each chewable tablet contains: Folic Acid……..…0.35mg Iron Polymaltose complex eq. to elemental Iron…..100mg
	Diary No. Date of R& I & fee	Dy. No.; 31-1-2017; Rs.20,000/- (31-1-2017)
	Pharmacological Group	Iron supplement
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Rubifer F tablet of M/s AGP
	GMP status	The firm M/s Reko Pharmacal Pvt Ltd has been inspected on 09.01.2019 and 31.03.2019, wherein FAIR level of GMP compliance was noted
	Previous remarks of the Evaluator.	International availability and me-too status could not be confirmed
	Previous decision(s)	Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Deferred for confirmation of formulation as applied by the firm (M-291).
	Evaluation by PEC	The firm has submitted Form-5 with revised strength of applied formulation alongwith submission of fee of Rs. 20,000/- (Deposit slip # 1900860) dated 19-09-2019.
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
400.	Name and address of manufacturer / Applicant	M/s Noa Hemis Plot #154, Sector 23, Korangi industrial area Karachi
	Brand Name +Dosage Form + Strength	Bianchi Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloirde……2.5 mg
	Diary No. Date of R& I & fee	Dy.No. 1569, 4-8-2016, Rs.20,000/-
	Pharmacological Group	Anti-Histaminic
	Type of Form	Form-5
	Finished product Specification	Innovators
	Pack size & Demanded Price	60 ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA approved.
	Me-too status	Letirix Syrup of M/s Alliance Pharmaceuticals
	GMP status	Last GMP Inspection dated 17-11-16 with conclusive remarks of cGMP compliance
	Previous remarks of the Evaluator.	Levocetirizine dihydrochloride 2.5mg/5ml oral solution is available in USFDA
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting (M-274). Deferred for submission of requisite fee for the revision of formulation (M-289).
	Evaluation by PEC	The firm has submitted dossier with revised strength of applied formulation alongwith fee challan of Rs. 5000/- (deposit slip # 0545425) dated 13-02-2019 and Rs. 15,000/- (deposit slip # 1931395) dated 17-09-2019.
	Decision: Approved.	

401.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	IBAN 150mg TABLETS
	Composition	Each film coated tablet contains: Ibandronate sodium monohydrate eq. to. Ibandronic acid …….150mg
	Diary No. Date of R& I & fee	Dy. No.308; 16-03-2016; Rs.20,000/- (15-03-2016)
	Pharmacological Group	Bisphosphonate
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 1's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Bongro 150mg Tablets of M/s Fassgen Pharma (073298)
	GMP status	Last GMP inspection report dated 02-01-2017 confirms good compliance to GMP
	Previous remarks of the Evaluator.	• Coating ingredients not mentioned in the master formulation. • No USP or BP monograph is available for applied formulation
	Previous decision(s)	Deferred for clarification of dosage form whether coated or uncoated as coating ingredients were not mentioned in the master formulation (M-274).
	Evaluation by PEC	The firm has submitted revised master formulation with film coating composition.
	Decision: Deferred for submission of fee for revision of formulation as per reference product.	
402.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	C-Pride 1mg Tablets
	Composition	Each tablet contains: Cinitapride as hydrogen tartrate……..1mg
	Diary No. Date of R& I & fee	Dy. No.2902 dated 14-05-2013 (Fast Track), 14-05-2013 Rs.60,000/-
	Pharmacological Group	Gastrointestinal drugs
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg uncoated tablet by Almirall, SA (Spain Approved)
	Me-too status	Cidine Tablets by M/s Highnoon Lab (Reg. # 052940)
	GMP status	Last GMP inspection report dated 02-01-2017 confirms good compliance to GMP
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for reviw of formulation by review committee (M-242). Deferred for for the following submission: • Change in formualation to uncoated tablet as per the reference product in Spain. • Fee for change of formulation. • Clarification of salt form of API of the product since the reference product contains Cinitapride as acid tartarate (M-277).
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation from film coated to uncoated tablet composition.
	Decision: Deferred for submission of fee for revision of formulation as per reference product.	

403.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Noin 100mg tablets
	Composition	Each film coated tablet contains: Nitrofurantoin …… 100mg
	Diary No. Date of R& I & fee	Dy. No.2337; 03-04-2015; Rs.20,000/- (03-04-2015)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	3 x 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA and US-FDA
	Me-too status	Furantin 100mg tablets of M/s Geofman
	GMP status	Last inspection report dated 02-01-2017 confirms good compliance to GMP.
	Previous remarks of the Evaluator.	➢ Marketing status in USFDA: discontinued ➢ The official monograph of product exists in BP and USP. ➢ Shortcomings • Clarification regarding whether the applied product is film coated or uncoated tablets, and composition of coating solution in case of coated tablets. • Evidence of approval of applied formulation as *film coated* tablets in reference regulatory authorities/agencies could not be confirmed.
	Previous decision(s)	Deferred for following: • Clarification regarding whether the applied product is film coated or controlled release tablets • Composition of coating solution in case of coated tablets. • Evidence of approval of applied formulation as film coated tablets in reference regulatory authorities /agencies.
	Evaluation by PEC	The firm has not revised form-5 as per reference product which is uncoated.
	Decision: Deferred for revision of formulation as per reference product alongwith applicable fee.	
404.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316 Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Muscide 4mg Capsules
	Composition	Each capsule contains:- Thicolchicoside…….4mg
	Diary No. Date of R& I & fee	Dy.No.996, 21-01-2013, Fee Rs.20,000
	Pharmacological Group	Anti-rheumatics (anti-inflammatory agents)
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MYOPLEGE 4 mg hard capsule of M/s GENEVRIER SA Laboratories approved by ANSM of France
	Me-too status	Myogen Capsules 4 mg by M/s Nimrall Pharmaceuticals, (Reg.# 066700)
	GMP status	Last inspection report dated 02-01-2017 confirms good compliance to GMP.
	Previous remarks of the Evaluator.	
	Previous decision(s)	The Registration Board after thorough deliberation decided to refer the case to the review committee for review of formulation (M-239).

	Evaluation by PEC	The firm has submitted international and me-too reference for applied formulation.
	Decision: Approved.	
405.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Vildamet Tablet 50/500mg
	Composition	Each film-coated tablet contains: Vildagliptin……50mg Metformin HCl……500mg
	Diary No. Date of R& I & fee	Dy. No.4023; 27-12-2016; Rs.20,000/- (23-12-2016)
	Pharmacological Group	Hypoglycemic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	Not provided & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Galvumet50mg/ 1000mg Tablet By Novartis, Australia (TGA Approved)
	Me-too status	Galvus Met 50mg/ 1000mg Tablet of M/s Novartis Pharma (Reg. # 066107)
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has clarified that current GMP status of the firm shall be considered as compliant.
	Decision: Approved with innovator's specifications.	
406.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Vildamet Plus Tablet
	Composition	Each film-coated tablet contains: Vildagliptin……50mg Metformin HCl……..1000mg
	Diary No. Date of R& I & fee	Dy. No.4024; 27-12-2016; Rs.20,000/- (23-12-2016)
	Pharmacological Group	Hypoglycemic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	Not provided & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Galvumet50mg/ 1000mg Tablet By Novartis, Australia (TGA Approved)
	Me-too status	Galvus Met 50mg/ 1000mg Tablet of M/s Novartis Pharma (Reg. # 066107)
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	• Date of inspection doesn't fall within one year.
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has clarified that current GMP status of the firm shall be considered as compliant.
	Decision: Approved with innovator's specifications.	
407.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Vildalin Tablets 50mg
	Composition	Each film-coated tablet contains: Vildagliptin ……..50mg
	Diary No. Date of R& I & fee	Dy. No.4021; 27-12-2016; Rs.20,000/- (27-12-2016)

	Pharmacological Group	Hypoglycemic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	Not provided & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Galvus uncoated of M/s Novartis Pharmaceuticals (UK)
	Me-too status	Galvus of M/s Novartis Pharmaceuticals , Pak
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	• Date of inspection doesn't fall within one year. • Approved in MHRA and Netherland as uncoated while is applied as film-coated.
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority Moreover Board directed the firm to submit clarification for dosage form since reference product is available as uncoated tablet whereas firm has applied for film coating tablet (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has clarified that current GMP status of the firm shall be considered as compliant. However, revision of formulation as per reference product is required.
	Decision: Deferred for revision of formulation as per reference product alongwith applicable fee.	
408.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Solo Tablet 5mg
	Composition	Each film-coated tablet contains: Solifenacin succinate……...5mg
	Diary No. Date of R& I & fee	Dy. No.2996; 19-12-2016; Rs.20,000/- (15-12-2016)
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	Not provided & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Vesicare of M/s Astellas Pharma (UK) MHRA Approved
	Me-too status	Solifen of M/s Getz Pharmaceuticals
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	• Fee-challan provided is of sitagliptin while applied as vildagliptin. • Date of inspection doesn't fall within one year.
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has clarified that current GMP status of the firm shall be considered as compliant.
	Decision: Approved with innovator's specifications.	
409.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Valopine Plus Tablet 10/160mg
	Composition	Each film-coated tablet contains: Amlodipine Besylate eq.to Amlodipine.....10mg Valsartan……160mg
	Diary No. Date of R& I & fee	Dy. No.3000; 19-12-2016; Rs.20,000/- (16-12-2016)
	Pharmacological Group	Antihypertensive

	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Exforge of M/s Novartis Pharmaceuticals (UK)/MHRA Approved
	Me-too status	Exforge of M/s Novartis Pharmaceuticals (Pak)
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance. Minor observations as advised were asked to be removed at the earliest.
	Previous remarks of the Evaluator.	• The firm has claimed manufacturer's specifications while it is available in U.S.P.
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has clarified that current GMP status of the firm shall be considered as compliant.
	Decision: Approved.	
410.	Name and address of manufacturer / Applicant	M/s Panacea Pharmaceuticals, Plot no.4, Street no. S-6, National Industrial Zone , Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Solo Tablet 10mg
	Composition	Each film-coated tablet contains: Solifenacin succinate……...10mg
	Diary No. Date of R& I & fee	Dy. No.2995; 19-12-2016; Rs.20,000/- (15-12-2016)
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	Not provided & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Vesicare of M/s Astellas Pharma (UK) MHRA Approved
	Me-too status	Solifen of M/s Getz Pharmaceuticals
	GMP status	Last GMP inspection was conducted on 08-12-2016 which concludes good level of GMP compliance.
	Previous remarks of the Evaluator.	• Date of inspection doesn't fall within one year. Firm needs to be inspected.
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-279).
	Evaluation by PEC	QA division vide letter No.F.4-5/2007-QA dated 26-08-2019 has clarified that current GMP status of the firm shall be considered as compliant.
	Decision: Approved with innovator's specifications.	
411.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited, F-319 SITE, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	HEMONSTIL 500mg/10ml INJECTION
	Composition	Each 10ml injection contains: Iron as Ferric Carboxymaltose……..500mg
	Diary No. Date of R& I & fee	1793, 12-01-2018, 20,000/-, 11-01-2018
	Pharmacological Group	Haematinic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1's x 10ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Injectafer 750 mg iron / 15 mL single-use vial by M/s Luitpold Pharms Inc (USFDA Approved)
	Me-too status	Ferinject 50mg/ml Injectable Vial (10ml) by M/s R.G Pharmaceutica (Reg#072548)
	GMP status	Copy of GMP certificate valid upto 05-2019, issued by Additional Director, DRAP, Karachi has been submitted.

	Previous remarks of the Evaluator.	• Label claim does not clarify quantity of iron in applied formulation is not as per Reference product. • Evidence of 10 ml pack size in Reference Regulatory Authorities is required to be submitted.
	Previous decision(s)	Deferred for revision of formulation and label claim as per the USFDA approved reference product and Evidence of 10 ml pack size in Reference Regulatory Authorities is required to be submitted (M-288). Deferred for submission of fee for revision of formulation (M-290).
	Evaluation by PEC	The firm has revised master formulation with correct salt form of applied formulation. The firm has deposited fee challan of Rs. 5000/- (Deposit slip # 1951366) dated 02-09-2019.
	Decision: Registration Board deferred the case for comments regarding patent status of applied formulation from legal division.	
412.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd. Plot No. 206 & 207. Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Fixef 200mg Capsule
	Composition	Each Capsule Contains: Cefixime (as trihydrate)……..200mg
	Diary No. Date of R& I & fee	Dy.No 13599 (11-04-2018) Rs.20,000/- 11-04-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	5's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	CEFIXIMA NORMON 200 mg CAPSULAS by M/s Laboratorios Normon, S.A., Spain approved
	Me-too status	Secure 200mg Capsules by M/s Wilshire (Reg#034883
	GMP status	
	Previous remarks of the Evaluator.	• Latest GMP status not confirmed.
	Previous decision(s)	Registration Board referred the case to QA & LT Division to update GMP status of Firm on priority (M-290).
	Evaluation by PEC	The firm was granted GMP certificate based on inspection conducted on 17-03-2017.
	Decision: Registration Board referred the case to QA & LT division for submission of updated GMP status of the firm.	
413.	Name and address of manufacturer / Applicant	M/s. Yas Chemical Industries Limited, Plot No.191, Road L10 Gadoon Industrial Estate, Distt.Swabi, KPK
	Brand Name +Dosage Form + Strength	Y-Flox IV Infusion 200mg
	Composition	Each 100ml contains: Ofloxacin…….200mg
	Diary No. Date of R& I & fee	Dy. No. 381, 22-10-2014 , Rs.20,000/- (20-10-2014)
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	100ml Glass vial : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tarivid IV infusion solution of Aventis Pharma (MHRA approved)
	Me-too status	Re-ved 200mg/100ml Infusion of M/s Rasco pharma (Reg#078932)
	GMP status	Not provided
	Previous remarks of the Evaluator.	• Not in ANSM, MHRA (glass vial), Health Canada, TGA, Germany. • Not in USP and BP. • Me too Glass vial available. • Last GMP inspection report missing.

	Previous decision(s)	Deferred for the following reasons: (M-274) • Submission of evidence of approval of applied formulation in plastic bags in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting. • Submission of latest GMP inspection report (which should have been conducted within the period of last one year).
	Evaluation by PEC	The firm has submitted revised Form-5 with glass vial packaging material alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1901556) dated 05-03-2019. Panel inspection dated 20-12-2018 recommends renewal of DML for following section only: • Liquid infusion 100ml in Glass bottles The firm shall resume production after producing valid registration letters of products in 100ml glass bottle for their registered products and shall also de-register their products having other volumes / packing.
	Decision: Approved. Registration Board also directed the Registration section to issue showcause to firm as to why not their products of "Liquid infusion", having other volumes / packing other than 100ml glass bottle, be de-registered.	
414.	Name and address of manufacturer / Applicant	M/s. Yas Chemical Industries Limited, Plot No.191, Road L10 Gadoon Industrial Estate, Distt.Swabi, KPK
	Brand Name +Dosage Form + Strength	Y-Liv IV Infusion 500mg
	Composition	Each 100ml contains: Levofloxacin as hemihydrate……..….500mg
	Diary No. Date of R& I & fee	Dy. No. 379, 22-10-2014 , Rs.20,000/- (20-10-2014)
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator
	Pack size & Demanded Price	100ml Plastic Bag: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levofloxacin 5mg/ml solution for infusion by Hospira (MHRA Approved).
	Me-too status	Levofloxa infusion of Rasco Pharma (Reg#078928)
	GMP status	Not provided.
	Previous remarks of the Evaluator.	• Me too Glass vial available. • Salt of levofloxacin not provided. • Last GMP inspection report missing. • 100ml, pack of 1 multilayer polyolefin bag containing either 1 or 2 polypropropylene infusion ports closed with isoprene rubber stoppers and snap caps with aluminium foil over-pouch with clear window. Each bag contains 100 ml. (MHRA)
	Previous decision(s)	Deferred for the following reasons: (M-274) • Submission of evidence of approval of applied formulation in plastic bags in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting. • Submission of latest GMP inspection report (which should have been conducted within the period of last one year).
	Evaluation by PEC	The firm has submitted revised Form-5 with correct salt form and glass vial packaging material alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1901557) dated 05-03-2019. Panel inspection dated 20-12-2018 recommends renewal of DML for following section only:

		• Liquid infusion 100ml in Glass bottles The firm shall resume production after producing valid registration letters of products in 100ml glass bottle for their registered products and shall also de-register their products having other volumes / packing.
	Decision: Approved. Registration Board also directed the Registration section to issue showcause to firm as to why not their products of "Liquid infusion", having other volumes / packing other than 100ml glass bottle, be de-registered.	
415.	Name and address of manufacturer / Applicant	M/s. Yas Chemical Industries Limited, Plot No.191, Road L10 Gadoon Industrial Estate, Distt.Swabi, KPK
	Brand Name +Dosage Form + Strength	Y-Cip IV Infusion 500mg
	Composition	Each 100ml contains: Ciprofloxacin……500mg
	Diary No. Date of R& I & fee	Dy. No. 380, 22-10-2014 , Rs.20,000/- (20-10-2014)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	100ml Plastic Bag: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ciprofloxacin 2mg/ml solution for infusion of Hikma farmaceutica (MHRA approved)
	Me-too status	Styx infusion for injection of Saaaf Pharma (Reg#080970)
	GMP status	Not provided
	Previous remarks of the Evaluator.	• Me too Glass vial available. • Salt of ciprofloxacin not provided. • Last GMP inspection report missing. • Each ml of solution for infusion contains 2 mg ciprofloxacin (as ciprofloxacin lactate*) 100 ml infusion bag contains 200 mg ciprofloxacin as 254.4 mg ciprofloxacin lactate*.(MHRA) • Clear flexible polyolefin bag with a polypropylene infusion port sealed with a synthetic isoprene rubber stopper and polypropylene snap-cap. The infusion bag is contained in an aluminium overpouch. (MHRA). • USP-Injection monograph • BP-Infusion monograph
	Previous decision(s)	Deferred for the following reasons: (M-274) • Submission of evidence of approval of applied formulation in plastic bags in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 249th meeting. • Submission of latest GMP inspection report (which should have been conducted within the period of last one year).
	Evaluation by PEC	The firm has submitted Form-5 with revised strength of applied formulation and salt form. Moreover, glass vial packaging material is now mentioned in revised Form-5. Fee challan of Rs. 5000/- (Deposit slip # 1901558) dated 05-03-2019 has been deposited. Revised formulation is: Each 100ml contains: Ciprofloxacin as lactate……200mg Panel inspection dated 20-12-2018 recommends renewal of DML for following section only: • Liquid infusion 100ml in Glass bottles The firm shall resume production after producing valid registration letters of products in 100ml glass bottle for their registered products and shall also de-register their products having other volumes / packing.

	Decision: Approved with following label claim: **Each 100ml contains:** **Ciprofloxacin as lactate……200mg** **Registration Board also directed the Registration section to issue showcause to firm as to why not their products of "Liquid infusion", having other volumes / packing other than 100ml glass bottle, be de-registered.**	
416.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Duranol 60mg Capsules
	Composition	Each capsule contains: Duloxetine as hydrochloride (enteric coated pellets 17.0%)……..…60mg
	Diary No. Date of R& I & fee	Dy.No 4547, 07-02-2018, Rs. 20,000/-, 17-01-2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cymbalta (Duloxetine 60 mg capsule) by M/s Eli Lilly, USFDA
	Me-too status	Dulan (Duloxetine 60 mg capsule) by M/s Hilton Pharma.(Reg#055448)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following: (M-288) • Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. • Revision of formulation and label claim as per the USFDA approved reference product.
	Evaluation by PEC	The firm has submitted stability studies data, GMP certificate of supplier from M/s.Vision pharma. The firm has revised label claim with submission of fee challan of Rs. 5000/-, (Deposit slip # 1952526) dated 18-07-2019.
	Decision: Approved.	
417.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Duranol 30mg Capsules
	Composition	Each capsule contains: Duloxetine as hydrochloride (enteric coated pellets 17.0%)……..…30mg
	Diary No. Date of R& I & fee	Dy.No 4546, 07-02-2018, Rs. 20,000/-, 17-01-2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cymbalta (Duloxetine 30 mg capsule) by M/s Eli Lilly, USFDA
	Me-too status	Dulan 30mg by M/s Hilton Pharma. (Reg#055447)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	Source of pellets
	Previous decision(s)	Deferred for following: (M-288) • Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of

		import of pellets. • Revision of formulation and label claim as per the USFDA approved reference product.
	Evaluation by PEC	The firm has submitted stability studies data, GMP certificate of supplier from M/s. Vision pharma. The firm has revised label claim with submission of fee challan of Rs. 5000/-, (Deposit slip # 1952525) dated 18-07-2019.
	Decision: Approved.	
418.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Duranol 20mg Capsules
	Composition	Each capsule contains: Duloxetine as hydrochloride (enteric coated pellets 17.0%)……..…20mg
	Diary No. Date of R& I & fee	Dy.No 4545, 07-02-2018, Rs. 20,000/-, 17-01-2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cymbalta (Duloxetine 20 mg capsule) by M/s Eli Lilly, USFDA
	Me-too status	Dulan 20mg by M/s Hilton Pharma.(Reg#055446)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following: (M-288) • Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets. • Revision of formulation and label claim as per the USFDA approved reference product.
	Evaluation by PEC	The firm has submitted stability studies data, GMP certificate of supplier from M/s.Vision pharma. The firm has revised label claim with submission of fee challan of Rs. 5000/-, (Deposit slip # 1952523) dated 18-07-2019.
	Decision: Approved.	
419.	Name and address of manufacturer / Applicant	M/s Standpharm Pakistan Pvt. Ltd., 20-km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Resque 500mg Tablet
	Composition	Each tablet contains: Azithromycin as dihydrate.……..…500mg
	Diary No. Date of R& I & fee	Dy.No. 4544, 07-02-2018, Rs. 20,000/-, 17-01-2018
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 500 mg Film-Coated Tablets by TEVA UK Limited (MHRA Approved)
	Me-too status	Zetro 500mg Tablet by Getz Pharma (Reg# 053120)
	GMP status	Last GMP inspection was conducted on 19-10-2017 and the report concludes a satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	

	Previous decision(s)	Deferred for revision of salt form of API as per reference product along with requisite fee for change of formulation (M-288).
	Evaluation by PEC	The firm has revised label claim with submission of fee challan of Rs. 5000/- (Deposit slip # 1952524) dated 18-07-2019.
	Decision: Approved.	
420.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals, Plot # 112-A, Industrial Estate, Hayatabad, KPK
	Brand Name +Dosage Form + Strength	RETIK 125mg/5ml Dry Suspension
	Composition	Each 5ml contains: Clarithromycin as taste masked granules 27.5%….125mg
	Diary No. Date of R& I & fee	33767, 11-10-2018, 20,000/-, 28-08-2018
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Biaxin granules for oral suspension 125mg/5ml by M/s Abbvie, USFDA approved.
	Me-too status	Rethro 125mg/5ml Dry Suspension by M/s Regal Pharmaceuticals
	GMP status	Panel inspection dated 30-08-2018 recommended for grant of GMP certificate. Licensing division vide letter No.F. 3-1/2002-Lic (Vol-1) dated 19th December, 2017 has approved the grant of additional sections: Dry Powder suspension (General) Capsule section (General)
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-287).
	Evaluation by PEC	Firm will use Clarithromycin 27.5% taste masked pellets, manufactured by M/s. Vision Pharmaceuticals. Firm has provided all required documents of pellets manufacturer.
	Decision: Approved.	
421.	Name and address of manufacturer / Applicant	M/s Alliance Pharmaceuticals, Plot # 112-A, Industrial Estate, Hayatabad, KPK
	Brand Name +Dosage Form + Strength	AZIZOX 200mg/5ml Dry Suspension
	Composition	Each 5ml contains (when reconstituted): Azithromycin as Dihydrate…….200mg
	Diary No. Date of R& I & fee	33750, 11-10-2018, 20,000/-, 13-08-2018
	Pharmacological Group	Macrolide
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	15ml, 30ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Zatrocin 200 mg Dry Suspension of M/S Pearl Pharmaceuticals
	GMP status	Panel inspection dated 30-08-2018 recommended for grant of GMP certificate. Licensing division vide letter No.F. 3-1/2002-Lic (Vol-1) dated 19th December, 2017 has approved the grant of additional sections: Dry Powder suspension (General) Capsule section (General).

	Previous remarks of the Evaluator.	The firm has submitted master formulation without overage.
	Previous decision(s)	Deferred for selection of finished product specifications whether USP or BP in view of available equipments with firm (M-287).
	Evaluation by PEC	The firm has submitted that they select USP monograph for Finished product specifications.
	Decision: Deferred for confirmation of availability of amphoteric ECD detector with dual glassy carbon electrodes required for azithromycin capsule and oral suspension.	
422.	Name and address of manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan (Pvt.) Ltd Plot 50/28, Korangi Industrial area, Karachi.
	Brand Name +Dosage Form + Strength	Nexor Tablet 275mg
	Composition	Each tablet contains: Naproxen sodium……..275mg
	Diary No. Date of R& I & fee	14499, 18-04-2018, 20,000/-, 13-04-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	3 × 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Naproxen sodium Tablets 275mg of M/s Watson Laboratories, USFDA
	Me-too status	XANBID Tablet of M/s Martin Dow Pharma
	GMP status	GMP inspection dated 13-07-2017 & 16-07-2017 concluded that the firm was considered to be operating at an acceptable level of compliance with GMP guidelines.
	Previous remarks of the Evaluator.	• Master formulation contains ingredients of film coating.
	Previous decision(s)	Deferred for revision of master formulation as per reference product (M-290).
	Evaluation by PEC	The firm has revised master formulation as per reference alongwith submission of fee challan of Rs. 5000/- (deposit slip # 0830944) dated 28-08-2019.
	Decision: Approved.	
423.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxila Plot # 31 & 32 Punjab Small Industrial Estate, Taxila Contract Manufactured by: M/s Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Dydowen Tablet 10mg
	Composition	Each film coated tablet contains: Dydrogesterone …10mg
	Diary No. Date of R& I & fee	Diary No:14882, 13/10/2017, Rs. 50,000/-
	Pharmacological Group	Antimigraine Preparations (Selective serotonin (5HT1) agonists)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zolmitriptan 2.5 mg film-coated tablets by M/s Teva UK Ltd,(MHRA Approved)
	Me-too status	Zomig Tablets 2.5mg by M/s ICI (Reg#021149)
	GMP status	Wenovo Pharmaceuticals: 19-10-2017 Routine GMP Inspection GMP compliance of firm is good Weather Folds Pharmaceuticals: Last GMP inspection was conducted on 15-09-2017 and the report concludes the firm to be GMP compliant.
	Previous remarks of the Evaluator.	• M/s Wenovo Pharmaceuticals has already applied for contract manufacturing of said product by M/s Dyson

		Research Laboratories Pvt, 28-km, Ferozepur Road, Lahore under brand name of Progest Tablets 10mg.
	Previous decision(s)	Deferred for Deferred for further deliberation upon Cis / Trans isomer of Dydrogesterone (M-281) Registration Board deferred the case for clarification from the firm since the applied formulation is already applied for contract manufacturing from M/s Dyson Research Laboratories (M-284).
	Evaluation by PEC	The firm has requested to withdraw application from M/s Dyson Research laboratories and proceed our application for contract manufacturing from M/s Weather Folds Pharmaceuticals.
	Decision: Registration Board approved the application for contract manufacturing from M/s Weather Folds Pharmaceuticals, Plot no. 69/2, Phase II, Industrial Estate, Hattar.	
424.	Name and address of manufacturer / Applicant	M/s Simz Pharmaceuticals 574-575 Sunder Industrial Estate Lahore.
	Brand Name +Dosage Form + Strength	Simvasc 5mg Tablets
	Composition	Each film coated tablet contains: Amlodipine (as besylate)…..5mg
	Diary No. Date of R& I & fee	Dy. No.24; 01-07-2014; Rs.20,000/- (18-06-2014)
	Pharmacological Group	Calcium channel blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Norvasc 5mg tablets (USFDA)
	Me-too status	Sofvasc 5mg tablet of M/s Wilson pharma
	GMP status	The firm is GMP compliant as per inspection conducted on 08-12-2015.
	Previous remarks of the Evaluator.	• Latest GMP inspection report is missing. However, the firm has also applied for issuance of cGMP certificate on 12-11-2016. • The evidence of applied formulation as film coated tablets in reference regulatory authorities could not be verified.
	Previous decision(s)	Deferred for latest GMP inspection report conducted during last one year and evidence of approval status of applied formulation in reference regulatory authorities (M-272).
	Evaluation by PEC	The firm has submitted revised Form-5 with uncoated formulation as per reference alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1948366) dated 06-08-2019. The firm was granted GMP certificate based on inspection conducted on 19-08-2017.
	Decision: Approved.	
425.	Name and address of manufacturer / Applicant	M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot no. 30, Phase I & II, Idustrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Ulsazole Capsule 40mg
	Composition	Each capsule contains: Omeprazole (as enteric coated pellets 8.5%) …20mg
	Diary No. Date of R& I & fee	Diary No:18247, 16/10/2017, Rs. 20,000/-
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Losec Capsule 40mg by M/s Astra Zaneca (MHRA Approved)

	Me-too status	Meprascot Capsules 40mg by M/s Scotmann Pharmaceuticals (Reg#028239)
	GMP status	GMP inspection conducted on 07-04-2018 with conclusive remarks that firm is operating at good level of cGMP
	Previous remarks of the Evaluator.	• Source of pellets not submitted by the firm.
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-284).
	Evaluation by PEC	The firm has submitted details of pellets from M/s Vision pharmaceuticals, Islamabad.
	Decision: Approved.	
426.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Xismal Flash Tablets 1mg
	Composition	Each dispersible tablet contains: Risperidone……1mg
	Diary No. Date of R& I & fee	Dy No.1294; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	10's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL Quicklet 1 mg orodispersible tablets of Janssen Cilag Ltd, (MHRA approved)
	Me-too status	Risp 3mg tablet of Adamjee
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Me-too provided by the firm is film coated tablet while the firm has applied for Risperidone dispersible tablet. It is not found as dispersible tablet in Pakistan. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • List of technical staff for Quality Control is not provided by the firm • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Evidence of applied formulation already approved by DRAP (generic / me-too status) as dispersible tablet alongwith registration number, brand name and name of firm. • Submission of list of technical staff working in Quality Control department. • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of

		Form-5 has not been submitted.
	Evaluation by PEC	• The firm has submitted me-too reference "Wizen Flash 1mg of M/s Werrick Pharma" (Reg#034340) verified from database. • List of technical staff working in Quality Control department has been submitted. • Form-5 with relevant annexures has been submitted. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
427.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Xismal Flash Tablets 2mg
	Composition	Each dispersible tablet contains: Risperidone……2mg
	Diary No. Date of R& I & fee	Dy No.1295; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	10's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL Quicklet 2 mg orodispersible tablets of Janssen Cilag Ltd, (MHRA approved)
	Me-too status	Risp 3mg tablet of Adamjee (as provided by the firm)
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Me-too provided by the firm is film coated tablet while the firm has applied for Risperidone dispersible tablet. It is not found as dispersible tablet in Pakistan. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • List of technical staff for Quality Control is not provided by the firm • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Evidence of applied formulation already approved by DRAP (generic / me-too status) as dispersible tablet alongwith registration number, brand name and name of firm. • Submission of list of technical staff working in Quality Control department. • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of

		Form-5 has not been submitted.
	Evaluation by PEC	• The firm has submitted me-too reference "Wizen Flash 2mg of M/s Werrick Pharma" (Reg#034341) verified from database. • List of technical staff working in Quality Control department has been submitted. • Form-5 with relevant annexures has been submitted. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
428.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Xismal Flash Tablets 3mg
	Composition	Each dispersible tablet contains: Risperidone……3mg
	Diary No. Date of R& I & fee	Dy No.1296; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	10's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL Quicklet 3 mg orodispersible tablets of Janssen Cilag Ltd, (MHRA approved)
	Me-too status	Risp 3mg tablet of Adamjee (as provided by the firm)
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Me-too provided by the firm is film coated tablet while the firm has applied for Risperidone dispersible tablet. It is not found as dispersible tablet in Pakistan. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • List of technical staff for Quality Control is not provided by the firm • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Evidence of applied formulation already approved by DRAP (generic / me-too status) as dispersible tablet alongwith registration number, brand name and name of firm. • Submission of list of technical staff working in Quality Control department. • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of

		Form-5 has not been submitted.
	Evaluation by PEC	• The firm has submitted me-too reference "Wizen Flash 3mg of M/s Werrick Pharma" (Reg#034342) verified from database. • List of technical staff working in Quality Control department has been submitted. • Form-5 with relevant annexures has been submitted. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
429.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Xismal Flash Tablets 4mg
	Composition	Each dispersible tablet contains: Risperidone……4mg
	Diary No. Date of R& I & fee	Dy No.1297; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	10's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	RISPERDAL Quicklet 4 mg orodispersible tablets of Janssen Cilag Ltd, (MHRA approved)
	Me-too status	Risp 3mg tablet of Adamjee (as provided by the firm)
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Me-too provided by the firm is film coated tablet while the firm has applied for Risperidone dispersible tablet. It is not found as dispersible tablet in Pakistan. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • List of technical staff for Quality Control is not provided by the firm • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Evidence of applied formulation already approved by DRAP (generic / me-too status) as dispersible tablet alongwith registration number, brand name and name of firm. • Submission of list of technical staff working in Quality Control department. • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of

		Form-5 has not been submitted.
	Evaluation by PEC	• The firm has submitted me-too reference "Wizen Flash 4mg of M/s Werrick Pharma" (Reg#034343) verified from database. • List of technical staff working in Quality Control department has been submitted. • Form-5 with relevant annexures has been submitted. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
430.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Zergex Tablets 100mg
	Composition	Each film coated tablet contains: Sertraline (as hydrochloride) …100mg
	Diary No. Date of R& I & fee	Dy No.1303; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	20's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	US-FDA approved
	Me-too status	ELLETTRA 100mg tablet by Wilshire
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of Form-5 has not been submitted.
	Evaluation by PEC	• Form-5 with relevant annexures has been submitted. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
431.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Zergex Tablets 50mg
	Composition	Each film coated tablet contains: Sertraline (as hydrochloride) …….50mg
	Diary No. Date of R& I & fee	Dy No.1302; 10-07-2014; Rs.20,000/-

	Pharmacological Group	Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	10's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	US-FDA approved
	Me-too status	ELLETTRA 50mg tablet by Wilshire
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • Firm has tablet (General) section.
	Previous decision(s)	Deferred for following: (M-271) • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of Form-5 has not been submitted.
	Evaluation by PEC	• Form-5 with relevant annexures has been submitted. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
432.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Sutin 20mg Tablet
	Composition	Each film coated tablet contains: Fluoxetine (as hydrochloride)……..……20mg
	Diary No. Date of R& I & fee	Dy No.1301; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	20's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	TGA approved
	Me-too status	Futine 20mg tablet of Wilshire
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules,

		1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of Form-5 has not been submitted.
	Evaluation by PEC	• Form-5 with relevant annexures has been submitted. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
433.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Gabalife Tablets 100mg
	Composition	Each film coated tablet contains: Gabapentin ……..100mg
	Diary No. Date of R& I & fee	Dy No.1309; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Ati-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	10's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Not confirmed
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of Form-5 has not been submitted.
	Evaluation by PEC	• Form-5 with relevant annexures has been submitted. • Evidence of approval of applied formulation in reference status and me-too could not be verified. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for

		visited sections as of today.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
434.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Gabalife Tablets 300mg
	Composition	Each film coated tablet contains: Gabapentin ……..300mg
	Diary No. Date of R& I & fee	Dy No.1310; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Ati-epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	20's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Gabamed Tablet 300mg of Medicure labs
	GMP status	Last GMP Inspection of M/s Gray's Pharmaceuticals conducted on 14-01-2016 with conclusive remarks of firm is complying GMP as of today. Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	• Firm has claimed Manufacturer specifications but the applied formulation exist in USP 2016. • Application for registration of said product is not in accordance with the format as prescribed by The Drugs (Licensing, Registering, and Advertising) Rules, 1976, and when it was communicated to the firm. The firm submitted following reply; • *"We do hereby undertake that dossier of said product submitted to registration board is correct and according to the law".* • Firm has tablet (general) section.
	Previous decision(s)	Deferred for following: (M-271) • Submission of application on Form-5 as per prescribed format as required by Drugs (Licensing, Registering, and Advertising) Rules, 1976, since only enclosures of form-5 have been submitted while Form-5 and undertaking of Form-5 has not been submitted.
	Evaluation by PEC	• First page of form-5 has been attached. • GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
435.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Es-itopram Tablet 20mg
	Composition	Each film coated tablet contains: Escitalopram (as oxalate)…….20mg
	Diary No. Date of R& I & fee	Dy No.1208; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	14's; As per PRC
	Approval status of product in Reference	Approved in USFDA.

	Regulatory Authorities.	
	Me-too status	Morcet 20mg tablet of Searle
	GMP status	Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	i. In reference agencies it is found as film coated tablet while the applied formulation is uncoated tablet. ii. Firm has claimed Manufacturer specifications but the applied formulation exist in USP. iii. Firm has tablet (general) section.
	Previous decision(s)	Deferred for clarification of composition since the product approved in reference authorities is "Film coated tablet." whereas firm has applied for "Uncoated tablet" (M-272).
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation with film coated label claim alongwith fee challan of Rs. 5000/- (Deposit slip# 1945316) dated 25-09-2019. GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
436.	Name and address of manufacturer / Applicant	M/s Gray's Pharmaceuticals, Plot #2, street # N3 RCCI Islamabad,
	Brand Name +Dosage Form + Strength	Quitalax Tablets 100mg
	Composition	Each film coated tablet contains: Quetiapine (as fumarate)……..100mg
	Diary No. Date of R& I & fee	Dy No.1307; 10-07-2014; Rs.20,000/-
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA approved.
	Me-too status	Qusel 100mg tablet of Hilton
	GMP status	Certificate of cGMP issued to the firm based on inspection conducted on 05-05-17 & is valid for a period of one year.
	Previous remarks of the Evaluator.	i. Firm has claimed Manufacturer specifications but has not submitted the data as required by the decision of 267th meeting of R.B. and the applied formulation does not exist in available USP and BP. ii. Evidence of approval of applied formulation as extended release tablet in reference agencies is required. iii. Firm has tablet (general) section.
	Previous decision(s)	Deferred for clarification of composition since product approved in reference authorities is (Quetiapine as fumerate…100mg tablet) different from that which is applied by applicant (Quetiapine as fumerate…100mg extended release tablet) (M-272).
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation from extended release tablet to immediate release film coated label claim alongwith fee challan of Rs. 5000/- (deposit slip # 1945315) dated 25-09-2019. GMP inspection report dated 23-05-2019 concludes that overall GMP compliance could be graded as good for visited sections as of today.
	Decision: Approved with USP specifications.	
437.	Name and address of manufacturer / Applicant	M/s Simz Pharmaceuticals 574-575 Sunder Industrial Estate Lahore.
	Brand Name +Dosage Form + Strength	Sitimibe 10/10mg Tablets

	Composition	Each tablet contains: Ezetimibe…….10mg Simvastatin…..….10mg
	Diary No. Date of R& I & fee	Dy. No.12; 01-07-2014; Rs.20,000/- (18-06-2014)
	Pharmacological Group	Cholesterol absorption inhibitor/ Statin
	Type of Form	Form-5
	Finished product Specification	As per innovator
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vytorin 10/10mg tablets (USFDA)
	Me-too status	Simib 10/10mg tablet of M/s Standpharm
	GMP status	The firm is GMP compliant as per inspection conducted on 08-12-2015.
	Previous remarks of the Evaluator.	• Latest GMP inspection report is missing. However, the firm has also applied for issuance of cGMP certificate on 12.11.16 • The evidence of applied formulation as film coated tablets in reference regulatory authorities could not be verified.
	Previous decision(s)	Deferred for latest GMP inspection report conducted during last one year and evidence of approval status of applied formulation in reference regulatory authorities. (M-272)
	Evaluation by PEC	The firm was granted GMP certificate based on inspection conducted on 19-08-2017. The firm has submitted revised Form-5 with uncoated formulation as per reference alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1948367) dated 06-08-2019. However, the manufacturing method is not as per innovator's formulation.
	Decision: Approved with innovator's specifications.	
438.	Name and address of manufacturer / Applicant	M/s Simz Pharmaceuticals, 574-575 Sunder Industrial Estate Lahore.
	Brand Name +Dosage Form + Strength	Ezetasim 10mg Tablets
	Composition	Each tablet contains: Ezetimibe ……....10mg
	Diary No. Date of R& I & fee	Dy. No.21; 01-07-2014; Rs.20,000/- (18-06-2014)
	Pharmacological Group	Cholesterol absorption inhibitor
	Type of Form	Form-5
	Finished product Specification	As per innovator
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ezetrol 10mg tablets (UK-MHRA)
	Me-too status	Ezita 10mg tablet of M/s Getz pharma
	GMP status	The firm is GMP compliant as per inspection conducted on 08-12-2015.
	Previous remarks of the Evaluator.	• Latest GMP inspection report is missing. However, the firm has also applied for issuance of cGMP certificate on 12-11-2016. • The evidence of applied formulation as film coated tablets in reference regulatory authorities could not be verified.
	Previous decision(s)	Deferred for latest GMP inspection report conducted during last one year and evidence of approval status of applied formulation in reference regulatory authorities. (M-272).

	Evaluation by PEC	The firm has submitted revised Form-5 with uncoated tablet formulation along with submission of fee challan of Rs. 5000/- (Deposit slip # 1948365) dated 06-08-2019. The firm was granted GMP certificate based on inspection conducted on 19-08-2017.
	Decision: Approved with USP specifications.	
439.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industries (Pvt.) Ltd. A-37, Small Industrial Estate Township Kohat Road Bannu.
	Brand Name +Dosage Form + Strength	PANZIN INJECTION 30mg/ml
	Composition	Each 1ml ampoule contains Pentazocine…30 mg
	Diary No. Date of R& I & fee	Diary No: 26548, 29/12/2017, Rs: 20,000/-
	Pharmacological Group	Analgesics opioids (benzomorphan derivatives)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1mlx5's/As per SRO
	Approval status of product in Reference Regulatory Authorities.	TALWIN (pentazocine) 30 mg/mL for injection by M/s Hospira, Inc. (Health canada Approved) Each mL contains pentazocine lactate equivalent to 30 mg base and 2.8 mg sodium chloride, in Water for Injection.
	Me-too status	SOSEGON Injection30mg/ml by M/s (SANOFI AVENTIS (Reg#002203)
	GMP status	05/10/2017 Grant of renewal of DML and additional sections. Panel recommends DML renewal and additional sections
	Previous remarks of the Evaluator.	• Applied formulation is not as per approved formulation by USFDA. (Each mL contains pentazocine lactate equivalent to 30 mg base and 2.8 mg sodium chloride, in Water for Injection.)
	Previous decision(s)	Deferred for submission of composition as per reference product (M-279). Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as submitted reference product is Discontinued by USFDA (M-287).
	Evaluation by PEC	The firm has submitted revised Form-5 and master formulation with following label claim: Each ml contains: Pentazocine lactate equivalent to Pentazocine……..30mg Fee challan of Rs. 5000/- (Deposit slip # 0824851) dated 17-12-2018 has been submitted. Approval status of applied formulation has been confirmed in Health canda. https://health-products.canada.ca/dpd-bdpp/dispatch-repartition.do;jsessionid=FD9A3CDA04092A0B3D89B9ED5EB31884
	Decision: Approved.	
440.	Name and address of manufacturer / Applicant	M/s. Greater Pharma. Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	G-Mith Lotion
	Composition	Each100 ml lotion Contains: Permethrin……0.5gm Crotamiton..……10 g
	Diary No. Date of R& I & fee	Dy.No 16708 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Scabicidal preparation
	Type of Form	Form-5

	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	100ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed.
	Me-too status	Not confirmed.
	GMP status	20-12-2017. Panel recommends grant of DML.
	Previous remarks of the Evaluator.	• The formulation applied by the firm is not approved by DRAP nor in Reference Regulatory Authorities. • The Firm has revised the formulation to: Each gram Contains: Permethrin……50mg (5%w/w) • Approval Status of revised product in Reference Regulatory Authorities is KWELLADA-P LOTION 5% w/w by M/s MEDTECH PRODUCTS INC (Health Canada Approved) • Me-too status of revised product is Bioscab lotion 5% by M/s Bio-Labs (Reg#054774)
	Previous decision(s)	Deferred for further deliberation (M-289).
	Evaluation by PEC	The firm has submitted that we have already revised the formulation and that has also been acknowledged by evaluation department.
	Decision: Registration Board deferred the case for further delibration upon revision of formulation.	
441.	Name and address of manufacturer / Applicant	M/s. Greater Pharma. Plot No 35,Street No SS-3, RCCI Industrial Estate, Rawat Rawalpindi.
	Brand Name +Dosage Form + Strength	D.Clor Lotion 20%w/v
	Composition	Each ml of Lotion contains Aluminium chloride hexahydrate……..200 mg (20% w/v)
	Diary No. Date of R& I & fee	Dy.No 16711 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Pharmacological Group	Other anti-acne preparations for topical use
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	60ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Anhydrol Forte 20% w/v Cutaneous Solution by M/s Diomed Developments Limited (MHRA Approved)
	Me-too status	Not confirmed.
	GMP status	20-12-2017. Panel recommends grant of DML.
	Previous remarks of the Evaluator.	• Firm has applied as lotion whereas formulation approved by MHRA is solution. • Me-too status not confirmed from available database.
	Previous decision(s)	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-289).
	Evaluation by PEC	The firm has submitted me-too reference of Driclor solution of M/s GSK (Reg#021133) verified from available database.
	Decision: Approved.	
442.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals, F-24/1, Eastern Industrial Zone, Port Muhammad Bin Qasim Karachi
	Brand Name +Dosage Form + Strength	Soseget Injection 30mg/ml
	Composition	Each 1ml ampoule contain: Pentazocine ……30mg
	Diary No. Date of R& I & fee	Dy No. 5150: 06-02-2019 PKR 20,000/-: 06-02-2019
	Pharmacological Group	Benzomorphan derivatives
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	5's /As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA
	Me-too status	Omsis 30mg/ml injection by SAMI Pharma (Reg#50746)
	GMP status	28-11-2018; Grant of DML Panel recommends Grant of DML
	Previous remarks of the Evaluator.	Approval Status of Product in Reference Regulatory Authorities not confirmed.
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting (M-289).
	Evaluation by PEC	Approval status of applied formulation has been confirmed in Health Canada. https://health-products.canada.ca/dpd-bdpp/dispatch-repartition.do;jsessionid=FD9A3CDA04092A0B3D89B9ED5EB31884 However, salt form of applied formulation is not mentioned.
	Decision: Deferred for revision of salt form of applied formulation as per reference product.	
443.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt. Ltd. L- 10-D, Block no. 21, Shaheed Rashid Minhas Rd. F.B industrial area, Karachi
	Brand Name +Dosage Form + Strength	Sipro DS Suspension 250mg/5ml
	Composition	Each 5ml after reconstitution contains: Ciprofloxacin……..…...250 mg
	Diary No. Date of R& I & fee	Dy.No.627, 31-12-2013, Rs. 20,000/-
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Rs.200/-, 60ml
	Approval status of product in Reference Regulatory Authorities.	Cipro By Bayer Hlthcare, USFDA approved.
	Me-too status	Ciplet by Indus Pharma (Reg # 073479)
	GMP status	GMP inspection conducted on 27-09-2018 concluded that all relevant activities in process areas, QC and ware house were found at good level of GMP compliance. Area FID vide letter No.F.SAA.02-06/2018-FID-V dated 30-08-2018 has confirmed that firm has purchased two stability chambers with capacity of 250L (accelerated) and 800L (Real time), placed in their QC department
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred in 262nd meeting as formulation is under review as per decision of 250th RB meeting. Deferred for the confirmation of valid DML status (Drug manufacturing License) from Licensing Division (M-282). Deferred for clarification of applied formulation since reference product contains Ciprofloxacin as base only whereas firm has applied for Ciprofloxacin as hydrochloride (M-285)
	Evaluation by PEC	The firm has submitted revised Form-5 with ciprofloxacin base form alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 0849160) dated 20-08-2019. Source of granules: M/s Surge laboratories
	Decision: Approved with USP specifications.	
444.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt. Ltd. L- 10-D, Block no. 21, Shaheed Rashid Minhas Rd. F.B industrial area, Karachi
	Brand Name +Dosage Form + Strength	SIPRO Dry suspension 125mg/5ml

	Composition	Each 5ml contains : Ciprofloxacin base……125mg
	Diary No. Date of R& I & fee	17557, 10-10-2017, 20,000/-, 25-09-2017
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml; Not mentioned
	Approval status of product in Reference Regulatory Authorities.	Not available
	Me-too status	Ciprin 125mg/5ml suspension of M/s Werrick pharmaceuticals
	GMP status	• GMP inspection conducted on 27-09-2018 concluded that all relevant activities in process areas, QC and ware house were found at good level of GMP compliance. • Area FID vide letter No.F.SAA.02-06/2018-FID-V dated 30-08-2018 has confirmed that firm has purchased two stability chambers with capacity of 250L (accelerated) and 800L (Real time), placed in their QC department.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-286).
	Evaluation by PEC	The firm has revised Form-5 and master formulation with fee challan of Rs.5,000/- (deposit slip#0619136) dated 26-10-2018. Source of Ciprofloxacin granules is M/s Surge laboratories. Stability studies data and GMP certificate are attached.
	Decision: Approved with USP specifications.	
445.	Name and address of manufacturer / Applicant	M/s. Medicraft Pharmaceuticals, Pvt Ltd, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Pizen Syrup
	Composition	Each 5ml contains:- Pizotifen (as hydrogen maleate)……....0.25mg
	Diary No. Date of R& I & fee	21-5-2012, Rs.8,000/-, Rs.12000/-, Dated 29-7-2013,
	Pharmacological Group	Anti-migraine
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20's, Rs. 265/-
	Approval status of product in Reference Regulatory Authorities.	Sanomigran Elixir 0.25mg /5ml by M/s phoenix, (MHRA approve)
	Me-too status	Pizotifen By Novartis Pharma
	GMP status	Panel inspection dated 30-01-2018 concluded that the management of the firm promised that they would continue improvement. In the light of observation at the time of inspection, documents reviewed and representatives of the firm commitment, the firm may be considered to be operative in good level of cGMP compliance.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for: (M-262) Finished product specs. Last GMP inspection report conducted within 1 year. Commitment & undertaking as per 251st DRB meeting. Deferred for following: (M-286) • Clarification of pharmacological group. • Submission of finished product specifications.
	Evaluation by PEC	The firm has submitted pharmacological group as "anti-migraine".

		The firm has claimed in-house specifications.
	Decision: Registration Board referred the case to QA & LT division for updated GMP status of the firm on priority.	

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

a. New/Additional section(s)

M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar

CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML # 000900 by way of formulation with following sections:
Tablet General Section: (10molecules/21products)
Cream/Ointment (General) section: (8molecules/ 8products)
Liquid ampoule (General) section: (10molecules/ 10products)
Dry Powder vial (General) section: (6molecules/ 8products)
Oral Powder Suspension (General) section (4molecules/ 4products)
Sachet (General) Section: (1molecule/ 1product)
Ophthalmic (General) Drop Section (10molecules/ 12products)
Capsule section (General) (9 molecules/ 12 products)

Capsule section (General) (9 molecules/ 12 products)		
446.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Esomep D 40mg Capsule
	Composition	Each hard gelatin capsule contains: Esomeprazole magnesium enteric coated pellets eq. to Esomeprazole…….40mg
	Diary No. Date of R& I & fee	16542, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Anti-peptic ulcerant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2×7's; not mentioned
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ulcicare 40mg capsules of M/s Jawa (Reg. # 050300)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	Source of pellets: M/s Vision pharma
	Decision: Approved.	
447.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Esomep 20mg Capsule
	Composition	Each hard gelatin capsule contains: Esomeprazole magnesium enteric coated pellets eq. to Esomeprazole…….20mg
	Diary No. Date of R& I & fee	14905, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-peptic ulcerant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2×7's; not mentioned
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Esante 20mg capsules of M/s Macter International (Reg # 050576)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has

		considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	Source of pellets: M/s Vision pharma
	Decision: Approved.	
448.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Dysozole 20mg Capsule
	Composition	Each capsule contains: Omeprazole enteric coated pellets eq. to omeprazole 8.5% ……20mg Source: M/s Vision Pharma
	Diary No. Date of R& I & fee	14928, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 20 mg gastro-resistant capsules of M/s Dexcel-pharma limited uk (MHRA approved)
	Me-too status	Alomep 20mg Capsule of M/s Alson
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	The firm had initially applied Form-5 with vial formulation while brand name is Dysozole 20mg capsule. Now the firm has submitted revised Form-5 with omeprazole capsule formulation alongwith fee challan of Rs. 5000/- (Deposit slip#1923655) dated 25-09-2019.
	Decision: Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation.	
449.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	OMEBRAIN 40mg Capsule
	Composition	Each capsule contains: Omeprazole enteric coated pellets eq. to omeprazole 22.5%…….40mg Source: M/s Vision pharma
	Diary No. Date of R& I & fee	14909, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Proton Pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Omepza 40mg capsule of M/s Simz Pharma Reg. # 079727)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	The firm has submitted master formulation of applied product alongwith fee challan of Rs. 5000/- (deposit slip # 1923654) dated 25-09-2019.
	Decision: Approved.	
450.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Pregaba 75mg Capsule
	Composition	Each capsule contains: Pregabalin……...75mg

	Diary No. Date of R& I & fee	16529, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lyrica Capsules by Pfizer Pharmaceuticals USFDA
	Me-too status	Gabica capsule 75mg by Getz pharmaceutical
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
451.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultagab 100mg Capsule
	Composition	Each capsule contains: Gabapentin……..100mg
	Diary No. Date of R& I & fee	16495, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Gabix capsule 100mg of M/s Getz Pharma (Reg. # 039398)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	
	Decision: Approved.	
452.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultagab 100mg Capsule
	Composition	Each capsule contains: Gabapentin……..300mg
	Diary No. Date of R& I & fee	16494, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Gababion 300mg Capsules of M/s Merck Marker, Karachi (Reg.#045346)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	
	Decision: Approved.	
453.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Alfa-Block 0.4mg Capsule

	Composition	Each capsule contains: Tamsulosin Hydrochloride pellets eq. to Tamsulosin…..……..0.4mg
	Diary No. Date of R& I & fee	16517, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Selective alpha-1 adrenergic blocking agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	FLOMAX RELIEF MR of Boehinger Ingelheim, UK (MHRA)
	Me-too status	Tamsolin 0.4mg of M/s GETZ Pharma (Reg#050392)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	The firm had initially applied 50mg tamsulosin hydrochloride, now the firm has revised the strength of applied formulation on Form-5 as per reference product alongwith fee challan of Rs. 5000/- (deposit slip # 1923652) dated 25-09-2019. Source of pellets: M/s Vision pharma
	Decision: Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation.	
454.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Arkcon 100mg Capsule
	Composition	Each capsule contains: Itraconazole……..…….100mg M/s : M/s Vision Pharma
	Diary No. Date of R& I & fee	16654, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Anti-fungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Itraconazole 100 mg capsules, hard by M/s Sandoz Limited (MHRA Approved)
	Me-too status	Rolac 100mg Capsules by M/s Sami (Reg#024491)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	The firm had initially applied 10mg Itraconazole, now the firm has revised the strength of applied formulation on Form-5 as per reference product alongwith fee challan of Rs. 5000/- (deposit slip # 1923653) dated 25-09-2019.
	Decision: Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation.	
455.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultolax 4mg Capsule
	Composition	Each capsule contains: Thiocolchicoside……..……4mg
	Diary No. Date of R& I & fee	16654, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	MYOPLEGE 4 mg hard capsule of M/s GENEVRIER SA Laboratories approved by ANSM of France
	Me-too status	Myogen Capsules 4 mg by M/s Nimrall, (Reg.# 066700)

	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	
	Decision: Approved.	
456.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Peptun 40mg Capsule
	Composition	Each capsule contains: Pantoprazole enteric coated pellets eq. to pantoprazole…….40mg
	Diary No. Date of R& I & fee	14910, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	Not mentioned
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Apran 40mg Capsule of Adam jee (Reg#076139)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authority is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting.	
457.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Azotan 250mg Capsule
	Composition	Each capsule contains: Azithromycin as dihydrate……..250mg
	Diary No. Date of R& I & fee	14906, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Zidor Capsule 250mg of M/s Winthrox Karachi. (Reg.# 074943)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Capsule section (General)
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of availability of amphoteric ECD detector with dual glassy carbon electrodes required for azithromycin capsule and oral suspension.	

b. Deferred (New License)

M/s Pharmasol (Pvt) Ltd., Lahore. (New Licence)
The firm has been granted approval of new DML by way of formulation by Central Licensing Board in its 256th meeting for following sections:

1. Liquid Injection (General) (Human)

Liquid Injection (General) (Human) (14 Products / 10 molecules)		
458.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Typhoxcin Injection 200mg/100ml
	Composition	Each 100ml vial contains: Ofloxacin (as hydrochloride)...200mg
	Diary No. Date of R& I & fee	Diary No: 24068, 13-12-2017 , Rs: 20,000/-
	Pharmacological Group	Quinolone Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx100ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tarivid IV Infusion Solution 2mg/ml by M/s Sanofi, MHRA approved
	Me-too status	Tariflox Infusion 200mg/100ml by M/s Bosch (Reg#021506)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Confirmed as glass vial
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	Area FID vide letter No.F.12048/2018-DRAP (L-1) has informed that the firm has provided an automatic Liquid vial filling, sealing & Rubber stoppering machine (Model No. LVFS-100) having in-built capacity of 100-300ml was installed. But to fill volumes of 10ml & 50ml , this machine was modified by: • Installing additional peristaltic pump and nozzles in the machine (DQ, IQ, & PQ of the peristaltic pump and SOP for operation of peristaltic pump is attached), for filling which was physically verified during inspection. • Installing change parts i.e., stars for filling, rubber stoppering & sealing unit and rubber stopper Bowl with magazine.
	Decision: Approved.	
459.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Ciproxol Infusion 200mg/100ml
	Diary No. Date of R& I & fee	Diary No: 24069, 13-12-2017, Rs: 20,000/-
	Composition	Each 100ml vial contains: Ciprofloxacin (as lactate)…200mg
	Pharmacological Group	Quinolone Antibacterial
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1'sx100ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ciprofloxacin 2 mg/ml solution for infusion by M/s Hikma Farmacêutica (Portugal), S.A.(MHRA Approved)
	Me-too status	Qilox 200mg/100ml Infusion by M/s Bosch (Reg#073417)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.

	Remarks of the Evaluator.	• Confirmed as glass vial
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	• Same as above
	Decision: Approved.	
460.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Ciproxol Infusion 400mg/100ml
	Diary No. Date of R& I & fee	Diary No: 24070, 13-12-2017, Rs: 20,000/-
	Composition	Each 100ml vial contains: Ciprofloxacin (as lactate)…400mg
	Pharmacological Group	Quinolone Antibacterial
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1'sx100ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro IV 400mg Bayer healthcare Pharmaceuticals Inc. New Jersey, USA (not confirmed)
	Me-too status	Novidat DS Injection 400mg/100ml by M/s Sami Phama (Reg#042270)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed.
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	• Same as above
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting	
461.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Levoxol Infusion 500mg/100ml
	Diary No. Date of R& I & fee	Diary No: 24071, 13-12-2017, Rs: 20,000/-
	Composition	Each 100ml vial contains: Levofloxacin (as hemihydrate)……500mg
	Pharmacological Group	Quinolone Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx100ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Evoxil 5 mg/ml solution for infusion by M/s Beacon Pharmaceuticals, (MHRA approved)
	Me-too status	Lorex Infusion 500mg/100ml by M/s Regal Pharmaceuticals (Reg#081996)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Confirmed as glass vial
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of L Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	• Same as above
	Decision: Approved.	
462.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Levoxol Infusion 750mg/150ml
	Diary No. Date of R& I & fee	Diary No: 24072, 13-12-2017 , Rs: 20,000/-

	Composition	Each 150ml of solution for infusion contains: Levofloxacin (as hemihydrate)…….750mg
	Pharmacological Group	Quinolone Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx150ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cravit IV by M/s Daiichi Sankyo, Japan (Pack size of 150ml not confirmed from approved website of PMDA)
	Me-too status	Leflox 750mg/150ml Infusion By Getz Pharma (Reg.No. 058590),
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Pack size of 150ml and packaging of applied formulation in vials not confirmed from RRA.
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals".
	Evaluation by PEC	• Pack size of applied formulation is not confirmed in reference regulatory authority. • Same as above
	Decision: Deferred for evidence of approval of applied pack size for formulation in reference regulatory authorities which were adopted by Registration Board in 275th meeting	
463.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	M-Flox Infusion 400mg/250ml
	Diary No. Date of R& I & fee	Diary No: 24073, 13-12-2017 , Rs: 20,000/-
	Composition	Each 250ml contains: Moxifloxacin (as hydrochloride)…..…400mg
	Pharmacological Group	Quinolone Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx250ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Avelox 400 mg/250 ml solution for infusion by M/s Bayer plc, (MHRA approved)
	Me-too status	Mofest Infusion 400mg/250ml by M/s Sami (Reg#053227)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Confirmed as glass vial from MHRA
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals".
	Evaluation by PEC	• Same as above
	Decision: Approved.	
464.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Linzol Infusion 200mg/100ml
	Diary No. Date of R& I & fee	Diary No: 24074, 13-12-2017 , Rs: 20,000/-
	Composition	Each 100ml solution for infusion contains: Linezolid…….200mg
	Pharmacological Group	Oxazolidone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx100ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 200mg/100mL injection infusion bag by M/s Pfizer Australia Pty Ltd, (TGA approved.)
	Me-too status	Ecasil Infusion 200mg/100ml by M/s Sami (Reg#067516)

	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	• Same as above
	Decision: Approved. "**In order to ensure, safety, efficacy and quality of Linezolid infusion, Registration Board decided as under;** **i) All the Manufacturers of Linezolid Infusion shall follow the packaging instructions of the innovator of the product i.e M/s Pfizer which has clearly mentioned the storage precautions in its Product Information Leaflet (PIL). They will also make sure that the solution is kept correctly in its box and foil wrapping in order to protect from light."**	
465.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Linzol Infusion 600mg/300ml
	Diary No. Date of R& I & fee	Diary No: 24075, 13-12-2017 , Rs: 20,000/-
	Composition	Each 300ml solution for infusion contains: Linezolid…….600mg
	Pharmacological Group	Oxazolidone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx300ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Linezolid 2 mg/ml solution for infusion by M/s Pfizer Limited , MHRA approved
	Me-too status	Zolrest Infusion 600mg/300ml by M/s Bosch (Reg#055916)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	• Same as above
	Decision: Approved. "**In order to ensure, safety, efficacy and quality of Linezolid infusion, Registration Board decided as under;** **i) All the Manufacturers of Linezolid Infusion shall follow the packaging instructions of the innovator of the product i.e M/s Pfizer which has clearly mentioned the storage precautions in its Product Information Leaflet (PIL). They will also make sure that the solution is kept correctly in its box and foil wrapping in order to protect from light."**	
466.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Linzol Infusion 400mg/200ml
	Diary No. Date of R& I & fee	Diary No: 24076, 13-12-2017 , Rs: 20,000/-
	Composition	Each 200ml solution for infusion contains: Linezolid……400mg
	Pharmacological Group	Oxazolidone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx200ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZYVOX linezolid 400mg/200mL injection infusion bag by M/s Pfizer Australia Pty Ltd, TGA approved.
	Me-too status	Linolid Infusion 400mg/200ml by M/s Bio-Labs (Reg#073088)
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML.

	Remarks of the Evaluator.	
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals".
	Evaluation by PEC	• Same as above
	Decision: Approved. "**In order to ensure, safety, efficacy and quality of Linezolid infusion, Registration Board decided as under;** **i) All the Manufacturers of Linezolid Infusion shall follow the packaging instructions of the innovator of the product i.e M/s Pfizer which has clearly mentioned the storage precautions in its Product Information Leaflet (PIL). They will also make sure that the solution is kept correctly in its box and foil wrapping in order to protect from light."**	
467.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Parasol Infusion 1g/100ml
	Diary No. Date of R& I & fee	Diary No: 24077, 13-12-2017, Rs: 20,000/-
	Composition	Each 100ml contains: Paracetamol……..…1000mg
	Pharmacological Group	Antipyretic/Analgesic
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	PERFALGAN 10 mg/ml, solution for infusion by M/s Bristol-Myers Squibb Pharmaceutical Limited, (MHRA approved)
	Me-too status	Falgan Infusion 1000mg/100ml by M/s Bosch (R#055540)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Confirmed as glass vial from MHRA
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals".
	Evaluation by PEC	• Same as above
	Decision: Approved.	
468.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Konacane Infusion 200mg/100ml
	Diary No. Date of R& I & fee	Diary No: 24078 , 13-12-2017 , Rs: 20,000/-
	Composition	Each ml contains: Fluconazole…….2mg
	Pharmacological Group	Anti-Fungal
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1'sx100ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diflucan 2 mg/ml solution for infusion by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Diflucan 2mg/ml IV infusion 50ml by M/s Pfizer (Reg. No.011830), (pack size not same as of applied formulation.)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Confirmed as glass vial from MHRA • Pack size of 100ml not confirmed from available me-too database. • Firm initially applied for 100ml pack size. When communicated with shortcoming, firm replied that they mistakenly wrote pack size 100ml instead of 50ml. Firm has submitted revised form-5 and master formulation.

	Previous Decision	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals". Moreover, Registration Board also directed the firm to submit fee for revision of formulation (M-278).
	Evaluation by PEC	• Same as above
	Decision: Deferred for submission of fee for revision of formulation.	
469.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Diazole Injection 500mg/100ml
	Diary No. Date of R& I & fee	Diary No: 24079 , 13-12-2017 , Rs: 20,000/-
	Composition	Each 100ml contains: Metronidazole…….500mg
	Pharmacological Group	Imidazole derivatives/ Antibacterial
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1'sx100ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Metronidazole Braun 5 mg / ml solution for infusion b M/s B. Braun Melsungen AG (Medical Products Agency, Sweden Approved)
	Me-too status	Metrosol I.V Infusion 100ml by M/s Atlantic (R.#055042)
	GMP status	13-07-2017 Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	• Confirmed as glass vial from MHRA
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	• Same as above
	Decision: Approved.	
470.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Combifer Infusion 500mg/10ml
	Diary No. Date of R& I & fee	Diary No: 24080 , 13-12-2017 , Rs: 20,000/-
	Composition	Each 10ml vial contain: Iron carboxymaltose complex eq.to Elemental Iron…500mg
	Pharmacological Group	**Haematinic**
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx10ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ferinject 50 mg iron/mL solution for injection/infusion. By M/s Vifor France (MHRA approved)
	Me-too status	Ferinject 500mg/10ml by M/s RG. Pharmaceuticals (Reg#072548)
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	Confirmed as 2ml, 10 ml and 20ml vial in MHRA, UK.
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals"
	Evaluation by PEC	• Same as above
	Decision: Registration Board deferred the case for comments regarding patent status of applied formulation from legal division.	
471.	Name and address of manufacturer / Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Tirosol Injection 12. 5mg/50ml
	Diary No. Date of R& I & fee	Diary No: 24081, 13-12-2017, Rs: 20,000/-

	Composition	Each ml contains Tirofiban (as hydrochloride monohydrate)….0.25mg
	Pharmacological Group	Antithrombotic agents (Platelet aggregation inhibitors excl. heparin)
	Type of Form	Form-5
	Finished Product Specification	Innovator's specifications
	Pack size & Demanded Price	1'sx50ml/As per SRO
	Approval status of product in Reference Regulatory Authorities.	AGGRASTAT (250 micrograms/ml) concentrate for solution for infusion 50ml vial by M/s Correvio (UK) Ltd (MHRA Approved)
	Me-too status	Aggrastat Injection 0.25mg/ml 50ml vial by M/s Atco Labs (Reg#025299),
	GMP status	13-07-2017; Grant of new DML, Panel recommends grant of new DML.
	Remarks of the Evaluator.	
	Previous Decision (M-278).	Deferred for confirmation whether manufacturing facility of Liquid Injection (General) (Human) is approved for "Small Volume Parenterals" or "Large Volume Parenterals".
	Evaluation by PEC	• Same as above
	Decision: Approved.	

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

a. New Cases

472.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	DELTAFAS SOLUTION
	Composition	Each ml contains: Deltamethrin……..25mg
	Diary No. Date of R& I & fee	847, 08-08-2016, 20,000/-, 03-08-2016
	Pharmacological Group	Insecticide
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml, 5000ml; Decontrolled
	Me-too status	DELTA-25 SOLUTION of M/s. Selmore Pharma (Reg#029608)
	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	The firm has provided General liquid section veterinary.
	Decision: Approved with innovator's specifications and label warning.	
473.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	LEVA 1125 Bolus
	Composition	Each bolus contains: Levamisole Hydrochloride……..1125mg
	Diary No. Date of R& I & fee	850, 08-08-2016, 20,000/-, 03-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50 Bolus packing: Decontrolled
	Me-too status	Levax Bolus of Epla Laboratory (Reg# 014525)
	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	The firm has provided Bolus section veterinary.
	Decision: Approved with innovator's specifications.	

474.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	FENBOFAS BOLUS
	Composition	Each Bolus contains: Fenbendazole……..750mg
	Diary No. Date of R& I & fee	849, 08-08-2016, 20,000/-, 03-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50 Bolus packing: Decontrolled
	Me-too status	FENBAL Bolus of Wimits pharma (Reg# 078319)
	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
475.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	ALBAFAS 2500 BOLUS
	Composition	Each Bolus contains: Albendazole…….2500mg
	Diary No. Date of R& I & fee	843, 08-08-2016, 20,000/-, 03-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50 Bolus packing: Decontrolled
	Me-too status	ZOBEN 2500 Bolus of Prix pharma (Reg# 041285)
	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
476.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	CLOSAFAS BOLUS
	Composition	Each Bolus contains: Closantel……500mg
	Diary No. Date of R& I & fee	848, 08-08-2016, 20,000/-, 03-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50 Bolus packing: Decontrolled
	Me-too status	FLUKINIL Bolus of Selmore Pharma (Reg#046571)
	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
477.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	LE-OXY BOLUS
	Composition	Each Bolus contains: Oxyclozanide…….2250mg Levamisole as hydrochloride…….1125mg
	Diary No. Date of R& I & fee	846, 08-08-2016, 20,000/-, 03-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50 Bolus packing: Decontrolled
	Me-too status	LEVACLOZ Bolus of M/s Wimits (Reg#078320)

	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
478.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	INTERQUINE BOLUS
	Composition	Each Bolus contains: Flumequine…….350mg
	Diary No. Date of R& I & fee	844, 08-08-2016, 20,000/-, 03-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50 Bolus packing: Decontrolled
	Me-too status	Flumine Bolus of Star Laboratories (Reg#031452)
	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

b. Deferred Cases

479.	Name and address of manufacturer / Applicant	M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila
	Brand Name +Dosage Form + Strength	Amantadine 10% Powder
	Composition	Form-5 Dy.No 5539 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018
	Diary No. Date of R& I & fee	Each 100g contains: Amantadine hydrochloride …10g
	Pharmacological Group	Anti-parkinson drugs
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg; Decontrolled
	Me-too status	ANTAMITS WATER SOLUBLE POWDER by M/s WIMITS PHARMACEUTICALS (Reg#078316)
	GMP status	10-10-2017; Renewal of DML Panel recommends renewal of DML.
	Previous remarks of the Evaluator.	
	Previous decision	Deferred for submission of correct pharmacological group (M-288).
	Evaluation by PEC	The firm has submitted correct pharmacological group as "Antiviral".
	Decision: Deferred for pharmacological group.	
480.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt Ltd. 542-A & B, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Fendox Plus Drench (Oral Liquid)
	Composition	Each ml Contains: Oxfendazole……22.65mg Cobalt Sulphate…..1.67mg Sodium Selenite…… 0.5mg
	Diary No. Date of R& I & fee	Dy. No.276; 7-9-2015; Rs.20,000/- (7-9-2015)
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1 Liter, 2.5Liter, 5 Liter; Decontrolled
	Me-too status	Punch Drench by Selmore Pharmaceuticals Reg # 032206 (Not Confirmed)

	GMP status	New Section Veterinary Oral Liquid
	Previous remarks of the Evaluator.	Me-too status could not be confirmed
	Previous decision	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-286).
	Evaluation by PEC	Me-too reference of Oxfoban SC suspension of Zakfas Pharma (Reg#046522) has been verified.
	Decision: Approved with innovator's specifications.	
481.	Name and address of manufacturer / Applicant	M/s Izfaar Pharmaceutical Pvt Ltd. 542-A & B, Sundar Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Doxysin-C Powder
	Composition	Each gm Contains: Doxycycline Hyclate……..…500mg Tylosin Tartarate……..…100mg Colistin Sulfate……..…30mg
	Diary No. Date of R& I & fee	Dy. No.284; 7-9-2015; Rs.20,000/- (7-9-2015)
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1000gm, 2.5kg, 5kg 10Kg, Decontrolled
	Me-too status	Doxy-Tol Powder by Lead Pharmaceuticals (Not Confirmed)
	GMP status	New Section Veterinary Powder (General&General Antibiotic)
	Previous remarks of the Evaluator.	Me-too status could not be confirmed.
	Previous decision	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-286).
	Evaluation by PEC	The firm has submitted Form-5 with revised strength of applied formulation as follows: Each gm Contains: Doxycycline Hyclate……..…200mg Tylosin Tartarate……..…100mg Colistin Sulfate……..…30mg Me-too reference of "Doxi-Tol Powder of M/s. Leads pharma (Reg# 057053)" has been verified. Fee challan of Rs. 5000/- (Deposit slip # 0792018) dated 06-08-2019 has been submitted.
	Decision: Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation.	
482.	Name and address of manufacturer / Applicant	M/s. A & K Pharmaceutical, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad
	Brand Name +Dosage Form + Strength	Akacin 50 Injection
	Composition	Each 1ml contains:- Oxytetracycline hydrochloride……..…..50gm
	Diary No. Date of R& I & fee	373,8-10-2015, 20,000/-, 18-09-2015
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP Specifications
	Pack size & Demanded Price	10ml, 20ml, 50ml, & 100ml,250ml,300ml,500ml; Decontrolled
	Me-too status	Santracycline-50 Injection of Sanna Laboratories
	GMP status	
	Previous remarks of the Evaluator.	• Applied formulation is present in USP & firm has claimed BP specifications. • Latest GMP inspection report is required. • Type of primary packaging material.

		• Approval of section/manufacturing facility by the Central Licensing Board.
	Previous decision	Deferred for following: (M-279) • Evidence of approval of a[pproval of required manufacturing facility from Licensing Division • Submission of latest GMP inspection report conducted within a period of last 1 year by DRAP. • Details of Primary Packaging Material for the applied formulation. • Separate registration applications for each applied pack size.
	Evaluation by PEC	The firm has provided liquid injectable section. Panel inspection dated 09-11-2018 recommends renewal of DML except in oral powder penicillin section. Details of primary packaging material are not submitted.
	Decision: Deferred for confirmation of composition of applied formulation whether quantity of API is in gm or mg.	
483.	Name and address of manufacturer / Applicant	M/s Farm Aid Group, Plot # 3/2, Phase I & II, Hattar industrial Estate, Haripur
	Brand Name +Dosage Form + Strength	THIACOL ORAL LIQUID
	Composition	Each ml contains: Thiamphenicol……200mg
	Diary No. Date of R& I & fee	Dy. No. 233; 22-11-2017 ; Rs.20,000/- (20-11-2017)
	Pharmacological Group	Amphenicols (Broad spectrum Antimicrobial)
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1L, 2.5 L, 5L, 10L, 15L, 20L, 25L; Decontrolled
	Me-too status	TRISAN 200 Liquid of M/s prix Pharma
	GMP status	Routine GMP inspection dated 07-09-2017 showed that the firm was working under satisfactory level of GMP.
	Previous remarks of the Evaluator.	
	Previous decision	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-288).
	Evaluation by PEC	The firm has submitted revised Form-5 with following label claim: Each 100ml of solution contains: Thiamphenicol……25g Me-too reference: TAF Oral Solution of M/s. Binsadiq international (Reg#088859). Firm has submitted fee challan of Rs. 5,000/- (deposit slip#0757431) dated 18-09-2018 and fee challan of Rs.15,000/- (Deposit slip#0816906) dated 03-01-2019.
	Decision: Approved.	
484.	Name and address of manufacturer / Applicant	M/s Aptly Pharmaceuticals, 5-Km Sargodha-Sidhar Bypass Road, Faisalabad.
	Brand Name +Dosage Form + Strength	TYDOCOL Liquid
	Composition	Each **100ml** Contains: Tylosin Tartrate……..100gm Colistin Sulphate……500IU Bromhexine……5gm Doxycyline (as Hyclate)…..200gm
	Diary No. Date of R& I & fee	Dy.No 29924 dated 05-09-2018 Rs.20,000/- Dated 05-09-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	In-house

	Pack size & Demanded Price	500ml, 1L, 2.5L, 5L plastic bottle; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	ZTYLO Plus Oral Liquid of Zoic Int. (Reg#080932)
	GMP status	New DML granted based on the inspection dated 06-8-2018
	Previous remarks of the Evaluator.	
	Previous decision (M-285).	Deferred for clarification/justification of quantities of active pharmaceutical ingredients (APIs) in grams per 100ml
	Evaluation by PEC	The firm has submitted Form-5 with revised composition as below Each **1000ml** Contains: Tylosin Tartrate……..100gm Colistin Sulphate……500IU Bromhexine……5gm Doxycyline (as Hyclate)…..200gm Fee of Rs 5000/-, (Deposit slip # 0794610) dated 05-3-2019 has been submitted. However, me-too reference of this composition could not be verified.
	Decision: Deferred for evidence of applied formulation already approved by DRAP (generic /me-too status) alongwith registration number, brand name and name of firm.	
485.	Name and address of manufacturer / Applicant	M/s. MYLAB Pvt. Ltd, Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	RUMICAL FORTE INJECTION
	Composition	Each 100ml contains: Calcium Gluconate……..38.71gm Boric acid…….7.29gm Calcium hydroxide…….1.32gm Magnesium chloride……6.50 gm
	Diary No. Date of R& I & fee	14091, 16-04-2018, 20,000/-, 19-02-2018
	Pharmacological Group	Calcium and magnesium supplement
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	50ml; Decontrolled
	Me-too status	Bovical Injection of M/s Grampiam Pharma (Reg#021268)
	GMP status	
	Previous remarks of the Evaluator.	Latest GMP inspection report which should have been conducted within period of 3 years is required to be submitted.
	Previous decision	Registration Board referred the case to QA & LT to update GMP status of the firm on priority (M-290).
	Evaluation by PEC	The panel of inspector dated 13-09-2018 recommends the renewal of DML no 000747 in respect to following approved sections: 1- Liquid Injectable (General vials) Veterinary 2- Oral Liquid (General) Veterinary 3- Oral Powder (General) Veterinary
	Decision: Approved.	
486.	Name and address of manufacturer / Applicant	M/s. MYLAB Pvt. Ltd, Khankah Shariff, Bahawalpur
	Brand Name +Dosage Form + Strength	TRIALIN Water Soluble Powder
	Composition	Each Kg contains: Oxytetracycline Hydrochloride……200gm Neomycin Sulphate……..250gm Colistin Sulphate……...300MIU
	Diary No. Date of R& I & fee	14089, 16-04-2018, 20,000/-, 19-02-2018
	Pharmacological Group	Broad Spectrum antibiotic
	Type of Form	Form-5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10gm, 500gm, 1Kg, 5Kg, 10kg, 25Kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Coxycol Forte Powder of Attabak pharma (Reg#071068)
	GMP status	Last GMP inspection conducted on 13-09-2018 and 14-09-2018 recommending the renewal of DML
	Previous remarks of the Evaluator.	
	Previous decision	Registration Board referred the case to QA & LT to update GMP status of the firm on priority (M-290).
	Evaluation by PEC	The panel of inspector dated 13-09-2018 recommends the renewal of DML no 000747 in respect to following approved sections: 1- Liquid Injectable (General vials) Veterinary 2- Oral Liquid (General) Veterinary 3- Oral Powder (General) Veterinary
	Decision: Approved.	

Case No. 04: Registration Applications of Import Cases.

a. New Cases (Human)

487.	Name and address of Applicant	M/s Zam Zam pharmaceuticals suit # 16, Beaumont Road, 6-cl-10 Beaumont Road, Karachi.
	Detail of Drug Sale License	Address: M/s s Zam Zam pharmaceuticals suit # 16, Beaumont Road, 6-cl-10 Beaumont Road, Karachi Validity: 15-Feb-2020 Status: Drug License by Way of wholesale
	Name and address of manufacturer	**Manufacture of Bulk product:** M/S Rottendorf pharma, GmbH ostenfelder dstraBe 51-6159320,enigerloh Germany **Packing of the finished product:** M/s Rottendorf pharma, GmbH ostenfelder dstraBe 51-6159320,enigerloh Germany **Quality testing and the quality release of the finished product:** M/s Medinova AG, eggbuhlstr 28 8050 zurich Switzerland **Microbiological quality testing:** M/s Labor Zollinger AG scarenmoostr 105 8050 zurich Switzerland M/s Labor LS SE & Co. KG mangelsfeld 4-6 97708 Bad Bocklet Germany
	Name and address of marketing authorization holder (Product license holder)	M/s Pierre fabre pharma gmbH Jechtinger str.13 79111 Freiburg Germany
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.29861 Dated 5-9-2018
	Fee including differential fee	Rs. 50,000/- Dated 3-9-20178
	Brand Name +Dosage Form + Strength	Fluomizin vaginal tablet
	Composition	Each tablet Contains: Dequalinium chloride ……10 mg
	Finished Product Specification	Manufacturer
	Pharmacological Group	Gynecological anti-infective and antiseptic.

	Shelf life	36 months
	Demanded Price	Rs. 1705/-
	Pack size	1 blister (PVC/PE/PVdc) of 6 vaginal tablet
	International availability	Fluomizin 10 mg vaginal tablets (MHRA approved)
	Me-too status	NA
	Detail of certificates attached	**CoPP** Original legalized CoPP confirms free sale status in the exporting country With following details: Certificate No: Pierre fabre phrma-005-2017 Certifying Authority: Regierungsprasidium Tubingen Leitstelle Arzneimitteluberwachung Baden-Wurttemberg Konrad-Adenauer-Strasse 20 D-72072 Tubingen Date of issue: 13-October-2017 **Letter of authorization** The firm has submitted notarized copy of letter of authorization between Medinova, AG Switzerland and Zam Zam pharmaceuticals Issue Date: 7-June 2018
	Remarks of the Evaluator.	The firm has submitted Stability study data for following 3 batches as per Zone IV-B conditions. 380088 380098 380152 Upon clarification, the firm has submitted that Medinova AG is the marketing authorization holder in Switzerland. Pierre fabre pharma GmbH located at Germany is the distribution partner of Medinova AG for Fluomizin Vaginal Tablets. Pierre fabre pharma GmbH is the marketing authorization holder in Germany and therefore the CoPP issued by German authorities is indicating Pierre Fabre GmbH as the product licence holder.
	Deferred for clarification regarding details of marketing authorization holder of applied formulation (M-291). **Evaluation by PEC:** The firm has submitted clarification from principal as below: "We, Medinova AG, located at Eggbühlastrasse 28, 8050 Zürich confirm that Medinova AG is the product owner of Floumizin vaginal tablets that is marketed currently in 60 countries. Medinova AG is the marketing authorization holder in Switzerland, however, has licensed the distribution of Fluomizin vaginal tablets to pharmaceutical companies in different countries. The collaboration between Medinova AG and Pierre fabre pharma GmbH is defined in distribution agreement like the one with Zam Zam Pharmaceuticals, our distribution partner for Pakistan. Pierre fabre pharma GmbH is the marketing authorization holder in Germany and therefore the CoPP issued by German authorities is indicating Pierre Fabre GmbH as the product licence holder."	
	Decision: Registration Board deferred the case for clarification regarding details of marketing authorization holder of applied product.	

Case no. 05 Registration Applications of Drugs for which Stability Study Data is Submitted.

a. Verification of Stability Study Data.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
488.	M/s Bio-Mark Pharmaceuticals. Plot No. 527-Sundar Industrial Estate, Lahore	DXZOLE Capsule 30mg Each capsule contains: Dexlansoprazole as dual delayed release pellets (22.5%) ……...30mg Proton Pump inhibitor In-house	Form 5-D Dy. No.7706 dated 06-07-2017 Rs. 20,000/- dated 05-07-2017 As per SRO	DEXILANT by M/s Takeda Pharms, USFDA. Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year.

STABILITY STUDY DATA

Drug	DXZOLE Capsule 30mg		
Name of Manufacturer	M/s Bio-Mark Pharmaceuticals. Plot No. 527-Sundar Industrial Estate, Lahore		
Manufacturer of API	M/s Vision pharmaceuticals (Pvt) Ltd. Plot no.22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	DLP363		
Description of Pack (Container closure system)	Alu-Alu Blister Foil		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C/ 75% ± 5% RH		
Time Period	Real time: 24 weeks Accelerated: 6 months		
Frequency	Accelerated : 0,2,4,6,8,10,12,14,16,18,20,22,24 (weeks) Real Time: 0,1,2,3,4,5,6 (months)		
Batch No.	DLP001T	DLP003T	DLP004T
Batch Size	700 Capsules	420 Capsules	420 Capsules
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	02-10-2018	02-10-2018	09-10-2018
No. of Batches	03		
Date of Submission	8538 (17/06/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # DLP363) from M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad issued by Additional Director (QA & LT), DRAP, Islamabad. The certificate is valid till 25-01-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes

4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of purchase of pellets from local vendor.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 24 weeks accelerated and 6 months real time stability data of three batches.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
489.	M/s Bio-Mark Pharmaceuticals. Plot No. 527-Sundar Industrial Estate, Lahore	DXZOLE Capsule 60mg Each capsule contains: Dexlansoprazole as dual delayed release pellets (22.5%) …….60mg Proton Pump inhibitor In-house	Form 5-D Dy. No.7705 dated 06-07-2017 Rs. 20,000/- dated 05-07-2017 As per SRO	DEXILANT by M/s Takeda Pharms, USFDA. Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year.

STABILITY STUDY DATA

Drug	DXZOLE Capsule 60mg		
Name of Manufacturer	M/s Bio-Mark Pharmaceuticals. Plot No. 527-Sundar Industrial Estate, Lahore		
Manufacturer of API	M/s Vision pharmaceuticals (Pvt) Ltd. Plot no.22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	DLP363		
Description of Pack (Container closure system)	Alu-Alu Blister Foil		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C/ 75% ± 5% RH		
Time Period	Real time: 24 weeks Accelerated: 6 months		
Frequency	Accelerated : 0,2,4,6,8,10,12,14,16,18,20,22,24 (weeks) Real Time: 0,1,2,3,4,5,6 (months)		
Batch No.	DLP002T	DLP004T	DLP005T
Batch Size	3500 Capsules	420 capsules	840 Capsules
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	03-10-2018	09-10-2018	03-10-2018
No. of Batches	03		

Date of Submission	8538 (17/06/2019)

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # DLP363) from M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad issued by Additional Director (QA & LT), DRAP, Islamabad. The certificate is valid till 25-01-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of purchase of pellets from local vendor.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 24 weeks accelerated and 6 months real time stability data of three batches.

Name of Manufacturer Physical address	M/s. Bio-Mark Pharmaceuticals Lahore Plot No. 527 Sunder Industrial Estate, Lahore.
Drug Manufacturing License No.	000863
Contact address Date of inspection	527 Sunder Industrial Estates, Lahore. 23-09-2019
Purpose of inspection	Verification of Authenticity of Stability Data for Purpose of Registration of Drugs with reference DRAP's letter No. F.13-11/2017-PECdated 29-08-2019.
Name of Inspector(s)	01. Mr. Shaheen Iqbal, Director, DTL, Lahore. 02. Ms. Anam Saeed, Area FID, DRAP, Lahore. 03. Ms. Maham Misbah, Assistant Director, DRAP, Lahore .
Name of firm's representative(s)	• Dr. Nasrullah Khan, Managing Director of the firm. • Dr. Ghulam Bari, Director Technical, Operations/ Production Incharge. • Mrs. Nourina Manzar, Quality Control Incharge • Dr. Misbah Mehmood, QA Incharge. .

1.1 <u>Focus of Inspection:</u>

The inspection was focused on a thorough evaluation of data for stability studies of following products namely:

Sr.#	Brand Name / Composition of Drugs
01	DXOZLE Capsule 30mg Each capsule contains: Dexlansoprazole as dual delayed release pellets (22.5%…….30mg
02	DXOZLE Capsule 60mg Each capsule contains: Dexlansoprazole as dual delayed release pellets (22.5%…….60mg

The data was evaluated according to the check list provided as given below:

Detail of investigation:

Sr.#	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import of API including approval from DRAP.	The firm had not imported the API. Rather, the firm had procured 2.2 kg Dexlansoprazole DDR pellets 22.5% locally from M/s Vision Pharmaceuticals, Islamabad, having Batch number DLP363 vide Invoice No. 500663 dated 24/09/2018.
2.	What was the rationale behind selecting the particular manufacturer of API?	Selection of the manufacturer was based upon its GMP, ISO 9001: 2015, 17025, 14001, PNAC Certification and already Approved DRAP source.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The Firm had procured working standard of API as well as Impurity Standard from Vision Pharmaceuticals Islamabad.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Yes
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, The Firm had cGMP Certificate of API's manufacturer (M/s Vision Pharmaceuticals, Islamabad) issued by Drug Regulatory Authority of Pakistan.
6.	authority of country of origin Do you use API manufacturer method of testing for testing API?	The Firm had not used complete manufacturer method for testing of Dexlansoprazole DDR pellets.
7.	Do you have stability studies reports on API?	Yes
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	No
9.	Do you have method for quantifying the impurities in the APIs?	Yes, The Firm had the method for quantifying the impurities in the API provided by M/s Vision Pharmaceuticals.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Yes, The Firm had remaining quantities of API, working standard of API and Impurity standard.
11.	Have you used pharmaceutical grade excipients?	Not Applicable; Only encapsulation of ready to fill pellets was being performed.
12.	Do you have documents confirming the import of the used excipients?	Not Applicable; Only encapsulation of ready to fill pellets had been performed.
13.	Do you have test reports and other records on the excipients used?	Not Applicable; Only encapsulation of ready to fill pellets had been performed.
14.	Do you have written and authorized protocols for the development of applied product?	Yes, Firm was advised to improve the protocols
15.	Have you performed Drug-excipients compatibility studies?	Not Applicable; Only encapsulation of ready to fill pellets had been performed.
16.	Have you performed comparative dissolution studies?	Yes, The Firm had performed comparative dissolution studies with DEXXOO Capsules 30mg and 60mg manufactured by M/s Horizon Healthcare (Pvt) Ltd. However, the firm used six vessel dissolution apparatus (Type II, Model of DS-2013 and Make by Curio Pakistan). The firm was advised to purchase twelve vessel dissolution apparatus for performing comparative dissolution studies. Firm was also advised to generate comparative dissolution profile.

<table>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>No</td></tr>
<tr><td>18.</td><td>Do you have necessary equipments available in product development section for development of applied product?</td><td>The firm used Semi-automatic Capsule filling machine of production area for manufacturing of trial batches.</td></tr>
<tr><td>19.</td><td>Are the equipments in product development section qualified?</td><td>Yes, the equipment used in production and testing of Dexzole 30mg and Dexzole 60mg was qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The equipment used in Product Development and Testing had been calibrated</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>Yes, The firm had qualified staff with suitable knowledge and training in production area.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of applied product as required?</td><td>The firm had manufactured three stability batch for the stability studies with following details:
<table>
<tr><td>Batch #</td><td>Mfg. Date</td><td>Batch Size</td></tr>
<tr><td colspan="3">DEXZOLE 30mg Capsule</td></tr>
<tr><td>DLP001T</td><td>October-2018</td><td>700 Capsules</td></tr>
<tr><td>DLP003T</td><td>October-2018</td><td>420 Capsules</td></tr>
<tr><td>DLP004T</td><td>October-2018</td><td>420 Capsules</td></tr>
</table>
<table>
<tr><td>Batch #</td><td>Mfg. Date</td><td>Batch Size</td></tr>
<tr><td colspan="3">DEXZOLE 60mg Capsule</td></tr>
<tr><td>DLP002T</td><td>October-2018</td><td>3500 Capsules</td></tr>
<tr><td>DLP005T</td><td>October-2018</td><td>840 Capsules</td></tr>
<tr><td>DLP006T</td><td>October-2018</td><td>840 Capsules</td></tr>
</table></td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches was based upon the number of Capsules per testing and testing frequencies and the availability of raw material</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>BMRs were available</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>Yes, The firm was firm was advised to improve protocols</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm had validated method for the testing of Dexzole 30mg and 60mg Capsules. However validation studies required improvement.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>N/A</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipments I instruments being used in the test and analysis of API and the finished drug?</td><td>Yes</td></tr>
<tr><td>29.</td><td>Is your method of analysis stability indicating?</td><td>No</td></tr>
<tr><td>30.</td><td>Is your HPLC software is 21CFR compliant? (Details of Model software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.)</td><td>No, The firm had performed assay and dissolution on UV-Visible spectrophotometer</td></tr>
</table>

31.	Can you show Audit Trail reports on stability studies testing?	No
32.	Do you have some remaining quantities of degradation products and stability batches?	Yes, The firm had remaining quantities of stability batches placed in stability chamber for ongoing stability studies.
33.	Do you have stability batches kept on stability testing?	The firm had completed the accelerated stability studies and kept three batches of Dexzole 30mg and 60mg capsules each for long term stability studies. There were two Stability Chambers with following details: <u>Stability Chamber No 1 ; for Long Run Studies</u> Make: Galvano Scientific Capacity: 400 Liters Temperature: 30 ± 2ºC & 65 % RH ±5% <u>Stability Chamber No 2 ; for Accelerated Studies</u> Make: Galvano Scientific Capacity: 400 Liters Temperature: 40 ± 2ºC & 65 % RH ±5%
34.	Do you have valid calibration status for the equipments used in production and analysis?	Yes
35.	Do proper and continuous monitoring control are available for stability chamber?	Power backup by UPS & 200kv Generator was available. Digital data logger was not installed for continuous monitoring and control of stability chambers. Storage conditions were being recorded twice a day, manually
36.	Do related manufacturing area, equipment personnel and utilities be rated as GMP compliant?	Yes, Last inspection to check cGMP compliance was conducted by DRAP on 16.08.2018

Conclusion:-

The panel inspection of M/s. Bio-Mark Pharmaceuticals, Plot No. 527 Sunder Industrial Estate, Lahore, for verification of authenticity of stability data of Dexzole 30mg and 60mg capsules was conducted on 23.09.2019, and the details are as given above. The panel also verified the following four points during inspection.

- Frequency of testing for real time and accelerated stability studies.
- Results of assay and dissolution with respective UV spectra for initial time point of all stability batches.
- Dissolution studies of ready to fill pellets to confirm dual delay release pattern of pellets.
- Revision of dissolution limit of NLT=75% (Q) in the finished pharmaceutical products testing method.

Decision: Registration Baord deferred for inquiring justifications for following observations reported by panle:

1. The firm had performed assay and dissolution on UV-Visible spectrophotometer.

2. The Firm had not used complete manufacturer method for testing of Dexlansoprazole DDR pellets.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
490.	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	TREOW 50mg Tablet Each Film coated tablet contains : Trelagliptin as succinate……..50mg	Form-5D Duplicate 50,000/- dated 28-03-2016 As per PRC	Zafatek by Takeda (PMDA approved) GMP inspection dated 23-02-2018 showed that the firm was considered

		Anti-Diabetic Manufacturer's specs		to be operating at an acceptable level of compliance with GMP standards.

STABILITY STUDY DATA			
Drug	TREOW 50mg Tablet		
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API	M/s Ruyuan HEC Co. Ltd., China.		
API Lot No.	TGLT-201803101		
Description of Pack (Container closure system)	Alu Alu Foil printed in unit Carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C/ 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated : 0, 3,6 (months) Real Time: 0,3,6 (Months)		
Batch No.	18PD-2413-02-T	18PD-2414-03-T	18PD-2415-04-T
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	12-10-2018	12-10-2018	12-10-2018
No. of Batches	03		
Date of Submission	8768 (18/06/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
•	COA of API	Copy of COA of Trelagliptin succinate (Batch # TGLT-201803101) from M/s Ruyuan HEC Pharm Co., Ltd China is submitted.
•	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Ruyuan HEC Pharm Co., Ltd China issued by Shaouguan Food and Drug Administration. The certificate is valid for 04-12-2021.
•	Protocols followed for conduction of stability study and details of tests.	Yes
•	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
•	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Trelagliptin succinate (0.9 Kg) attested by ADC DRAP, Karachi dated 09-05-2018.
•	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
•	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
•	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months accelerated and 6 months real time stability data of three batches.

Sr. No.	Observations	Response of the applicant
1.	Reference product is film coated tablet while label claim on Form-5D is uncoated tablet. Revision of formulation as per reference product is required.	Submitted.
2.	Clarification is required regarding rationale behind selection of dissolution parameters such as dissolution medium (i.e., 0.01 N HCL) since the solubility of trelagliptin is 1mg/ml in PBS pH 7.2.	The firm has referred to a patent of trelagliptin for selection of dissolution medium which is as below: Dissolution media: 0.01 N HCl in 900ml.
3.	Justify the dissolution limit NLT 75% without mentioning time since FDA defines value of Q from 75% to 80%.	The firm has submitted we have have set the dissolution specifications NLT 75% (Q) as per USFDA and USP general chapter (1092), and for dissolution medium and release time specifications we have followed the patent of Trelagliptin. Previously submitted specifications data show dissolution specifications NLT 75% without mentioning Q.
4.	Valid GMP certificate from relevant authority is required since it is expired on 31-05-2019.	Submitted.

Decision: Deferred for following:

- **Scientific justification for selection of dissolution medium (i.e. 0.01N HCl having pH 2.0), since the solubility of trelagliptin is 1mg/ml in Phosphate Buffer solution pH 7.2.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
491.	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	Memura SR 7mg Capsule Each Capsule contains: Memantine Hydrochoride SR pellets eq. to Memantine HCl .....… 7mg Anti-Alzheimer Manufacturer's specifications	Form 5-D Duplicate 24-09-2010, 15,000/- (attested photocopy) dated 12-03-2011 35,000/- dated 19-11-2014 7's; Rs. 345.00/pack 14's Rs. 600.00/pack 28's Rs. 1075.00/pack	Namenda XR capsule 7mg of Forest Laboratories **(USFDA approved)** .

STABILITY STUDY DATA

Drug	Memura SR 7mg Capsule
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.
Manufacturer of API	M/s Alphamed Formulations Pvt. Limited, Telangana, India
API Lot No.	RD0008-004
Description of Pack (Container closure system)	Alu Alu Foil printed in unit Carton
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5% RH Accelerated: 40°C ± 2°C/ 75% ± 5% RH
Time Period	Real time: 6 months Accelerated:6 months

Frequency	Real Time: 0 , 3, 6 (Months) Accelerated : 0 , 3, 6 (months)		
Batch No.	18PD-2381-01-T	18PD-2382-02-T	18PD-2383-03-T
Batch Size	2500	2500	2500
Manufacturing Date	07-2018	07-2018	07-2018
Date of Initiation	24-07-2018	24-07-2018	24-07-2018
No. of Batches	03		
Date of Submission	8768 (18/06/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch #RD0008-004) from M/s Alphamed Formulations Pvt. Limited, Telangana, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Alphamed Formulations, India issued by Drugs Control Administration, Government of Telangana on 03-05-2017. The certificate is valid for a period of two years from the date of issue.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Memantine HCl SR pellets 10% (7.0 Kg) attested by ADC-DRAP, Karachi dated 13-1-17
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months accelerated and 6 months real time stability data of three batches.
The firm has submitted that:
We would like to inform your good office that authenticity of stability data of other applied strengths of same molecule (Memantine HCl) i.e., Memura XR 14mg capsule, Memura XR 21mg capsule and Memura XR 28mg capsule has been verifiedthrough inspection of our factory premsies on 2nd August, 2019 in reference to letter n.F.13-11/2017-PEC (Vol-1) dated 26th June, 2019 (Copy attached) and deemed verifiable to satisfactory level in the agenda of 291st meeting held from 2-4 september , 2019.
Documentation submitted with stability data of Memura XR 7mg capsule on june 10, 2019 with regards to import of API, certificate of analysis of API, Form 6, Form 7, Form-3, Goods declaration and commercial invoice are same as the one already verified in the inspection conducted for other aforementioned strengths of Memura XR.
In the light of above, we request your good office to waive of inspection of verification of authenticity of stability data of Memura XR 7mg Capsule and include in agenda of next DRB meeting for approval.

Decision: Registration Board did not accede to the firm's request and gave the choice to the firm to submit data for exemption from onsite inspection or go for onsite inspection for confirmation of data.

b. Exemption from onsite verification of stability data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
492.	M/s Indus Pharma (Pvt.) Ltd. 26-27 & 63-67, Sector 27, Korangi Industrial Area 74900., Karachi.	Indazin Tablet 10mg Each film coated tablet contains:- Dapagliflozin as propanediol monohydrate..... …….10mg (SGLT2 inhibitor) In-house	Form 5-D Dairy No. 21211 dated 13-06-2018 Rs.50,000/- dated 17-04-2018 As per DPC	Farxiga 10mg Tablets by Astrazaneca (**USFDA approved)** GMP compliant dated 16-8-2017.	The Firm has claimed Manufacturer's Specifications.

STABILITY STUDY DATA			
Drug	Indazin Tablet 10mg		
Name of Manufacturer	M/s Indus Pharma (Pvt.) Ltd. 26-27 & 63-67, Sector 27, Korangi Industrial Area 74900., Karachi.		
Manufacturer of API	M/s Lianyungang Jari pharmaceutical Co., Ltd, China		
API Lot No.	20170421		
Description of Pack (Container closure system)	Alu Alu Blister strips		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0,3,6 (Month) Real Time: 0,3,6 (Month)		
Batch No.	TR-01/Dap 10mg tab	P-1/Dap 10mg tab	P-2/Dap 10mg tab
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
Manufacturing Date	12-2017	12-2017	12-2017
Date of Initiation	02-12-2017	14-12-2017	14-12-2017
No. of Batches	03		
Date of Submission	24-06-2019 (Dy. No. 9428)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA (Batch # 20170421) from M/s Lianyungang Jari pharmaceutical Co., Ltd, China has been submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate for M/s Lianyungang Jari pharmaceutical Co., Ltd, China issued by Jiangsu Food and Drug Administration, China is submitted.
3.	Protocols followed for conduction of stability	Yes

	study and details of tests.	
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin Propanediol Monohydrate (125g) attested by ADC DRAP, Karachi dated 09-06-2019.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

PREVIOUS REMARKS OF EVALUATOR

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REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 24-06-2019 vide diary no. 9428

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Canazin 100mg and 300mg (Canagliflozin) Tablets", which was presented in 289th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Indus Pharma (Pvt.) Ltd., Karachi. **Date of inspection**: 14-03-2019 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin Propanediol Monohydrate (125g) attested by ADC DRAP, Karachi dated 09-06-2019.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted local purchase invoice from Neon Chemicals for the procurement of Dapagliflozin propanediol monohydrate working standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate for M/s Lianyungang Jari pharmaceutical Co., Ltd, China issued by Jiangsu Food and Drug Administration, China is submitted.
5.	Mechanism for Vendor pre-qualification	The firm has submitted documents regarding supplier evaluation checklist.
6.	Certificate of analysis of the API, reference standards and impurity standards	Copy of COA (Batch # 20170421) from M/s Lianyungang Jari pharmaceutical Co., Ltd, China has been submitted. COA of working standard (WS01) has been submitted.
7.	Documents for the procurement of excipients	The firm has submitted photocopy of Commercial

<table>
<tr><td></td><td>used in product development?</td><td>invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Dapagliflozin Tablets 10mg”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TR-01/Dap 10mg tab</td><td>2500 Tablets</td><td>17-11-2017</td></tr>
<tr><td>P-1/Dap 10mg tab</td><td>2500 Tablets</td><td>05-12-2017</td></tr>
<tr><td>P-2/Dap 10mg tab</td><td>2500 Tablets</td><td>06-12-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>TR-01/Dap 10mg tab</td><td>137packs</td><td>41 packs</td><td>96 packs</td></tr>
<tr><td>P-1/Dap 10mg tab</td><td>157 Packs</td><td>45 packs</td><td>112 packs</td></tr>
<tr><td>P-2/Dap 10mg tab</td><td>160 packs</td><td>41 packs</td><td>119 packs</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-12-2017 to 01-06-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Dapagliflozin.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Dapagliflozin Tablet 10mg” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s Lianyungang Jari pharmaceutical Co., Ltd, China. The storage conditions under which long term stability studies were conducted are 25ºC±2ºC/60±5%RH.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted we used all the ingredients same as used in reference product Farxiga Tablet 10mg.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution for “Dapagliflozin tablet 10mg & Farxiga Tablet 10mg” and concludes that both, reference product and test product shows more than 85% dissolution release within 15 minutes in three recommended mediums at</td></tr>
</table>

		pH 1.2, pH 4.5, pH 6.8. Dissolution profiles of both products were considered similar.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of " " from.

The firm has submitted 6 months accelerated and 6 months real time stability studies data of 3 batches.

Observations	**Response of the applicant**
Method used for analysis of Dapagliflozin propanediol monohydrate is not submitted. Relevant information is required to be submitted.	Submitted
Justify the dissolution specifications NLT 75% (Q) in 20 min since the dissolution specifications of FDA approved product (**FARXIGA Tablet)** is NLT Q in 15 min.	The firm has submitted that at the time of development, we select three time points 10, 20, and 30min. Indazin 10mg tablet dissolved more than 80% of the label claim in pH 4.5 buffer at 20min time interval rather than 10 min, so we select 20min time interval. However, results of comparative dissolution for Farxiga 10mg Tablet and Indazin 10mg Tablet at 15 min time interval gives the evidence that both products i.e., Farxiga 10 Tablet and indazin 10mg Tablet shows more than 85% dissolution release in three recommended mediums.
Storage conditions under which long term stability studies were conducted are 25ºC±2ºC/60±5%RH which are not as per Zone-IVA. Clarification is required.	Submitted with revised storage conditions as per Zone-IVA.
Audit trail reports of applied formulation on all time points are required to be submitted.	Submitted
Justification is required for purchasing the working standard Dapagliflozin propanediol monohydrate from local manufacturer Neon Chemicals.	Neon chemicals are the indentor who provides Dapagliflozin propanediol monohydrate working standard and materials from M/s liqanyungang Jari pharmaceutical Co., Ltd. China.
Clarification is required for not carrying out impurity profiling for applied formulation.	Related impurities method of manufacturer of Dapagliflozin propanediol monohydrate API does not define any specific impurity, but define only unknown impurities in the method. Analysis of indazin 10mg Tablet was done with related impurities method at all time points.

Decision: Registration Board decided to approve registration of Indazin Tablet 10mg by M/s Indus Pharma (Pvt.) Ltd. 26-27 & 63-67, Sector 27, Korangi Industrial Area 74900, Karachi. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size**	**International Availability / Local Availability** **GMP Inspection Report Date**
493.	M/s. Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi	AGLIZON-MET TABLETS 5/850mg Each film coated tablet contains: Dapagliflozin as propanediol…….5mg Metformin hydrochloride….850mg	Form 5-D Dy. No.19546 dated 31-10-2017 Rs. 50,000/- dated 30-10-2017 1×10's, 2×10's, 3×10's: As per PRC	Ebymect 5 mg/850 mg film-coated tablets by M/s AstraZeneca AB (EMA approved)

		Antidiabetic agent In-house specifications		

STABILITY STUDY DATA			
Drug	AGLIZON-MET TABLETS 5/850mg		
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi		
Manufacturer of API	**Dapagliflozin Propanediol monohydrate:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China **Metformin Hydrochloride:** M/s Abhilasha Pharma Pvt. Ltd. Gujarat India		
API Lot No.	**Dapagliflozin Propanediol monohydrate:** DGF20180101 **Metformin Hydrochloride:** MET116/17		
Description of Pack (Container closure system)	Alu Alu Blister 3× 10's		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C/75%±5% RH Real Time: 30˚C ± 2˚C/75%±5% RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real Time: 0,3, & 6 (months) Accelerated: 0,1,2,3,4, & 6 (months)		
Batch No.	TF001	TF002	TF003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05/2018	05/2018	05/2018
Date of Initiation	26/05/2018	26/05/2018	26/05/2018
No. of Batches	03		
Date of Submission	8529 (17-06-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	**Dapagliflozin Propanediol monohydrate:** Copy of COA (Batch # DGF20180101) from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China is submitted. **Metformin Hydrochloride:** Copy of COA (MET116/17) from M/s Abhilasha Pharma Pvt. Ltd. Gujarat India, is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Dapagliflozin Propanediol monohydrate**: Copy of GMP certificate (certificate No.JS20140321) issued by Jiangsu Food & Drug Administration, India. It is valid until 18/08/2019. **Metformin Hydrochloride**: Copy of GMP certificate (certificate No.1706138) issued by Food & Drugs Control Administration, Gujarat state India. It is valid until 01/06/2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

5.	Documents confirming import of API etc.	**Dapagliflozin Propanediol monohydrate**: The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin propanediol monohydrate attested by DRAP, Karachi dated 14-05-2018. **Metformin Hydrochloride**: The firm has submitted copy of export invoice from M/s Abhilasha Pharma (Pvt.) Ltd, India for metformin hydrochloride **not attested by DRAP.**
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 17-06-2019 vide diary no. 8529

Administrative Portion

•	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was presented in 273rd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Helix Pharma (Pvt.) Limited, Karachi. **Date of inspection**: 18-08-2017 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
•	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin Propanediol monohydrate**: The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin propanediol monohydrate attested by DRAP, Karachi dated 14-05-2018. **Metformin Hydrochloride**: The firm has submitted copy of export invoice from M/s Abhilasha Pharma (Pvt.) Ltd, India for metformin hydrochloride **not attested by DRAP.**
•	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of COA for following working standard & impurity Standards: Dapagliflozin Propanediol monohydrate reference standard Dapagliflozin Propanediol monohydrate working standard Dapagliflozin impurity A
•	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Dapagliflozin Propanediol monohydrate**: Copy of GMP certificate (certificate No.JS20140321) issued by Jiangsu Food & Drug Administration, India. It is valid until 18/08/2019.

<table>
<tr><td></td><td></td><td>Metformin Hydrochloride: Copy of GMP certificate (certificate No.1706138) issued by Food & Drugs Control Administration, Gujarat state India. It is valid until 01/06/2019.</td></tr>
<tr><td>•</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for evaluation of vendors.</td></tr>
<tr><td>•</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Dapagliflozin Propanediol monohydrate: Copy of COA (Batch # DGF20180101) from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China is submitted.
Metformin Hydrochloride: Copy of COA (MET116/17) from M/s Abhilasha Pharma Pvt. Ltd. Gujarat India, is submitted.
Copy of COA of Dapagliflozin propanediol impurity A is submitted.</td></tr>
<tr><td>•</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>•</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
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<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>TF001</td><td>1000 Tablets</td><td>22-05-2018</td></tr>
<tr><td>TF002</td><td>1000 Tablets</td><td>22-05-2018</td></tr>
<tr><td>TF003</td><td>1000 Tablets</td><td>22-05-2018</td></tr>
</table></td></tr>
<tr><td>•</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
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<tr><td>TF002</td><td>1000 tabs</td><td>(33 packs, 3×10’s)</td><td>21 packs</td></tr>
<tr><td>TF003</td><td>1000 tabs</td><td>(33 packs, 3×10’s)</td><td>17 packs</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>•</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from……..</td></tr>
<tr><td>•</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Metformin HCl and Dapagliflozin propanediol monohydrate.</td></tr>
<tr><td>•</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Aglizon-Met Tablets 5/850mg” along with Stability Study Reports.</td></tr>
<tr><td>•</td><td>Reports of stability studies of API from manufacturer.</td><td>Dapagliflozin propanediol monohydrate: The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03</td></tr>
</table>

		Batches from M/s M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China according to zone IVA conditions. **Metformin hydrochloride:** The firm has submitted photocopy of 06 months Accelerated and 60 months Real Time Stability Study Data of 03 Batches from M/s Abhilasha Pharma Pvt. Ltd. India according to zone IVA conditions.
•	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
•	Drug-excipients compatibility studies.	The firm has used the excipients of innovator.
•	Record of comparative dissolution data.	The firm has performed comparative dissolution profile at pH 1.2, pH 4.5, pH 6.8 between Aglizon-Met 5/850mg tablet (Batch#TF001) and Xigduo Tablet 5/850mg (Batch # V867A). However, firm did not calculate similarity factor (f2).
•	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of "Aglizon-Met 5/850mg Tablet" from 24-05-2018 to 26-11-2018.

The firm has submitted 6 months accelerated and 6 months real time stability studies data for 3 trial batches.

Sr. No.	Observations	Response of the applicant
1.	Documents confirming import of metformin HCl is required.	Submitted
2.	In comparative dissolution studies, similarity factor (f2) is not calculated. Justification is required.	Calculation of f2 factor has been provided.
3.	Digital data logger record for chambers used in real time and accelerated stability studies need to be submitted.	Submitted
4.	Authorized protocols/SOP for the development of applied formulation is required.	The firm has submitted product development protocol.
5.	Justification of not performing content uniformity test as recommended by USP general chapter <905>.	The firm has submitted that content uniformity test was carried out for initial test & 06 months test for both stability conditions. There is no significant difference in content of tablets in both stability conditions.
6.	Justification of dissolution limit NLT 75% since USP general chapter defines typical value of Q from 75% to 80%. Moreover, time for dissolution and analytical procedures for dissolution test are required to be submitted.	The firm replied we have already submitted following dissolution specifications that: Dapagliflozin: NLT 80% of label claim in 30min Metformin HCL: NLT 80% of label claim in 30min Instrument: USP apparatus I (basket) at 100 rpm Dissolution media: 1000ml of pH 6.8 phosphate buffer (50mM). However, FDA has defined above dissolution testing method for XR tablet while firm has applied for immediate release combination product.

Decision: Registration Baord deferred the case for clarification of follwong observation:

- **Scientific justification how the dissolution method of FDA approved formulation can be used since FDA approved formulation is extended release formulation while applied formulation is immediate release combination product.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date
494.	M/s. Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi	AGLIZON-MET TABLETS 5/1000mg Each film coated tablet contains: Dapagliflozin as propanediol…….5mg Metformin hydrochloride….1000mg Antidiabetic agent In-house specifications	Form 5-D Dossier required dated 31-10-2017 Rs. …… dated 30-10-2017 1×10's, 2×10's, 3×10's: As per PRC	Ebymect 5 mg/850 mg film-coated tablets by M/s AstraZeneca AB (EMA approved)

STABILITY STUDY DATA

Drug	AGLIZON-MET TABLETS 5/1000mg		
Name of Manufacturer	M/s. Helix Pharma (Pvt.) Ltd., Hakimsons House, A/56, S.I.T.E Manghopir Road, Karachi		
Manufacturer of API	**Dapagliflozin Propanediol monohydrate:** M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China **Metformin Hydrochloride:** M/s Abhilasha Pharma Pvt. Ltd. Gujarat India		
API Lot No.	**Dapagliflozin Propanediol monohydrate:** DGF20180101 **Metformin Hydrochloride:** MET116/17		
Description of Pack (Container closure system)	Alu Alu Blister 3× 10's		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/75%±5% RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real Time: 0,3, & 6 (months) Accelerated: 0,1,2,3,4, & 6 (months)		
Batch No.	TF001	TF002	TF003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	05/2018	05/2018	05/2018
Date of Initiation	26/05/2018	26/05/2018	26/05/2018
No. of Batches	03		
Date of Submission	8530 (17-06-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	**Dapagliflozin Propanediol monohydrate:** Copy of COA (Batch # DGF20180101) from M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China is submitted. **Metformin Hydrochloride:** Copy of COA (MET116/17) from M/s Abhilasha Pharma Pvt. Ltd. Gujarat India, is submitted.

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Dapagliflozin Propanediol monohydrate**: Copy of GMP certificate (certificate No.JS20140321) issued by Jiangsu Food & Drug Administration, India. It is valid until 18/08/2019. **Metformin Hydrochloride**: Copy of GMP certificate (certificate No.1706138) issued by Food & Drugs Control Administration, Gujarat state India. It is valid until 01/06/2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin Propanediol monohydrate**: The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin propanediol monohydrate attested by DRAP, Karachi dated 14-05-2018. **Metformin Hydrochloride**: The firm has submitted copy of export invoice from M/s Abhilasha Pharma (Pvt.) Ltd, India for metformin hydrochloride **not attested by DRAP.**
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 17-06-2019 vide diary no. 8530

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Ramelton Tablets 8mg", which was presented in 273rd meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Helix Pharma (Pvt.) Limited, Karachi. **Date of inspection**: 18-08-2017 According to inspection report, following points were confirmed. • The firm has 21CFR compliant HPLC software. • The firm has audit trail reports available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin Propanediol monohydrate**: The firm has submitted copy of commercial invoice for the purchase of Dapagliflozin propanediol monohydrate attested by DRAP, Karachi dated 14-05-2018. **Metformin Hydrochloride**: The firm has submitted copy of export invoice from M/s Abhilasha Pharma (Pvt.) Ltd, India for metformin hydrochloride **not attested by DRAP.**

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copies of COA for following working standard & impurity Standards:
Dapagliflozin Propanediol monohydrate reference standard
Dapagliflozin Propanediol monohydrate working standard
Dapagliflozin impurity A</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Dapagliflozin Propanediol monohydrate: Copy of GMP certificate (certificate No.JS20140321) issued by Jiangsu Food & Drug Administration, India. It is valid until 18/08/2019.
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Metformin Hydrochloride: Copy of COA (MET116/17) from M/s Abhilasha Pharma Pvt. Ltd. Gujarat India, is submitted.
Copy of COA of Dapagliflozin propanediol impurity A is submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
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<tr><td>TF002</td><td>1000 Tablets</td><td>22-05-2018</td></tr>
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<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
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<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
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<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-11-2018 to 23-05- 2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Metformin HCl and Dapagliflozin propanediol monohydrate.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Aglizon-Met Tablets 5/1000mg” along with Stability Study Reports.</td></tr>
</table>

	data sheets etc.)	
15.	Reports of stability studies of API from manufacturer.	**Dapagliflozin propanediol monohydrate:** The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s M/s Shanghai Pharma Group Changzhou Kony Pharmaceutical Co., Ltd. Jiangsu China according to zone IVA conditions. **Metformin hydrochloride:** The firm has submitted photocopy of 06 months Accelerated and 60 months Real Time Stability Study Data of 03 Batches from M/s Abhilasha Pharma Pvt. Ltd. India according to zone IVA conditions.
16.	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has used the excipients of innovator.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution profile at pH 1.2, pH 4.5, pH 6.8 between Aglizon-Met 5/1000mg tablet (Batch#TF001) and Xigduo Tablet 5/1000mg (Batch # V867A). However, firm did not calculate similarity factor (f2).
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of "Aglizon-Met 5/1000mg Tablet" from 24-05-2018 to 26-11-2018.

The firm has submitted 6 months accelerated and 6 months real time stability studies data for 3 trial batches.

Sr. #	Observations	Response of the applicant
1.	Documents confirming import of metformin HCl is required.	Submitted
2.	In comparative dissolution studies, similarity factor (f2) is not calculated. Justification is required.	Calculation of f2 factor has been provided.
3.	Digital data logger record for chambers used in real time and accelerated stability studies need to be submitted.	Submitted
4.	Authorized protocols/SOP for the development of applied formulation is required.	The firm has submitted product development protocol.
5.	Justification of not performing content uniformity test as recommended by USP general chapter <905>.	The firm has submitted that content uniformity test was carried out for initial test & 06 months test for both stability conditions. There is no significant difference in content of tablets in both stability conditions.
6.	Justification of dissolution limit NLT 75% since USP general chapter defines typical value of Q from 75% to 80%. Moreover, time for dissolution and analytical procedures for dissolution test are required to be submitted.	The firm replied we have already submitted following dissolution specifications that: Dapagliflozin: NLT 80% of label claim in 30min Metformin HCL: NLT 80% of label claim in 30min Instrument: USP apparatus I (basket) at 100 rpm Dissolution media: 1000ml of pH 6.8 phosphate buffer (50mM). However, FDA has defined above dissolution testing method for XR tablet while firm has applied for immediate release combination product.

Decision: Registration Baord deferred the case for clarification of follwong observation:

- **Scientific justification how the dissolution method of FDA approved formulation can be used since FDA approved formulation is extended release formulation while applied formulation is immediate release combination product.**

495. Application on CTD format

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy.No. 1528, dated 22-03-2019, 50,000/- dated 04-02-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Martin Dow Limited., Plot 37, Sector 19, Korangi Industrial Area, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. M/s Nabiqasim Industries Pvt. Ltd., 17/24, Korangi industrial Area, Karachi
	1.3.3	Specify whether the Applicant is: a. □ Manufacturer b. □ Importer **c. ☐ Is involved in none of the above (contract giver)**
	1.3.4	Valid Drug Manufacturing License (DML) of manufacturer / Applicant or Drug Sale License, whichever is applicable. Copy of DML of manufacturing site is submitted. Submitted
	1.3.5	Evidence of approval of manufacturing facility / Approved Section from Licensing Authority Submitted
	1.3.6	List of already approved registered drugs in this section Not submitted.
	1.3.7	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance Not submitted
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Not applicable
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: □ New Drug Product (NDP) **☐ Generic Drug Product (GDP)**
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale □ Export sale **☐ Domestic and Export sales**
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import □ Bulk Import and local repacking (specify status of bulk) □ Bulk Import Local Repacking for Export purpose only
	1.4.3	Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976. **☐ Domestic Manufacturing** □ Export Purpose Only
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug.
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **Each vial contains:** **Esomeprazole as sodium……40mg**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance. **Esomax IV 40mg Injection**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1 vial; As per PRC

	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Proton pump inhibitor (WHO ATC code= A02BC05)
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration Intravenous (IV)
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Acireg of Barret hodgson Pakistan
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Nexium IV Injection (MHRA Approved)
	1.5.10	Dosage form of applied drug Esomax IV Injection 40mg/ml Sterile , freeze –dried white colored powder in 5ml vial contains: Esomeprazole sodium eq. to Esomeprazole……40mg
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & color scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Attached
	1.5.12	Description of Batch numbering system Not submitted
	1.5.13	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form). Not submitted
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption /

		withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Not submitted
	1.5.20	Other commitment e.g., regarding stability studies etc. Submitted
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer. Not submitted
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company. Not submitted
1.6		Miscellaneous Information Not submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: a. Name and address of API manufacturer. b. Approval of manufacturing facility of API by regulatory body of country and validity. c. Vendor qualification / audit is □ Document based □ Site inspection based d. Reason for point c.
		The firm has submitted copy of contract manufacturing agreement dated 12th March, 2019 between M/s Martin Dow Limited, Karachi and Nabiqasim Industries Pvt. Ltd., Karachi.

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content *Submitted*

2.2 CTD Introduction *Submitted*

2.3 Quality Overall Summary (QOS)* *Submitted*

(Detailed information regarding QOS may be found at the following link)
https://extranet.who.int/prequal/sites/default/files/documents/82%20Module%202.3%20QOS_March2017.docx

1.3 QUALITY OVERALL SUMMARY (QOS)

2.3	**2.3.S**	Drug substance (API)
	2.3.S.1	General information *Submitted*
	2.3.S.2	Manufacture *Submitted*
	2.3.S.3	Characterization *Submitted*
	2.3.S.4	Control of drugsubstance *Submitted*
	2.3.S.5	Reference standards *Submitted*
	2.3.S.6	Container closure system *Submitted*
	2.3.S.7	Stability *Submitted*
	Comments	

	2.3.P Drug product 2.3.P.1 Description and composition of the drug product Submitted 2.3.P.2 Pharmaceutical development Submitted 2.3.P.2.1 Components of the drug product 2.3.P.2.1.1 Drug substance (API) Submitted 2.3.P.2.1.2 Excipients Submitted 2.3.P.2.2 Finished Pharmaceutical Product Submitted 2.3.P.2.3 Manufacturing process development Submitted 2.3.P.2.4 Container closure system Submitted 2.3.P.3 Manufacture Submitted 2.3.P.4 Control of excipients Submitted 2.3.P.5 Control of drug product Submitted 2.3.P.6 Reference standards and materials Submitted 2.3.P.7 Container closure system Submitted 2.3.P.8 Stability Submittted
	Comments
2.4	Non-Clinical Overview Not applicable
2.5	Clinical Overview Not applicable
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Not applicable
2.7	Clinical summary Not applicable

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 ***Submitted***

3.2 Body of Data ***Submitted***

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature *Submitted*
	3.2.S.1.2	Structure *Submitted*
	3.2.S.1.3	General properties *Submitted*
	Comments	
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) *Submitted*
	3.2.S.2.2	Description of Manufacturing Process and Process Controls *Submitted*
	3.2.S.2.3	Control of Materials *Not submitted*
	3.2.S.2.5	Process Validation and/or Evaluation *Not submitted*
	The firm has not submitted information of control of materials and Process validation or evaluation as specified in 3.2.S.2.3 and 3.2.S.2.5. The firm has claimed that this information is confidential hence it will be covered in closed part of DMF.	
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics *Submitted*
	3.2.S.3.2	Impurities *Submitted*

	Comments	
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification *Submitted*
		Comments
	3.2.S.4.2	Analytical procedures *Submitted*
		Comments
	3.2.S.4.3	Validation of analytical procedures *Submitted* (API that meets Pharmacopeia standards MUST provide verification of procedures) 1. Spectra and chromatograms for reference standards and test samples *(ref. std. can be located in 3.2.S.5)*
		Comments
	3.2.S.4.4	Batch analysis 1. Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) 2. Drug product manufacturer's certificate of analysis with API lot numbers
		Comments
	3.2.S.4.5	Justification of specifications *Submitted*
		Comments
3.2.S.5		REFERENCE STANDARDS OR MATERIALS (Do NOT refer to DMF) *Submitted*
		Comments
3.2.S.6		CONTAINER CLOSURE SYSTEMS *Submitted*
		Storage temperature of the API is between 2°C and 8°C.
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions *Submitted*
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment *Submitted*
	3.2.S.7.3	Stability Data *Submitted*
	Stability study completed up to 6 months at accelerated condition Viz. 25°C±2°C/ 60% ±5% RH and study completed up to 60 months at long term condition Viz.5°C±3°C.	

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT *Submitted* 1. Unit composition with indication of the function of the inactive ingredient(s) 2. Formulation	
	Comments	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance *Submitted*
		3.2.P.2.1.2 Excipients *Submitted*
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development *Submitted*
		Pharmaceutical Equivalence through Comparative Dissolution Profile *Not submitted*
		3.2.P.2.2.2 Overages *Not applicable*

		3.2.P.2.2.3 Physicochemical and Biological Properties *Submitted*
	3.2.P.2.3	Manufacturing Process Development *Submitted*
	3.2.P.2.4	Container Closure System *Submitted*
	3.2.P.2.5	Microbiological Attributes *Submitted*
	3.2.P.2.6	Compatibility *Submitted*
	The firm has submitted following: Stability of this product under various conditions has been monitored since compatibility study was not performed. Results from stability studies proved that active ingredients and packaging material are well suited, and do not exert any adverse impact on finished pharmaceutical product performance.	
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) *Submitted* 1. Name and full address(es) of the facility(ies) 2. Contact name, phone and fax numbers, email address
		Comments
	3.2.P.3.2	Batch formula *Submitted* Largest intended commercial batch size
		Comments
	3.2.P.3.3	Description of manufacturing process and process controls *Submitted* 1. Description of the manufacturing process and facility 2. Master production batch record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified 3. Master packaging records for intended marketing container(s)
		Comments
	3.2.P.3.4	Controls of critical steps and intermediates *Submitted*
		Comments
	3.2.P.3.5	Process validation and/or evaluation *Submitted*
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications *Submitted* 1. Testing specifications (including identification and characterization) 2. Supplier's COA (specifications and test results)
		Comments
	3.2.P.4.2	Analytical procedures *Submitted*
		Comments
	3.2.P.4.3	Validation of analytical procedures *Submitted*
		Comments
	3.2.P.4.4	Justification of specifications (as applicable) *Submitted*
	3.2.P.4.5	Excipients of Human or Animal Origin *Not applicable*
	3.2.P.4.6	Novel Excipients *Not applicable*
	Comments	
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) *Submitted*
		Comments

	3.2.P.5.2	Analytical procedures *Submitted* Comments
	3.2.P.5.3	Validation of analytical procedures *Not submitted* (if using Pharmacopoeial procedure, must provide verification of Pharmacopoeial procedure) You have not submitted validation of analytical procedures under control of drug product. It is very important to submit the data as specified in 3.2.P.5.3 especially where in-house method is developed.
	3.2.P.5.4	Batch analysis *Submitted* Certificates of Analysis for finished dosage form Comments
	3.2.P.5.5	Characterization of impurities *Submitted* All potential degradation products should be listed in a tabular format Comments
	3.2.P.5.6	Justification of specifications *Submitted* All potential degradation products should be listed in a tabular format Comments
3.2.P.6		Reference Standards or Materials *Not submitted* Comments
3.2.P.7		CONTAINER CLOSURE SYSTEM *Submitted* 1. Summary of container closure system 2. Component specifications and test data 3. Packaging configuration(s) and size(s) 4. Container/Closure Testing (recommended additional testing for all plastic) a. Solid orals: water permeation, light transmission b. Liquids: leachables, extractables, light transmission i. Injectables with rubber stoppers: extractables Information in various sections from 3.2.P.5.3 to 3.2.P.5.6 as well as 3.2.P.6 of module III is not submitted. Relevant information is required to be submitted.
3.2.P.8		STABILITY
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) *Submitted* • Stability protocol submitted • Expiration dating period for marketed packaging • Expiration dating period for bulk packaging (if applicable) Comments
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment *Submitted* Comments
	3.2.P.8.3	Stability *Submitted* The firm has submitted stability sheets for 6 months at accelerated conditions and 24 months at real time conditions for three batches of their already marketed product Es-Loprot 40mg IV Injection. However, the firm has not submitted raw data sheets and chromatograms.

Sr.#	Observations communicated	Response of the applicant
1.	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance is not submitted.	Submitted
2.	Quantitative composition of applied formulation contains Mannitol as mentioned	The firm has submitted revised formulation which does not contain mannitol. Accordingly

		in 2.3.P.1 and 3.3.P.1. However, reference product in MHRA does not mention such excipient. Justification / Clarification is required and also the compatibility studies of API with this excipient is required.	firm has submitted BMR and formulation for Esomeprazole 40mg injection. However, firm has just submitted template for BMR which does not contain actual formulation development.
	3.	You have not submitted validation of analytical procedures under control of drug product. It is very important to submit the data as specified in 3.2.P.5.3 especially where in-house method is developed.	Not submitted
	4.	Information in various sections from 3.2.P.5.3 to 3.2.P.5.6 as well as 3.2.P.6 of module III is not submitted. Relevant information is required to be submitted.	The firm has submitted Batch Analyses, Characterization of impurities and justification of finished product specifications.
	5.	You have not submitted supporting documents like raw data sheets and chromatograms against submitted stability summary sheets of applied formulation.	The firm has not submitted chromatograms of initial time point of applied formulation. The firm has submitted the data of already marketed product Es-Loprot 40mg IV Injection of M/s NabiQasim Industries Pvt. Ltd. karachi.
	6.	Commitments as specified in sections 1.5.15, 1.5.16, 1.5.17, 1.5.19 and protocols as specified in sections 1.5.21, 1.5.22 of module I are required to be submitted.	Submitted

Decision: Registration Board deferred the case for following observations:

- **Scientific justification for the relevance of previously submitted data in section 3.2.P against recently revised master formulation.**
- **Submisssion of validation of analytical procedures as specified in 3.2.P.5.3 of module III of CTD.**
- **Submission of chromatograms and raw data sheets of three batches of stability study data of initial time and details of reference standards and materials as specified in 3.2.P.6.**

496. **Application on CTD format**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy.No.7859 , dated 31-05-2019, 50,000/- dated 29-05-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s. Martin Dow Marker Limited, 7- Jail Road, Quetta.
	1.3.2	Name, address and contact details of Manufacturing site. M/s Nabiqasim Industries Pvt. Ltd., 17/24, Korangi industrial Area, Karachi
	1.3.3	Specify whether the Applicant is: d. □ Manufacturer e. □ Importer **f. □ Is involved in none of the above (contract giver)**
	1.3.4	Valid Drug Manufacturing License (DML) of manufacturer / Applicant or Drug Sale License, whichever is applicable. Copy of DML of manufacturing site is submitted.
	1.3.5	Evidence of approval of manufacturing facility / Approved Section from Licensing Authority Submitted
	1.3.6	List of already approved registered drugs in this section Not submitted

	1.3.7	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance Not submitted
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Not applicable
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: □ New Drug Product (NDP) □ **Generic Drug Product (GDP)**
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale □ Export sale □ **Domestic and Export sales**
	1.4.2	For imported products, please specify one of following: □ Finished Pharmaceutical Product Import □ Bulk Import and local repacking (specify status of bulk) □ Bulk Import Local Repacking for Export purpose only
	1.4.3	Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976. □ **Domestic Manufacturing** □ Export Purpose Only
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug.
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit **Each vial contains:** **Esomeprazole as sodium……40mg**
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance. **ESVIN INJECTION 40mg**
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1 vial; As per PRC
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Proton pump inhibitor (WHO ATC code= A02BC05)
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration Intravenous (IV)
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. Acireg of Barret hodgson Pakistan
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Nexium IV Injection (MHRA Approved)
	1.5.10	Dosage form of applied drug ESVIN Injection 40mg Sterile , freeze –dried white colored powder in 5ml vial contains: Esomeprazole sodium eq. to Esomeprazole……40mg
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & color scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Attached
	1.5.12	Description of Batch numbering system Not provided
	1.5.13	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form). Not provided

	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Attached
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. Submitted
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. Submitted
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc. Submitted
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer. Not applicable
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company. Not submitted
1.6		Miscellaneous Information Not submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: e. Name and address of API manufacturer. f. Approval of manufacturing facility of API by regulatory body of country and validity. g. Vendor qualification / audit is □ Document based □ Site inspection based h. Reason for point c.
		The firm has submitted copy of contract manufacturing agreement dated 12th March, 2019

		between M/s Martin Dow Limited, Karachi and Nabiqasim Industries Pvt. Ltd., Karachi.

MODULE 2: CTD SUMMARIES

2.1 Overall CTD Table of Content *Submitted*

2.2 CTD Introduction *Submitted*

2.3 Quality Overall Summary (QOS)* *Submitted*

(Detailed information regarding QOS may be found at the following link)
https://extranet.who.int/prequal/sites/default/files/documents/82%20Module%202.3%20QOS_March2017.docx

1.4 QUALITY OVERALL SUMMARY (QOS)

2.3	**2.3.T**	Drug substance (API)
	2.3.T.1	General information *Submitted*
	2.3.T.2	Manufacture *Submitted*
	2.3.T.3	Characterization *Submitted*
	2.3.T.4	Control of drugsubstance *Submitted*
	2.3.T.5	Reference standards *Submitted*
	2.3.T.6	Container closure system *Submitted*
	2.3.T.7	Stability *Submitted*
	Comments	
	2.3.Q	Drug product
	2.3.Q.1	Description and composition of the drug product Submitted
	2.3.Q.2	Pharmaceutical development Submitted
	2.3.Q.2.1	Components of the drug product
		2.3.P.2.1.1 Drug substance (API) Submitted
		2.3.P.2.1.2 Excipients Submitted
	2.3.Q.2.2	Finished Pharmaceutical Product Submitted
	2.3.Q.2.3	Manufacturing process development Submitted
	2.3.Q.2.4	Container closure system Submitted
	2.3.Q.3	Manufacture Submitted
	2.3.Q.4	Control of excipients Submitted
	2.3.Q.5	Control of drug product Submitted
	2.3.Q.6	Reference standards and materials Submitted
	2.3.Q.7	Container closure system Submitted
	2.3.Q.8	Stability Submittted
	Comments	
2.4	Non-Clinical Overview Not applicable	
2.5	Clinical Overview Not applicable	
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Not applicable	
2.7	Clinical summary Not applicable	

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 ***Submitted***

3.2 Body of Data ***Submitted***

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature *Submitted*
	3.2.S.1.2	Structure *Submitted*
	3.2.S.1.3	General properties *Submitted*
	Comments	
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) *Submitted*
	3.2.S.2.2	Description of Manufacturing Process and Process Controls *Submitted*
	3.2.S.2.3	Control of Materials *Not submitted*
	3.2.S.2.5	Process Validation and/or Evaluation *Not submitted*
	The firm has not submitted information of control of materials and Process validation or evaluation as specified in 3.2.S.2.3 and 3.2.S.2.5. The firm has claimed that this information is confidential hence it will be covered in closed part of DMF.	
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics *Submitted*
	3.2.S.3.2	Impurities *Submitted*
	Comments	
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification *Submitted*
		Comments
	3.2.S.4.2	Analytical procedures *Submitted*
		Comments
	3.2.S.4.3	Validation of analytical procedures *Submitted* (API that meets Pharmacopeia standards MUST provide verification of procedures) 2. Spectra and chromatograms for reference standards and test samples *(ref. std. can be located in 3.2.S.5)*
		Comments
	3.2.S.4.4	Batch analysis 3. Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) 4. Drug product manufacturer's certificate of analysis with API lot numbers
		Comments
	3.2.S.4.5	Justification of specifications *Submitted*
		Comments
3.2.S.5		REFERENCE STANDARDS OR MATERIALS (Do NOT refer to DMF) *Submitted*
		Comments
3.2.S.6		CONTAINER CLOSURE SYSTEMS *Submitted*
		Storage temperature of the API is between 2°C and 8°C.
3.2.S.7	STABILITY	

	3.2.S.7.1	Stability Summary and Conclusions *Submitted*
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment *Submitted*
	3.2.S.7.3	Stability Data *Submitted*
	Stability study completed up to 6 months at accelerated condition Viz. 25ºC±2ºC/ 60% ±5% RH and study completed up to 60 months at long term condition Viz.5ºC±3ºC.	

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT *Submitted* 3. Unit composition with indication of the function of the inactive ingredient(s) 4. Formulation	
	Comments	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance *Submitted*
		3.2.P.2.1.2 Excipients *Submitted*
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development *Submitted* Pharmaceutical Equivalence through Comparative Dissolution Profile *Not submitted*
		3.2.P.2.2.2 Overages *Not applicable*
		3.2.P.2.2.3 Physicochemical and Biological Properties *Submitted*
	3.2.P.2.3	Manufacturing Process Development *Submitted*
	3.2.P.2.4	Container Closure System *Submitted*
	3.2.P.2.5	Microbiological Attributes *Submitted*
	3.2.P.2.6	Compatibility *Submitted*
	The firm has submitted following: Stability of this product under various conditions has been monitored since compatibility study was not performed. Results from stability studies proved that active ingredients and packaging material are well suited, and do not exert any adverse impact on finished pharmaceutical product performance.	
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) *Submitted* 3. Name and full address(es) of the facility(ies) 4. Contact name, phone and fax numbers, email address
		Comments
	3.2.P.3.2	Batch formula *Submitted* Largest intended commercial batch size
		Comments
	3.2.P.3.3	Description of manufacturing process and process controls *Submitted* 4. Description of the manufacturing process and facility 5. Master production batch record(s) for largest intended production runs (no more than 10x pilot batch) with equipment specified 6. Master packaging records for intended marketing container(s)
		Comments
	3.2.P.3.4	Controls of critical steps and intermediates *Submitted*
		Comments
	3.2.P.3.5	Process validation and/or evaluation *Submitted*

3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications *Submitted* 3. Testing specifications (including identification and characterization) 4. Supplier's COA (specifications and test results)
		Comments
	3.2.P.4.2	Analytical procedures *Submitted*
		Comments
	3.2.P.4.3	Validation of analytical procedures *Submitted*
		Comments
	3.2.P.4.4	Justification of specifications (as applicable) *Submitted*
	3.2.P.4.5	Excipients of Human or Animal Origin *Not applicable*
	3.2.P.4.6	Novel Excipients *Not applicable*
	Comments	
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) *Submitted*
		Comments
	3.2.P.5.2	Analytical procedures *Submitted*
		Comments
	3.2.P.5.3	Validation of analytical procedures *Not submitted* (if using Pharmacopoeial procedure, must provide verification of Pharmacopoeial procedure)
		You have not submitted validation of analytical procedures under control of drug product. It is very important to submit the data as specified in 3.2.P.5.3 especially where in-house method is developed.
	3.2.P.5.4	Batch analysis *Submitted* Certificates of Analysis for finished dosage form
		Comments
	3.2.P.5.5	Characterization of impurities *Submitted* All potential degradation products should be listed in a tabular format
		Comments
	3.2.P.5.6	Justification of specifications *Submitted* All potential degradation products should be listed in a tabular format
		Comments
3.2.P.6		Reference Standards or Materials *Not submitted*
		Comments

3.2.P.7		CONTAINER CLOSURE SYSTEM *Submitted* 5. Summary of container closure system 6. Component specifications and test data 7. Packaging configuration(s) and size(s) 8. Container/Closure Testing (recommended additional testing for all plastic) a. Solid orals: water permeation, light transmission b. Liquids: leachables, extractables, light transmission i. Injectables with rubber stoppers: extractables
		Information in various sections from 3.2.P.5.3 to 3.2.P.5.6 as well as 3.2.P.6 of module III is not submitted. Relevant information is required to be submitted.
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) *Submitted* • Stability protocol submitted • Expiration dating period for marketed packaging • Expiration dating period for bulk packaging (if applicable)
		Comments
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment *Submitted*
		Comments
	3.2.P.8.3	Stability *Submitted*
		The firm has submitted stability sheets for 6 months at accelerated conditions and 24 months at real time conditions for three batches of their already marketed product Es-Loprot 40mg IV Injection. However, the firm has not submitted raw data sheets and chromatograms.

Sr.#	Observations communicated	Response of the applicant
1.	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance is not submitted.	Submitted
2.	Quantitative composition of applied formulation contains Mannitol as mentioned in 2.3.P.1 and 3.3.P.1. However, reference product in MHRA does not mention such excipient. Justification / Clarification is required and also the compatibility studies of API with this excipient is required.	The firm has submitted revised formulation which does not contain mannitol. Accordingly firm has submitted BMR and formulation for Esomeprazole 40mg injection. However, firm has just submitted template for BMR which does not contain actual formulation development.
3.	You have not submitted validation of analytical procedures under control of drug product. It is very important to submit the data as specified in 3.2.P.5.3 especially where in-house method is developed.	Not submitted
4.	Information in various sections from 3.2.P.5.3 to 3.2.P.5.6 as well as 3.2.P.6 of module III is not submitted. Relevant information is required to be submitted.	The firm has submitted Batch Analyses, Characterization of impurities and justification of finished product specifications.
5.	You have not submitted supporting documents like raw data sheets and chromatograms against submitted stability summary sheets of applied formulation.	The firm has not submitted chromatograms of initial time point of applied formulation. The firm has submitted the data of already marketed product Es-Loprot 40mg IV Injection of M/s NabiQasim Industries Pvt. Ltd. karachi.
6.	Commitments as specified in sections 1.5.15, 1.5.16, 1.5.17, 1.5.19 and protocols as specified in sections 1.5.21, 1.5.22 of module I are required to be submitted.	Submitted

Decision: Registration Board deferred the case for following observations:

- **Scientific justification for the relevance of previously submitted data in section 3.2.P against recently revised master formulation.**
- **Submisssion of validation of analytical procedures as specified in 3.2.P.5.3 of module III of CTD.**
- **Submission of chromatograms and raw data sheets of three batches of stability study data of initial time and details of reference standards and materials as specified in 3.2.P.6.**

Agenda of Evaluator PEC-X

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

a. New cases

497.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Sulfazon 500mg film coated Tablet
	Composition	Each tablet contains: Sulfasalazine……..500mg
	Diary No, Date of R & I & fee	Dy. No. 22440 dated 27-06-2018 Rs20,000/- 27-06-18
	Pharmacological Group	anti-rheumatic drug
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's, 20's & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Salazopyrin Tablets of M/s Pfizer (UK)
	Me-too status	Zalaz Tablets of M/s Mediate Pharmaceutical Karachi
	GMP Status	DML by way of formulation No. 000871 dated 13-9-2017.
	Remarks of the Evaluator	
	Decision: Approved	
498.	Name and address of Manufacturer / Applicant	M/s AAA Health pharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Exapro film coated Tablet 5mg
	Composition	Each tablet contains: Escitalopram as Oxalate……..5mg
	Diary No, Date of R & I & fee	Dy. No. 22444 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	antidepressant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	CIPRALEX® 5 mg film-coated tablets of M/s H. Lundbeck A/S Denmark
	Me-too status	Exapro of M/s CCL Pharmaceuticals (Pvt.) Ltd.
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved	
499.	Name and address of Manufacturer / Applicant	M/s AAA Health pharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Exapro film coated Tablet 10mg
	Composition	Each tablet contains: Escitalopram as Oxalate……..10mg
	Diary No, Date of R & I & fee	Dy. No. 22445 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	antidepressant
	Type of Form	Form-5
	Finished Product Specification	USP

	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	CIPRALEX® 10 mg film-coated tablets of M/s H. Lundbeck A/S Denmark
	Me-too status	Escital Tablets of M/s Nabiqasim Indus Karachi
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved	
500.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Prixen Tablet 500mg
	Composition	Each tablet contains: Naproxen as sodium……500mg
	Diary No, Date of R & I & fee	Dy. No. 22441 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	Alu-Alu pack of 2x10 tablets
	Approval Status of product in Reference Regulatory Authorities.	Naproxen Tablets BP 500mg (UK)
	Me-too status	PROXEN 500MG TAB of M/s (SYNTEX UK) alpha
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved	
501.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Fero-F chewable Tablet
	Composition	Each tablet contains: Iron polymaltose Eq to 100mg Iron Folic acid...0.35mg
	Diary No, Date of R & I & fee	Dy. No. 22436 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	Antianemic agent
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	Alu-Alu pack of 3x10's Tablets
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
502.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Zepix film coated Tablet 10mg
	Composition	Each tablet contains: Olanzapine……..10mg
	Diary No, Date of R & I & fee	Dy. No. 22435 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	antipsychotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10'S & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Olanzapine Accord 10 mg film-coated tablets (UK)
	Me-too status	Psyclan 10mg Tablet of M/s PharmEvo (Pvt) Ltd,

	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved	
503.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	4GAD 5mg Tablet
	Composition	Each tablet contains: Buspirone Hydrochloride USP…….5mg
	Diary No, Date of R & I & fee	Dy. No. 22439 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	antianxiety
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	3x10's
	Approval Status of product in Reference Regulatory Authorities.	BUSPIRONE 5mg TABLETS (UK)
	Me-too status	Busron Tablets Each Tablet Contains:- Buspirone Hcl.....5mg of M/s SJ & G Fazul Ellahie (Pvt) Ltd,
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved	
504.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Pregab 75mg capsule
	Composition	Each capsule contains: Pregabalin……..75mg
	Diary No, Date of R & I & fee	Dy. No. 22437 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	14's
	Approval Status of product in Reference Regulatory Authorities.	Alzain 75 mg Capsules, Hard (UK)
	Me-too status	Lyrica Capsule 75mg of M/s Pfizer Pakistan, Karachi
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
505.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories, Plot # 9A, St#N-5, National Industrial Zone, (RCCI) Rawat, Islamabad.
	Brand Name + Dosage Form + Strength	Soulpride 50mg Tablet
	Composition	Each tablet contains: Levosulpride……..50mg
	Diary No, Date of R & I & fee	Dy. No. 22438 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished Product Specification	Inovator's specification
	Pack Size & Demanded Price	20's & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	Sulprex Tablets 50mg of M/s Global Pharmaceuticals
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
506.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat,

		Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Ezocin 250mg capsule
	Composition	Each capsule contains: Azithromycin as dihydrate USP…….250mg
	Diary No, Date of R & I & fee	Dy. No. 22447 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	6'S
	Approval Status of product in Reference Regulatory Authorities.	Azithromycin 250 mg Capsules (Ireland)
	Me-too status	Azomax Capsules 250 mg of M/s Sandoz (Pakistan)
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved	
507.	Name and address of Manufacturer / Applicant	M/s AAA Healthpharmaceuticals Laboratories Plot # 9A, Street # N-5, National Industrial Zone, (RCCI) Rawat, Islamabad, Pakistan
	Brand Name + Dosage Form + Strength	Ezocin 200mg/5ml (dry powder for oral suspension)
	Composition	Each 5ml of suspension contains: Azithromycin as monohydrate…..200mg
	Diary No, Date of R & I & fee	Dy. No. 22446 dated 27-06-2018 Rs20,000/-Dated 27-06-18
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Azithromycin 200 mg/ 5 ml Powder for Oral Suspension (UK)
	Me-too status	Romycin Suspension 200mg of M/s Surge Lab.
	GMP Status	DML by way of formulation No. 000871 dated 13-09-2017.
	Remarks of the Evaluator	
	Decision: Approved	
508.	Name and address of Manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan Pvt. Ltd. Plot 50/28 Korangi Industrial Area Karachi
	Brand Name + Dosage Form + Strength	Acofen 50mg/200mcg Tablet
	Composition	Each tablet contains: Diclofenac Sodium (Enteric coated) …..50mg Misoprostol……..200mcg
	Diary No, Date of R & I & fee	Dy. No. 22695 dated 29-06-2018 Rs. 20,000/- 29-06-18
	Pharmacological Group	NSAID/Prostaglandins
	Type of Form	Form-5
	Finished Product Specification	Firm claims innovators specification's
	Pack Size & Demanded Price	2x10's & As per SRO
	International availability	Arthrotec 50 modified-release tablets (UK)
	Me-too status	Erwin 50mg of M/s Sami Pharmaceuticals (Pvt) Ltd, F-95 Off Hub River Road , SITe, Karachi
	GMP Status	GMP inspection dated 13-07-2017 & 16-07-2017 by inspectors which confirm the GMP compliance of the firm.
	Remarks of the Evaluator	
	Decision: Approved with USP specification.	
509.	Name and address of Manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan Pvt. Ltd. Plot 50/28 Korangi Industrial Area Karachi
	Brand Name + Dosage Form + Strength	Acofen 75mg/200mcg Tablet
	Composition	Each tablet contains: Diclofenac Sodium (Enteric coated) …..75mg Misoprostol……..200mcg
	Diary No, Date of R & I & fee	Dy. No. 22696 dated 29-06-2018 Rs. 20,000/- 29-06-18

	Pharmacological Group	NSAID/Prostaglandins
	Type of Form	Form-5
	Finished Product Specification	Firm claims innovators specification's
	Pack Size & Demanded Price	2x10's & As per SRO
	International availability	Arthrotec 75 modified-release tablets (UK)
	Me-too status	Cytopan-75 of M/s Getz
	GMP Status	GMP inspection dated 13-07-2017 & 16-07-2017 by inspectors which confirm the GMP compliance of the firm.
	Remarks of the Evaluator	
	Decision: Approved with USP specification.	
510.	Name and address of Manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan Pvt. Ltd. Plot 50/28 Korangi Industrial Area Karachi
	Brand Name + Dosage Form + Strength	Algene 20mg Capsule
	Composition	Each capsule contains: Piroxicam USP……20mg
	Diary No, Date of R & I & fee	Dy. No. 22696 dated 29-06-2018 Rs. 20,000/- 29-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x10's, 2x10's, 3x10's 4x10's & As per SRO
	International availability	FELDENE 20mg CAPSULES (UK)
	Me-too status	FELDENE 20MG CAP of M/s Pfizer
	GMP Status	GMP inspection dated 13-07-2017 & 16-07-2017 by inspectors which confirm the GMP compliance of the firm.
	Remarks of the Evaluator	Product monograph available in USP and firm claim innovator specifications
	Decision: Approved	
511.	Name and address of Manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan Pvt. Ltd. Plot 50/28 Korangi Industrial Area Karachi
	Brand Name + Dosage Form + Strength	Algene 0.5% w/v Gel
	Composition	Each capsule contains: Piroxicam ……0.5% w/v
	Diary No, Date of R & I & fee	Dy. No. 22699 dated 29-06-2018 Rs. 20,000/- 29-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	25g & As per SRO
	International availability	Feldene 0.5% w/w Gel (UK)
	Me-too status	FELDENE GEL 0.5% of M/s Pfizer
	GMP Status	GMP inspection dated 13-07-2017 & 16-07-2017 by inspectors which confirm the GMP compliance of the firm.
	Remarks of the Evaluator	Product monograph available in USP and firm claim innovator specifications
	Decision: Approved	
512.	Name and address of Manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan Pvt. Ltd. Plot 50/28 Korangi Industrial Area Karachi
	Brand Name + Dosage Form + Strength	Algene tablet 20mg
	Composition	Each tablet contains: Piroxicam as betacyclodextrin 191.2mg eq. to Piroxicam….20mg
	Diary No, Date of R & I & fee	Dy. No. 22698 dated 29-06-2018 Rs. 20,000/- 29-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	Firm claim innovator specifications
	Pack Size & Demanded Price	1x10's , 4x10's & As per SRO
	International availability	
	Me-too status	STEVAL TABLETS of M/s Stanley Pharma (Pvt) Ltd

	GMP Status	GMP inspection dated 13-07-2017 & 16-07-2017 by inspectors which confirm the GMP compliance of the firm.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
513.	Name and address of Manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan Pvt. Ltd. Plot 50/28 Korangi Industrial Area Karachi
	Brand Name + Dosage Form + Strength	H2Block Tablet
	Composition	Each tablet contains: Ranitidine (As HCl)……75mg
	Diary No, Date of R & I & fee	Dy. No. 22693 dated 29-06-2018 Rs. 20,000/- 29-06-18
	Pharmacological Group	H2 (histamine-2) blockers
	Type of Form	Form-5
	Finished Product Specification	B.P
	Pack Size & Demanded Price	10's & As per SRO
	International availability	Ranitidine 75mg film coated tablets (UK)
	Me-too status	Renata Tablet 75mg of M/s Platinum
	GMP Status	GMP inspection dated 13-07-2017 & 16-07-2017 by inspectors which confirm the GMP compliance of the firm.
	Remarks of the Evaluator	Reference product is film coated and firm apply plain tablet.
	Decision: Deferred for further deliberation for NDMA impurities	
514.	Name and address of Manufacturer / Applicant	M/s CKD Pharmaceuticals Pakistan Pvt. Ltd. Plot 50/28 Korangi Industrial Area Karachi
	Brand Name + Dosage Form + Strength	Incosta 1mg/ml Suspension
	Composition	Each 5ml contains: Domperidone …….5mg
	Diary No, Date of R & I & fee	Dy. No. 22694 dated 29-06-2018 Rs. 20,000/- 29-06-18
	Pharmacological Group	antiemetic
	Type of Form	Form-5
	Finished Product Specification	Firm claim innovator's specification
	Pack Size & Demanded Price	60ml, 120ml & As per SRO
	International availability	Domperidone 1mg/ml Oral Suspension (UK)
	Me-too status	Almedon Suspenion Each ml contains:- Domperidone...1mg of M/s Alina Combine Pakistan (Pvt) Ltd,
	GMP Status	GMP inspection dated 13-07-2017 & 16-07-2017 by inspectors which confirm the GMP compliance of the firm.
	Remarks of the Evaluator	
	Decision: Approved innovator's specification	
515.	Name and address of manufacturer/Applicant	M/s Welmark Pharmaceuticals Plot No. 122, Block-B, Phase-V, industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Candesar 16mg tablet
	Composition	Each tablet contains: Candesartan cilexetil ……16mg
	Diary No. Date of R& I & fee	Dy. No 28913 Dated 29-08-2018, Rs. 20,000/- 29-08-2018
	Pharmacological Group	angiotensin receptor blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan 16mg Tablets (UK)
	Me-too status	Advant Tablets 16mg of M/s Getz
	GMP status	DML by way of formulation dated 11-04-2012 renewal apply dated 10-02-2017 & Last GMP inspection dated 16th September 2017 by area FID Peshawar shows GMP compliant status of the firm.
	Remarks of the Evaluator	
	Decision: Approved	

516.	Name and address of manufacturer/Applicant	M/s Welmark Pharmaceuticals Plot No. 122, Block-B, Phase-v, industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Candesar 32mg tablet
	Composition	Each tablet contains: Candesartan cilexetil ……32mg
	Diary No. Date of R& I & fee	Dy. No 28914 Dated 29-08-2018, Rs. 20,000/- 29-08-2018
	Pharmacological Group	angiotensin receptor blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Candesartan 32mg Tablets (UK)
	Me-too status	Cansaar 32mg Tablets of M/s Pharmatec Pakistan Ltd
	GMP status	DML by way of formulation dated 11-04-2012 renewal apply dated 10-02-2017 & Last GMP inspection dated 16th September 2017 by area FID Peshawar shows GMP compliant status of the firm.
	Remarks of the Evaluator	
	Decision: Approved	
517.	Name and address of manufacturer/Applicant	M/s Welmark Pharmaceuticals Plot No. 122, Block-B, Phase-v, industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	Candesar HCT 16/12.5mg tablet
	Composition	Each tablet contains: Candesartan cilexetil ……16mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy. No 28915 Dated 29-08-2018, Rs. 20,000/- 29-08-2018
	Pharmacological Group	angiotensin receptor blocker/diuretic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**CANDESARTAN CILEXETIL AND HYDROCHLOROTHIAZIDE (USFDA)**
	Me-too status	Cansaar Plus Tablets of M/s M/s Pharmatec,
	GMP status	DML by way of formulation dated 11-04-2012 renewal apply dated 10-02-2017 & Last GMP inspection dated 16th September 2017 by area FID Peshawar shows GMP compliant status of the firm.
	Remarks of the Evaluator	
	Decision: Approved	
518.	Name and address of manufacturer/Applicant	M/s Welmark Pharmaceuticals Plot No. 122, Block-B, Phase-v, industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	VOXAT 200mg tablet
	Composition	Each film coated tablet contains: Flavoxate HCl……..200mg
	Diary No. Date of R& I & fee	Dy. No 28912 Dated 29-08-2018, Rs. 20,000/- 29-08-2018
	Pharmacological Group	Anticholinergic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Urispas 200 mg Film-coated Tablets (Uk)
	Me-too status	Flavus Tablets 200mg of M/s PDH Pharmaceutical (Pvt) Ltd, Lahore
	GMP status	DML by way of formulation dated 11-04-2012 renewal apply dated 10-02-2017 & Last GMP inspection dated 16th September 2017 by area FID Peshawar shows GMP compliant status of the firm.

	Remarks of the Evaluator	
	Decision: Approved	
519.	Name and address of manufacturer/Applicant	M/s Helix Pharma Pvt. Ltd. A-56, Manghopir Road S.I.T.E Karachi
	Brand Name +Dosage Form + Strength	Ridall Injection 30mg/ml
	Composition	Each ml contains: Ketorolac Tromethamine……30mg
	Diary No. Date of R& I & fee	Dy. No 22684 Dated 29-06-2018, Rs. 20,000/- 29-06-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ampoul x1ml
	Approval status of product in Reference Regulatory Authorities.	**KETOROLAC TROMETHAMINE 30MG/ML (USFDA)**
	Me-too status	Toralac Injection 30mg of M/s Vision Pharmaceuticals,
	GMP status	DML by way of formulation dated 24-04-2015 & GMP inspection dated 10-08-2017.
	Remarks of the Evaluator	
	Decision: Approved	
520.	Name and address of manufacturer/Applicant	M/s Helix Pharma Pvt. Ltd. A-56, Manghopir Road S.I.T.E Karachi
	Brand Name +Dosage Form + Strength	Ridall Tablets 10mg
	Composition	Each film coated tablet contains: Ketorolac Tromethamine……..10mg
	Diary No. Date of R& I & fee	Dy. No 22685 Dated 29-06-2018, Rs. 20,000/- 29-06-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**KETOROLAC TROMETHAMINE TABLET;ORAL (USFDA)**
	Me-too status	Toralac Injection 30mg of M/s Vision Pharmaceuticals,
	GMP status	DML by way of formulation dated 24-04-2015 & GMP inspection dated 10-08-2017.
	Remarks of the Evaluator	
	Decision: Approved	
521.	Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, FaisalabadRoad Bikhi, District Sheikhupura Pakistan
	Brand Name +Dosage Form + Strength	TEMSUNATE 30mg Injection
	Composition	Each vial contains: Artesunate ……30mg
	Diary No. Date of R& I & fee	Dy. No 28673 Dated 27-08-2018, Rs. 50,000/- 27-08-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification's
	Pack size & Demanded Price	1's & As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO approves injectable artesunate 30mg (WHO Approved formulation)
	Me-too status	Gen-M 30mg Injection of M/s Genix Pharma (Pvt) Ltd.
	GMP status	M/s Nabiqasim Industries Pvt. Ltd: DML by way of formulation 12-07-2014 & GMP inspection by inspectors dated 03-08-2017 shows the acceptable level of compliance of GMP M/s Surge Laboratories Pvt. Ltd:

		cGMP inspection dated 05-05-2019 shows good level of cGMP compliance of the firm.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
522.	Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, FaisalabadRoad Bikhi, District Sheikhupura Pakistan
	Brand Name +Dosage Form + Strength	TEMSUNATE 60mg Injection
	Composition	Each vial contains: Artesunate ……60mg
	Diary No. Date of R& I & fee	Dy. No 28674 Dated 27-08-2018, Rs. 50,000/- 27-08-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification's
	Pack size & Demanded Price	1's & As per PRC
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Gen-M 60mg Injection of M/s Genix Pharma (Pvt) Ltd.
	Remarks of the Evaluator	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
523.	Name and address of manufacturer/Applicant	M/s Nabiqasim Industries Pvt. Ltd. 17/24, Korangi Industrial Area, Karachi, Pakistan Manufacturer: M/s Surge Laboratories Pvt. Ltd., 10th Km, FaisalabadRoad Bikhi, District Sheikhupura Pakistan
	Brand Name +Dosage Form + Strength	TEMSUNATE 120mg Injection
	Composition	Each vial contains: Artesunate ……120mg
	Diary No. Date of R& I & fee	Dy. No 28675 Dated 27-08-2018, Rs. 50,000/- 27-08-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification's
	Pack size & Demanded Price	1's & As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO approves injectable artesunate 120mg (WHO Approved formulation)
	Me-too status	Gen-M 120mg Injection of M/s Genix Pharma (Pvt) Ltd.
	Remarks of the Evaluator	
	Decision: Approved with International pharmacopoeia specification	
524.	Name and address of manufacturer/Applicant	M/s Jenner Pharmaceuticals Pvt. Ltd. Address: Plot#2, M-2, Pharma zone 28th Km Lahore Sharaqpur Road distt Sheikhupura.
	Brand Name +Dosage Form + Strength	MECOMAL tablet 500mcg
	Composition	Each sugar-coated tablet contains: Mecobalamin…….500mcg
	Diary No. Date of R& I & fee	Dy. No 28677 Dated 27-08-2018, Rs. 20,000/- 20-08-2018
	Pharmacological Group	vitamin B12
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mecobalamin (PMDA)
	Me-too status	Anemovit Tablet of Pharmacare
	GMP status	DML by way of formulation dated 30-07-2015 & last GMP inspection report dated 06-11-2017 shows overall

		compliance status of manufacturer.
	Remarks of the Evaluator	Address of manufacturer on DML and form 5 is different and firm reply that: M/s Jenner Pharmaceuticals Pvt. Ltd. submit a letter dated 29-11-2017 to Deputy drug controller Licensing on subject typing mistake/correction in address on DML. **Address on DML:** Address: Plot#2, M-2, Pharma zone 28th Km Lahore Sharaqpur Road distt Sheikhupura. Requested Correct address: Plot#3, M-2, Pharmazone 26th Km Lahore Sharaqpur Road Sheikhupura.
	Decision: Approved. Registration Board further decided that Registration letter will be issued upon submission of revised DML with correct address.	
525.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt. Ltd. Plot # 150, 151 sector 24, Korangi Industrial Area Karachi, Pakistan
	Brand Name +Dosage Form + Strength	MITAMED Tablet
	Composition	Each film coated tablet contains: Mirtazapine……30mg
	Diary No. Date of R& I & fee	Dy. No 22679 Dated 29-06-2018, Rs. 20,000/- 29-06-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specification	B.P.
	Pack size & Demanded Price	1x20's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Mirtazapine 30 mg Film-coated Tablets (UK)
	Me-too status	Remeron Tablets 30mg of M/s Organon Pakistan (Pvt) Ltd,
	GMP status	GMP inspection dated 20-07-2018 by area FID show good compliance with GMP.
	Remarks of the Evaluator	
	Decision: Approved	
526.	Name and address of manufacturer/Applicant	M/s Reliance Pharma Plot No. 8 Street No. S-8 Industrial Estate, Rawat Islamabad
	Brand Name +Dosage Form + Strength	RELI-REFAX-200mg
	Composition	Each film coated tablet contains: Rifaximin……200mg
	Diary No. Date of R& I & fee	Dy. No 28538 Dated 24-08-2018, Rs. 20,000/- 24-08-2018
	Pharmacological Group	antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	XIFAXANTA 200 mg film-coated tablets of M/s Norgine Pharmaceuticals Ltd Moorhall Road, Harefield, Middlesex,
	Me-too status	Rifaxa 200mg Tablets of M/s Ferozesons Labs,
	GMP status	Panel inspection for revised layout plan & DML renewal dated 27th April 2018 showed the approval of revised laout plan and DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
527.	Name and address of manufacturer/Applicant	M/s Reliance Pharma Plot No. 8 Street No. S-8 Industrial Estate, Rawat Islamabad
	Brand Name +Dosage Form + Strength	RELI-REFAX-550mg
	Composition	Each film coated tablet contains: Rifaximin……550mg
	Diary No. Date of R& I & fee	Dy. No 28538 Dated 24-08-2018, Rs. 20,000/- 24-08-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	TARGAXAN 550 mg film-coated tablets, (UK)
	Me-too status	Xifaxa 550mg Tablet of M/s Brookes Pharmaceuticals,
	GMP status	Panel inspection for revised layout plan & DML renewal dated 27th April 2018 showed the approval of revised laout plan and DML.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
528.	Name and address of manufacturer/Applicant	M/s Linta Pharmaceuticals Pvt. Limited Plot No. 03, street no S-5, National Industrial Zone Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	ANTIFIB 250mg
	Composition	Each hard gelatin capsule contains: Tranexamic acid……250mg
	Diary No. Date of R& I & fee	Dy. No 28164 Dated 17-08-2018, Rs. 20,000/- 17-08-2018
	Pharmacological Group	Antifibrinolytic agent
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	tranex capsule, hard 250 mg Italy
	Me-too status	TRANXA CAPSULES 250MG of M/s AIR GREEN CO LTD
	GMP status	Last GMP certificate dated 10-07-2019 by QA & LT Division Islamabad shows cGMP compliance status of firm.
	Remarks of the Evaluator	
	Decision: Approved	
529.	Name and address of manufacturer/Applicant	M/s Linta Pharmaceuticals Pvt. Limited Plot No. 03, street no S-5, National Industrial Zone Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	ANTIFIB 500mg
	Composition	Each hard gelatin capsule contains: Tranexamic acid……500mg
	Diary No. Date of R& I & fee	Dy. No 28165 Dated 17-08-2018, Rs. 20,000/- 17-08-2018
	Pharmacological Group	Antifibrinolytic agent
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRANEX 500 mg capsule (Italy)
	Me-too status	RANSAMIN 500MG CAP of M/s Hilton
	Remarks of the Evaluator	
	Decision: Approved	
530.	Name and address of manufacturer/Applicant	M/s Linta Pharmaceuticals Pvt. Limited Plot No. 03, street no S-5, National Industrial Zone Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	BINA 250mg Tablets
	Composition	Each tablet contains: Terbinafine (as the hydrochloride salt)….250mg
	Diary No. Date of R& I & fee	Dy. No 28163 Dated 17-08-2018, Rs. 20,000/- 17-08-2018
	Pharmacological Group	antifungal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil® Tablets 250mg (UK)
	Me-too status	LAMISIL SANDOZ 250MG TAB Each tablet contains:- TERBINAFINE 250mg
	Remarks of the Evaluator	
	Decision: Approved	

531.	Name and address of manufacturer/Applicant	M/s Linta Pharmaceuticals Pvt. Limited Plot No. 03, street no S-5, National Industrial Zone Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	AZITA 250mg Tablets
	Composition	Each film coated tablets contains: Azithromycin……250mg
	Diary No. Date of R& I & fee	Dy. No 28162 Dated 17-08-2018, Rs. 20,000/- 17-08-2018
	Pharmacological Group	antibacterial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 250 mg film-coated tablets of M/s Sandoz Limited
	Me-too status	Plazo Tablets 250mg of M/s Platinum Pharmaceuticals (Pvt) Ltd, Karachi
	Remarks of the Evaluator	
	Decision: Approved	
532.	Name and address of manufacturer/Applicant	M/s Linta Pharmaceuticals Pvt. Limited Plot No. 03, street no S-5, National Industrial Zone Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	FINDA 120mg Tablet
	Composition	Each film coated tablet contains: Fexofenadine hydrochloride….120mg
	Diary No. Date of R& I & fee	Dy. No 28161 Dated 17-08-2018, Rs. 20,000/- 17-08-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fexofenadine Hydrochloride 120 mg film-coated tablets (UK)
	Me-too status	Telfast Tablets 120mg of M/s Hoechst Marion Roussel
	Remarks of the Evaluator	
	Decision: Approved	
533.	Name and address of Manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	SAFETAC OINTMENT 0.03%
	Composition	Each gram contains: Tacrolimus (as monohydrate) U.S.P……..0.3mg
	Diary No, Date of R & I & fee	Dy. No. 22626 dated 28-06-2018 Rs20,000/- 28-06-18
	Pharmacological Group	immunosuppressant
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	1x10gm & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Protopic 0.03% ointment (Denmark)
	Me-too status	Eczemus 0.03% Ointment of M/s Brookes Pharma
	GMP Status	DML by way of formulation dated 06-02-2015 Last inspection dated 07th April 2018 by panel of inspectors rated as Good.
	Remarks of the Evaluator	
	Decision: Registration Board approved registration of applied product as per Innovator's specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
534.	Name and address of Manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	SAFETAC OINTMENT 0.1%
	Composition	Each gram contains: Tacrolimus (as monohydrate) U.S.P……..1mg

	Diary No, Date of R & I & fee	Dy. No. 22627 dated 28-06-2018 Rs20,000/- 28-06-18
	Pharmacological Group	immunosuppressant
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	1x10gm & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Protopic 0.1% ointment (Denmark)
	Me-too status	Eczemus 0.1% Ointment of M/s Brookes Pharma
	GMP Status	DML by way of formulation dated 06-02-2015 Last inspection dated 07th April 2018 by panel of inspectors rated as Good.
	Remarks of the Evaluator	
	Decision: Registration Board approved registration of applied product as per Innovator's specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
535.	Name and address of Manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	Pyrodol tablet 20mg
	Composition	Each film coated tablet contains: Piroxicam betacyclodextrine eq. to Piroxicam…20mg
	Diary No, Date of R & I & fee	Dy. No. 22624 dated 28-06-2018 Rs20,000/- 28-06-18
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	& As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Piroxicam (Italy)
	Me-too status	STEVAL TABLETS of M/s Stanley Pharmaceuticals
	GMP Status	DML by way of formulation dated 06-02-2015 Last inspection dated 07th April 2018 by panel of inspectors rated as Good.
	Remarks of the Evaluator	Reference formulation is uncoated and firm apply film coated.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
536.	Name and address of Manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	SAFETAC OINTMENT 0.03%
	Composition	Each gram contains: Tacrolimus (as monohydrate) U.S.P……..0.3mg
	Diary No, Date of R & I & fee	Dy. No. 22626 dated 28-06-2018 Rs20,000/- 28-06-18
	Pharmacological Group	immunosuppressant
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	1x10gm & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Protopic 0.03% ointment (Denmark)
	Me-too status	Eczemus 0.03% Ointment of M/s Brookes Pharma
	GMP Status	DML by way of formulation dated 06-02-2015. Last inspection 07th April 2018 by panel of inspectors rated as Good.
	Remarks of the Evaluator	
	Decision: Registration Board approved registration of applied product as per Innovator's specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	

537.	Name and address of Manufacturer / Applicant	M/s Safe Pharmaceuticals Pvt. Ltd, Plot No. C-1-20, Sector 6-B, North Karachi Industrial Area, Karachi
	Brand Name + Dosage Form + Strength	SAFETAC OINTMENT 0.1%
	Composition	Each gram contains: Tacrolimus (as monohydrate) U.S.P……..1mg
	Diary No, Date of R & I & fee	Dy. No. 22627 dated 28-06-2018 Rs20,000/- 28-06-18
	Pharmacological Group	immunosuppressant
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	1x10gm & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Protopic 0.1% ointment (Denmark)
	Me-too status	Eczemus 0.1% Ointment of M/s Brookes Pharma
	GMP Status	DML by way of formulation dated 06-02-2015 Last inspection dated 07th April 2018 by panel of inspectors rated as Good.
	Remarks of the Evaluator	
	Decision: Registration Board approved registration of applied product as per Innovator's specifications in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.	
538.	Name and address of manufacturer/Applicant	M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	VIDAMET 50/500mg Tablet
	Composition	Each film coated tablet contains: Vildagliptin……..50mg Metformin Hydrochloride……500mg
	Diary No. Date of R& I & fee	Dy. No 28780 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification
	Pack size & Demanded Price	14'S, 30'S & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Galvus Met 50/500 film-coated tablet of M/s Novartis Pharma Germany
	Me-too status	Galvus Met 50/500mg Tablets of M/s Novartis
	GMP status	GMP compliance status (recommendation) by inspection dated 27th April 2017.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
539.	Name and address of manufacturer/Applicant	M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	VIDAMET 50/850mg Tablet
	Composition	Each film coated tablet contains: Vildagliptin……..50mg Metformin Hydrochloride……850mg
	Diary No. Date of R& I & fee	Dy. No 28781 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification
	Pack size & Demanded Price	14'S, 30'S & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Galvus Met 50/850 film-coated tablet of M/s Novartis Pharma Germany
	Me-too status	Galvus Met 50/850mg Tablets of M/s Novartis
	GMP status	GMP compliance status (recommendation) by inspection dated 27th April 2017.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	

540.	Name and address of manufacturer/Applicant	M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	VIDAMET 50/1000mg Tablet
	Composition	Each film coated tablet contains: Vildagliptin……..50mg Metformin Hydrochloride……1000mg
	Diary No. Date of R& I & fee	Dy. No 28782 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	Firm claim manufacturer specification
	Pack size & Demanded Price	14'S, 30'S & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Galvus Met 50/1000 film-coated tablet of M/s Novartis Pharma Germany
	Me-too status	Galvus Met 50/1000mg Tablets of M/s Novartis
	GMP status	GMP compliance status (recommendation) by inspection dated 27th April 2017.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
541.	Name and address of manufacturer/Applicant	M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	OLANTINE 3/25mg Capsule
	Composition	Each capsule contains: Olanzapine……3mg Fluoxetine as Hydrochloride…….25mg
	Diary No. Date of R& I & fee	Dy. No 28777 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Antipsychotic/ antidepressant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**SYMBYAX (USFDA)**
	Me-too status	Co-Depricap 3/25 Capsule of M/s Nabiqasim Industries
	GMP status	GMP compliance status (recommendation) by inspection dated 27th April 2017.
	Remarks of the Evaluator	
	Decision: Approved	
542.	Name and address of manufacturer/Applicant	M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	OLANTINE 6/25mg Capsule
	Composition	Each capsule contains: Olanzapine……6mg Fluoxetine as Hydrochloride…….25mg
	Diary No. Date of R& I & fee	Dy. No 28778 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Antipsychotic/ antidepressant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**SYMBYAX (USFDA)**
	Me-too status	Co-Depricap 6/25 Capsule of M/s Nabiqasim Industries
	GMP status	GMP compliance status (recommendation) by inspection dated 27th April 2017.
	Remarks of the Evaluator	
	Decision: Approved	
543.	Name and address of manufacturer/Applicant	M/s EPHARM Laboratories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi

	Brand Name +Dosage Form + Strength	OLANTINE 12/25mg Capsule
	Composition	Each capsule contains: Olanzapine……12mg Fluoxetine as Hydrochloride…….25mg
	Diary No. Date of R& I & fee	Dy. No 28779 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Antipsychotic/ antidepressant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**SYMBYAX (USFDA)**
	Me-too status	Olanco Capsules of M/s Genome Pharmaceuticals (Pvt,) Ltd.
	GMP status	GMP compliance status (recommendation) by inspection dated 27th April 2017.
	Remarks of the Evaluator	
	Decision: Approved	
544.	Name and address of manufacturer/Applicant	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore-Gujranwala Road Khori District Sheikhupura
	Brand Name +Dosage Form + Strength	Calcium chloride Injection
	Composition	Each 10ml contains: Calcium chloride $2H_2O$……..2000mg
	Diary No. Date of R& I & fee	Dy. No 28768 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10mlx10Ampoules, 10mlx5 Ampoules & As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	CALCIUM CHLORIDE INJ of M/s LC&PW Lahore
	GMP status	DML by way of formulation dated 02-12-2014 & GMP compliance inspection dated 21-02-2018
	Remarks of the Evaluator	Inter?
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
545.	Name and address of manufacturer/Applicant	M/s Bajwa Pharmaceuticals Pvt. Ltd. 36-Km, Lahore-Gujranwala Road Khori District Sheikhupura
	Brand Name +Dosage Form + Strength	Verapamil HCl Injection
	Composition	Each 2ml contains: Verapamil HCl……5mg
	Diary No. Date of R& I & fee	Dy. No 28769 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	calcium channel blockers
	Type of Form	Form-5
	Finished product Specification	B.P.
	Pack size & Demanded Price	5 Ampoule / Rs. 2500/-
	Approval status of product in Reference Regulatory Authorities.	Verapamil Hydrochloride BP 2.5 mg/m (UK)
	Me-too status	Vepamil Injection of M/s Searle IV Solutions (Pvt) Ltd.
	GMP status	DML by way of formulation dated 02-12-2014 & GMP compliance inspection dated 21-02-2018
	Remarks of the Evaluator	
	Decision: Approved.	
546.	Name and address of manufacturer/Applicant	M/s Nova Med Pharmaceuticals Pvt. Ltd. 28-km Ferozepur Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	URISAT TABLET
	Composition	Each film coated tablet contains: Febuxostat……..40mg

	Diary No. Date of R& I & fee	Dy. No 28775 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Anti-gout
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	2x10's, 3x10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**FEBUXOSTAT (USFDA)**
	Me-too status	Zurig 40mg Tablet of M/s Getz
	GMP status	DML by way of formulation 08-04-2016 & GMP inspection by inspectors dated 5th & 27th December 2017 shows the good compliance of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
547.	Name and address of manufacturer/Applicant	M/s Nova Med Pharmaceuticals Pvt. Ltd. 28-km Ferozepur Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	URISAT TABLET
	Composition	Each film coated tablet contains: Febuxostat……..80mg
	Diary No. Date of R& I & fee	Dy. No 28776 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Anti-gout
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	2x10's, 3x10's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**FEBUXOSTAT (USFDA)**
	Me-too status	Zurig 80mg Tablet of M/s Getz
	GMP status	DML by way of formulation 08-04-2016 & GMP inspection by inspectors dated 5th & 27th December 2017 shows the good compliance of GMP.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
548.	Name and address of manufacturer/Applicant	M/s Nova Med Pharmaceuticals Pvt. Ltd. 28-km Ferozepur Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	T-Zole 10% Vaginal Cream
	Composition	Each tube contains: Clotrimazole……10% w/w
	Diary No. Date of R& I & fee	Dy. No 28774 Dated 28-08-2018, Rs. 20,000/- 28-08-2018
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Canesten 10% w/w Vaginal Cream of M/s Bayer plc 400 South Oak Way
	Me-too status	Gynosporin 10% Vaginal Cream of M/s Nabiqasim Industries,
	GMP status	DML by way of formulation 08-04-2016 & GMP inspection by inspectors dated 5th & 27th December 2017 shows the good compliance of GMP.
	Remarks of the Evaluator	
	Decision: Approved	

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

b. Deferred cases

549.	Name and Address of the Manufacturer/ Applicant	Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage form + Strength	TIOCARDIS-AM 40mg/5mg Tablet
	Composition	Each bilayered tablet contains: Amlodipine (as amlodipine besylate)…….…… 5mg Telmisartan……..40mg
	Diary No. Date of R&I & Fee	Dy: 31244, 18-09-2018; Fee in PKR: 20,000/- 14-09-2018.
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP
	Packed Size and Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/40mg by M/s Mylan Pharms Inc. (USFDA Approved).
	Me-too Status	Amtas 5mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd. Karachi. (Reg. # 066943)
	GMP Status	Latest GMP inspection: 09-02-2018. Conclusion: "Overall GMP of the firm is rated as GOOD."
	Remarks of Evaluator	Availability of Bilayered compression tablet facility have to confirmed?
	Decision of 286th meeting of Registration Board: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet bi-layered machine. Firm has submitted the GMP inspection report dated 09-07-2019 showing the installation of Bi-layered tablets Press compression machines. **Decision: Approved**	
550.	Name and Address of the Manufacturer/ Applicant	Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage form + Strength	TIOCARDIS-AM 40mg/10mg Tablet
	Composition	Each bilayered tablet contains: Amlodipine (as amlodipine besylate)…….…... 10mg Telmisartan……..40mg
	Diary No. Date of R&I & Fee	Dy: 31245, 18-09-2018; Fee in PKR: 20,000/- 14-09-2018.
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP
	Packed Size and Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities	Telmisartan and Amlodipine Tablets 10mg/40mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too Status	Amtas 10mg + 40mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 066945)
	GMP Status	Latest GMP inspection: 09-02-2018. Conclusion: "Overall GMP of the firm is rated as GOOD."
	Remarks of Evaluator	Status of Availability of Bilayered compression tablet facility have to confirmed?
	Decision of 286th meeting of Registration Board: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet bi-layered machine. Firm has submitted the GMP inspection report dated 09-07-2019 showing the installation of Bi-layered tablets Press compression machines. **Decision: Approved**	
551.	Name and Address of the Manufacturer/ Applicant	Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage form + Strength	TIOCARDIS-AM 80mg/5mg Tablet

	Composition	Each bilayered tablet contains: Amlodipine (as amlodipine besylate)……..... ..5mg Telmisartan……..80mg
	Diary No. Date of R&I & Fee	Dy: 31246, 18-09-2018; Fee in PKR: 20,000/- 14-09-2018.
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP
	Packed Size and Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities	Telmisartan and Amlodipine Tablets 5mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too Status	Amtas 5mg + 80mg Tablet of M/s Getz Pharma (Pvt) Ltd (Reg. # 0669434)
	GMP Status	Latest GMP inspection: 09-02-2018. Conclusion: "Overall GMP of the firm is rated as GOOD."
	Remarks of Evaluator	Status of Availability of Bilayered compression tablet facility have to confirmed?
	Decision of 286th meeting of Registration Board: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet bi-layered machine. Firm has submitted the GMP inspection report dated 09-07-2019 showing the installation of Bi-layered tablets Press compression machines. **Decision: Approved**	
552.	Name and Address of the Manufacturer/ Applicant	Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage form + Strength	TIOCARDIS-AM 80mg/10mg Tablet
	Composition	Each bilayered tablet contains: Amlodipine (as amlodipine besylate)……..... 10mg Telmisartan……..80mg
	Diary No. Date of R&I & Fee	Dy: 31247, 18-09-2018; Fee in PKR: 20,000/- 14-09-2018.
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP
	Packed Size and Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities	Telmisartan and Amlodipine Tablets 10mg/80mg by M/s Mylan Pharms INC (USFDA Approved)
	Me-too Status	Misar-Am 80/10mg Tablet of M/s Highnoon Pharma (Pvt) Ltd (Reg. # 069151)
	GMP Status	Latest GMP inspection: 09-02-2018. Conclusion: "Overall GMP of the firm is rated as GOOD."
	Remarks of Evaluator	Status of Availability of Bilayered compression tablet facility have to confirmed?
	Decision of 286th meeting of Registration Board: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet bi-layered machine. Firm has submitted the GMP inspection report dated 09-07-2019 showing the installation of Bi-layered tablets Press compression machines. **Decision: Approved**	
553.	Name and Address of the Manufacturer/ Applicant	Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage form + Strength	CO-TIOCARDIS 40mg/12.5mg Tablet
	Composition	Each bilayered tablet contains: Hydrochlorthiazide……..... 12.5mg Telmisartan……..40mg
	Diary No. Date of R&I & Fee	Dy: 31248, 18-09-2018; Fee in PKR: 20,000/- 14-09-2018.
	Pharmacological Group	Anti-Hypertensive

	Type of Form	Form-5
	Finished Product Specification	USP
	Packed Size and Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities	Micardis HCT. (USFDA Approved)
	Me-too Status	Misar-H 40/12.5 Tablets of 'Highnoon Laboratories, lahore.. (Reg. # 065688)
	GMP Status	Latest GMP inspection: 09-02-2018. Conclusion: "Overall GMP of the firm is rated as GOOD."
	Remarks of Evaluator	Status of Availability of Bilayered compression tablet facility have to confirmed?
	Decision of 286th meeting of Registration Board: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet bi-layered machine. Firm has submitted the GMP inspection report dated 09-07-2019 showing the installation of Bi-layered tablets Press compression machines. **Decision: Approved**	
554.	Name and Address of the Manufacturer/ Applicant	Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage form + Strength	CO-TIOCARDIS 80mg/25mg Tablet
	Composition	Each bilayered tablet contains: Hydrochlorthiazide…….…….... 25mg Telmisartan……..80mg
	Diary No. Date of R&I & Fee	Dy: 31250, 18-09-2018; Fee in PKR: 20,000/- 14-09-2018.
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP
	Packed Size and Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities	Micardis HCT. (USFDA Approved)
	Me-too Status	Misar-H 40/12.5 Tablets of 'Highnoon Laboratories, lahore.. (Reg. # 065684)
	GMP Status	Latest GMP inspection: 09-02-2018. Conclusion: "Overall GMP of the firm is rated as GOOD."
	Remarks of Evaluator	Status of Availability of Bilayered compression tablet facility have to confirmed?
	Decision of 286th meeting of Registration Board: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet bi-layered machine. Firm has submitted the GMP inspection report dated 09-07-2019 showing the installation of Bi-layered tablets Press compression machines. **Decision: Approved**	
555.	Name and Address of the Manufacturer/ Applicant	Atco Laboratories Limited, B-18, S.I.T.E., Karachi.
	Brand Name + Dosage form + Strength	CO-TIOCARDIS 80mg/12.5mg Tablet
	Composition	Each bilayered tablet contains: Hydrochlorthiazide…….…….... 12.5mg Telmisartan……..80mg
	Diary No. Date of R&I & Fee	Dy: 31249, 18-09-2018; Fee in PKR: 20,000/- 14-09-2018.
	Pharmacological Group	Anti-Hypertensive
	Type of Form	Form-5
	Finished Product Specification	USP
	Packed Size and Demanded Price	As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities	Micardis HCT. (USFDA Approved)

	Me-too Status	Misar-H 40/12.5 Tablets of 'Highnoon Laboratories, lahore.. (Reg. # 065685)
	GMP Status	Latest GMP inspection: 09-02-2018. Conclusion: "Overall GMP of the firm is rated as GOOD."
	Remarks of Evaluator	Status of Availability of Bilayered compression tablet facility have to confirmed
	Decision of 286th meeting of Registration Board: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet bi-layered machine. Firm has submitted the GMP inspection report dated 09-07-2019 showing the installation of Bi-layered tablets Press compression machines. **Decision: Approved**	

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

a. New Cases

556.	Name and address of manufacturer /Applicant	M/s. Elko Organization (Pvt) Ltd, Plot No. 27 & 28, sector 12-B North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Link injection IM/IV
	Diary No. Date of R& I & fee	Dy.No.24288, 12-6-7, Rs. 15,000/- (12, July 2018), 5000 (12 July 2018)
	Composition	Each ml contains: - Buserelin acetate…0.0042mg eq to 0.004mg Buserelin
	Pharmacological Group	Gonadotropin releasing hormone analogues
	Type of Form	Form-5
	Finished Product Specification	In house
	Pack size & Demanded Price	5ml; Decontrolled
	Me-too status	Conceptal Injection of Star Laboratories (Pvt) Ltd, Lahore (Reg # 058939).
	GMP status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today
	Remarks of the Evaluator:	
Decision: Approved with innovator's specification		

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

b. Deferred Cases

557.	Name and address of manufacturer /Applicant	MYLAB Pvt. Ltd, Khankah Shariff Bahawalpur.
	Brand Name +Dosage Form + Strength	Duralin Complex Injection
	Composition	Each ml Contains: Oxytetracycline HCL……10mg Dexamethasone as Sodium Phosphate……..0.5mg
	Diary No. Date of R& I & fee	Dy. No 13038, dated 06-04-2018 Rs.20,000/- Dated 27-02-2018
	Pharmacological Group	Anti-Inflammatory-Anti biotic combination
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10 ml Clear Glass vial, 20 ml Clear Glass vial, 30 ml Clear Glass vial, 40 ml Clear Glass vial, 50 ml Clear Glass vial, Decontrolled.
	Me-too status	OXY COMPLEX INJECTION 150MG
	GMP status	As recorded for above application
	Remarks of the Evaluator	The Firm was asked to clarify Me-too and formulation, firm

		in reply submitted revised formulation from 100mg to 10mg as per Me-toowithout submission of fee.
Decision of 289th meeting of RB: Deferred for submission of differential fee for revised formulation i.e. Rs.5000/- Now the firm has submitted the fee Rs. 5000/- **Decision: Registration Board referred the case regarding the composition to the expert working group on veterinary drugs.**		

Case No. 06: Registration applications of import cases

a. New Cases (Human)

558. **APPLICATION ON FORM 5-F**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 14162 Dated 05-08-2019 (Rs. 50,000/- Dated 05-08-2019) Dy. No 14163 Dated 05-08-2019 (Rs. 50,000/- Dated 05-08-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Genetics Pharmaceuticals pvt. Ltd. Ltd 539-A, Sundar Industrial Estate, Raiwind Road Lahore
	1.3.2	Name, address and contact details of Manufacturing site. M/s Kwality Pharmaceuticals Ltd Vill. Nag Kalan, Majitha Road, Amritsar-143601 India
	1.3.3	Specify whether the Applicant is: Importer
	1.3.4	**Drug Sale License** No: 0011000 0000696 valid upto 12-December-2019
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Risperidone Extended-release Microspheres for injection 25mg/vial Risperidone Extended-release Microspheres for injection 37.5mg/vial
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Risperidone ……...25mg 2nd Strength Each vial contains: Risperidone ……...37.5mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Vepridone (Risperidone Prolonged Release Powder for Injection)
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's

	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Antipsychotic
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration IM
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. RISPERDAL CONSTA 25 mg powder and solvent for prolonged-release suspension for injection (UK) RISPERDAL CONSTA 37.5 mg powder and solvent for prolonged-release suspension for injection
	1.5.10	Dosage form of applied drug Powder for Injection
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. **Submitted**
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the

		Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. M/s Jubilant Lifesciences Limited Block 133, village samlaya, Taluka Savli, Distt. Vadodara-391520, Gujrat India
	• Copy of Legalized, Notarized CoPP for Risperidone Pronged Release Powder for Injection 25mg (Certificate#. 4892/2019) dated 03-04-2019 issued by Commissionerate, FDA Punjab India declaring the free sale of applied product and GMP compliant status of the manufacturer i.e M/s Kwality Pharmaceuticals Ltd Vill. Nag Kalan, Majitha Road, Amritsar-143601 India Certificate valid upto: 11/03/2021 • Copy of Legalized, Notarized CoPP for Risperidone Pronged Release Powder for Injection 37.5mg (Certificate#. 4893/2019) dated 03-04-2019 issued by Commissionerate, FDA Punjab India declaring the free sale of applied product and GMP compliant status of the manufacturer i.e M/s Kwality Pharmaceuticals Ltd Vill. Nag Kalan, Majitha Road, Amritsar-143601 India Certificate valid upto: 11/03/2021 **(Firm has submitted in reply of photocopy of CoPP legalized and Notarized"The Pakistan Embassy & notary public in India do not attest the original CoPP, they only attest the photocopy")** • Sole agency agreement Between Product License Holder M/s Kwality Pharmaceuticals Ltd Vill. Nag Kalan, Majitha Road, Amritsar-143601 India and Importer M/s Genetics Pharmaceuticals pvt. Ltd. Ltd 539-A, Sundar Industrial Estate, Raiwind Road Lahore dated 28-12-2018	

MODULE 2: CTD SUMMARIES

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

QUALITY OVERALL SUMMARY (QOS)

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

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

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

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

3.2.P DRUG PRODUCT

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

	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Not applicable
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(i.e.) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
	3.2.P.4.5	Excipients of human or animal origin Submitted
	3.2.P.4.6	Novel excipients Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	**Characterization of impurities Not submitted** **Firm submit substance related impurities and claim that "we confirm impurities in finished product will be well within the limit.**
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 36 months at 30 ± 2^0C,75%RH and 6 months at 40^0C±75%RH for three batches for applied strengths separately.

Decision: Deferred due to following:

i. **Importable from India as per IPO**
ii. **Provided photocopy of CoPP legalized not original.**
iii. **Submissionof relevant informationagainst section 3.2.P.5.5 (Characterization of Impurities.)**

559. **APPLICATION ON FORM 5-F**

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 8161 Dated 12-06-2019 PKR: 100,000/- dated 12-06-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Pfizer Pakistan Limited (Formerly Parke davis & co. Ltd.) B-2, S.I.T.E, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. **Bulk Filled vial:** M/s Gland Pharma Limited, Unit-II, Block C, Phase I, Visakhapatnam Special Economic Zone (VSEZ), Duvvada, 530049 Visakhapatnam, India **Secondary Packaging (including Pakistan specific vial labelling) & Release Site:** M/s Pfizer Pakistan Limited B-2, S.I.T.E., Karachi Marketing authorization holder: M/s Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium
	1.3.3	Specify whether the Applicant is: Importer will import bulk filled vial from Belgium
	1.3.4	**Drug Sale License** Drug License by Way of Wholesale No. 10578 valid upto 17-Feb-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: □ Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Bortezomib
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Bortezomib (As mannitol boronic ester) …….3.5mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Bortezomib
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's single use vial & As per SRO
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anticancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration Solution for injection
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price Bortezomib Pharmidea 3.5mg Powder For Solution For Iv Injection (093929)
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries.

		The status in reference regulatory authorities is mandatory to mention. **BORTEZOMIB 3.5MG/VIAL (USFDA)**
	1.5.10	Dosage form of applied drug Powder for solution for injection
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. Submitted
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. Submitted
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. Submitted
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity. M/s Laurus Labs Limited Plot No. 21, Jawaharlal Nehru Pharma City, Parawada,

		Visakhapatnam, Andhra Pradesh, India
	• Original Legalized CoPP (Certificate#. 03/19/128940) dated 27-09-2018 by **European Medicine Agency** 30 Churchill Place, Canary Wharf, London E14 5EU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer i.e M/s Gland Pharma Limited, Unit-II, Block C, Phase I, Visakhapatnam Special Economic Zone (VSEZ), Duvvada, 530049 Visakhapatnam, India	

MODULE 2: CTD SUMMARIES

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

QUALITY OVERALL SUMMARY (QOS)

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

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

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted

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

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	

	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 36 months at 30 ± 2^0C, 75±5%RH and 6 months at 40^0C±75%RH for three batches.

Decision: Deferred for following:

i. **Clarification regarding final QC release site.**

ii. **Evidence of facility for secondary packaging (including Pakistan specific vial product) & release site for anti-cancer solution for injection dosage form.**

b. Deferred cases

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

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 5417 Dated 27-05-2019 PKR: 50,000/- dated 07-05-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Eli Lilly Pakistan Private Limited 5-A, 5th Office Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e- Faisal, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. M/s Lilly del Caribe Inc., 12.6 km 65th Infantry road, Carolina, Puerto Rico 00985 (also Quality control). Site responsible for batch release, QC, Primary & Secondary packaging: Lilly, S.A., Avda. De la Industria, 30, 28108 Alcobendas, Madrid, Spain Marketing Authorization Holder: M/s Eli Lilly Nederland B.V., Panendorpseweg 83, 3528BJ Utrecht, the Netherlands.
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	**Drug Sale License** License to Sell Drugs by way of Wholesale valid till: 02-01-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: □ **New Drug Product (NDP)**
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Abemaciclib

	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each film coated tablet contains: Abemaciclib……..50mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Verzenio 50mg Film coated Tablets
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. Aluminium /aluminium perforated Unit dose blisters of 28x1 film coated tablets
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anti-Cancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house (Innovator)
	1.5.7	Route of administration Oral
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Spain, Netherland…
	1.5.10	Dosage form of applied drug Tablet
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined.
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant.
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals.

	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity.
	• Original Legalized CoPP of Verzenio 50mg Film coated Tablets (Certificate#. 02/19/128773) dated 18-02-2019 by **European Medicine Agency** 30 Churchill Place, Canary Wharf, London E14 5EU, UK declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Lilly del Caribe Inc., 12.6 km 65th Infantry road, Carolina, Puerto Rico 00985 (also Quality control). Site responsible for batch release, QC, Primary & Secondary packaging: Lilly, S.A., Avda. De la Industria, 30, 28108 Alcobendas, Madrid, Spain	

MODULE 2: CTD SUMMARIES

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

QUALITY OVERALL SUMMARY (QOS)

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

2.7	Clinical summary Submitted

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

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

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	

	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Verzenio 50mg Film coated Tablets Firm has submitted three batches long term stability data 2 batches 18 months and one batch 12 months at 30^0C±75%RH and 6 months at 40^0C±75%RH for three batches.
4.P		(Non-clinical / Safety) Submitted
5.P		(Clinical / Efficacy) Submitted

Decision of 290th meeting of RB:
Deferred for submission of stability data of three batches for both accelerated and long-term stability studies at Zone IV-a conditions

Now firm has submitted 24 months stability data of applied three strengths (three batches long term stability data at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches)
Decision: Keeping in view valid legalized CoPP and approval of EMA (Reference Regulatory Authority); Registration Board approved the product as per current Import Policy for Finished Drugs.

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

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 5418 Dated 27-05-2019 PKR: 50,000/- dated 07-05-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Eli Lilly Pakistan Private Limited 5-A, 5th Office Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e- Faisal, Karachi
	1.3.2	Name, address and contact details of Manufacturing site.

		M/s Lilly del Caribe Inc., 12.6 km 65th Infantry road, Carolina, Puerto Rico 00985 (also Quality control). Site responsible for batch release, QC, Primary & Secondary packaging: Lilly, S.A., Avda. De la Industria, 30, 28108 Alcobendas, Madrid, Spain Marketing Authorization Holder: M/s Eli Lilly Nederland B.V., Panendorpseweg 83, 3528BJ Utrecht, the Netherlands.
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	**Drug Sale License** License to Sell Drugs by way of Wholesale valid till: 02-01-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: □ **New Drug Product (NDP)**
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Abemaciclib
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each film coated tablet contains: Abemaciclib……..100mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Verzenio 100mg Film coated Tablets
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. Aluminium /aluminium perforated Unit dose blisters of 28x1 film coated tablets
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anti-Cancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house (Innovator)
	1.5.7	Route of administration Oral
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Spain, Netherland…
	1.5.10	Dosage form of applied drug Tablet
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & Adverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information

		(which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard.
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined.
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant.
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals.
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity.
	• Original Legalized CoPP of Verzenio 100mg Film coated Tablets (Certificate#. 02/19/128785) dated 18-02-2019 by **European Medicine Agency** 30 Churchill Place, Canary Wharf, London E14 5EU, UK declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Lilly del Caribe Inc., 12.6 km 65th Infantry road, Carolina, Puerto Rico 00985 (also Quality control). Site responsible for batch release, QC, Primary & Secondary packaging: Lilly, S.A., Avda. De la Industria, 30, 28108 Alcobendas, Madrid, Spain	

MODULE 2: CTD SUMMARIES

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

QUALITY OVERALL SUMMARY (QOS)

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

MODULE 3: QUALITY

3.1 Table of Contents of Module 3 Submitted

3.2 Body of Data Submitted

3.2.S DRUG SUBSTANCE (API)

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

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

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted
3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted

	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Verzenio 100mg Film coated Tablets Firm has submitted two batches long term stability data one batch 18 months and one batch 12 months at 30^0C±75%RH and two batches 6 months at 40^0C±75%RH.
4.P		(Non-clinical / Safety) Submitted
5.P		(Clinical / Efficacy) Submitted

Decision of 290th meeting of RB:
Deferred for submission of stability data of three batches for both accelerated and long term stability studies at Zone IV-a conditions

Now firm has submitted 24 months stability data of applied three strengths (three batches long term stability data at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches)
Decision: Keeping in view valid legalized CoPP and approval of EMA (Reference Regulatory Authority); Registration Board approved the product as per Import Policy for Finished Drugs.

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

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 5419 Dated 27-05-2019 PKR: 50,000/- dated 07-05-2019
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Eli Lilly Pakistan Private Limited 5-A, 5th Office Floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e- Faisal, Karachi
	1.3.2	Name, address and contact details of Manufacturing site. M/s Lilly del Caribe Inc., 12.6 km 65th Infantry road, Carolina, Puerto Rico 00985 (also Quality control). Site responsible for batch release, QC, Primary & Secondary packaging: Lilly, S.A., Avda. De la Industria, 30, 28108 Alcobendas, Madrid, Spain Marketing Authorization Holder: M/s Eli Lilly Nederland B.V., Panendorpseweg 83, 3528BJ Utrecht, the Netherlands.
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	**Drug Sale License** License to Sell Drugs by way of Wholesale valid till: 02-01-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: □ **New Drug Product (NDP)**
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Abemaciclib
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each film coated tablet contains: Abemaciclib……..150mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Verzenio 150mg Film coated Tablets

	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. Aluminium /aluminium perforated Unit dose blisters of 28x1 film coated tablets
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anti-Cancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house (Innovator)
	1.5.7	Route of administration Oral
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Spain, Netherland…
	1.5.10	Dosage form of applied drug Tablet
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
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	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
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	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined.
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so.
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant.
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals.
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted

	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. Approval of manufacturing facility of API by regulatory body of country and validity.
	• Original Legalized CoPP of Verzenio 150mg Film coated Tablets (Certificate#. 02/19/128797) dated 18-02-2019 by **European Medicine Agency** 30 Churchill Place, Canary Wharf, London E14 5EU, UK declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Lilly del Caribe Inc., 12.6 km 65th Infantry road, Carolina, Puerto Rico 00985 (also Quality control). Site responsible for batch release, QC, Primary & Secondary packaging: Lilly, S.A., Avda. De la Industria, 30, 28108 Alcobendas, Madrid, Spain	

MODULE 2: CTD SUMMARIES

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

QUALITY OVERALL SUMMARY (QOS)

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

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

3.2.S DRUG SUBSTANCE (API)

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

3.2.P DRUG PRODUCT

3.2.P.1	DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT Submitted	
3.2.P.2	PHARMACEUTICAL DEVELOPMENT	
	3.2.P.2.1	Components of the Drug Product
		3.2.P.2.1.1 Drug Substance Submitted
		3.2.P.2.1.2 Excipients Submitted
	3.2.P.2.2	Drug Product
		3.2.P.2.2.1 Formulation Development Submitted
		3.2.P.2.2.2 Overages Submitted
		3.2.P.2.2.3 Physicochemical and Biological Properties Submitted
	3.2.P.2.3	Manufacturing Process Development Submitted
	3.2.P.2.4	Container Closure System Submitted
	3.2.P.2.5	Microbiological Attributes Submitted
	3.2.P.2.6	Compatibility Submitted
3.2.P.3	MANUFACTURE	
	3.2.P.3.1	Manufacturer(s) Submitted Name and full address(es) of the facility(ies) Contact name, phone and fax numbers, email address
	3.2.P.3.2	Batch formula Submitted
	3.2.P.3.3	Description of manufacturing process and process controls Submitted
	3.2.P.3.4	Controls of critical steps and intermediates Submitted
	3.2.P.3.5	Process validation and/or evaluation Submitted

3.2.P.4	CONTROL OF EXCIPIENTS	
	3.2.P.4.1	Specifications Submitted
	3.2.P.4.2	Analytical procedures Submitted
	3.2.P.4.3	Validation of analytical procedures Submitted
	3.2.P.4.4	Justification of specifications (as applicable) Submitted
3.2.P.5	CONTROLS OF DRUG PRODUCT	
	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Not applicable
	3.2.P.8.3	Stability Submitted
		Verzenio 150mg Film coated Tablets Firm has submitted three batches long term stability data 2 batches 18 months and one batch 12 months at 30^0C±75%RH and 6 months at 40^0C±75%RH for three batches.
4.P		(Non-clinical / Safety) Submitted
5.P		(Clinical / Efficacy) Submitted

Decision of 290th meeting of RB:
Deferred for submission of stability data of three batches for both accelerated and long term stability studies at Zone IV-a conditions

Now firm has submitted 24 months stability data of applied three strengths (three batches long term stability data at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches)
Decision: Keeping in view valid legalized CoPP and approval of EMA (Reference Regulatory Authority); Registration Board approved the product as per Import Policy for Finished Drugs.

Imported Human Application on form 5

563.	**Name and address of Applicant**	M/s Himmel Pharmaceuticals Pvt. Limited 793-D Block C Faisal Town Lahore Pakistan
	Detail of Drug Sale License	License to Sell drugs as a Distributor No: 0011000 0001520 valid upto 06-Feb-2020
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Tic. A.S. Kosuyolu, Cad No:34, 34718 Kosuyolu kadikoy Istanbul, Turkey Manufacturing site: Onk Ilac Sanayi ve Tacaret A.S Gebze Organize Sanayi Bolgesi, 1700 Sokak, No: 1703 Gebze, Kocaeli, Turkey
	Name and address of marketing authorization holder	M/s Onko Ilac Sanayi ve Tic. A.S. Kosuyolu, Istanbul, Turkey Manufacturing site: Onk Ilac Sanayi ve Ticaret A.S Gebze Organize Sanayi Bolgesi, 1700 Sokak, No: 1703 Gebze, Kocaeli, Turkey
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 30556 Dated 11-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 11-09-2018
	Brand Name +Dosage Form + Strength	Zomtu 4mg/5ml Concentrated Solution for IV Infusion
	Composition	Each ml contains:

		Zoledronic acid monohydrate….0.853 (Eq. to 0.8mg/ml zoledronic acid)
	Finished Product Specification	In-house
	Pharmacological Group	Bisphosphonates (Tumour induced hypercalcemia)
	Shelf life	24 Months
	Pack size & Demanded Price	As per SRO
	International availability	Zometa® 4 mg/5 ml concentrate for solution for infusion (UK)
	Me-too status	Zometa 4mg/5Ml Concentrate For Solution For Infusion. Of M/s Novartis
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC, 65±5%RH & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP (Certificate#. 2018/1163)** issued on 22-03-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Tic. A.S. Kosuyolu, Istanbul, Turkey Manufacturing site: Onk Ilac Sanayi ve Tacaret A.S Gebze Organize Sanayi Bolgesi, 1700 Sokak, No: 1703 Gebze, Kocaeli, Turkey This certificate valid until 22-03-2020 **Copy of Sole agency agreement with Product license holder**
	Remarks of the Evaluator.	
	Decision: Keeping in view the legalized CoPP provided by the firm indicating the product is available in country of origin; Registration Board approved the product with innovator' Specifications subject to the compliance of current Import Policy for Finished Drugs	

Case No. 06 Registration Applications of Imported cases

b. New Cases (Veterinary)

565.	**Name and address of Applicant**	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Detail of Drug Sale License	Drug License by way of Wholesale no. 0952 valid till 28-Apr-2021 Qualify person is Dispenser.
	Name and address of manufacturer	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26826 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	MYCOFLOR 200 Oral Solution Solution for use in drinking water
	Composition	Each ml contains: Florfenicol……..200mg
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	2 years store below 30^0C
	Demanded Price	Decontrolled
	Pack size	500ml, 1L,5L
	Me-too status	Flurotin Liquid of M/s Elegance Pharmaceuticals
	Stability studies	Firm has submitted long term (24 months) at 30ºC 75±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
	Detail of certificates attached	**i. Original Legalized CoPP dated 11th May 2018** by ministry of health, social services and equality

		(Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain **ii.** Copy of Sole agency agreement with product license holder
	Remarks of the Evaluator.	
	Decision: Keeping in view the legalized CoPP provided by the firm indicating the product is available in country of origin; Registration Board approved the product with innovator's Specifications subject to the compliance of current Import Policy for Finished Drugs.	
566.	**Name and address of Applicant**	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26825 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	COLMYC 20% Oral solution for administration in drinking water
	Composition	Each ml contains: Enrofloxacin…….200mg
	Finished Product Specification	USP
	Pharmacological Group	Antibacterial
	Shelf life	3 years store below 30^0C
	Demanded Price	Decontrolled
	Pack size	500ml, 1L,5L
	Me-too status	EL-FLOXACIN LIQUID of M/s ELKO ORGANISATION,
	Stability studies	Firm has submitted long term (36 months) at 30ºC 75±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 14th May 2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Remarks of the Evaluator.	Applied product is Suspension as per USP monograph but applied product is solution dosage form.
	Decision: Deferred for following: **Applied product is suspension as per USP monograph but applicant apply solution dosage form.**	
567.	**Name and address of Applicant**	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26822 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	HIDROCOL

		Solution for use in drinking water
	Composition	Each ml contains: Colistin …….4.000.000 IU
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100ml, 250ml, 1L, 5L
	Me-too status	COLISER WATER SOLUBLE POWDER of M/s ATTABAK PHARMACEUTICALS, ISLAMABAD.
	Stability studies	Firm has submitted long term (24 months) at 30ºC 65±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 11th May 2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Remarks of the Evaluator.	Firm submitted accelerated stability data conclusion shows that product store at 25^0C and fulfil specification for 24 months.
	Decision: Deferred for clarification of submitted accelerated stability data conclusion shows that product store at 25^0C and fulfil specification for 24 months	
568.	**Name and address of Applicant**	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	M/s S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	M/s Global vet Health sl c/capcanes, n^0 12-baixos Poligon Agro-Reus REUS 43203 SPAIN
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26824 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	AMOXICILINA 50% S.P.V. Powder for use in drinking water
	Composition	Each g contains: Amoxicillin …….500mg
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	100g, 500g, 1kg
	Me-too status	Rymox-50 Water Soluble Powder of M/s Zumras Pharma
	Stability studies	Firm has submitted long term (24 months) at 30ºC 65±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 14th May 2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Remarks of the Evaluator.	
	Decision: Keeping in view the legalized CoPP provided by the firm indicating the product is available in country of origin; Registration Board approved the product with innovator's Specifications subject to the compliance of current Import Policy for Finished Drugs.	

569.	Name and address of Applicant	M/s Poul Med Enterprises 9-C, Amber Estate Building, Balouch colony, main shahrah-e-Faisal, Karachi Pakistan
	Name and address of manufacturer	M/s S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Marketing authorization holder	M/s S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 26823 Dated 06-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 06-08-2018
	Brand Name +Dosage Form + Strength	DOXIPULVIS S.P. 500mg/g Powder for administration in drinking water or Milk replacer
	Composition	Each g contains: Doxycycline……500mg
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	200g, 500g,1kg
	Me-too status	WEALDOX FORTE POWDER of M/s MALLARD PHARMACEUTICAL,
	Stability studies	Firm has submitted long term (36 months) at 30ºC 65±5%RH & accelerated (06 months) stability data at 40ºC, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP dated 11th May 2018** by ministry of health, social services and equality (Department of veterinary medicines) declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., S.P. VETERINARIA, S.A. Crta. Reus-Vinyols, Km. 4.1 P.O. Box 60 43330 Riudoms (Tarrangona) Spain
	Remarks of the Evaluator.	
	Decision: Keeping in view the legalized CoPP provided by the firm indicating the product is available in country of origin; Registration Board approved the product with innovator's Specifications subject to the compliance of current Import Policy for Finished Drugs.	

Agenda of Evaluator PEC-VIII

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

a. New cases

570.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Flarither Tablet 80/480
	Composition	Each tablet contains: Arthemether…80mg Lumefantrine…480mg
	Diary No. Date of R& I & fee	Dy No. 5733: 16-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	International Pharmacopoeial Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM
	Me-too status	Trikat MR Tablets of M/s. Novamed Pharmaceuticals.

	GMP status	GMP Inspection conducted on 29-01-2019 concluding that firm is overall GMP compliant.
	Remarks of the Evaluator:	
	Decision: Approved.	
571.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Aceflan Tablet 100mg
	Composition	Each film coated tablet contains: Aceclofenac…100mg
	Diary No. Date of R& I & fee	Dy No. 5732: 16-02-18 ; Rs. 20,000
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Acfonac 100mg Tablets of Medicraft Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP Inspection conducted on 29-01-2019 concluding that firm is overall GMP compliant.
	Remarks of the Evaluator:	
	Decision: Approved as per Innovator's Specifications.	
572.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, KPK"
	Brand Name +Dosage Form + Strength	Novril 1mg tablet
	Composition	"Each film coated tablet contains: Risperidone …1mg"
	Diary No. Date of R& I & fee	Dy. No. 23813 dated 10-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	atypical antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Becalm 1mg Tablet of Maple Pharmaceuticals, Karachi
	GMP status	Copy of GMP Inspection report of M/s Aries Pharmaceuticals, conducted on 4th June 2018 confirms satisfactory level of GMP
	Decision: Approved.	
573.	Name and address of manufacturer / Applicant	"M/s Harrison Pharmaceuticals. 10-km, Lahore Road, Sargodha By: M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Neuromin 500mcg/ml Injection
	Composition	Each Ampoule Contains: Mecobalamin…500mcg
	Diary No. Date of R& I & fee	Dy.No 24517 dated 14-12-2017 Rs. 50,000/- 14-12-2017 Duplicate Dossier
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved in PMDA (as provided by the firm)
	Me-too status (with strength and dosage form)	Nervpower of 500mcg of Swiss Pharmaceuticals
	GMP status	For M/s Astellas Pharmaceuticals: Date: 13-11-2018, Overall the GMP Compliance of the firm is Good.
	Decision: Deferred for the following: • **Details about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **For assessment and confirmation of manufacturing capacity of M/s Astellas Pharmaceuticals.**	
574.	Name and address of manufacturer / Applicant	"M/s Harrison Pharmaceuticals. 10-km, Lahore Road, Sargodha By: M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Harifer 100mg/5ml Injection
	Composition	Each Ampoule Contains: Iron III Hydroxide Sucrose Complex…100mg/5ml
	Diary No. Date of R& I & fee	Dy.No. 24516 dated 14-12-2017 Rs. 50,000/- 14-12-2017 Duplicate Dossier
	Pharmacological Group	Iron Supplement
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in PMDA (as provided by the firm)
	Me-too status (with strength and dosage form)	Vesofer Injection 100mg/5ml of Vision Pharmaceuticals
	GMP status	For M/s Astellas Pharmaceuticals: Date: 13-11-2018, Overall the GMP Compliance of the firm is Good.
	Decision: Deferred for the following: • **Details about total number of sections & total number of products already approved on contract manufacturing of applicant.** • **For assessment and confirmation of manufacturing capacity of M/s M/s Astellas Pharmaceuticals.**	
575.	Name and address of manufacturer / Applicant	"M/s Harrison Pharmaceuticals. 10-km, Lahore Road, Sargodha By: M/s Astellas Pharmaceuticals pvt Ltd. 15-C Industrial Estate, Hayatabad, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Harriflox 400mg/250ml Infusion
	Composition	Each Vial Contains: Moxifloxacin (as hydrochloride)…400mg
	Diary No. Date of R& I & fee	Dy.No 24511 dated 14-12-2017 Rs. 50,000/- 14-12-2017 Duplicate Dossier
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Izilon 400mg/250ml Infusion of Bosch Pharmaceuticals
	GMP status	For M/s Astellas Pharmaceuticals: Date: 13-11-2018, Overall the GMP Compliance of the firm is Good.

Decision: Deferred for the following:

- **Details about total number of sections & number of products already approved on contract manufacturing of applicant.**
- **For assessment and confirmation of manufacturing capacity of M/s M/s Astellas Pharmaceuticals.**

576.

Name and address of manufacturer / Applicant	"M/s Welwrd Pharmaceuticals. Plot # 3, Block A, Phase I-II, Industrial Estate Hattar, KPK"
Brand Name +Dosage Form + Strength	Welfax SR 50mg Tablet
Composition	"Each Extended Release Film Coated Tablet Contains: Desvenlafaxine (as Succinate)…50mg"
Diary No. Date of R& I & fee	Dy. No. 21237 dated 13-06-2018 Rs.20,000/- 12-06-2018
Pharmacological Group	Antidepressants
Type of Form	Form-5
Finished product Specifications	As per innovator's specification
Pack size & Demanded Price	As per SRO
Approval status of product in Reference Regulatory Authorities	Approved USFDA
Me-too status	Qrist 50mg Tablet of Nabiqasim Karachi.
GMP status	GMP Inspection conducted on 14-07-2017 concluded that the firm is GMP compliant over all.

Remarks of Evaluator :

Remarks	Response
Applied formulation is extended release tablet; name the extended release polymers as it is not present in master formulation.	Firm has submitted a master formulation having extended release polymer incorporated into core & coat of tablet.

Decision: Deferred for clarification/justification regarding addition of extended release polymer in core & coat of tablet or else submission of master formulation & manufacturing method in-line with innovator.

577.

Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
Brand Name +Dosage Form + Strength	Misofen Tablet 50mg+200mcg
Composition	"Each enteric coated tablet contains: Diclofenac sodium…50mg Misoprostol…200mcg"
Diary No. Date of R& I & fee	Dy. No. 23941 dated 11-07-2018 Rs.20,000/- 27-06-2018
Pharmacological Group	Nonsteroidal Anti-Inflammatory Drug
Type of Form	Form-5
Finished product Specifications	USP Specifications
Pack size & Demanded Price	20's : As per PRC
Approval status of product in Reference Regulatory Authorities	Approved in MHRA
Me-too status (with strength and dosage form)	Tector Plus 50 Tablet of Macter International
GMP status	GMP Inspection conducted on 08-07-2019 & 25-07-2019 concluded that firm was operating at satisfactory level of GMP compliance.

Remarks of Evaluator:

Remarks	Response
Provide evidence of required manufacturing equipment for producing tablet in tablet (inner enteric coated core of Diclofenac sodium & outer immediate release coat of misoprostol).	Firm has submitted photocopy of invoice for core covered rotary tablet press machine ZPW26.
What is purpose of enteric coating over misoprostol mantle; Clarify/justify, as innovator doesn't have it.	Applicant has submitted revised manufacturing method.

Decision: Deferred for following:

- **Submission of requisite fee for revisionof formulation.**
- **Submission of IQ, OQ & PQ reports for the Bilayer compression machine.**

578.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dboost Oral Solution 1mcg/ml
	Composition	"Each ml contains: Calcitriol…1mcg"
	Diary No. Date of R& I & fee	Dy. No. 23963 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Pharmacological Group	Vitamin D Analogs
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	15ml, 30ml, 60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Alcitrol Solution of Platinum Pharmaceutical
	GMP status	GMP Inspection conducted on 08-07-2019 & 25-07-2019 concluded that firm was operating at satisfactory level of GMP compliance.
	Remarks of Evaluator:	

Remarks	**Response**
Reference product is packed in amber glass bottle but you have mentioned glass bottle.	Firm has submitted that we have mistakenly write glass bottles now we have clarified that it is amber colored glass bottle.
Reference product also contains anti-oxidants in it but applied formulation does not have it, clarify/justify	Applicant has submitted revised master formulation.

Decision: Approved as per innovator's specification.

579.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Diclosol Injection 75mg/3ml
	Composition	"Each 3ml ampoule contains: Diclofenac sodium…75mg"
	Diary No. Date of R& I & fee	Dy. No. 23911 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	5's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Dianic Injection of M/s. Novamed Pharmaceuticals
	GMP status	GMP Inspection conducted on 08-07-2019 & 25-07-2019 concluded that firm was operating at satisfactory level of GMP compliance.
	Remarks of Evaluator:	

Remarks	**Response**
Reference product is packed in type I glass container but you have mentioned Type II glass container, Clarification is required.	Firm has submitted that we have mistakenly write glass ampoule of Type II, while it was type I.

Decision: Approved as per innovator's specification.

580.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Ciproxol-D 0.3%+0.1% Otic Solution
	Composition	"Each ml contains: Ciprofloxacin (as hydrochloride)…3mg Dexamethasone…1mg"

	Diary No. Date of R& I & fee	Dy. No. 23992 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Pharmacological Group	Antibiotic/Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Aultocip-D Eye Drop of Aulton Pharmaceuticals
	GMP status	Panel Inspection conducted on 29-05-17, 30-5-17,13-07-2017 recommended grant of DML.

Remarks of Evaluator:

EPAR: The drug product is manufactured by steam sterilization of the suspension of dexamethasone in aqueous tyloxapol solution, ball milling of dexamethasone slurry, steam sterilization of the solution of ciprofloxacine and the other excipients, aseptic mixing and filling. It has been justified that terminal sterilization is not applicable for the drug product. The overage of 3% benzalkonium chloride isexplained by production data.

The manufacturing process is described and a flow chart is provided. In-process controls are given.

Steam sterilisation of the ciprofloxacin solution done is performed at not less than 121 - 128°C for 60 – 80 minutes. The dexamethasone slurry is steam sterilized at 121-131°C for not less than 145 minutes.

Remarks	**Response**
Mention the procedure for carrying out sterility of applied formulation & submit manufacturing method.	Firm has submitted that we have mistakenly write solution instead of suspension. We have submitted the procedure of sterility of applied formulation, type of primary packaging material & corrected Oral Solution to Oral Suspension.
Mention type of primary packaging material of applied formulation.	Plastic bottle, Nozzles & Caps.
Reference product is suspension you are claiming solution. Clarify/Justify.	Firm has submitted that we have mistakenly write solution instead of suspension. We have submitted the procedure of sterility of applied formulation, type of primary packaging material & corrected Oral Solution to Oral Suspension.

Decision: Deferred for the following:

- **Clarification/justification regarding sterilization method that how a suspension can be filtered through membrane filtration or else submission of sterilization method in line with innovator product.**
- **Mention type of primary packaging material of applied formulation as you have only mentioned plastic bottle.**

581.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Zithrocin Tablet 500mg
	Composition	Each film coated tablet contains: Azithromycin (as dihydrate)…500mg
	Diary No. Date of R& I & fee	Dy. No. 23958 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	6's, 10,s: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Plivazith 500 mg Tablet of Pliva Baluchistan
	GMP status	Panel Inspection conducted on 29-05-17, 30-05-17, 13-07-2017 recommended grant of DML.

Remarks of Evaluator:

Remarks	**Response**
Submit outline of manufacturing method of applied formulation.	Applicant has submitted outline of manufacturing method which does not contain step of coating.

	Decision: Clarification regarding applied formulation whether it is coated or uncoated & submission of master formulation & manufacturing method accordingly & in line with innovator.	
582.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Sebastin Tablet 10mg
	Composition	"Each film coated tablet contains: Ebastine…10mg"
	Diary No. Date of R& I & fee	Dy. No. 23946 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Pharmacological Group	Antihistamines For Systemic Use
	Type of Form	Form-5
	Finished product Specifications	
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM
	Me-too status (with strength and dosage form)	Desid Tablets of Gillman Pharmaceuticals,
	GMP status	Panel Inspection conducted on 29-05-17, 30-05-17, 13-07-2017 recommended grant of DML.
	Remarks of Evaluator	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
583.	Name and address of manufacturer / Applicant	"M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	"Eyesol 0.1% W/V+0.3% Opthalmic solution"
	Composition	"Each ml contains: Dextran 70…1mg Methylcellulose…3mg"
	Diary No. Date of R& I & fee	Dy. No. 23983 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Pharmacological Group	Lubricant /Artificial Tear
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	(15ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Ashk Eye Drops of Ray Pharma, Karachi.
	GMP status	Panel Inspection conducted on 29-05-17, 30-05-17, 13-07-2017 recommended grant of DML.
	Remarks of Evaluator: Mention type of primary packaging material of applied formulation. | Plastic bottle, Nozzles & Caps.	
	Decision: Deferred for the following: **Mention type of primary packaging material of applied formulation as you have only mentioned plastic bottle.**	
584.	Name and address of Manufacturer / Applicant	"M/s Hilton Pharma Pvt Ltd. Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi, Pakistan"
	Brand Name +Dosage Form +Strength	Citanew 20mg/ml Oral Drops
	Composition	"Each ml Contains: Escitalopram (as oxalate)…20mg"
	Diary No. Date of R&I & fee	Dy. No. 29137 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Selective Serotonin Reuptake Inhibitors
	Type of Form	Form-5
	Finished Product Specification	Specification
	Pack Size & Demanded Price	10ml, 15ml, 20ml, 30ml: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Cipralex Oral Drops 10mg/ml of Lundbeck Pakistan Pvt.

		Ltd., (as provided by the firm)
	GMP status	GMP Inspection conducted on 19-07-2017 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as provided evidence is not of applied strength.
	Decision: Deferred for eevidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as provided evidence is not of applied strength.	
585.	Name and address of Manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form +Strength	Attentra 10mg Capsule
	Composition	"Each Capsule Contains: Atomoxetine (as hydrochloride)…10mg"
	Diary No. Date of R&I & fee	Dy.No 29150 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Centrally Acting Sympathomimetic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	14's, 28's, 30's, 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Moxitine Capsules 10mg Of CCL
	GMP status	Date: 29-03-2019. Recommendations: The firm M/s Genetics Lahore was evaluated for facilities, like building, flow, HVAC. Personnels, Quality control/QA and production operations. Keeping in view the abservations, made on the day of inspection and after going through the documentations and overll assessment, the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved.	
586.	Name and address of Manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form +Strength	Attentra 25mg Capsule
	Composition	"Each Capsule Contains: Atomoxetine (as hydrochloride)…25mg"
	Diary No. Date of R&I & fee	Dy.No 29151 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Centrally acting sympathomimetic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	14's, 28's, 30's, 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Moxitine capsules 25mg of CCL
	GMP status	Same as recorded for above Application.
	Remarks of Evaluator	
	Decision: Approved.	
587.	Name and address of Manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form +Strength	Attentra 40mg Capsule
	Composition	"Each Capsule Contains: Atomoxetine (as hydrochloride)…40mg"
	Diary No. Date of R&I & fee	Dy.No 29152 dated 31-08-2018 Rs.20,000/- 30-08-2018

	Pharmacological Group	Centrally acting sympathomimetic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	14's, 28's, 30's, 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Moxitine capsules 40mg of CCL
	GMP status	Same as recorded for above Application.
	Remarks of Evaluator	
	Decision: Approved.	
588.	Name and address of Manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form +Strength	Attentra 60mg Capsule
	Composition	"Each Capsule Contains: Atomoxetine (as hydrochloride)…60mg"
	Diary No. Date of R&I & fee	Dy.No 29153 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Centrally acting sympathomimetic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	14's, 28's, 30's, 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Moxitine capsules 60mg of CCL
	GMP status	Same as recorded for above Application.
	Remarks of Evaluator	
	Decision: Approved.	
589.	Name and address of Manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form +Strength	Attentra 80mg Capsule
	Composition	"Each Capsule Contains: Atomoxetine (as hydrochloride)…80mg"
	Diary No. Date of R&I & fee	Dy.No 29154 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Centrally acting sympathomimetic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	14's, 28's, 30's, 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Moxitine capsules 80mg of CCL
	GMP status	Same as recorded for above Application.
	Remarks of Evaluator	
	Decision: Approved.	
590.	Name and address of Manufacturer / Applicant	"M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore"
	Brand Name +Dosage Form +Strength	Attentra 100mg Capsule
	Composition	"Each Capsule Contains: Atomoxetine (as hydrochloride)……100mg"
	Diary No. Date of R&I & fee	Dy.No 29155 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Centrally acting sympathomimetic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	14's, 28's, 30's, 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Moxitine capsules 100mg of CCL

	GMP status	Same as recorded for above Application.
	Remarks of Evaluator	
	Decision: Approved.	
591.	Name and address of Manufacturer / Applicant	"M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan"
	Brand Name +Dosage Form +Strength	Exval-A 5/320 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine (as besylate)…5mg Valsartan…320mg"
	Diary No. Date of R&I & fee	Dy.No 29046 dated 30-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Anti-Hypertensive Formulation
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	7's, 14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Address 5/320mg tablet of M/s Scotmann Pharmaceuticals
	GMP status	GMP Inspection Conducted On 16-02-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved.	
592.	Name and address of Manufacturer / Applicant	"M/s Genix Pharma Pvt Ltd. 44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan"
	Brand Name +Dosage Form +Strength	Exval-A 10/320 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine (as besylate)…10mg Valsartan…320mg"
	Diary No. Date of R&I & fee	Dy.No 29047 dated 30-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Anti-Hypertensive Formulation
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	7's, 14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Address 10/320mg tablet of M/s Scotmann Pharmaceuticals
	GMP status	GMP Inspection Conducted On 16-02-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved.	
593.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Xicogab 25mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…25mg"
	Diary No. Date of R&I & fee	Dy.No 29146 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Anticonvulsant Drug
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Dygab 25mg Capsules of M/s. Dyson Research Laboratories (Pvt) Ltd.
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	

594.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Xicogab 150mg Capsule
	Composition	"Each Capsule Contains: Pregabalin……150mg"
	Diary No. Date of R&I & fee	Dy.No 29147 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Anticonvulsant Drug
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Dygab 150mg Capsules of M/s. Dyson
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
595.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Orlifold 60mg Capsule
	Composition	"Each Capsule Contains: Orlistat……..60mg"
	Diary No. Date of R&I & fee	Dy.No 29148 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Peripherally acting antiobesity products
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Slimfit 60mg Capsule of Amarant Pharmaceuticals
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	• COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred submission of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	
596.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Orlifold 120mg Capsule
	Composition	"Each Capsule Contains: Orlistat…120mg"
	Diary No. Date of R&I & fee	Dy.No 29149 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Peripherally acting antiobesity products
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Vetnor 120mg Capsule of Amarant Pharmaceuticals
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred submission of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	

597.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Carbofold 375mg Capsule
	Composition	"Each Capsule Contains: Carbocisteine…375mg"
	Diary No. Date of R&I & fee	Dy.No 29144 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA (granular powder)
	Me-too status	Carbosicteine Capsules Of Aligohar & Company
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
598.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Nimlide 100mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nimesulide…100mg"
	Diary No. Date of R&I & fee	Dy.No 29145 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	anti-inflammatory and anti rheumatic agents, non-steroids
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Nimesota Tablets 100mg of M/s Orta Laboratories,
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Deferred for submission of evidence of reference product as film coated tablet or else revision of formulation in line with reference product i.e. uncoated tablet alongwith submission of requisite Fee.	
599.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Itrafon 100mg Capsule
	Composition	"Each Capsule Contains: Itraconazole ….100mg" (as IR Pellets)
	Diary No. Date of R&I & fee	Dy.No 29142 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Itrax Capsule 100mg of Ferozsons Labs.
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	• COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred submission of COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.	

600.	Name and address of Manufacturer / Applicant	"M/s Weather Folds Pharmaceuticals. Plot # 69, Phase-II, Industrial Estate, Hattar"
	Brand Name +Dosage Form +Strength	Erdos 150mg Capsule
	Composition	"Each Capsule Contains: Erdosteine……..150mg"
	Diary No. Date of R&I & fee	Dy.No 29143 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Mucolytics
	Type of Form	Form-5
	Finished Product Specification	As per Innovator's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in AIFA (Erdotin Capsule 150mg)
	Me-too status	Erdozet Capsules 150mg of S.J&G Karachi.
	GMP status	GMP inspection conducted on 15-09-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
601.	Name and address of Manufacturer / Applicant	"M/s Well & Well Pharma Pvt Ltd. Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form +Strength	Antideb 2.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Saxagliptin (as hydrochloride)……..2.5mg"
	Diary No. Date of R&I & fee	Dy.No 29138 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's: Rs.296.00/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Saxagen 2.5mg Tablet of Genix Karachi
	GMP status	GMP Inspection conducted on 08-02-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	
	Decision: Registration Board decided as follow: • **Deferred for clarification from the firm regarding manufacturing method of applied formulation & steps taken to avoid cyclization process of Saxagliptin. The Board further, decided to get clarification from previous registration holders of same formulation.**	
602.	Name and address of Manufacturer / Applicant	"M/s Well & Well Pharma Pvt Ltd.Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form +Strength	Antideb 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Saxagliptin(as hydrochloride)……..5mg"
	Diary No. Date of R&I & fee	Dy.No 29139 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's: Rs.493.00/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Saxagen 5mg Tablet of Genix Karachi
	GMP status	GMP Inspection conducted on 08-02-18 concluded that firm is operating at fair level of GMP compliance.
	Remarks of Evaluator	
	Decision: Registration Board decided as follow: **Deferred for clarification from the firm regarding manufacturing method of applied formulation & steps taken to avoid cyclization process of Saxagliptin. The Board further, decided to get clarification from previous registration holders of same formulation.**	

603.	Name and address of Manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad""
	Brand Name +Dosage Form +Strength	Duox 60mg Capsule
	Composition	"Each Delayed Release Capsule Contains: Duloxetine (as enteric coated pellets)…60mg"
	Diary No. Date of R&I & fee	Dy. No. 28928 dated 29-08-2018 Rs.20,000/- 28-08-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Swenta 60mg Capsule of Martin Dow, Karachi.
	GMP status	Panel Inspection for renewal of DML conducted on 30-11-17 recommended renewal of DML for following sections: Tablet section General (revised) Capsule section general (revised) Eye drop section Eye ointment/cream section
	Remarks of Evaluator	• Reference product is approved as Duloxetine hydrochloride 60mg capsule which is different from applied formulation Duloxetine 60mg capsule; submit master formulation, manufacturing method in line with innovator product after correction alongwith submission of requisite fee. • COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred for the following: • **Reference product is approved as Duloxetine hydrochloride 60mg capsule which is different from applied formulation Duloxetine 60mg capsule; submit master formulation, manufacturing method in line with innovator product after correction alongwith submission of requisite fee.** • **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.**	
604.	Name and address of Manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad""
	Brand Name +Dosage Form +Strength	Incer 50mg Capsule
	Composition	"Each Hard Capsule Contains: Diacerein…50mg"
	Diary No. Date of R&I & fee	Dy.No. 28922 dated 29-08-2018 Rs.20,000/- 28-08-2018
	Pharmacological Group	Anti-inflammatory and anti-rheumatic agents, non-steroids
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's, 20's, 30's, 50's. As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Dibro 50mg Capsules of Winbrain Research Laboratories,
	GMP status	Panel Inspection for renewal of DML conducted on 30-11-17 recommended renewal of DML for following sections: Tablet section General (revised) Capsule section general (revised) Eye drop section Eye ointment/cream section
	Remarks of Evaluator	
	Decision: Registration Board approved the formulation as per Innovator's Specification & for the following clinical indication only. **"Treatment of symptoms of osteoarthritis of the hip or knee joint."**	

605.	Name and address of Manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad""
	Brand Name +Dosage Form +Strength	Tramik 250mg Capsule
	Composition	"Each Hard Capsule Contains: Tranexamic Acid…250mg"
	Diary No. Date of R&I & fee	Dy.No 28921 dated 29-08-2018 Rs.20,000/- 28-08-2018
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form-5
	Finished Product Specification	Japanese Pharmacopoeial Specifications
	Pack Size & Demanded Price	
	Approval status of product in Reference Regulatory Authorities	Approved in Italy
	Me-too status	Brino 250mg Capsules of Sami Pharmaceuticals
	GMP status	Panel Inspection for renewal of DML conducted on 30-11-17 recommended renewal of DML for following sections: Tablet section General (revised) Capsule section general (revised) Eye drop section Eye ointment/cream section
	Remarks of Evaluator	
	Decision: Approved.	
606.	Name and address of Manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad""
	Brand Name +Dosage Form +Strength	Tusin 0.4mg Capsule
	Composition	"Each Hard Capsule Contains: Tamsulosin …0.4mg" (Pellets 0.2%)
	Diary No. Date of R&I & fee	Dy.No 28920 dated 29-08-2018 Rs.20,000/- 28-08-2018
	Pharmacological Group	Alpha-adrenoreceptor antagonists
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	10's, 20's, 30's,50's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Eziflo 0.4mg Capsule of Asian Continental (Pvt.) Ltd.
	GMP status	Panel Inspection for renewal of DML conducted on 30-11-17 recommended renewal of DML for following sections: Tablet section General (revised) Capsule section general (revised) Eye drop section Eye ointment/cream section
	Remarks of Evaluator	• Reference product is approved as Tamsulosin hydrochloride 0.4mg capsule which is different from applied formulation Tamsulosin 0.4mg capsule; submit master formulation, manufacturing method in line with innovator product after correction alongwith submission of requisite fee. • COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.
	Decision: Deferred for the following: • **Reference product is approved as Tamsulosin hydrochloride 0.4mg capsule which is different from applied formulation Tamsulosin 0.4mg capsule; submit master formulation, manufacturing method in line with innovator product after correction alongwith submission of requisite fee.** • **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.** •	

607.	Name and address of Manufacturer / Applicant	"M/s Wilson's Pharmaceuticals. Plot No. 387-388, Sector I-9, Industrial Area, Islamabad"
	Brand Name +Dosage Form +Strength	Talergin-C 2% Syrup
	Composition	"Each 5ml Contains: Carbocisteine…100mg"
	Diary No. Date of R&I & fee	Dy.No 29043 dated 30-08-2018 Rs.20,000/- Dated 30-08-2018
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	60ml, 90ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM
	Me-too status	Muflex 250mg/5ml Syrup of Kaizen Pharmaceuticals (as provided by the firm).
	GMP status	Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection.
	Remarks of Evaluator	• Evidence of reference product packed in pet bottle. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as provided evidence is not verifiable.
	Decision: Deferred for Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as provided evidence is not verifiable.	
608.	Name and address of Manufacturer / Applicant	"M/s Jaens Pharmaceutical Industries Pvt Limited. 28-km Lahore-Sheikhupura Road, Sheikhupura"
	Brand Name +Dosage Form +Strength	Funazole 150mg Capsule
	Composition	"Each Capsule Contains: Fluconazole…150mg"
	Diary No. Date of R&I & fee	Dy.No 29126 dated 31-08-2018 Rs.20,000/- 31-08-2018
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Flu-Z Capsule 150mg of Z-JANS Pharmaceuticals,
	GMP status	GMP inspection conducted on 20-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved with International Pharmacopoeia Specifications.	
609.	Name and address of Manufacturer / Applicant	"M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore"
	Brand Name +Dosage Form +Strength	NiYLTE Infusion
	Composition	"Each 100ml Contains: Dextrose anhydrous…3.3g" Sodium Chloride…0.3g
	Diary No. Date of R&I & fee	Dy. No. 29133 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Electrolytes
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	(1000ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA (as provided by firm)
	Me-too status	Sterifluid N/3 Infusion of Frontier Dextrose Ltd.
	GMP status	Panel Inspection for renewal of DML conducted on 21 & 23

		August 2017 recommended renewal of DML.
	Remarks of Evaluator	What does meant by Dextrose A.H? Clarify
	Decision: Approved	
610.	Name and address of Manufacturer / Applicant	"M/s Neutro Pharma (Pvt) Ltd. 9.5 km, Sheikhupura Road,Lahore"
	Brand Name +Dosage Form +Strength	Neusold 0.9% Infusion
	Composition	"Each 100ml Contains: Sodium Chloride…0.9%"
	Diary No. Date of R&I & fee	Dy.No. 29134 dated 31-08-2018 Rs.20,000/- 30-08-2018
	Pharmacological Group	Diluent/ Electrolyte
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	(20ml) LDPE bottle: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in Germany (as provided by firm)
	Me-too status	Sodium Chloride 0.9% Injection of Zafa Pharmaceuticals
	GMP status	Panel Inspection for renewal of DML conducted on 21 & 23 August 2017 recommended renewal of DML.
	Remarks of Evaluator	
	Decision: Approved	

b. Deferred cases

611.	Name and address of Manufacturer/Applicant	"M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi"
	Brand Name + Dosage Form + Strength	Aricid 250mg/5ml granules for oral suspension
	Composition	"Each 5ml of reconstituted suspension contains: Clarithromycin…250mg" (Taste masked granules) Source of granules: Surge Laboratories.
	Diary No. D of R & I & Fee	Dy.No. 16873 dated 07-05-2018 Rs.20,000/-
	Pharmacological group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack Size & demanded price	(60ml): As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Loud 250mg/5ml Dry Suspension of Sigma Pharma, Karachi.
	GMP Status	GMP Inspection conducted on 24-04-2019 concluded that firm is operating at acceptable level of GMP Compliance.
	Remarks of Evaluator:	

Sr.No.	Queries	Response by the Applicant
1.	Evidence of reference product packed in HDPE Bottle?	Applicant has submitted evidence of approval of applied formulation in HDPE bottle in MHRA of UK.
2.	Submit valid GMP certificate of Granule Manufacturer.	---------

	Previous Decision (M-290): Registration Board in its 290th meeting deferred the case for submission of valid GMP certificate of granule manufacturer.
	Evaluation by PEC: Applicant has submitted GMP certificate of granule manufacturer.
	Decision: Approved.

612.	Name and address of Manufacturer/Applicant	"M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi"
	Brand Name + Dosage Form + Strength	Aricid 125mg/5ml granules for oral suspension
	Composition	"Each 5ml of reconstituted suspension contains: Clarithromycin…125mg" (Taste masked granules)

		Source of granules: Surge Laboratories.
	Diary No. D of R & I & Fee	Dy.No. 16872 dated 07-05-2018 Rs.20,000/-
	Pharmacological group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack Size & demanded price	(60ml): As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Loud 125mg/5ml Dry Suspension of Sigma Pharma, Karachi.
	GMP Status	GMP Inspection conducted on 24-04-2019 concluded that firm is operating at acceptable level of GMP Compliance.

Remarks of Evaluator:

Sr.#	Queries	Response by the Applicant
1.	Evidence of reference product packed in HDPE Bottle?	Applicant has submitted evidence of approval of applied formulation in HDPE bottle in MHRA of UK.
2.	Submit valid GMP certificate of Granule Manufacturer.	---------

Previous Decision (M-290): Registration Board in its 290th meeting deferred the case for submission of valid GMP certificate of granule manufacturer.

Evaluation by PEC: Applicant has submitted GMP certificate of granule manufacturer.

Decision: Approved.

613.	Name and address of Manufacturer/Applicant	"M/s Scilife Pharma Pvt Ltd.Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi"
	Brand Name+ Dosage Form + Strength	Nezo 100mg/5ml Dry Powder Suspension
	Composition	"Each 5ml of reconstituted suspension contains: Linezolid…100mg"
	Diary No. D of R & I & Fee	Dy. No. 16870 dated 07-05-2018 Rs.20,000/-
	Pharmacological group	Anti-bacterial
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack Size & demanded price	(60ml): As per SRO
	Approval status of product in reference regulatory authorities	Approved in MHRA
	Me-too status	Linzol 100mg /5ml oral dry suspension of
	GMP Status	GMP Inspection conducted on 24-04-2019 concluded that firm is operating at acceptable level of GMP Compliance.

Remarks of Evaluator:

Sr.No.	Queries	Response by the Applicant
1.	Evidence of reference product packed in HDPE Bottle as reference product is packed in amber glass bottle.	----------

Previous Decision (M-290):
Registration Board in its 290th meeting deferred the case for evidence of approval of applied formulation in HDPE bottle in reference agencies.

Evaluation by PEC: Applicant has submitted that we want to inform you that we will follow the packing of reference product.

Decision: Approved as per innovator's specification.

614.	Name and address of Manufacturer/Applicant	"M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi"
	Brand Name+ Dosage Form + Strength	Timer 15/90 mg/5ml Suspension
	Composition	"Each 5ml of reconstituted suspension contains: Artemether…15mg Lumefantrine…90mg"
	Diary No. D of R & I & Fee	Dy.No 16869 dated 07-05-2018 Rs.20,000/-
	Pharmacological group	Anti-bacterial

	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack Size & demanded price	(30ml, 60ml): As per SRO
	Approval status of product in reference regulatory authorities	WHO recommended formulation
	Me-too status	Astin Dry Suspension of MBL Karachi
	GMP Status	GMP Inspection conducted on 24-04-2019 concluded that firm is operating at acceptable level of GMP Compliance.
	Remarks of Evaluator	Evidence of reference product packed in HDPE Bottle?
	Previous Decision (M-290): Registration Board in its 290th meeting deferred the case for evidence of approval of applied formulation in HDPE bottle in reference agencies.	
	Evaluation by PEC: Applicant has submitted that we want to inform you that we will follow the packing of reference product.	
	Decision: Approved with International Pharmacopoeia Specifications.	
615.	Name and address of Manufacturer/ Applicant	Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore. Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore.
	Brand Name + Dosage Form + Strength	ITON Tablets 50mg
	Composition	Each Tablet Contains: Itopride hydrochloride…50mg
	Diary No. D of R & I & Fee	Dy No. 6134 ; 19-02-18: Rs.20,000
	Pharmacological group	Gastrokinetic
	Type of Form	Form 5
	Finished product Specifications	Innovator
	Pack Size & demanded price	10's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in PMDA
	Me-too status	Ganaton by M/s Abbott Pakistan
	GMP Status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	Reference product in approved as film coated tablet but you have applied for uncoated tablet. Submit form 5, master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as uncoated tablet. Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd.
	Previous Decision(M-288th):	Registration Board deferred the case for the following: • For submission of evidence of approval of applied formulation as "uncoated tablets" in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting or else the formulation may be revised in accordance with reference product along with submission of requisite fee.
	Evaluation by PEC:	Applicant has submitted the following: Fee challan of Rupee 5000/- dated 20th May, 2019 for revision of formulation from uncoated to coated.
	Decision: Approved as per Innovator's Specification.	
616.	Name and address of Manufacturer/ Applicant	Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore. Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore.
	Brand Name + Dosage Form + Strength	ITON Tablets 150mg
	Composition	Each Tablet Contains: Itopride hydrochloride …150mg

	Diary No. D of R & I & Fee	Dy No. 6143 ; 19-02-18: Rs.20,000
	Pharmacological group	Gastrokinetic
	Type of Form	Form 5
	Finished product Specifications	Innovator
	Pack Size & demanded price	10's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Ganaton by Abbott USA (as provided by the firm)
	Me-too status	Ganaton by M/s Abbott Pakistan (pharmaguide, as provided by the firm)
	GMP Status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	Evidence of approval of applied formulation i.e. Itopride hydrochloride 150mg uncoated tablet in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required. Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd.
	Previous Decision(M-288th):	Registration Board deferred the case for the following: • For submission of evidence of approval of applied formulation as i.e. Itopride hydrochloride 150mg uncoated tablet in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of Me Too instead of evidence of approval of applied formulation ***Itopride hydrochloride 150mg uncoated tablet*** in reference regulatory authorities/agencies
	Decision: Deferred for submission of evidence of approval of applied formulation as i.e. Itopride hydrochloride 150mg uncoated tablet in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
617.	Name and address of Manufacturer/ Applicant	Previously Wellness Pharmaceuticals Plot # 33 Sundar Industrial Estate Lahore. Now: M/s Horizon Healthcare (Pvt) Ltd. Plot # 33, Sundar Industrial Estate Lahore.
	Brand Name + Dosage Form + Strength	ITON Capsule 50mg
	Composition	Each Capsule Contains: Itopride hydrochloride …50mg
	Diary No. D of R & I & Fee	Dy No. 6143 ; 19-02-18: Rs.20,000
	Pharmacological group	Gastrokinetic
	Type of Form	Form 5
	Finished product Specifications	Innovator
	Pack Size & demanded price	10's,30's: As per SRO
	Approval status of product in reference regulatory authorities	Ganaton by Abbott USA (as provided by the firm)
	Me-too status	Ganaton by M/s Abbott Pakistan (pharmaguide, as provided by the firm)
	GMP Status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	Evidence of approval of applied formulation i.e. Itopride hydrochloride 50mg capsule in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. Applicant has submitted the fee challan of Rupee Rs. 20,000 dated 08th of January, 2019 in the name of M/s Horizon Healthcare (Pvt Ltd.
	Previous Decision(M-288th):	Registration Board deferred the case for the following: Evidence of approval of applied formulation in reference

		regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of Me Too instead of evidence of approval of applied formulation in reference regulatory authorities/agencies.
	Decision: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
618.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faisalabad"
	Brand Name +Dosage Form + Strength	Doplet-3 400IU Oral Drops
	Composition	"Each drop Contains: Cholecalciferol (Vitamin D3)…400IU
	Diary No. Date of R& I & fee	Dy.No.21230 dated 13-06-2018 Rs.20,000/- 12-06-2018
	Pharmacological Group	Vitamin-D
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10ml,15ml,20ml: Rs.1500/-, Rs.2000/-, Rs.3000/-,
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	Panel inspection for renewal of DML conducted on 13-10-2017 recommended renewal of DML BEARING No.00616.
	Remarks of Evaluator:	

Remarks	**Response**
Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	Sapvit-D 400 IU/ drops of MHRA
Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	D-4U Drops of Genix Pharma (as provided by the firm) Miura-D Drops of Getz Pharma (as provided by the firm, not verifiable) Calciferol Drops of Global Drops (as provided by the firm, not verifiable)

Pervious Decision:
Deferred for the following:

- Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as formulation of provided generic is in milligrams/ml.

Evaluation by PEC:
Applicant has submitted following:
D-4U Drops of Genix Pharma

Decision: Registration Board deferred the case for further deliberation whether it has to be considered in PE&R Division as drug or in HOTC Division as nutraceutical.

619.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals Pvt Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gastocon Liquid
	Composition	Each 10ml Contains: Sodium Alginate…500mg Calcium Carbonate…160mg Sodium Bicarbonate…267mg
	Diary No. Date of R& I & fee	Dy.No. 17720 dated 14-05-2018 Rs.20,000/- 14-05-2018
	Pharmacological Group	Antacid
	Type of Form	Form-5

	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA (as provided by the firm)
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	GMP Inspection conducted on 07-09-17 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.
	Previous Decision(M-288th):	The case was deferred for the following: Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of Me Too. Brand Name: Gaviscon Liquid. Registration No. 016024
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting as the provided evidence is not verifiable.	
620.	Name and address of manufacturer / Applicant	M/s. Elko Organization (Pvt) Ltd , Plot No. 27 & 28, sector 12-B North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	El-Vit-E Liquid
	Composition	Each gram contains: Vitamin E Oil (98%)…….400IU
	Diary No. Date of R& I & fee	108, 03-08-2015, 20,000/-, 02-07-2015
	Pharmacological Group	Antioxidant
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1000ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Vitamin E 40 % dispersible Liquid concentrate of Clear View Enterprises.
	GMP status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remarks of the Evaluator.	• The submitted me-too reference could not be verified.
	Previous Decision:	Registration Board in its 279th meeting decided as follow: • Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name & name of firm.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of international availability. Approved in USFDA Brand Name: Vitamin E 40 %Liquid.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as submitted evidence is of approval of drug in USFDA which is not verifiable.	
621.	Name and address of manufacturer / Applicant	M/s. Elko Organization (Pvt) Ltd , Plot No. 27 & 28, sector 12-B North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	El-Vit-S Dispersible liquid
	Composition	Each ml contains: Vitamin E as tocopherol acetate……25mg Selenium as sodium Selenate…….1.1mg

	Diary No. Date of R& I & fee	875, 21-12-2015, 20,000/-, 21-12-2015
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	In-house specification
	Pack size & Demanded Price	10ml, 50ml, 100ml, 250ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Selcen-E Liquid of Vapps International, Karachi.
	GMP status	Routine GMP inspection conducted on 13-6-2017 & 6-7-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remarks of the Evaluator.	• The submitted me-too reference could not be verified.
	Previous Decision:	Registration Board in its 279th meeting decided as follow: • Deferred for evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name & name of firm.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of international availability. Approved in Czech Republic. Brand Name: Vita E Selen solution for Injection.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as submitted evidence is of approval of drug in Czech Republic which is not verifiable.	
622.	Name and address of manufacturer / Applicant	M/s. Elko Organization (Pvt) Ltd , Plot No. 27 & 28, sector 12-B North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Clant 10% Injection
	Composition	Each ml contains: Closantel…….100mg`
	Diary No. Date of R& I & fee	86, 26-01-2016, 20,000/-, 26-01-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	10ml, 50ml, 100ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Closantel Injection 10% Unovet Pharma, China
	Me-too status	Clozanox 10% Injection of Credence Remedies
	GMP status	Routine GMP inspection conducted on 13-06-2017 & 06-07-2017 concluded that the firm is operating at good level of GMP compliance as of today.
	Remarks of the Evaluator.	• The submitted me-too reference could not be verified.
	Previous Decision:	Registration Board in its 279th meeting decided as follow: • Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of international availability. Available in India Brand Name: Clozanox 10 %Liquid.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as submitted evidence is of approval of drug in India which is not verifiable & also not required.	
623.	Name and address of Manufacturer / Applicant	M/s. Ipram international Plot No. 26, S.S-3., National industrial zone Rawat, Islamabad.
	Brand Name +Dosage Form +Strength	Ipron Injection 4mg/2ml
	Composition	Each 2ml contains: Ondansetron (as hydrochloride)… 4mg

	Diary No. Date of R&I & fee	DyNo. 8691; 13-07-2017; Rs. 20,000/-
	Pharmacological Group	Anti-emetic (5-HT3 receptor antagonist)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	5's (2ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Ondanles Injection 4mg/2ml of Neomedix Rawalpindi
	GMP status	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018.
	Remarks of Evaluator	Applied formulation is present in USP 2016. Terminal sterilization is not being performed, Clarify/Justify.
	Previous Decision	Registration Board in its 290th meeting decided as follow: Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation.
	Evaluation By PEC	Applicant has submitted the following: • Terminal sterilization is not being carried out because it is not necessary or ideal to sterilize any product terminally nor it is the only & one way of sterilization. • Our sterilization process is filtration sterilization.
	Decision: Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation.	
624.	Name and address of Manufacturer / Applicant	M/s. Ipram international Plot No. 26, S.S-3., National industrial zone Rawat, Islamabad.
	Brand Name +Dosage Form +Strength	Ipron Injection 8mg/4ml
	Composition	Each 4ml contains: Ondansetron (as hydrochloride)… 8mg
	Diary No. Date of R&I & fee	DyNo. 8695; 13-07-2017; Rs. 20,000/-
	Pharmacological Group	Anti-emetic (5-HT3 receptor antagonist)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	5's (4ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Ondanles Injection 8mg/4ml of Neomedix Rawalpindi
	GMP status	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018
	Remarks of Evaluator	Applied formulation is present in USP 2016. • Terminal sterilization is not being performed, Clarify/ Justify.
	Previous Decision	Registration Board in its 290th meeting decided as follow: • Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation.
	Evaluation By PEC	Applicant has submitted the following: • Terminal sterilization is not being carried out because it is not necessary or ideal to sterilize any product terminally nor it is the only & one way of sterilization. • Our sterilization process is filtration sterilization.
	Decision: Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation.	

625.	Name and address of Manufacturer / Applicant	M/s. Ipram international Plot No. 26, S.S-3., National industrial zone Rawat, Islamabad.
	Brand Name +Dosage Form +Strength	Spasmo- P Injection 40mg
	Composition	Each 4ml ampoule contains: Phloroglucinol hydrated…40mg Trimethylphloroglucinol…0.04mg
	Diary No. Date of R&I & fee	DyNo. 8694; 13-07-2017; Rs. 20,000/-
	Pharmacological Group	Antispasmodic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	6's (4ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Couldn't confirmed
	Me-too status	Couldn't confirmed
	GMP status	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018
	Remarks of Evaluator	Applied formulation is not present in available USP & BP. • Terminal sterilization is not being performed. • Evidence Of International Availability • Evidence of me too with registration number.
	Previous Decision	Registration Board in its 290th meeting decided as follow: • Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation. • Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting. • Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation By PEC	Applicant has submitted the following: • Terminal sterilization is not being carried out because it is not necessary or ideal to sterilize any product terminally nor it is the only & one way of sterilization. • Our sterilization process is filtration sterilization. • Evidence of approval in RRA. Not Verifiable. • Evidence of Me Too. Brand Name: Spasrid Injection by Barrett Hodgson. Registration No. 034744
	Decision: • **Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation.** • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275thmeeting.**	
626.	Name and address of Manufacturer / Applicant	M/s. Ipram international Plot No. 26, S.S-3., National industrial zone Rawat, Islamabad.
	Brand Name +Dosage Form +Strength	Mecloram Injection 10mg
	Composition	Each 2ml ampoule contains: Metoclopramide (as hydrochloride)….10mg
	Diary No. Date of R&I & fee	DyNo. 8693; 13-07-2017; Rs. 20,000/-

	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's (2ml): As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Vominor 10mg Injection of Nortech Pharmaceuticals.
	GMP status	Certificate of cGMP is issued to the firm based on inspection conducted on 20th December, 2018
	Remarks of Evaluator	Applied formulation is available in USP. • Terminal sterilization is not being performed.
	Previous Decision	Registration Board in its 290th meeting decided as follow: • Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation.
	Evaluation By PEC	Applicant has submitted the following: • Terminal sterilization is not being carried out because it is not necessary or ideal to sterilize any product terminally nor it is the only & one way of sterilization. • Our sterilization process is filtration sterilization.
	Decision: Deferred for clarification/justification on scientific grounds for not performing terminal sterilization during manufacturing of applied formulation.	
627.	Name and address of Manufacturer / Applicant	M/s A.H. Pharmaceuticals (Pvt) Ltd, 865/A. S.I.T.E, Sargodha Road, Faislabad
	Brand Name +Dosage Form +Strength	Gastodine Suspension
	Composition	"Each 5ml contains: Famotidine…10mg"
	Diary No. Date of R&I & fee	Dy.No. 5728 dated 16-02-2018 Rs. 20,000/- 16-02-2018
	Pharmacological Group	Histamine-2 receptor blocker
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Dinex 10 mg / 5ml syrup of GulfPharmaceuticals,
	GMP status	GMP Inspection conducted on 04-07-2017 recommended renewal of DML by the way of formulation.
	Remarks of Evaluator	Evidence of reference Product in plastic container is required.
	Previous Decision	Registration Board in its 290th meeting decided as follow: Registration Board deferred the case for evidence of approval of applied formulation in HDPE Bottle in reference agencies.
	Evaluation By PEC	Applicant has submitted the following: We will use highly resistant amber glass bottles along with aluminium seal cap.
	Decision: Deferred for clarification from the firm regarding applied formulation whether it is Liquid suspension or dry powder for suspension.	
628.	Name and address of Manufacturer / Applicant	M/s A.H. Pharmaceuticals (Pvt) Ltd, 865/A. S.I.T.E, Sargodha Road, Faislabad
	Brand Name +Dosage Form +Strength	H-Merz Oral Liquid
	Composition	"Each 5ml contains: L-Ornithine L-Asparate…300mg Nicotinamide…24mg Riboflavin Sodium Phosphate…0.76mg"
	Diary No. Date of R&I & fee	Dy.No. 5729 dated 16-02-2018 Rs. 20,000/-

	Pharmacological Group	Vitamins & amino acid supplement
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in Germany (needs verification) Hepa-Merz Syrup Merz Pharma
	Me-too status	Could not be confirmed
	GMP status	GMP Inspection conducted on 04-07-2017 recommended renewal of DML by the way of formulation.
	Remarks of Evaluator	Evidence of reference Product in plastic container is required. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.
	Previous Decision	Registration Board in its 290th meeting decided as follow: • For evidence of approval of applied formulation in HDPE Bottle in reference agencies. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation By PEC	Applicant has submitted the following: We will use highly resistant amber glass bottles along with aluminium seal cap. Evidence of Me too: not verifiable Evidence of International availability:
	Decision:Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required as provided evidence contains some other quantities of ingredients.** • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as provided evidence contains only one ingredient.**	
629.	Name and address of Manufacturer / Applicant	M/s A.H. Pharmaceuticals (Pvt) Ltd, 865/A. S.I.T.E, Sargodha Road, Faislabad
	Brand Name +Dosage Form +Strength	Keaphen Syrup 15mg/5ml
	Composition	"Eachn 5ml contains: Pheniramine maleate…15mg"
	Diary No. Date of R&I & fee	Dy.No 5730 dated 16-02-2018 Rs. 20,000/-
	Pharmacological Group	Anti-allergic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	60ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved (needs verification)
	Me-too status	Could not be confirmed
	GMP status	GMP Inspection conducted on 04-07-2017 recommended renewal of DML by the way of formulation.
	Remarks of Evaluator	Evidence of reference Product in plastic container is required.
	Previous Decision	Registration Board in its 290th meeting decided as follow: • For evidence of approval of applied formulation in HDPE Bottle in reference agencies. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration

		number, brand name and name of firm is required. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation By PEC	Applicant has submitted the following: We will use highly resistant amber glass bottles along with aluminium seal cap. Evidence of Me too: Q-Rifin Syrup of M/s Fynk Pharmaceuticals. Evidence of International availability: Approved in MHRA
	Decision: Approved as per Innovator's Specification.	
630.	Name and address of Manufacturer / Applicant	M/s A.H. Pharmaceuticals (Pvt) Ltd, 865/A. S.I.T.E, Sargodha Road, Faislabad
	Brand Name +Dosage Form +Strength	Keachlor Syrup
	Composition	"Each 5ml Contains: Chlorpheniramine maleate …2mg"
	Diary No. Date of R&I & fee	Dy.No. 5731 dated 16-02-2018 Rs. 20,000/-
	Pharmacological Group	Anti-allergic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Staiton Syrup of Standard Drug Company, Hyderabad.
	GMP status	GMP Inspection conducted on 04-07-2017 recommended renewal of DML by the way of formulation.
	Remarks of Evaluator	Evidence of reference Product in plastic container is required.
	Previous Decision	Registration Board in its 290th meeting decided as follow: • For evidence of approval of applied formulation in HDPE Bottle in reference agencies. • Evidence of applied formulation/drug already approved by DRAP (generic/me-too status) alongwith registration number, brand name and name of firm is required.
	Evaluation By PEC	Applicant has submitted the following: We will use highly resistant amber glass bottles along with aluminium seal cap. Evidence of Me too: Evidence of International availability:
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm is required.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	

Case no. 02 Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

631.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Sarotex Oral Solution
	Composition	"Each 100ml Contains: Sulphadiazine…35.500mg Sulphadimidine…28.400mg Neomycin Sulphate…1.800mg Hyoscine Methylbromide…0.040mg Pectin…7.100mg

		Kaolin…10.330gm Vit. B1…0.150mg Vit. B2…0.220mg"
	Diary No. Date of R& I & fee	Dy.No 18960 dated 24-05-2018 Rs.20,000/- Dated 24-05-2018
	Pharmacological Group	Anti-diarrhoeal
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status (with strength and dosage form)	Scour-X Oral Suspension Of Selmore Pharmaceuticals EACH 100ML CONTAINS:- SULPHADIAZINE 3.550GM. SULPHADIMIDINE 2.840GM. NEOMYCIN SULPHATE 0.180GM. HYOSCINE METHYLBROMIDE 0.004GM. PECTIN 0.710GM. KAOLIN 10.330GM. VITAMIN B-1 0.015GM. VITAMIN B-2 0.022GM.
	GMP status	GMP Inspection conducted on 03-11-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	• Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as provided Me too contains quantities of APIs in some other units.
	Decision: Deferred for the following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as provided Me too contains quantities of APIs in some other units.** • **Registration Board decided to defer the case for clarification regarding approval of required manufacturing facility & manufacturing equipment for applied drug product from Licensing Divisions.**	
632.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Neuro-B Injection
	Composition	"Each 3ml Contains: Thiamine Hydrochloride (Vitamin B1)…100mg Pyridoxine Hydrochloride (Vitamin B6)…100mg Cyanocobalamin (Vitamin B12)…500mcg"
	Diary No. Date of R& I & fee	Dy.No 18961 dated 24-05-2018 Rs.20,000/- 24-05-2018
	Pharmacological Group	Vitamin B- Complex
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status (with strength and dosage form)	Neurofos Injection Of Zakfas Pharmaceuticals
	GMP status	GMP Inspection conducted on 03-11-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Registration Board deferred the case for clarification regarding approval of required manufacturing facility & manufacturing equipment for applied drug product from Licensing Divisions.	
633.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Carboxy-10% Injection
	Composition	"Each ml Contains: Marbofloxacin…100mg"

	Diary No. Date of R& I & fee	Dy.No 18975 dated 24-05-2018 Rs.20,000/- 24-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status (with strength and dosage form)	Marbostar 10% Solution of M/S Huzaifa International.
	GMP status	GMP Inspection conducted on 03-11-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator: • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Clarification is required regaling method used for sterilization of applied drug product.	
	Decision: Registration Board decided to defer the case for following. • **Clarification is required from Licensing Division regarding approval of required manufacturing facility & manufacturing equipment for applied drug product** • **Clarification is required from firm regarding method used for sterilization of applied drug product.**	
634.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Quinocox WSP Oral Powder
	Composition	"Each 1000gm Contains: Sulphaquinoxaline Sodium…200gm Sulphadimidine Sodium…82.5gm Diaverdine…40gm Vitamin A…2.8 M.I.U Vitamin K3…2gm"
	Diary No. Date of R& I & fee	Dy.No 18977 dated 24-05-2018 Rs.20,000/- 24-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	Decontrolled
	Me-too status (with strength and dosage form)	Trigun Water Soluble Powder of Attabak Pharmaceuticals.
	GMP status	GMP Inspection conducted on 03-11-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator	
	Decision: Registration Board deferred for clarification regarding approval of required manufacturing facility & manufacturing equipment for applied drug product from Licensing Divisions.	
635.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Syanokomin 250mcg/ml Injection
	Composition	"Each ml Contains: Cyanocobalamine (Vitamin B12)…250mcg"
	Diary No. Date of R& I & fee	Dy.No 18966 dated 24-05-2018 Rs.20,000/- 24-05-2018
	Pharmacological Group	Vitamin
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Cyanocob 250 Injection of "Prix Pharmaceuticals (Pvt) Ltd.
	GMP status	GMP Inspection conducted on 03-11-2017 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator: • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Clarification is required regaling method used for sterilization of applied drug product.	
	Decision: Registration Board deferred for following. • **Clarification is required from Licensing Division regarding approval of required manufacturing facility & manufacturing equipment for applied drug product** • **Clarification is required from firm regarding method used for sterilization of applied drug product.**	
636.	Name and address of manufacturer / Applicant	"M/s Wimits Pharmaceuticals (Pvt.) Ltd. Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Gentasol Injection 10gm/100ml
	Composition	"Each 100ml Contains: Gentamycin Sulphate…10gm"
	Diary No. Date of R& I & fee	Dy.No 18962 dated 24-05-2018 Rs.20,000/- 24-05-2018
	Pharmacological Group	Aminoglycoside antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status (with strength and dosage form)	Gentin 10% Injection of Pliva Pakistan (Pvt) Ltd., Baluchistan
	GMP status	GMP Inspection conducted on 03-11-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator: **Remarks** / **Response** Mention type of glass container whether it is Type-I, II or III. / Clarification is required regaling method used for sterilization of applied drug product. /	
	Decision: Registration Board deferred the case for following. • **Clarification is required from Licensing Division regarding approval of required manufacturing facility & manufacturing equipment for applied drug product** • **Clarification is required from firm regarding method used for sterilization of applied drug product.**	

b. Deferred Cases

637.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Tylo-Wal Powder
	Composition	"Each gm contains: Tylosin Tartrate…980mg"
	Diary No. Date of R& I & fee	Dy No. 6249: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Tylotar-98 of M/s. Evergreen Reg. #081736 (From M-285th RB)
	GMP status	GMP Inspection conducted on 29-10-2018 concluded that firm is compliant to current Good manufacturing requirements with the need of some improvements which

		have been discussed and agreed with the management.
	Remarks of the Evaluator	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided me-too is not verifiable. Applicant has claimed BP specifications.
	Previous Decision (M-):	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided me-too is not verifiable.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of Me Too: Tylo Fort W/S Powder Registration Number: 088629 Meeting No. 289th RB.
	Decision: Approved as per innovator's Specification.	
638.	Name and address of manufacturer / Applicant	"M/s Nawal Pahrmaceuticals. Plot No. 11-A, Punjab Small Industrial Estate,Taxila"
	Brand Name +Dosage Form + Strength	Wal-Fen 25% Liquid
	Composition	"Each 100ml contains: Florfenicol…25g"
	Diary No. Date of R& I & fee	Dy No. 6242: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre: Decontrolled
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Florfenicol Oral Liquid of M/S. Attabak Pharmaceuticals, Islamabad.
	GMP status	GMP Inspection conducted on 29-10-2018 concluded that firm is compliant to current Good manufacturing requirements with the need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator	
	Previous Decision (M-):	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, as the provided me-too is not verifiable.
	Evaluation by PEC:	Applicant has submitted the following: Evidence of Me Too: Nebiflor 25% Registration Number: 063639
	Decision: Approved as per innovator's Specification.	

Case no. 03 Registration applications of import cases

a. New Cases (Human)

639.	Name and address of Applicant	M/s Network Marketing Services, 14C (Commercial) P.C.H.S., Defence Road, Lahore.
	Detail of Drug Sale License	Address: M/s Network Marketing Services, Plaza No. 14, Block C, Commercial P.C.H.S, Defence Road, Lahore. Validity: 11-12-2020 Status: License to sell drug as distributor.
	Name and address of manufacturer	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu, China
	Name and address of marketing authorization holder	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu, China

	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 1774 Dated 12/01/2018
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form + Strength	Angiovision Injection
	Composition	Each ml contains: Iohexol…. 755mg (equivalent to 350mg of iodine)
	Finished Product Specification	USP Specifications
	Pharmacological Group	Water-soluble, nephrotropic, low osmolar X-ray contrast media/ Non Ionic Contrast Media
	Shelf life	24months (Stability studies submitted according to Zone IVA conditions)
	Demanded Price	As per SRO
	Pack size	100ml (Iohexol 77.5g equivalent to 350mg of iodine)
	International availability	Approved in US-FDA (OMNIPAQUE 350 mg iodine/mL (755 mg of iohexol/mL)
	Me-too status	Iobrix-350 Injection Of Hoffmann Human Health Pak Ltd Lahore
	Detail of certificates attached	**Original legalized COPP:** Certificate No: F-2016-06001. Certified by: Jiangsu Food & Drug Administration, China. Date for Issuance: June 7, 2016. Validity: Two Years From Issuance (it is not valid now). **Free sale in exporting country:** Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Original legalized GMP Certificate:** Certificate No. CN20140268 Certified by: China Food & Drug Administration Date for Issuance: 05/06/2014 Valid till**:** 05/06/2019
	Remarks of the Evaluator	Submit Stability study of one more batch of applied formulation both accelerated & real time conducted in accordance with zone IV-A conditions as you have submitted stability studies of two batches of applied formulation. Submit Valid Original legalized COPP as submitted COPP is not valid now. Submit Original Legalised Letter of authorization as it is not submitted. Submit differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but you have submitted Rs. 50,000/- only. Submit Valid Copy of DSL as it is not submitted. Explain the reason on scientific grounds that why you have not performed sterility testing of applied formulation at any time point in the submitted stability studies.
	Previous Decision: Deferred for the following: •	
	Evaluation by PEC:	

Remarks	**Response**
For submission of Stability study data of one more batch of applied formulation both accelerated & real	Firm has submitted stability study data of three more batches.

		time conducted in accordance with zone IV-A conditions as stability studies data of only two batches of applied formulation is submitted.	
		For submission of Original Legalized COPP for applied drug product as it is not valid now & Original Legalised Letter of authorization as well.	Now the applicant has submitted original legalized COPP having following information on it. Certificate No: 20190058. Certified by: Jiangsu Drug Administration, China. Date for Issuance: 02-08-2019. Validity: 31-05-2020.
		For submission of differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but submitted fee is Rs. 50,000/- only.	Firm has submitted Fee challan of Rs. 50,000/- dated 02-08-2019.
		For Submission of Valid Copy of DSL as it is not submitted.	Address: M/s Network Marketing Services, Plaza No. 14, Block C, Commercial P.C.H.S, Defence Road, Lahore. Validity: 11-12-2020 Status: License to sell drug as distributor.
		Justification/ clarification on scientific grounds for not carrying out sterility testing of applied formulation at any time point in the submitted stability studies.	Firm has submitted stability study data of three more batches showing performance of sterility test.
	Decision: Approved as per innovator's specification & as per policy of inspection of manufacturer abroad.		

640.	Name and address of Applicant	M/s Network Marketing Services, 14C (Commercial) P.C.H.S., Defence Road, Lahore.
	Detail of Drug Sale License	Address: M/s Network Marketing Services, Plaza No. 14, Block C, Commercial P.C.H.S, Defence Road, Lahore. Validity: 11-12-2020 Status: License to sell drug as distributor.
	Name and address of manufacturer	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu,China
	Name and address of marketing authorization holder	M/s Yangtze River Pharmaceutical Group Co., Ltd. 1 South Yangtze River Road, Taizhou, Jiangsu,China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 1775 Dated 12/01/2018
	Fee including differential fee	Rs. 100,000/-
	Brand Name +Dosage Form + Strength	Angiovision Injection
	Composition	Each ml contains: Iohexol…. 755mg (equivalent to 350mg of iodine)
	Finished Product Specification	USP Specifications
	Pharmacological Group	Water-soluble, nephrotropic, low osmolar X-ray contrast media/ Non Ionic Contrast Media
	Shelf life	24months
	Demanded Price	As per SRO
	Pack size	50ml (Iohexol 77.5g equivalent to 350mg of iodine)
	International availability	Approved in US-FDA

	(OMNIPAQUE 350 mg iodine/mL (755 mg of iohexol/mL)
Me-too status	Iobrix-350 Injection Of Hoffmann Human Health Pak Ltd Lahore
Detail of certificates attached	**Original legalized COPP:** Certificate No: F-2016-06001. Certified by: Jiangsu Food & Drug Administration, China. Date for Issuance: June 7, 2016. Validity: Two Years From Issuance (it is not valid now). **Free sale in exporting country:** Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to GMP as recommended by WHO as per CoPP. **Original legalized GMP Certificate:** Certificate No. CN20140268 Certified by: China Food & Drug Administration Date for Issuance: 05/06/2014 Valid till**:** 05/06/2019

Remarks of the Evaluator:
Submit Valid Original legalized COPP as submitted COPP is not valid now.
Submit Original Legalised Letter of authorization as it is not submitted.
Submit differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but you have submitted Rs. 50,000/- only.

Previous Decision: Deferred for the following:

- For submission of Original Legalized COPP for applied drug product as it is not valid now & Original Legalised Letter of authorization as well.
- For submission of differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but submitted fee is Rs. 50,000/- only.
- For Submission of Valid Copy of DSL as it is not submitted.

Evaluation by PEC:

Remarks	**Response**
For submission of Original Legalized COPP for applied drug product as it is not valid now & Original Legalised Letter of authorization as well.	Now the applicant has submitted original legalized COPP having following information on it. Certificate No: 20190059. Certified by: Jiangsu Drug Administration, China. Date for Issuance: 02-08-2019. Validity: 31-05-2020.
For submission of differential fee of Rs. 50,000/- as fee for registration of imported drug product is Rs. 100, 000/-, but submitted fee is Rs. 50,000/- only.	Firm has submitted Fee challan of Rs. 50,000/- dated 02-08-2019.
For Submission of Valid Copy of DSL as it is not submitted.	Address: M/s Network Marketing Services, Plaza No. 14, Block C, Commercial P.C.H.S, Defence Road, Lahore. Validity: 11-12-2020 Status: License to sell drug as distributor.

Decision: Decision: Approved as per innovator's specification & as per policy of inspection of manufacturer abroad

Case no. 04 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

641.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma (Pvt) Ltd. Plot No. E-178, S.I.T.E., Super highway Phase-II, Karachi.
	Brand Name +Dosage Form + Strength	Clarix Soft Gelatin Capsule 40mg
	Composition	Each soft gelatin capsule contains: Isotretinoin… 40mg
	Diary No. Date of R& I & fee	Dy No. 1338: 24-11-16: Rs.50, 000/-
	Pharmacological Group	Retinoic acid derivative
	Type of Form	Form 5D
	Finished product Specification	Manufacturers Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	N/A

STABILITY STUDY DATA			
Drug	Clarix Soft Gelatin Capsule 40mg		
Name of Manufacturer	M/s Maxitech Pharma (Pvt) Ltd. Plot No. E-178, S.I.T.E., Super highway Phase-II, Karachi.		
Manufacturer of API	Isotretinoin: Taizhou Bona Chemical Co., Ltd.		
API Lot No.	Isotretinoin: 20170706		
Description of Pack (Container closure system)	Alu/Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months Accelerated: 06 months		
Frequency	Accelerated: 0,1, 3,6 (month) Real Time: 0,1, 3,6 (month)		
Batch No.	TR001	TR002	TR003
Batch Size	Pilot Scale Batch	Pilot Scale Batch	Pilot Scale Batch
Manufacturing Date	08-2017	08-2017	08-2017
Date of Initiation	-----	-----	----
No. of Batches	03		
Date of Submission	Dy. No. 769 (15-03-19)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Applicant has submitted the following: **For API** (Isotretinoin)**:** Copy of COA **From:** Taizhou Bona Chemical Co., Ltd. Yantou Industrial Park Jiaojiang District, Taizhou City, Zhejiang China. **Batch #:** 20170706

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: **For API** (Isotretinoin)**:** Copy of GMP certificate: **Certificate No.** ZJ20150148 **Issued To:** Taizhou Bona Chemical Co. Ltd, **Issued By:** China Food & Drug Administration. **Valid up to:** 12-03- 2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**For API (Isotretinoin):** Copy of commercial invoice attested by ADC, Karachi, having following details on it is submitted by the firm: **Invoice Number:** 20170704 **Batch No:** 20170706 **Attested ON:** 26-07-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes.

Evaluation by PEC:

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Clarix Soft Gelatin Capsule 40mg (Isotretinoin) by M/s. Mexitech Pharma (Pvt). Ltd., S.I.T.E, Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 30th July, 2019.
Investigation Date and Time: 26th September, 2019 (Morning).
Investigation Site: Factory premises of M/s. Mexitech Pharma (Pvt). Ltd., Plot No. E-178, S.I.T.E, Super High, Phase-II, Karachi.

Background:
Chairman Registration Board considered the applications of M/s. Mexitech Pharma (Pvt). Ltd., S.I.T.E, Karachi for registration of Clarix Soft Gelatin 40mg Capsules (Isotretinoin) and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:
1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board).
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Ms. Mahrukh, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:
The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence

physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

CLARIX SOFT GELATIN 40MG CAPSULE

Sr.#	Question	Observation by panel
1.	Do you have documents confirming the import of API including approval from DRAP?	The firm has developed three stability batches of Clarix 40mg Softgel capsules from commercial import, invoice No. 20170704 dated 11-07-2017 & have a proper approval from DRAP office Karachi. The source of the API is Taizhou Bona chemicals china.
2.	What was the rationale behind selecting the particular manufacturer of API?	The firm has vendor certification program with established criteria including GMP certification of the source, existence of stability monitoring program with the API manufacturer along with QMS and provision of sample for trials, API and impurities reference standards.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has documents confirming the import of working standard of the API & one impurity standard (Tretinoin) from the API manufacturer
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificate of Analysis of the API, reference standard and impurity standard.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of the API manufacturer (for Isotretinoin) issued by China FDA.
6.	Do you use API manufacturer method of testing?	The firm is using USP method for testing API.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on the API generated by the API manufacturer.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The method is stability indicating and the major degradation product (Tretinoin) has been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm is using USP method for quantifying the impurity (Tretinoin) in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Some remaining quantities of the API, its reference standard and impurity standard are available with firm.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients. The following excipients have been used in the production of Clarix capsules: Hydrogenated Soya bean oil, Soya bean oil, Bees Wax, Glycerine, Methyl Paraben, Propyl Paraben, titanium dioxide, EDTA sodium, BHA, sorbitol & Gelatin powder (Bovine source)
12.	Do you have documents confirming the import of the used excipients?	Hydrogenated Soya bean oil is imported. While rest of excipients are procured locally.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and relevant records of the excipients used.
14.	Do you have written and authorized protocols for the product development	The firm has written and authorized protocol for the product development.
15.	Have you performed Drug-excipient compatibility studies?	The firm has not performed drug excipient compatibility as the formulation is same to that of the innovator product (Accutane softgel capsules 40mg).

16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies against Oratane (Douglas pharma, New Zealand (Batch: A1970). The firm's product has comparable dissolution profile with the comparator product. The absolute dissolution is more than 98% in all the three batches within 60mins.
17.	Do you have product development (R&D) section	The firm has product development section however this product has been manufactured in commercial manufacturing area keeping the sensitivity and technicality of the product.
18.	Do you have necessary equipment available in product development section for development of new product?	N/A
19.	Are the equipments in product development section qualified?	N/A
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	N/A
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	At present there is no dedicated person for product development however the quality control & production staff has ample knowledge of product development and have developed this product. The firm is advised to recruit dedicated personnel with proper knowledge and training of product development to carry out the product development activities properly.
22.	Have you manufactured three stability batches for the stability studies of new product as required?	The firm has manufactured three stability batches with following details: 1. Batch No. TR-01 (1000 capsules) MFG DATE 08-2017: , EXP DATE 08-2019 2. Batch No. P-01 (10000 capsules) MFG DATE 08-2017 , EXP DATE 08-2019 3. Batch No. P-02 (10000 capsules) MFG DATE 08-2017, EXP DATE 08-2019 The capsules are packed in Alu/Alu blisters of pack size of 3X10's
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria is primarily based on the national and international guidelines.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has protocol for stability testing. The protocol need up gradation in terms of quantification of the impurities.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has used USP method supported by forced degradation studies to indicate its stability indicating nature. The method has been verified however before 24 months studies. The 24 months studies show acceptable results for the Assay of the parent compound and the degradation product along with other test parameters.

27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	The verification of the USP method has been performed in this area.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	The firm has documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug
29.	Do your method of analysis stability indicating?	The firm's method of analysis for testing the stability batches is stability indicating supported by forced degradation & spiking studies.
30.	Do you were HPLC software 21CFR Compliant?	As per relevant documents the HPLC software is 21CFR compliant.
31.	Can you show Audit trail reports on new product testing?	The audit trail reports on the API and the finished products were shown to the panel.
32.	Do you have some remaining quantities of degradation products and stability batches?	Some quantity of the degradation product (Tretinoin) is available with the firm. The real time on all the three stability batches is already over.
33.	Do you have stability batches kept on stability testing?	24 months real time stability testing is already over.
34.	Do you have valid calibration status for the equipment's used for production and analysis of new product?	The firm has valid calibration status of equipment used in production and analysis of the new product.
35.	Do proper and continuous monitoring and control are available for stability chamber?	proper and continuous monitoring and control are available for stability chamber.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities are GMP compliant.
37.	Any remark of PEC? 1. For not performing leakage test for semi solid & liquid ingredients from soft gelatin capsules. 2. For adopting a dissolution method different from that of US FDA recommended method.	1. The product is pharmacopial and there is no such test in the pharmacopeia, however, since the specifications for appearance of the soft gel capsules contain requirement regarding the shape which actually indicate that the capsules should not be deformed due to any leakage etc. 2. USP method for dissolution has been performed on the capsules as the product is included in USP pharmacopeia. The US FDA method for dissolution was published in June, 2008 whereas, the USP method was introduce in 2009 hence, the USP method is more relevant in this case.

Conclusion and Recommendations:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Clarix Soft Gelatin 40mg Capsules (Isotretinoin) is verifiable to satisfactory level.
2. Registration of the product "Clarix Soft Gelatin 40mg Capsules" is recommended in the name ` manufacturer.

Decision: Registration Board decided to approve registration of "Clarix Soft Gelatin Capsule 40mg" by M/s Maxitech Pharma, Karachi. Manufacturer shall place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
642.	M/s. Scilife Pharma, Karachi.	Nibo-Val 5/80mg Tablet Each tablet contains: Nebivolol…5mg Valsartan….80mg	Duplicate dossier As per SRO	Approved in US-FDA

STABILITY STUDY DATA

Drug	Nibo-Val 5/80mg Tablet		
Name of Manufacturer	M/s. Scilife Pharma, Karachi		
Manufacturer of API	**For Nebivolol Hydrochloride:** M/s. Zhejiang Ausun Pharmaceuticals Co., Ltd. No. 5 Dhongai 4th Avenue, Zhejiang Chemical Materials Base Linhai Zone, Zhejiang China. **For Valsartan:** M/s. Zhuhai Rundu Pharmaceuticals Co. Ltd, No. 6 North Airport Road, Sanzao Town, Jinwan District Zhuhai, Ghangdong China.		
API Lot No.	**For Nebivolol Hydrochloride:** Lot No. P-0231-20160101P2 **For Valsartan:** Lot No. 64617110611		
Description of Pack (Container closure system)	Alu/alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 06 months	Accelerated: 06 months	
Frequency	Accelerated: 0,1, 3,6 (month)	Real Time: 0,1, 3,6 (month)	
Batch No.	044B18	045B18	046B18
Batch Size	5000 tablets	5000 tablets	5000 tablets
Manufacturing Date	05-04-2018	05-04-2018	05-04-2018
Date of Initiation	02-07-2018	02-07-2018	02-07-2018
No. of Batches	03		
Date of Submission	11-03-19 (Dy. No. 260)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted the following: **For Nebivolol Hydrochloride:** Copy of COA **From**: Zhejiang Ausun Pharmaceuticals Co., Ltd. **Batch No**: No. . P-0231-20160101P2 **For Valsartan:** Copy of COA **From**: M/s. Zhuhai Rundu Pharmaceuticals Co. Ltd, **Batch No**: No. CY201712060

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: **For Nebivolol Hydrochloride:** Copy of GMP Certificate: **Certificate No:** Not Mentioned **Issued To**: Zhejiang Ausun Pharmaceuticals Co., Ltd. **Issued ON**: 25-07-2016 **Valid Till**: 24-07-2019 **Issued By**: Zhejiang Taizhou Drug & Chemical Administration. **For Valsartan:** Copy of GMP Certificate: **Certificate No:** GD20160649 **Issued To**: M/s. Zhuhai Rundu Pharmaceuticals Co. Ltd, **Issued ON**: 14-11-2016 **Valid Till**: 13-11-2021 **Issued By**: China Food & Drug Administration.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted following: **For Nebivolol Hydrochloride:** Coy of Commercial invoice attested by ADC on 04-08-17 having following information on it: **Invoice Number**: AX2017F133 **Manufacturer of API**: Zhejiang Ausun Pharmaceuticals Co., Ltd Nebivolol hydrochloride API: 0.2kg(200gm) **For Valsartan:** Coy of Commercial invoice attested by ADC on 8-02-18 having following information on it: **Invoice Number**: RIS17094 **Batch Number:** 64617110611 **Manufacturer of API**: M/s. Zhuhai Rundu Pharmaceuticals Co. Ltd
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

Evaluation by PEC:

Remarks	**Response**
Submit Valid GMP Certificate for Nebivolol hydrochloride (API) manufacturer issued by concerned regulatory authority of country of origin, as it is not valid now.	Firm has submitted following: Written confirmation for active substance (Nebivolol hydrochloride) exported to EU. Confirmation No. ZJ190058 Manufacturer's License No. 20120001 Issued by: Zhejiang Food & drug Administration. Valid Till. Jul 24th, 2022.
Submit evidence that Zhejiang Taizhou Drug & Chemical Administration is concerned regulatory authority for	Applicant has submitted following : Written confirmation for active substance (Nebivolol hydrochloride) exported to EU.

Nebivolol hydrochloride (API) manufacturer.	Confirmation No. ZJ190058 Manufacturer's License No. 20120001 Issued by: Zhejiang Food & drug Administration. Valid Till. Jul 24th, 2022.
Submit lot number of API Nebivolol hydrochloride imported for production of trial batches of applied formulation.	Nebivolol hydrochloride Lot No. P-0231-20160101P2
Submit master formulation of each of your trial batches.	Firm has submitted master formulation for a bilayer tablet, however evidence of reference product as bilayer tablet is not found.
Submit analytical method used for test/analysis of applied drug product before further processing of case.	Firm has submitted an analytical method for test/analysis of applied formulation declaring their dissolution method as per USFDA recommended dissolution parameters.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Nibo-Val 5/80mg Tablets (Nebivolol + Valsartan) by M/s. Scilife Pharma (Pvt). Ltd., Karachi.

Reference No: F.13-11/2017-PEC (Pt) dated 26th September, 2019.
Investigation Date and Time: 27th September, 2019 (Morning).
Investigation Site: Factory premises of M/s. Scilife Pharma (Pvt). Ltd., Korangi Creek, Industrial State, Karachi.

Background:
Chairman Registration Board considered the applications of M/s. Scilife Pharma (Pvt). Ltd., Korangi Creeck, Industrial State, Karachi for registration of Nibo-Val 5/80mg Tablets (Nebivolol + Valsartan) and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:
1. Dr. Rafeeq Alam Khan, Dean Faculty of Pharmacy, Ziauddin University, Karachi. (Member Registration Board).
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Ms. Sanam Kauser, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:
Investigation of the authenticity / genuineness of data (import of raw material and stability data), manufacturing of stability batches and stability studies on these batches.

Tools for Investigation:
The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

NIBO-VAL 5/80MG TABLETS

Q.#	Question	Observation by panel
1.	Do you have documents confirming the import of API?	Firm has imported 200g Nebivolol HCl from M/s Zhejiang Ausan Pharmaceutical Co. Ltd, China. For stability batches of the product material from commercial import of 300 kg Valsartan imported from M/s Zhuhai Rundu Pharmaceutical company Limited, China has been used. **Nebivolol HCl:** Taken approval 04-08-2017 Invoice No AX2017F133 Dated: 26-07-2017 issued by M/s Zhejiang Ausan Pharmaceutical **Valsartan:** Taken approval 08-02-2018 Invoice No RIS17094 Dated: 28-12-2017 issued by M/s Zhuhai Rundu Pharmaceutical is submitted.
2.	What was the rationale behind selecting the particular	There is proper vendor evaluation form being implemented by the firm. The parameters included in this form are, DMF

	manufacturer of API?	status, GMP certificate, Stability data, provision of reference standard of API and impurities standards etc. The firm has evaluated on this criteria and has been selected accordingly. The source for valsartan was requested for estimation of nitroso compounds for the batches sent earlier to Scilife after the issue of nitroso compounds in the valsartan API.
3.	Do you have documents confirming the import of reference standard and impurity standards?	The firm has documents confirming the import of reference standards. **Nebivolol HCl:** Reference standard and full set of impurities of Nebivolol have been imported from M/s Zhejiang Ausan Pharmaceutical China. **Valsartan:** Firm has imported the reference standard and impurities of Valsartan from United State Pharmacopeia.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis of both the API, reference standard and impurities standards. Subsequent COA for Valsartan API containing the test for NDMA (Major impurity) has also been obtained by the firm from the manufacturer for the same batch they received earlier for manufacturing of their stability batches.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has GMP certificates of both APIs manufacturers issued by regulatory authorities of their respective country of origin.
6.	Do you use API manufacturer method of testing?	Firm has used API manufacturer`s method of testing for Nebivolol HCl whereas Valsartan has been tested as per USP monograph.
7.	Do you have stability studies reports on API?	Firm had stability studies reports on both the API provided by the manufacturers.
8.	If yes, whether the stability testing have been performed as per SIM method and degradation products have been quantified?	Stability testing have been performed as per Stability Indicating Methods (SIM) and impurities/related substances/degradation products have been quantified for both API by their respective manufacturers.
9.	Do you have method for quantifying the impurities in the API?	The firm has used manufacturer methods for Nebivolol HCl and USP method for Valsartan. Both the methods have the capacity to quantify the respective impurities.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of both the API, their reference standards and impurities standards.
11.	Have you used pharmaceutical grade excipients?	Firm has used pharmaceutical grade excipients including; lactose monohydrate, Microcrystalline cellulose 101, Microcrystalline cellulose 102, Copovidone, Croscarmellose Sodium, Magnesium stearate, talcum powder, HPMC, Polysorbate 80, PEG 6000, Titanium dioxide and Ferric oxide yellow.
12.	Do you have documents confirming the import of the used excipients?	Firm has purchased all the excipients from the local market although they have certificate of analysis for all the excipients available with them.
13.	Do you have test reports and other records on the excipients used?	Firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of the product?	Firm has written and authorized protocol for the development of the product.
15.	Have you performed Drug-excipients compatibility studies?	Firm has not performed Drug-excipients compatibility studies as their formulation is similar to that of the innovator formulation (Byvalson Tablets of M/S. ALLERGAN USA).

<table>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>Firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers with Byvalson 5/80mg tablets manufactured by M/S. ALLERGAN USA. The firm‘s product results are comparable to that of the
Reference product which are given below,

<table><tr><td>Reference Product</td><td colspan="2">Byvalson</td></tr><tr><td>Batch number</td><td colspan="2">W00551</td></tr><tr><td>CDP Results Obtained</td><td>Nebivolol</td><td>Valsartan</td></tr><tr><td>Similarity Factor at pH 1.2</td><td>53.90</td><td>66.39</td></tr><tr><td>Similarity Factor at pH 4.5</td><td>69.78</td><td>55.56</td></tr><tr><td>Similarity Factor at pH 6.8</td><td>58.49</td><td>63.82</td></tr><tr><td>Limit</td><td>F□ ≥ 50</td><td>F2 ≥ 50</td></tr><tr><td>Remarks</td><td>Satisfactor</td><td>Satisfactory</td></tr></table></td></tr>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>Firm has equipped product development (R&D) section.</td></tr>
<tr><td>18.</td><td>Do you h ve necessary equipment’s avail ble in product development section for deve opment of the p oduct?</td><td>Firm has necessary equipment’s for production of tablets in product development section. However compression and blistering have been done in production area.</td></tr>
<tr><td>19.</td><td>Are the equipments in product development section qualified?</td><td>The relevant equipment in product development section are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>Firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has trained and qualified staff in product development section with proper knowledge and training in product development Including 03 Pharmacist, 04 Chemist and 01 Bio technologist.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of the product as required?</td><td>Firm has manufactured three stability batches for the stability studies of Neb-Val 5/80mg tablets with batch number 044B18, 045B18 and 046B18 with batch size of 5,000 tablets each. The tablets are packed in ALu-ALu blisters with pack size of 2 x 7s.</td></tr>
<tr><td>23.</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches, as informed by the firm, was based on the quantity required for stability study (i.e. number of tablets per testing frequency and number of testing frequencies / intervals) and minimum working
Capacity of the equipment.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>Firm has completed record of production of stability batches.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>Firm has detailed protocol for stability testing of stability batches.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The Firm has developed and performed detailed analytical method validation studies for testing of stability batches.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has not conducted method transfer studies, however, they have validated their method properly.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipments /</td><td>Firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis</td></tr>
</table>

	instruments being used in the test and analysis of API and the finished drug?	of API and the finished drug.
29.	Do your method of analysis stability indicating?	Firm's method of analysis is stability indicating as evidence by force degradation studies.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record of the firm. Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available.
31.	Can you show Audit Trail reports on product testing?	Audit trail reports were available and randomly checked.
32.	Do you have some remaining quantities of degradation products and stability batches?	Firm has remaining quantities of stability batches.
33.	Do you have stability batches kept on stability testing?	Firm has completed the accelerated stability testing on the three stability batches however the real time stability testing is in progress on all the three stability batches. Currently 12 months study has been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment's used in production and analysis?	Firm has valid calibration status for the equipment used in production and analysis of the product.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment's, personnel and utilities be rated as GMP compliant.
37.	Any observation/Clarification by PEC: 1. Justification for development of Bilayer tablets as evident from submitted master formulation and manufacturing method as reference product is not bilayer tablet or otherwise evidence is needed from Firm of reference product as bilayer product	The available literature at USFDA website with the name of Byvalson product, which shows that the product is bilayer.The innovator product (Byvalson 5/80mg tablets) were physically checked. It was confirmed that the tablets are bilayer in which one layer is white and second layer is light yellow and finally coated with Opadry film coat. It is further informed that the bilayer tablets as designed and produced by the innovator technically reflect the difference of physico chemical characteristics of both the API. Valsartan is a fluffy API and not suited wet granulation where as Nebivolol HCl is crystalline material suited for wet granulation with polysorbate 80 as solubilizer. Hence the firm developed the product with bilayer formulation and final coat with film coating material as per innovator product.

Conclusion and Recommendations:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Nibo-Val 5/80mg Tablets (Nebivolol + Valsartan) is verifiable to satisfactory level.
2. Registration of the product "Nibo-Val 5/80mg Tablets" is recommended in the name of the manufacturer.

Decision: Registration Board decided to approve registration of "Nibo-Val 5/80mg Tablet" by M/s. Scilife Pharma, Karachi (Each tablet contains: Nebivolol…5mg, Valsartan….80mg). Manufacturer shall place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.

d. Exemption from onsite verification of stability data

643.	Name and address of manufacturer / Applicant	M/s. Genix Pharma (Pvt.) Ltd, Karachi
	Brand Name +Dosage Form + Strength	Flumil Tablet 500mcg
	Composition	Each Tablet Contains: - Roflumilast….500mcg
	Diary No. Date of R& I & fee	Dy No .
	Pharmacological Group	systemic drugs for obstructive airway diseases
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA Daliresp (Roflumilast) tablet
	Me-too status	N/A
	GMP status	GMP inspection 16-02-2018 concluded as follow: In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other CGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an satisfactory level of compliance with CGMP GUIDLINES as of today. The management was also suggested to further strengthen stability and analytical sections

STABILITY STUDY DATA

Drug	Flumil Tablet 500mcg		
Name of Manufacturer	Genix Pharma (Pvt.) Ltd, Karachi		
Manufacturer of API	**For Roflumilast:** M/s. Glenmark Pharmaceutical Ltd, India		
API Lot No.	Roflumilast: Lot #: 83180037		
Description of Pack (Container closure system)	Alu /alu Blister		
Stability Storage Condition	Accelerated:40˚C ± 2˚C/75%±5% RH Real Time: 30˚C ± 2˚C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated:0,1,2,3,4,6(Months) Real Time:0,3,6,9,12,18,24(Months)		
Batch No.	18SB-124-01	18SB-133-02	18SB-134-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	16-07-2018	16-07-2018	16-07-2018
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Photocopy of COAs of Roflumilast, working standard. Detail is as under : **Particulars** / **Batch No** Roflumilast / 83180037

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: **For Roflumilast:** GMP Certificate No: 6081505 Issued to: Glenmark Pharmaceuticals Ltd. A-80, MIDC KURKUMBIL, TAL-DAUND, DIST, PUNE-413802 Issued by: Food & Drug Administration, Maharashtra State. Issued for: Purpose of Export Registration. Validity: Until 03-05-2019
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted the following: **For Roflumilast:** Copy of commercial Invoice declaring following information on it: Invoice No: F20000002444 Date.01-03-2018 Attested by: ADC Karachi Attested on: 14-03-2018 Quantity: 0.1 Kg From: M/s M/s. Glenmark Pharmaceuticals, India.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
Data for Exemption from onsite investigation		
Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their Product "WYMLY Tablets 25mg (TenofovirAlafenamide)", which was conducted on 06-02-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (TenofovirAlafenamide), of M/s. Genix Pharma (Pvt.) Ltd., Karachi. Following two points are reported inside the above stated inspection report: • The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. • Audit trail on the testing reports of WYMLY Tablets 25mg (TenofovirAlafenamide) is available. (Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well).

<table>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Applicant has submitted the following:
<u>For Roflumilast:</u>
Copy of commercial Invoice declaring following information on it:
Invoice No: F20000002444 Dt. 01-03-2018
Attested by: ADC Karachi
Attested on: 14-03-2018
Quantity: 0.1 Kg
From: M/s M/s. Glenmark Pharmaceuticals, India.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td><u>For Roflumilast:</u>
The firm has submitted copy of letter from M/s. Mogan Chemicals addressed to M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following working standard.<table><tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th><th>Supplier</th></tr><tr><td>Roflumilast WS</td><td>WL00301</td><td>1gm</td><td>M/s. Glenmark Pharmaceuticals.</td></tr></table></td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Applicant has submitted the following:
<u>For Roflumilast:</u>
GMP Certificate No: 6081505
Issued to: Glenmark Pharmaceuticals Ltd.
A-80, MIDC KURKUMBIL, TAL-DAUND, DIST, PUNE-413802
Issued by: Food & Drug Administration, Maharashtra State.
Issued for: Purpose of Export Registration.
Validity: Until 03-05-2019</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy for the following:
“SOP for Selection of manufacturer for Vendor Certification.
SOP No: QA/SOP/SY/037 with effective date 07-10-2016.
Version no: 01
Copy of “Vendor’s Certification Questionnaire” filled for M/s Glenmark Life Sciences, India.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of Roflumilast, working standard. Detail is as under :<table><tr><th>Particulars</th><th>Batch No</th></tr><tr><td>Roflumilast</td><td>83180037</td></tr><tr><td colspan="2">Working Standards</td></tr><tr><td>Roflumilast WS</td><td>Wl00301.00</td></tr><tr><td colspan="2"></td></tr></table></td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development comprising of 04 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for trial batch manufacturing of Flumil Tablets (500mcg).

The firm claimed that master formulation and manufacturing method mentioned in development protocol is same as that of Innovator product.</td></tr>
</table>

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of the following 03 Batches:
<table>
<tr><th>BATCH NO</th><th>BATCH SIZE</th><th>MFG DATE</th></tr>
<tr><td>18SB-124-01</td><td>1500 Tablets</td><td>04-2018</td></tr>
<tr><td>18SB-133-02</td><td>1500 Tablets</td><td>04-2018</td></tr>
<tr><td>18SB-134-03</td><td>1500 Tablets</td><td>04-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has attached Record of remaining quantities of stability batches:</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 01-07-2018 to 31-01-2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td><u>For Roflumilast:</u>
The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Roflumilast.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure (QC-FPNS-138 issued on 13-07-2018) for Roflumilast 500mcg tablets along with Stability Study Report of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td><u>For Roflumilast:</u>
The firm has submitted photocopy of Empagliflozin 06 Months Accelerated (40oC+2 oC, RH 75+5%) & 60 month real time stability study data of 03 batches from M/s Glenmark Life Sciences, India.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for excipients used in product development of Flumil Tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies</td><td>The firm has stated that the composition of developed product is similar to the innovator’s product formulation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted F2 factor protocol (QC/PRO/CD/24) & reports. The details of reference product & Sample product are as follows:
<table>
<tr><th>feature</th><th>Reference product</th><th>Product of M/S Genix Pharma</th></tr>
<tr><td>Brand name</td><td></td><td>Flumil Tablet 500mcg</td></tr>
<tr><td>Batch No</td><td></td><td></td></tr>
<tr><td>Expiry Date</td><td></td><td></td></tr>
</table>
Comparative dissolution studies have been performed in following mediums:
i. pH 0.1N HCl buffer
ii. pH 4.5 Acetate buffer
iii. pH 6.8 Phosphate buffer
In pH 0.1 N HCl buffer similarity factory is 87.083
In pH 4.5 Acetate buffer similarity factory is 84.201
In pH 6.8 Phosphate buffer similarity factory is 83.539</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports of stability studies of applied formulation.</td></tr>
</table>

Remarks of Evaluator :
Submit valid copy of GMP certificate of API manufacturer, as it is not valid now.
COA & documents for procurement of Impurity Standard is not submitted.
Submit evidence of procurement of reference product.
Clarification is required regarding particle size of Roflumilast API, as reference product contains micronized form of API.
Upon communication of above observations firm has submitted requisite documents.

Decision: Registration Board decided to approve registration of "Flumil Tablet 500mcg (Roflumilast 500mcg) by M/s Genix Pharma (Pvt.) Ltd, Karachi. **Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six month.**

Case No.1 De-Registration of Locally Manufactured Products of M/s Sami Pharmaceuticals (Pvt) Ltd, Karachi

M/s Sami Pharmaceuticals (Pvt) Ltd, F-95, Off. Hub River Road, S.I.T.E, Karachi has applied for de-registration of their following registered products.

S/ N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	009922	Pencit 500mg Injection Each vial contains: Sterile Ampicillin Sodium BP eq. to Anhydrous Ampicillin……..250mg Sterile Cloxacillin Sodium BP eq. to anhydrous Cloxacillin……500mg	The firm does not have dedicated section manufacturing of this product.	Ampiclox/ GlaxosmithKline Ampicloxacillin/ Haji Mediccine Co Amplus/ Bosch Pharmaceuticals	15-09-1988 12-07-2018
2.	014249	Moxypen 1000mg Injection Each vial contains: Sterile Amoxycillin Sodium BP equivalent to Amoxycillin….1000mg base	The firm does not have dedicated section manufacturing of this product.	Medioxil/ Mediceena Pharma Penbro/ P.D.H Pharmaceuticals Supramox/ Bosch Pharmaceuticals	05-08-1993 08-05-2018
3.	015062	Moxypen DS Syrup Each 5ml contains: Amoxycillin Trihydrate BP equivalent to 250mg Amoxycillin base	The firm does not have dedicated section manufacturing of this product.	Amocillin/ Consolidated Chemical Laboratories. Amolexin/ Lexicon Pharmaceuticals Amoxascot/ Scotmann Pharmaceuticals	27-02-1994 31-10-2018
4.	010389	Moxypen 500mg Capsules Each capsules contains: Amoxycillin …..250mg (as Amoxycillin Trihydrate)	The firm does not have dedicated section manufacturing of this product.	ABAC/ Rakaposhi Pharmaceuticals Adamox/ Adamjee Pharmaceuticals Almox/ Alson Pharmaceuticals	19-02-1990 25-01-2005

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

a. Copy of Registration Letter & Last Renewal Status.
b. List of alternate brands available in the country.
c. Justification.
d. An Undertaking that:
    i. No case is pending at any forum/ court of law regarding above mentioned products.
    ii. Provided information/ documents are true/ correct.

Decision: Registration Board acceded to the request of M/s Sami Pharmaceuticals (Pvt) Ltd., Karachi for de-registration of their above mentioned products.

CaseNo.2: De-Registration of Locally Manufactured Products of M/s Bloom Pharmaceuticals (Pvt) Ltd, Hattar

M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot No. 30, Phase I & II Industrial Estate Hattar has applied for de-registration of their following registered products.

S/ N	Reg.No.	Brand name and composition	Justification	Alternate Brands/ Registration Holders submitted by the firm.	Date of Registration & Last Renewal Status
1.	022364	Conil Tablets Each tablet contains: Paracetamol…325mg Pseudoephedrine HCl……15mg Dextromethorphan HBr……10mg Chlorpheniramine Maleate……..1mg	➢ The product didn't have satisfactory response from market due to availability of better generics in therapy. ➢ Furthermore, the firm has stated that they have not submitted renewal of product registration in September 2018 and onwards, on purpose.	Epinol-DM Tablets/ Consolidated Chemicals Laboratories Coldrex Tablets/ Standpharm Pakistan (Pvt) Ltd	15-09-1998 18-09-2013

In the light of SOP approved vide 283rd meeting, the firm has submitted following documents:

a. Copy of Registration Letter & Last Renewal Status.
b. List of alternate brands available in the country.
c. Justification.
d. An Undertaking that:
   i. No case is pending at any forum/ court of law regarding above mentioned products.
   ii. Provided information/ documents are true/ correct.

Decision: Registration Board acceded to the request of M/s Bloom Pharmaceuticals (Pvt) Ltd, Hattar for de-registration of their above mentioned products.

Case No.03: Request of M/s Martin Dow Limited, Karachi for import of Controlled Drug Substance for Trial/ Development & Stability Purposes.

M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi has requested for permission to import a controlled drug substance " Buprenorphine" for developing their product "Subrenor Tablet" i.e., under process of registration. Details are as under:

S.No	Name of Drug(s) with composition	Submission Date/ Remarks	Quantity required for trial, development & stability batches
1.	Subrenor Sublingual Tablets 4mg Each tablet contains: Buprenorphine……4mg	11-05-2018 Form-5D Fee Rs. 50,000/-	0.341kg
2.	Subrenor Sublingual Tablets 8mg Each tablet contains: Buprenorphine……8mg	Application to be submitted on form-5F after completion of stability. The firm has stated that as per requirement of Form-5F Module 3.2.P.2 & 3.2.P.8 the development and stability studies are required to be submitted with Form-5F.	0.658kg

S.No	Controlled Drug Substance	Quantity required for trial, development & stability batches	Source
1	Buprenorphine HCl API	0.999kg	Johnson Matthey

2	Buprenorphine HCl Reference Standard	500mg	(Macfarlan Smith) Wheatfield Road, Edinburgh, EH11 2QA, Scotland
3	Buprenorphine Related compound A RS	25mg	
4	Buprenorphine HCl System Suitability mixture RS	50mg	

The firm has submitted break up of quantities required for trial, development & stability batches i.e., as under:

S. No.	Product	API	mg/ Tab	No. of Tab/ batch	No. of batches	Quantity of API required		
					Trial + Stability	For formulation development	For QC testing & Retention	Total
						kg	g	kg
1.	Subrenor Sublingual Tablets 4mg	Buprenorphine HCl	4.32	Batch size for trial batch(1x10) (13,302 tablets) Batch size of Lab scale batch (20,000 tablets) Batch size for Pilot batch 1 (20,000 tablets) Pilot batch 2 (20,000 tablets)	Trial batches (10) Stability batches (03)	0.316	For chemical testing: 12.500 Retention Sample: 12.500 Total: 25.000	0.341
2.	Subrenor Sublingual Tablets 8mg	Buprenorphine HCl	8.64	Batch size for trial batch(1x10) (13,302 tablets) Batch size of Lab scale batch (20,000 tablets) Batch size for Pilot batch 1 (20,000 tablets) Pilot batch 2 (20,000 tablets)	Trial batches (10) Stability batches (03)	0.633	For chemical testing: 12.500 Retention Sample: 12.500 Total: 25.000	0.658

Decision: Registration Board deferred the case and directed the firm to submit justification for using 10 trial batches of 13,302 Tablets.

Case No.4: Correction in Minutes of 290th Meeting of Registration Board.

Following products of M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi were considered by the Registration Board in its 290th meeting held on 3rd-4th July, 2019 as per following details:

S/ N	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price /Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1.	M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi	Experta Tablet 90 mg Each film coated tablet contains: Ticagrelor… 90 mg (Anti-coagulant) In-house Specifications	Form-5D Dy. No. 09-04-2015 Rs. 50,000/- Pack Size: 14‘s 178.57/	BRILINTA of Astrazenica USFDA Approved. Not applicable GMP compliant dated 07/02/18 —On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection.

2.	M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi	Experta Tablet 60 mg Each film coated tablet contains: Ticagrelor… 60 mg (Anti-coagulant) In-house Specifications	Form-5D Dy. No. 31835 16-Nov-2015 Rs. 50,000/- Pack Size: 14‘s 142.87/-	BRILINTA of Astrazenica USFDA Approved. Not applicable

Decision: *Registration Board decided to approve registration of "**Experta Tablet 90mg (Ticagrelor)** by M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi." Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months*.

Approval for "Experta 60mg Tablet" is not mentioned in above stated decision of 290th meeting. However, it seems to be a typo-error since complete details & requisite data submission of both the strengths (i.e., Ticagrelor 60 mg & 90mg) are mentioned in minutes. Accordingly, the case has been placed for correction in minutes of M-290.

Decision: Registration Board noted the information for following correction in minutes of 290th meeting w.r.t the above mentioned case:

Registration Board decided to approve registration of "Experta Tablet 90mg (Ticagrelor) & Experta Tablet 60mg (Ticagrelor) by M/s Tabros Pharma (Pvt) limited, L-20/B, Sector-22, Federal B Industrial Area, Karachi." Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Case No.5: Request for Change in Registration Status of Products From M/s OBS Pakistan (Pvt.) Ltd, Karachi To M/s. Aspin Pharma, Karachi.

Registration Board, in its 287th meeting held on 3rd & 4th January, 2019, deferred the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No.10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 for change of registration status of following product from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name "***till the case regarding correction in registration certificates (as mentioned alongside the case) is under process"***. Details are given as under:

S. No.	Reg.No.	Brand name and composition	Registration History	Remarks
I	**II**	**III**	**IV**	**V**
1.	090926	Misort 100mg Tablet Each tablet contains: Misoprostol as 1% HPMC dispersion .....100mcg (International Pharmacopeia Specification’s)	Initial date of Reg. 30-07-2018	The firm has now applied for 100mcg tablet. However, the case for correction in strength (mentioned alongside the brand name) is under process.

Management of the firm has provided following documents:-

i. Original challan Fee of Rs. 20,000/- for each product.
ii. Copies of initial letters of registration and renewal status as stated in column IV above.
iii. Section approval of M/s Aspin verified from Licensing Division’s letter for renewal of DML (dated 09th June, 2016) confirming following sections;
   - Tablet (General)
   - Capsule (General)
   - Liquid Syrup
   - Ointment/ Cream.
iv. Copy of last GMP inspection report of M/s Aspin, Karachi dated 08th August, 2018 indicating "Satisfactory" level.

v. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 19th November, 2018.
vi. DML of M/s Aspin dated 31st May, 2015.

The firm has now submitted corrigendum for correction in brand name of above mentioned product issued vide letter No.F.31-PRVC/2019 (PR-1) dated 02-09-2019, stating correct strength alongside the brand name i.e., "**100mcg**"

Decision: Registration Board decided as follows:

i. **Cancellation of registration of Misort 100mg Tablet (R#090926) from the name of M/s OBS Pakistan (Pvt.) Ltd., Karachi.**
ii. **Approved registration of product Misort 100mg Tablet in the name of M/s Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area Karachi-74900.**
iii. **Reference will be sent to Cost and Pricing Division for confirmation of maximum retail price (MRP).**

Case No.6: Approved Products of M/s Medicon Pharmaceuticals Peshawar.

Following products of M/s Medicon Pharmaceuticals, Peshawar were approved by the Registration Board, in its 238th meeting held on 05-06th August, 2013, as per below mentioned details:

S.No.	Name of Firms	Name of Drugs /label Claim	AU	Price	Date	Remarks	Current Status
1.	M/s. Medicon Pharmaceuticals, Peshawar	Medixim Dry Powder Suspension Each 5 ml contains:- Cephalexin monohydrate ≡ Cephalexin…125 mg (Cephalosporin)	60 ml	As Per SRO	24-5-2011	Approved. The Registration Board advised the Registration sections to again review the Registration Dossiers before issuance of Registration letters	UK MHRA Approved formulation
2.	M/s. Medicon Pharmaceuticals, Peshawar	Medixim Dry Powder Suspension Each 5 ml contains:- Cephalexin monohydrate ≡ Cephalexin ……250 mg (Cephalosporin)	60 ml	As Per SRO	-do-	do	USFDA Approved formulation
3.	M/s. Medicon Pharmaceuticals, Peshawar	Medixim Dry Powder Suspension Each ml contains:- Cephalexin monohydrate ≡ Cephalexin ……..…100 mg (Cephalosporin)	60 ml	As Per SRO	-do-	do	UK MHRA Approved formulation
4.	M/s. Medicon Pharmaceuticals, Peshawar	Mediclor Drops Each ml contains:- Cefaclor monohydrate ≡Cefaclor…100mg (Cephalosporin)	15 ml	As Per SRO	-do-	do	RRA status couldn't be confirmed.
5.	M/s. Medicon Pharmaceuticals, Peshawar	Mediclor Dry Powder Suspension Each 5 ml contains:- Cefaclor	60 ml	As Per SRO	-do-	do	USFDA Approved formulation

		monohydrate ≡ Cefaclor …….250 mg (Cephalosporin)					
6.	M/s. Medicon Pharmaceuticals, Peshawar	Cefadream Dry Powder Suspension Each 5 ml contains:- Cefadroxil hemihydrate ≡ Cefadroxil ……125 mg (Cephalosporin)	60 ml	As Per SRO	-do-	do	In duplicate dossiers provided by the firm, they have mentioned: "Cefadroxil monohydrate ≡ Cefadroxil …125 mg" i.e., USFDA Approved formulation
7.	M/s. Medicon Pharmaceuticals, Peshawar	Medinazole Capsules Each capsule contains:- Fluconazole..150mg (Anti-fungal)	1's 4's	As Per SRO	-do-	do	UK MHRA Approved formulation

Original dossiers couldn't be retrieved from available record. However, the firm has now provided following documents for further consideration:-

i. Duplicate dossiers for each product (Dy.No. 19018 dated 27-09-2019) along-with photocopy of fee deposit slip of Rs.84,000/-.
ii. Panel Inspection Report for renewal of DML dated **18-03-2011** stating following Sections:
    - Capsule (General)
    - Dry Suspension (Ceph)
iii. Copy of last GMP inspection report dated 03-10-2017 indicating "Satisfactory" level.
iv. Copy of DML issued/renewed dated 14-06-2011.

Decision: Registration Board deferred for following:

- **Confirmation of relevant manufacturing sections.**
- **Confirmation of product at S.No.4 for submission of evidence of approval status of applied formulation by Reference Regulatory Authorities.**

Case No.7: Request for Change In Registration Status of Product(s) From M/s. GlaxoSmithKline Pakistan Ltd, Karachi to M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Jamshoro.

Registration Board in its 291st meeting held on 02nd- 04th September, 2019 deferred the request of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd [Formerly M/s GSK OTC (Pvt) Ltd.], Petaro Road Jamshoro (DML #000010) for change of registration status of following products from M/s. GlaxoSmithKline Pakistan Ltd, Karachi to their name *"**for confirmation of approval status of required manufacturing facilities from** Licensing Division. The Board also advised the firm **for submission of evidence of approval status of applied formulations in Reference Regulatory Authorities (**w.r.t products at S.No. 1 & 4 of below table)"*. Details are given as under:

S/N	Reg. No.	Brand Name & Composition of Registered Products	Initial letter of registration with renewal status.	Registration Holder/ Manufacturer	Dy. No. & Date/ Remarks
I	**II**	**III**	**IV**	**V**	**VI**
1.	000394	Iodex CMS Ointment (As per copy of Registration Letter dated 24-03-1976 the	1- Letter No.Nil dated 24-03-1976 in the name of M/s Smith Kline and French of Pakistan Ltd,	GlaxoSmithKline Pakistan Limited F-268, S.I.T.E,	Duplicate Applications on From-5 along with photocopy fee

		composition is not mentioned)	Karachi. 2- Transfer from M/s Glaxowellcome to M/s GSK Pakistan Ltd., D/43, Textile Avenue, SITE, Karachi vide Letter No.3-3/2003-Reg-II (M-179) dated 30th August, 2003. 3- Last Renewal Application Dated 13-06-2018. **Remarks of RRR Section** Registration Board granted the renewal w.e.f 30-08-2018 to 29-08-2023 (Ref. F.No.3-10/2019-RRR (M-288 Dated 26-06-2019)	Karachi (DML#000233)	challan of Rs.360,000/- (6-6-2016) & Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560) Label claim as applied on Form-5: Iodex CMS Ointment Sublime Iodine …4%w/w Methylsalicylate ……..5%w/w **As per information submitted by the firm, formulation is approved in Mexico**
2.	019645	ENO Orange Each 5gm contains: Sodium Bicarbonate BP…….2.274gm Citric Acid BP……2.153gm	1-F.No.3-5/96-Reg-II (M-121) dated 07-08-1996 in the name of M/s Beecham Pakistan (Pvt) Ltd, Karachi. 2- Transfer from M/s Galxowellcome to M/s GSK Pakistan Ltd., D/43, Textile Avenue, SITE, Karachi vide Letter No.3-3/2003-Reg-II (M-179) dated 30th August, 2003. 3- Last Renewal Application Dated 13-6-2018 **Remarks of RRR Section (27-07-2019)** ENO Fruit Salt Orange Reg No. 019645 as mentioned by the concerned section and documents referred, is registered on 07-08-1996 with a post registration variation on 30-08-2003 the application is received on 13-06-2018 i.e within time under Rule 27 Drug (LR&A).	M/s GSK Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (DML#000017)	Duplicate Applications on From-5 along with photocopy fee challan of Rs.360,000/- (06-06-2016) and Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560) Label claim as applied on Form-5: Each 5gm contains: Sodium Bicarbonate ……2.32gm Sodium Carbonate anhydrous..0.5gm Citric Acid.2.18gm Registration Board in its 263rd meeting approved the same composition of ENo Orange & case is under process of MRP confirmation/ fixation.
3.	000180	ENo Fruit Salt Regular (As per copy of Registration Letter dated 16-04-1976 the composition is not mentioned)	1- Letter. No. Ni. Dated 16-04-1976 in the name of M/s Beecham Pakistan Ltd, Karachi. 2- Transfer of Registration from M/s Galxowellcome to M/s GSK Pakistan Ltd., D/43, Textile Avenue, SITE, Karachi vide Letter No.3-3/2003-Reg-II (M-179) dated 15-9-2003.	M/s GSK Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (DML#000017)	Duplicate Applications on From-5 along with photocopy fee challan of Rs.360,000/- (06-06-2016) & Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560)

			3- Last Renewal application Dated 13-6-2018 **Remarks of RRR Section (27-07-2019)** ENO Fruit Salt Regular Reg. No. 000180 is registered as mentioned by concerned section and documents referred, on 16-04-1976. With a post registration variation on 15-09-2003. The application for renewal is received on 13-06-2018 i.e within time under Rule 27 Drug (L,R,A)		Label claim as applied on Form-5: Each 5gm contains: Sodium Bicarbonate ……2.32gm Sodium Carbonate anhydrous..0.5gm Citric Acid2.18gm Registration Board in its 263rd meeting approved the same composition of ENo Orange & case is under process of MRP confirmation /fixation.
4.	022549	Acne Aid Cream Sulphur….2.50% w/w Resorcinol USP ……..1.25% PCMX (ParaChloroMetaXylenol) ….0.38% w/w Sulphur Precipitated …..2.50%w/w	1- F.No.6-33/94-Reg-II (M-133) dated 27-11-1998 in the name of M/s Stiefel Laboratories, Gujranwala. 2- Corrigendum for correction in composition dated 22-12-2004. 3-Transfer of Registration in the name of M/s GSK Pakistan Ltd., 35- Dockyard Road, West Wharf, Karachi vide Letter No.1-20/2011-Reg-II (Vol-I) dated 10th June, 2011. 4- Last Renewal application Dated 24-11-2017 **Remarks of RRR Section (27-07-2019)** Acne Aid Cream Reg. No. 022549 is not available with this section. However, as per documents attached by the section the product is registered in the name of M/s Stiefel Laboratories later on transferred to glaxosmithKline,35 Dockyard, Karachi on 16-06-2011 (Post Reg. Variation) and renewal application is consider vide SRO 1005(I) and was considered in meeting of Registration Board for the regularization of renewal application of 2016 & validity granted till 9-6-2021	M/s GSK Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (DML#000017)	Duplicate Applications on From-5 along with photocopy fee challan of Rs.360,000/- (06-06-2016) and Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560) Label claim as applied on Form-5: Acne Aid Cream Sulphur Precipitated BP …..2.500%w/w Resorcinol BP ……..1.250% Chloroxylenol (PCMX) BP ….0.380% w/w **As per information submitted by the firm, formulation is approved in Malaysia.**
5.	029329	Hydrozole Cream Hydrocortisone…….1% w/w Clotrimazole…1%	1- F.No3-7/2002-Reg-II (M-175) dated 14-12-2002 in the name of M/s Stiefel Laboratories, Gujranwala.	M/s GSK Pakistan Limited, 35-Dockyard	Duplicate Applications on From-5 along with photocopy fee

		w/w	2- Transfer of Registration in the name of M/s GSK Pakistan Ltd., 35- Dockyard Road, West Wharf, Karachi vide Letter No.F.1-20/2011-Reg-II (Vol-I) dated 10th June, 2011. 3- Last Renewal Application Dated 28-11-2017 & 12-10-2017. **Remarks of RRR Section (27-07-2019)** Hydrocozole Cream Reg # 029329, the registration date as per referred documents and record is 14-12-2002 registered in the name of M/s Stiefel Laboratories Gujrawala and later on transfer to GlaxosmithKline, 35 Dockyard, Karachi on 10-06-2011. The last renewal as per available computer record is received on 12-10-2017, starting/considering from the date of registration is received within time under Rule 27 of Drug (L,R,A). Furthermore, Registration letter and post registration may be verified at the end of concerned section.	Road, West Wharf, Karachi (DML#000017)	challan of Rs.360,000/- (06-06-2016) and Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560) TGA approved formulation.
6.	019464	Brevoxyl Cream Contains: Benzoyl Peroxide ……4.00% w/w	1- F.No.3-3/96-Reg-I (M-121) dated 11-8-1996 in the name of M/s Stiefel Laboratories, Lahore. 2- Transfer of Registration in the name of M/s GlaxoSmithKline Pakistan Ltd, 35- Dockyard Road, West Wharf Karachi (on contract from M/s Akhai) vide Letter No.1-20/ 2011-Reg-II (Vol-I) dated 31st January 2013. Permission is valid upto 30.06.2020. 3- Approval for manufacturing at M/s GlaxoSmithKline Pakistan Ltd, 35- Dockyard Road, West Wharf Karachi dated **26-06-2019**	M/s GlaxoSmithKline Pakistan Ltd, 35-Dockyard Road, West Wharf Karachi (DML#000017)	Duplicate Applications on From-5 along with photocopy fee challan of Rs.360,000/- (06-06-2016) and Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560) UK MHRA approved formulation.

The firm has provided following documents:-

1. Applications on From-5 along with fee of Rs.360,000/- (06-06-2016) and Rs.900,000/- (27-06-2016) (Duplicate)

2. Copies of initial letter of registration and renewal status.
3. Evidence for approval of "Tablet (General)" & "Liquid (General)" sections of M/s Pharmatec, Karachi vide Licensing Division's letter dated 16-02-2016.
4. Copy of last GMP inspection report of M/s GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi dated 11-09-2018 and 04-10-2018 (**Good** Level of Compliance).
5. Copy of last inspection report of M/s GlaxoSmithKline Pakistan Ltd, 35- Dockyard Road, West Wharf Karachi.
6. Copy of last GMP inspection report of M/s Pharmatec Paksitan (Pvt) Ltd, D-86/A, S.I.T.E, Karachi dated 21-05-2019 (**Good** Level of Compliance).
7. Evidence of approval for change in title from "GSK OTC (Pvt) Ltd Jamshoro" to "M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro (DML #000010)" dated 14-05-2019.
8. NOC from M/s. GlaxoSmithKline Pakistan Ltd, Karachi dated 25-06-2019.
9. Consent from contract manufacturers dated 03-07-2019 and 04-07-2019.

In line with the decision taken by the board, case has been referred to Licensing Division for confirmation regarding approval status of requisite manufacturing facilities. However, the firm has now provided copy of Panel Inspection Report for regularization & renewal of DML as per following details:

a. Panel Inspection Report for regularization & renewal of DML for M/s GSK Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (DML#000017), dated 05-09-2019 stating recommendation for renewal of DML for following sections:
    i. Ointment (General)
    ii. Oral Powder Eno (General) Section.
    iii. Eye/Ophthalmic Ointment Section.
    iv. Ear/ Otic Drops.
    v. Capsule/ Spansule (General)
    vi. Non-Pareil Seeds (NPS)- In house use only.

b. Panel Inspection Report for renewal of DML for GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi (DML#000233), dated 26,27-03-2019 & 01-04-2019 stating recommendation for renewal of DML and following sections:
    i. Iodex Section/ Ointment Section
    ii. Liquid (General) Section.
    iii. Tablet (General) Section.
    iv. Penicillin Tablet Section
    v. Penicillin Capsule Section
    vi. Penicillin Dry Suspension Section.

The Board was further informed that M/s GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Jamshoro has been granted approval for 02 sections, therefore, entitled for contract manufacturing of 10 products as per policy of 5 products per section while the firm has already been granted approval for registration of 04 products.

Decision: Registration Board decided as follows:

i. Cancellation of registration of products at S.No. 2, 3, 5 & 6 from the name of M/s GSK Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (DML#000017).

ii. Approved registration of products at S.No. 2, 3, 5 & 6 in the name of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro (DML #000010) through contract manufacturing by M/s GSK Pakistan Limited, 35-Dockyard Road, West Wharf, Karachi (DML#000017). For products at S.No. 2 & 3, composition will be mentioned as approved by the Registration Board in its 263rd meeting (i.e., stated in last column of above table). Furthermore, for verification of

duplicate fee deposit slips, procedure shall be adopted as approved by the Registration Board in its 285th meeting

iii. **Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).**

iv. **Deferred the products at S.No. 1 & 4 for submission of evidence of approval status of applied formulations in Reference Regulatory Authorities.**

Case No.8: Request for Change In Registration Status of Products from M/s Macter International Ltd, Karachi To M/s Cibex (Pvt.) Ltd, Karachi.

Registration Board, in its 248th meeting considered the request of M/s Cibex (Pvt.) Ltd Plot No. F-405, S.I.T.E, Karachi wherein it was informed by the firm that have developed their facility for manufacturing of Tablet (General), Capsule (General), Sachet (General), Tablet (General Antibiotics), Liquid Manufacturing, Capsule (General Antibiotics), Dry Syrup (General Antibiotics), Ointment-I (Steriods) and Ointment-II (Non Steriods) located at Plot No. F-405, S.I.T.E, Karachi vide Drug Manufacturing License No.000784.

The firm has requested for transfer of their following registered drugs from M/s Macter International Ltd, Karachi to their name as per following details: -

Sr. No.	Reg. No.	Brand Name(s)	Formulation / Generic Name	Date of Registration	Remarks
1.	027108	Famobex Suspension	Each 5ml contains:- Famotidine….10mg	13-06-2001	The applied formulation is not approved in SRA's
2.	039198	Catafen Tablets 100mg	Each sugar coated tablet contains:- Diclofenac Potassium…….100mg	26-05-2005	Formalities required as per Form-5 are complete

Registration Board in its 248th meeting approved the product at Sr.No.2 and deferred the product at Sr.No.1 for review of formulation.

For product at Sr.No.1 the firm has submitted that the same formulation is freely available, manufactured and marketed by multiple firms in Pakistan. These products are old registered products and were registered prior from the implementation of SRA regime. DRAP has not taken any action to withdraw this product from the market or stop its manufacturing. DRAP has also awarded price increase for same product (Al-Famot) to Ali Industries vide SRO.08(I)/2017 dated 07-09-2017, which demonstrate DRAP's intention to patronize selected companies which unfortunately is discriminating. W.r.t. product at Sr.No.2, the firm has stated that multiple companies are still manufacturing the 75mg and 100mg strength of this molecule without any hindrance from DRAP. Therefore, non-issuance of registration is unconstitutional and illegal. They have requested to grant them registration of above products.

Furthermore, the firm has submitted that "if DRAP issues registration letters of above mentioned two products, we are ready to withdraw the suit (CP Suit No.1545/2017, Cibex vs DRAP & others) filed by us against DRAP and also undertake to stop manufacturing and marketing these two products if other companies are compelled by DRAP to withdraw these products from market."

The case was deferred in 14th meeting of PRVC for deliberation in next meeting. Later on the case was reconsidered in 19th PRVC with following decision taken:

Decision of 19th PRVC:

The Committee deferred the case for presentation before registration board in next meeting with complete background, record and updated status of WP No 1695/2017 filed in

Islamabad High Court Islamabad by M/s. Quaper Pharma V/S Federation of Pakistan, in the case of Diclofenec Potassium 100 mg Tablets.

Background

W.r.t above mentioned two formulations, the Registration Board has already taken following decisions:

Sr. No.	Formulation	Ref. Meeting No. of Reg. Board	Decision/Remarks
1.	Famotidine 10mg/5ml Suspension	M-250	***Remarks:*** Not approved by reference drug regulatory agencies. Internationally available formulation is dry powder for suspension in the strength of 40 mg/ 5 ml. (Ref: US FDA) **Decision:** i. Applicants shall revise their formulation as per innovator (new registration application with complete fee) within six months if manufacturing facility is approved by CLB. ii. For already registered drugs, same procedure as mentioned above (at Sr. No. i) shall be adopted. Otherwise show cause notice shall be issued for de-registration of registered drugs in this formulation. iii. All such application shall be processed on priority basis.
2.	Diclofenac Potassium 75mg & 100mg	M-258	**Decision:** Diclofenac Potassium is not registered in any reference country in dose more than 50mg, thus Registration Board decided to issue show cause notices to manufacturers of Diclofenac Potassium (75 and 100mg) for de-registration of these products.

In this regard, manufactures of Diclofenac Potassium 75mg & 100mg Tablets have already been issued show cause notice including following firms:

Sr.#	Reg. No.	Firm Name	Name of drug(s) & Composition
1.	021634	M/s Global Pharmaceuticals, Plot no.204-205, Industrial Triangle, Kahuta Road, Islamabad.	Artinil-K Tablets 75mg Each tablet contains: Diclofenac Potassium……..75mg
2.	066670	M/s. Medizan Labs. (Pvt) Ltd. P.No. 313, Industrial Triangle Kahuta Road, Islamabad	Qrelif-75 Tablets Each tablet contains: Diclofenac Potassium…….75mg
3.	027876	M/s. Valor Pharmaceuticals, 124/A Kahuta Road, Industrial Triangle Zone, Islamabad.	Vaclo-Pot Tablets Each tablet contains: Diclofenac Potassium…….75mg
4.	028340	M/s. Robins Pharmaceuticals Industries, 43, Industrial Triangle, Kahutta Road, Islamabad	Dinak Tablets Each tablet contains: Diclofenac Potassium…….75mg
5.	031800	Technovision Pharmaceuticals 295-Industrial Triangle, Kahuta Road.	Ketagesic-75 Tablets Each tablet contains: Diclofenac Potassium…….75mg
6.	037415	Makson Pharmaceuticals Plot No.80-B, Street No.6I-10/3, Industrial Area Islamabad	Makaid-K 75Mg Tablets Each tablet contains: Diclofenac Potassium…….75mg
7.	056845	Webros Pharmaceuticals, Plot # 1, Street # 10, RCCI, Industrial Estate, Rawat, Islamabad	Deltaflam Tablets 75mg. Each Tablet Contains :- Diclofenac Potassium.....75mg.
8.	038437	Pearl Pharmaceuticals, Plot No.204, Street No.1, I-10/3, Islamabad	Phlodic-K Each Tablet Contains :- Diclofenac Potassium.....75mg.

9.	024333	Candid Pharmaceutical, Opposite Pasrur Suagr Mills Sialkot Road, Pasru	Kalfen Tablets Each tablet contains:- Diclofenac Potassium.....75mg
10.	047860	M/s. Wise Pharmaceuticals, Plot no.3-A, S-1, RCCI Industrial Estate, Rawat, Islamabad.	Achex-75mg Tablets Each film coated tablet contains: Diclofenac Potassium.....75mg
11.	049385	M/s Shawan Pharmaceuticals, Plot no.37, road NS-1, National Industrial Zone Rawat Islamabad	Lofen Tablets Each tablet contains: Diclofenac Potassium.....75mg
12.	043655	Miracle Pharmaceuticals (Pvt.) Ltd. Pharmaceuticals (Pvt) Ltd	Marinac-P 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
13.	043987	M/s Neomedix Pharmaceuticals, Islamabad	Neofenik- 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
14.	037574	M/s Vision Pharmaceuticals, Islamabad	Deflam 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
15.	038553	M/s Glitz Pharmaceuticals, Islamabad	Glif-K 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
16.	050019	M/s Caraway Pharmaceuticals, Islamabad	Carafenac-P 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
17.	050107	M/s Harrison Pharmaceuticals, Islamabad	Diclokam-K 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
18.	050953	M/s Leads Pharma, Islamabad	Diclosoft-K 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
19.	052552	M/s Panacea Pharmaceuticals, Islamabad	Tasilex 75 Tablets Each tablet contains:- Diclofenac Potassium 75mg
20.	052727	M/s Paramount Pharmaceuticals, Islamabad	Ronset SRTablets Each tablet contains:- Diclofenac Potassium 75mg

Status of WP No 1695/2017

M/s Quaper Pharmaceuticals (Pvt) Ltd, Sargodha filed a Writ Petition bearing no. 1695/2017 dated 02-05-2017 in Islamabad High Court against issuance of show cause notice dated 13-04-2017 and requested for suspension of further proceedings on the basis of that show cause notice. Islamabad High Court, vide an order dated 08-05-2017, directed that "no final order shall be passed with respect to the proceedings in pursuance of show cause notice 13-04-2017" and the case was not taken up for a long time. As the matter is of Public Health importance, thus Drug Regulatory Authority of Pakistan (DRAP) requested Islamabad High Court that the instant Writ Petition No.1695/2017 may be fixed for early hearing in the best interest of justice. Subsequently, the case was heard on 06-05-2019 and the honorable court has directed to fix the case after summer vacations.

Decision of M-288:

Registration Board decided that all registration holders of "Diclofenac Potassium 75mg & 100mg" shall be called for personal hearing.

Foregoing in view, the case has been placed before the Registration Board for deciding the matter.

Decision: Registration Board deferred the case for further deliberation in light of DRAP's Authority decision.

Case No.9: Extension in Contract Manufacturing of Drug of M/s. Xenium Pharmaceuticals, P-62-A, St # 11, Afghanabad # 1, Faisalabad Through Contract Manufacturing by M/s Medicaids Pakistan (Pvt.) Ltd; Karachi.

M/s. Xenium Pharmaceuticals, Faisalabad has requested for extension of contract manufacturing of following product. The details are as under:-

S.#	***Regn. No.***	***Existing Name***	***Remarks***
I	II	III	VII
1.	020439	Spor-3 Injection 1gm Each vial of dry substance contains:- Ceftriaxone Sodium eq. to Ceftraxone base ……. 1gm	Dy # 205 Dated 23-01-2018

Brief of the case is as under:-

i. The products was registered in import vide letter dated 13-07-1998.
ii. The product was transferred from import to local contract manufacturing for 05 years vide letter dated 27-1-2004 through contract manufacturing by M/s Medicaids Pakistan (Pvt.) Ltd; Karachi.
iii. The firm applied for further extension and application was received on 29-9-2010 but the firm did not provide fee for this purpose and the firm requested to grant them interim permission till 30-06-2015.
iv. The firm again applied extension for contract manufacturing vide dairy dated 19-06-2015 and not deposited fee for this purpose.
vi. Now the firm has deposited fee of **Rs. 1,50,000/-** for above stated product along with undertaking and requested to grant them extension in contract manufacturing by M/s. Medicaids Pakistan (Pvt.) Ltd; Karachi.
vii. The firm has also provided Form-5 from M/s. Medicaids Pakistan (Pvt.) Ltd; Karachi and contract agreement.

The case was considered in the 4th meeting of PRVC where it was deferred for presentation before Registration Board and the Board in its 279th meeting deferred the case for the opinion of Legal Affairs Division.

The Legal Affairs Division opined that ***"it is clarified that the S.R.O. 1005(I)/2017 dated 19-07-2018 only cover the renewal of regular registered products and not the extension of contract manufacturing."*** However, the firm has submitted fee of Rs.1,50,000/- for above said product.

Registration Board again deliberated in 286th meeting on the matter in its deferred the case for further deliberation in coordination with Legal Affairs Division of DRAP. The Deputy Director (Legal Affairs) may be called during meeting for the case to discuss the case and opined about the case.

Decision: Registration Board deferred the case for further deliberation.

Case No.10: Registration of deferred products of M/s. Dyson Pharma, Sheikhupura.

M/s. Dyson Pharma, Lahore has requested for registration of following products which were considered in 263rd meeting.

Sr. No	**Name of Drug**	**Demanded MRP and Pack size**	**Application detail**	**International availability**
1	Dyston Tablets 10mg Each film coated tablet contains:- Dydrogesterone….10mg (Progestogen)	As per SRO 20's	Rs. 8000/- (25 May, 2011) Rs. 12000/- (24 Jan,2014)	MHRA approved (Duphaston)

The above mentioned applied products were approved in 236th meeting subject to comparative dissolution profile and related documents and confirmation about anabolic/non anabolic section approval.

The firm had submitted all required documents and case was resubmitted in 260th meeting of R.B but deferred the case for further deliberation in next meeting.

i. Differential Fee of Rs. 12000/per product
ii Comparative dissolution profile
iii. Undertaking as per decision of Registration Board in 251st meeting.

Registration Board in 263rd meeting again deferred for clarification of source of API (whether biological or synthetic).The firm clarified that above mentioned products are of anabolic nature and provided references of pharmacopeia (European, British and US) and Certificate of Analysis for confirmation of synthetic nature of above mentioned API

Registration Board in its 265th deferred the product for confirmation of isomer of API.

Registration Board in its 286th meeting decided as under:-

Registration Board deliberated the case in the light of above stated facts and findings and decided as under:

Since USP monograph for Dydrogesterone states CAS No. "152-62-5" i.e assigned to "Trans Isomeric Form; 6-Dehydroretroprogesterone" and as per Drugs Specification Rules 1978, "drug products registered with any official pharmacopoeial specifications shall follow specifications present in the latest edition of that publication". Furthermore, as per information available on web, approval status of "Cis Isomeric Form" of dydrogesterone could neither be confirmed in any Reference Regulatory Authority nor in Syria and Israel. Therefore, the Board referred the case to the Appellate Board with the request to review the decision taken vide its 134th meeting, held on 17-06-2008.

Accordingly, the case was considered by the Appellate Board and the Board agreed with the scientific opinion/justification and interpretation of the drugs (Specifications) rules,1986 by the registration board in its 286th meeting held on 14th-16th November, 2018. The board directed the pharmaceutical Evaluation and Registration Division to ensure that all registered formulation/products and evaluation of Dydrogesterone products must comply with the official pharmacopeial monograph i.e USP. The board further directed the division of QA&LT to allow the import of API for registered products of Dydrogesterone as per official monograph only and to issue a circular for information of all concerned.

Decision of 289th meeting of Registration Board:

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

The firm has stated that they have applied Trans isomeric form of Dydrogesterone which is as per USP monograph. They have requested to them registration of the product.

Decision: Registration Board approved the registration of above product in the name of M/s. Dyson Pharma, Sheikhupura with USP specification.

Case No.11: Registration of deferred products of M/s. Fynk Pharmaceuticals, Lahore.

The Registration Board in its 228th meeting deferred the following product of M/s. Fynk Pharma, Lahore for review committee.

S.No.	Name of Drug(s) with Composition	Demanded MRP and Pack Size	Decision of RB	Remark
1.	Piram Injection Each 5ml contains:- Piracetam….1gm	As Per SRO 12'sx5ml	Deferred for review committee.	The product is available in ANSN France & Italy.
2.	Piram Capsules Each capsule contains:- Piracetam….400mg	As Per SRO 6x10's	Deferred for review committee	The product is available in ANSN France.

The firm has requested to grant them registration of above products. The firm need to provide copies of challans of Rs. 8000/- & Rs.12,000/- for each product.

Decision: Registration Board approved registration of products at Sr.1-2 in the name of M/s. Fynk Pharmaceuticals, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.

Case No.12: Registration of deferred products of M/s. BJ Pharmaceuticals, Lahore.

The Registration Board in its 237th meeting approved the following product of M/s. BJ Pharmaceuticals, Lahore. The details are given as under:-

S.No.	Name of Drug(s) with Composition	Demanded MRP and Pack Size	Decision of RB
1.	Betalyte Liquid Each 1000ml contains:- Sodium chloride….3.5gm Sodium citrate….2.9gm Potassium chloride….1.5gm Dextrose anhydrous……20gm (Oral electrolyte replacer)	As per SRO 1000ml 500ml 250ml	WHO approved low osmolarity formula as under, Sodium chloride …. 2.6gm Trisodium citrate citrate…. 2.9gm Potassium chloride…. 1.5gm Dextrose anhydrous…… 13.5gm

The firm has provided copies of challan of Rs.8000/- & Rs.12,000/- along with copy of From-5.

Decision: Registration Board approved registration of above product in the name of M/s. BJ Pharmaceuticals, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.

Case No.13: Registration of Deferred Products of M/s. Shrooq Pharmaceuticals, Lahore.

The registration Board decided the following applications of M/s. Shrooq Pharma Lahore. The details are given as under:-

Sr. No	Brand Name/Label claim	Demanded Pack size	Demanded Price	Decision	Remarks
1.	OSB Sachet Each sachet contains:- Omeprazole….20mg Sodium bicarbonate…1680mg	10's	As Per SRO	Approved Subject to humidity control system monitoring\ (M-228)	USFDA HVAC system verified by Inspection report for GMP Compliance dated 12-05-2016
2.	OSB Sachet Each sachet contains:- Omeprazole….40mg Sodium bicarbonate...1680mg	10's	As Per SRO	Approved Subject to humidity control system monitoring (M-228)	USFDA HVAC system verified by Inspection report for GMP Compliance dated 12-05-2016

3.	Pal Tablets Each tablet contains:- Palperidone…..3mg	10's	-do-	Deferred for expert opinion (M-228)	USFDA
4.	Pal tablets Each tablet contains:- Palperidone…..6mg	20's	-do-	Deferred for expert opinion (M-228)	USFDA
5.	Cinol Tablets. Each tablet contains:- Phloroglucinol……..80mg Trimethyl Phloroglucinol…….80mg.	30's	Rs. 400.00	Deferred as the panel of inspector not recommended the products for registration comprising concerned F.I.D and the Dr. Jamshed, member of the Drugs Registration Board dated 24-10-2007	ANSM France

The firm has provided copy of GMP inspection dated 30-04-2019 and requested to grant them registration of above mentioned products. The needs to provide proof of submission of fee challans as per procedure of Registration Board.

Decision: **Registration Board approved registration of above product in the name of M/s. Shrooq Pharmaceuticals, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting**.

Case No.14:- Request of M/s. Vet Line International, Lahore for change of address (Local) for their already registered veterinary drugs.

M/s. Vet Line International, Lahore has requested for change of local address for their following registered/approved veterinary products as per following details:-

S. No.	Reg. No.	Name of Drug(s)	Name & Address of Importer (as per Registration Letters)	Name & Address of Importer (as per New DSL)	Initial date of Registration & date of last renewal
1.	049749	Tylo-Suscit Powder	M/s. Vet Line International, Flat # 55/5, First Floor, Shadman Market, Lahore.	M/s. Vet Line International, Plot No.939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore. **Godown Address as per new DSL:-**Basement & Ground Floor, 939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore.	25-09-2008 29-01-2013 04-07-2018
2.	049750	Sulfaclozin Na 60% Powder	-do-	-do-	25-09-2008 Firm applied for renewal on 31-10-2017 with fee of Rs.60,000 availing SRO.No.1005 (I) /2017
3.	088146	BELACOL 24% Oral Liquid	-do-	-do-	23-02-2018
4.	088651	Aciphen Oral Powder	-do-	-do-	06-04-2018
5.	093226	Pyanosid Powder	-do-	-do-	02-11-2018
6.	-	Belacol 100% Kompaktat (Water Soluble Granules)	-do-	-do-	Approved in (M-287)
7.	-	Gentacin Solution for Injection	-do-	-do-	Approved in (M-287)
8.	-	Neomycin sulfat Water Soluble Powder	-do-	-do-	Approved in (M-289)
9.	-	Neocin 49% Powder	-do-	-do-	Approved in (M-289)
10.	-	Quinosol 20% solution	-do-	-do-	Approved in (M-289)
11.	-	Mucolin 1% Powder (oral)	-do-	-do-	Approved in (M-289)
12.	-	Lincofeed 4.4% Powder	-do-	-do-	Approved in (M-287)
13.	-	Moxi 50% Powder	-do-	-do-	Approved in (M-287)
14.	-	Doxsure 50% Powder	-do-	-do-	Approved in (M-287)

The firm has deposited fee of Rs.5000 x 14 = Rs. 70,000/- and submitted following documents:-

a) Copies of initial Registration letters alongwith renewal status.
b) Copy of previous Drug Sale License is submitted.
c) Copy of new Drug Sale License is submitted.

Decision:- **Registration Board approved firm's request for change of local storage facility address from "*Flat # 55/5, First Floor, Shadman Market, Lahore*" to "*Basement & Ground Floor, 939-A, Block-J, Phase-I, LDA Avenue-1, District Lahore*" for above mentioned imported veterinary products in accordance with DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site.**

Case No.15: Request of M/s. Prix Pharmaceutica, Lahore for Change of Address (Local) for Their Already Registered Veterinary Drugs.

M/s. Prix Pharmaceutica, Lahore has requested for change of local address for their following registered imported products as per following details:-

S. No.	Reg. No.	Name of Drug(s)	Name & Address of Importer (as per Registration Letters)	Name & Address of Importer (as per New DSL)	Initial date of Registration & date of last renewal
1.	049578	Oxtra Effervescent Pessaries	M/s. Prix Pharmaceutica, 26-Abbot Road, Lahore.	M/s. Prix Pharmaceutica, 26-Abbot Road, Lahore. **Godown:-** Plot No. 5, Pharmacity 30 Km, Multan Road, District Lahore.	02-09-2008 15-08-2018
2.	012989	Oxtra LA Injection	-do-	-do-	08-12-1991 Initial date 02-12-1993 Transfer of Regn. date 15-10-2018
3.	049589	Micospectone	-do-	-do-	02-09-2008 15-08-2018
4.	033221	Neodiaristin Oral Powder	-do-	-do-	11-11-2004 28-10-2014
5.	020760	Toloxan Plus Drench	-do-	-do-	04-12-1997 16-11-2017
6.	015404	Aagent 10% Injectable Solution	-do-	-do-	08-06-1994 04-06-2014
7.	020757	Dalmarelin Injection	-do-	-do-	04-12-1997 16-11-2017
8.	020758	Bacolam Injectable Suspension	-do-	-do-	04-12-1997 16-11-2017
9.	020759	Bacolam Water Soluble Powder	-do-	-do-	04-12-1997 16-11-2017
10.	012339	FA Try Banil	-do-	-do-	04-04-1991 Initial date

					12-01-1995 Transfer of Regn. date 18-12-2014
11.	027476	FA TRY Banil R.T.U. Injection	-do-	-do-	25-04-2002 04-04-2017
12.	027477	Bicormicina L.A. Injection	-do-	-do-	25-04-2002 04-04-2017
13.	043109	Metabolase Forte Injectable Solution	-do-	-do-	26-04-2006 04-04-2016
14.	023495	Selevit Injectable Solution	-do-	-do-	30-10-1999 11-09-2014
15.	048129	Fatroximin Intrauterine Foam	-do-	-do-	03-03-2008 12-02-2018
16.	048130	Dalmavital Solution for Injection	-do-	-do-	03-03-2008 12-02-2018
17.	012896	Hepagen Injection	-do-	-do-	1991 Initial date 16-10-1995 Transfer of Regn. date 10-09-2015
18.	018842	Dalmazin Injectable Solution	-do-	-do-	07-04-1996 15-03-2016
19.	018843	Calcio PH Injectable Solution	-do-	-do-	07-04-1996 15-03-2016
20.	019904	Metabolase Injectable Solution	-do-	-do-	20-10-1995 26-09-2016
21.	019905	Cefaximin-L Ointment	-do-	-do-	20-10-1995 26-09-2016
22.	019906	Cefaximin-L Spray	-do-	-do-	20-10-1995 26-09-2016
23.	025321	Fatroximin Intrauterine Passaries	-do-	-do-	03-02-2000 12-01-2015
24.	021263	Fatroximin Topic Spray	-do-	-do-	16-05-1998 16-04-2018
25.	021492	Aminolife Poultry Water Soluble Powder	-do-	-do-	16-09-1998 15-08-2018

26.	015403	Atiquine P 50 Water Soluble Powder	-do-	-do-	08-06-1994 04-06-2014
27.	013246	Xylaz Veterinary Injection	-do-	-do-	25-05-1992 05-05-2017
28.	013247	Dexafar Veterinary Injection	-do-	-do-	25-05-1992 05-05-2017
29.	026451	Tridox L.A. Injection	-do-	-do-	06-02-2001 25-01-2016
30.	022175	Vitamin AD3E Injection	-do-	-do-	04-12-1998 15-10-2018
31.	015448	Gentafar 10% Injectable Solution	-do-	-do-	19-10-1994 11-09-2014
32.	032212	Soludox 50% Water Soluble Powder	-do-	-do-	22-07-2004 01-07-2019
33.	043110	CTC Spray	-do-	-do-	27-04-2006 04-04-2016
34.	084842	Alivios Solution for Injection	-do-	-do-	16-08-2017

The firm has deposited fee of Rs.5000 x 34 = Rs.170,000/- and submitted following documents:-

d) Copies of initial Registration letters.
e) Renewals of above drugs..
f) Copy of previous Drug Sale License is submitted.
g) Copy of new Drug Sale License is submitted.

It is pertinent to mention that local storage facility of firm located at "Plot No. 5, Pharmacity 30 Km, Multan Road, District Lahore" has already been verified by area FID.

Decision:- Registration Board approved firm's request for change of local storage facility address from "*26-Abbot Road, Lahore"* to *"Plot No. 5, Pharmacity 30 Km, Multan Road, District Lahore*" for above mentioned imported veterinary products in accordance with DSL, on same terms and conditions.

Case No.16: Contract Manufacturing of Already Registered Products

M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5Km Sheikhupura Road, Lahore has requested for contract manufacturing of their following already registered products from M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura as per details mentioned below. Citing the reason for the contract manufacturing, the firm stated that they are in process of developing new dedicated facilities for Oral and Injectable veterinary sections which hopefully will be completed within the period of two and half years.

S. No.	Name of Applicant and Manufacturer	Name of Drug(s)/ Composition& Pack Size	Reg. No./ Date of Initial Registration & Renewal status	Approval status in RRAs and Me-too status	Remarks/ Shortcomings	Reply of the firm
1.	M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5KmSheikhupura Road, Lahore **contract manufacturing** from M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura.	Rimoxyn Injection (Vet) Each ml contains:- Oxytetracycline HCI eq. Oxytetracycline …..50mg (Composition as perForm-5) 2ml 50ml 100ml	002152 Renewal submitted as per copies provided. 24-09-1985 (MOH letter renewal dates not specified) 05-10-1986 25-09-1991 08-09-1996 25-09-2001 (Receipt in MOH not provided). 19-10-2006 02-11-2011 16-11-2016	Limoxin-50 Injection (Holland, InterchemieWerken) Me-too B.G. Oxy-50 Injection M/s. BiogenPharma Rawat.	**i)** Initial registration letter not provided. **ii)** The registration renewal letter (issued in 1985) does not contain detail. **iii)** Composition and renewal date in National Formulary of Pakistan the product appear as Oxytetracycline injection having composition each 2ml contains Oxytetracycline (as HCI) 50mg. **iv)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. **v)** Finished product specification not provided.	**i)** Initial registration certificate is not available at this time. **ii)** Regarding the renewal letter (issued in 1985) does not contain composition, it is to inform you that this practice had not practiced by the MOH that time. **iii)** The composition as per National Formulary of Pakistan of Oxytetracycline injection is written by mistake. The actual formulation is "Each ml contains Oxytetracycline (as HCI) 50mg**"** which is appliedat the time of registration. Copy of letters for approval of additional pack and new design/color scheme are attached for reference. **iv)** Form 5 dully signed by the contract giver/registration holder provided. **v)** Finished product specification provided.
2.	-do-	Evomec Injection 1% W/V Contains:- Ivermectin……1% w/v	043506 18-07-2006 Renewal submitted 06-08-2011 (Last	a. Bimectin (Canada, Bimeda-MTC Animal Health Inc)	**i)** First renewal due on 17-7-2011 was submitted on 06-08-2011	**i)**Submitted renewal on 06-08-2011 with late fee (Rs.8000) within the validity period of 60 days after

		(Composition as per initial registration letter) 10ml 50ml 100ml	renewal application submission) 15-07-2016	Me-too Ivotek Injection 1% W/V M/s. Star Laboratories (Pvt) Ltd. Lahore.	with fee of Rs.8000/- **ii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. **iii)** Finished product specification not provided.	expiry date of renewal. Copy of challan form is attached for reference. **ii)** Form 5 dully signed by the contract giver/registration holder provided. **iii)** Finished product specification provided.
3.	-do-	Levopower Drench Contains:- Levamisole HCI B.P…… 1.5% w/v Oxyclozanide B.P (Vet)……. 3.0% w/v Cobalt Sulphate……0.382% w/v **(Composition as per initial registration letter)** 100ml 500ml 1000ml 5000ml	043507 18-07-2006 Last renewal application submission date 15-07-2016.	**a.** LevafasCluke and Worm (Drench. Rep. of Ireland. NorbrookLaboratorries (Ireland) Ltd.) **Me-too** Levozan Plus Suspension M/s. Star Laboratories (Pvt) Ltd. Lahore.	**i)** First renewal due on 17-07-2011 was submitted on 06-08-2011 with fee of Rs.8000/- **ii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. **iii)** Finished product specification not provided. **iv)** Latest inspection report of M/s. Intervac for Liquid Section. **v)** Master formula is not correct.	**i)**Submitted renewal on 06-08-2011 with late fee (Rs.8000) within the validity period of 60 days after expiry date of renewal. Copy of challan form is attached for reference. **ii)** Form 5 dully signed by the contract giver/registration holder provided. **iii)** Finished product specification provided. **iv)** Latest inspection report of M/s. Intervac(Pvt) Ltd. For liquid section. **v)** Master formula of Levopower Drench provided.
4.	-do-	Levozide Solution Contains:- Levamisole HCI B.P. (Vet)……1.5 % w/v (Composition as per Form-5)	008038 27-02-1985 Already renewed upto 26-02-2015. Last renewal application submitted on 10-02-2015.	a. Chanaverm Plus Oral Solution (Ireland. Chanelle Pharmaceuticals Manufacturing Ltd.)	**i)** As per Form-5 the firm has changed brand name to Levozide Worm Drench 1.5% w/v (vet). **ii)** Moreover,	**i)** Regarding change of brand name, it is a typographic mistake. We feel sorry for that and again submitting the Form-5. **ii)** Regarding

		100ml 250ml 500ml 1 Litre		Me-too Nayverm 1.5% W/V Oral Solution M/s. Saymans Pharmaceuticals (Pvt) Ltd. Lahore.	the initial original registration letter (issued in 1985) does not contain detail composition. **iii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. **iv)** Latest inspection report of M/s. Intervac for Liquid Section.	initial original registration letter does not contain detail composition, it is not practiced by the MOH that time. **iii)** Form 5 dully signed by the contract giver/registration holder provided. **iv)** Latest inspection report of M/s. Intervac (Pvt) Ltd. For liquid section provided.
5.	-do-	Fendanid Plus Liquid Contains:- Oxfendazole..2.265% w/v Oxyclozanide..6.25% w/v Selenium…….0.05% w/v Cobalt...0.167% w/v (Composition as per initial registration letter) 100ml 250ml 500ml 1000ml 5000ml	031478 06-10-2003 26-09-2008 03-10-2013	a. N.A Me-too Oxarex Gold Drench M/s. Star Laboratories (Pvt) Ltd., Lahore,	**i)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor. **ii)** Latest inspection report of M/s. Intervac for Liquid Section. **iii)** Master formula is not correct.	**i)** Form 5 dully signed by the contract giver/registration holder provided. **ii)** Latest inspection report of M/s. Intervac (Pvt) Ltd. For liquid section provided. **iii)** Master formula of Fendanid Plus Liquid provided.
6.	-do-	Sulphadin Injection (Vet) Each 100ml contains:- Sulphadimidine Sodium…….33.33gm (Composition as per Form-5) 100ml	000789 01-07-1976 Last renewal application submission date 29-06-2016.		**i)** Initial registration letter not provided. **ii)** The change of brand name letter (issued in 2002) does not contain detail composition. However the composition	**i)**Initial registration certificate is not available at this time. We are submitting a copy of "The Gazette of Pakistan, Extra dated October, 14, 1981". **ii)** Regarding the change of brand name letter does not contain details composition, it is

					can be confirmed from National Formulary of Pakistan. **iii)** Form-5 is signed and submitted by M/s. Intervac i.e. contract acceptor.	not practiced by the MOH that time. For detail composition we are submitting a copy of "The Gazette of Pakistan, Extra dated October, 14, 1981". **iii)** Form 5 dully signed by the contract giver/registration holder provided.

The firm has provided following documents for this purpose:

i. Application on Form-5 with fee of Rs.50,000/- for each product.
ii. Copy of initial registration letters.
iii. Copy of last renewal status.
iv. Latest GMP inspection report of M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura (dated 28.02.2017 & 17-03-2017). Having evidence of section availability of M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura.
v. Copy of DML M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5Km Sheikhupura Road, Lahore & M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura.
vi. Undertaking contract manufacturing through M/s. Intervac (Pvt) Ltd. for two and half years for above mentioned drugs.
vii. Copy of contract manufacturing agreement b/w M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5Km Sheikhupura Road, Lahore & M/s. Intervac (Pvt) Ltd., 18 Km Lahore Sheikhupura Road, Sheikhupura. (dated 08-08-2017).
viii. Copy of CRF of M/s. Intervac (Pvt) Ltd. valid upto 31-12-2017.

Registration Board in its 279th meeting deferred M/s. P.D.H Laboratories (Pvt.) Ltd, 9.5 Km Sheikhupura Road, Lahore request for confirmation of status of renovation plan and timelines of their oral and injectable veterinary sections from Licensing Division of DRAP.

Letter issued to Licensing Division for confirmation of status of renovation plan and timelines of their oral and injectable veterinary section. In response Licensing Division has informed that layout plan for following sections of M/s. PDH Laboratories (Pvt) Ltd, Lahore was approved on 08-01-2019.

1. Tablet (Penicillin) Section (New).
2. Capsule (Penicillin) Section (New).
3. Dry Powder Suspension (Penicillin) Section (New).
4. Dry Powder Injection (Cephalosporin) (Revised).
5. Syrup (General) Section (New).
6. Capsule (General) Section (New).
7. Sachet (General) Section (New).
8. Tablet (General) Section (New).
9. Narcotics (General) (Human) (Revised).
10. Drench (General) (Veterinary) Section (Revised).
11. Injectable (Vial) (General) (Veterinary) Section (Revised).

Registration Board in its 288th meeting decided to defer the case for seeking following clarifications:

- Timelines for completion of renovation of Oral and Injectable veterinary sections.
- Status of other registered products of Oral and Injectable veterinary sections as firm has not applied for contract manufacturing.

In response the firm submitted that the completion of the construction and installation of the machinery will be completed in the period of two years and six months. Furthermore, firm provided list of other registered products for toll manufacturing.

Sr. No.	***Regn. No.***	***Name of Drug(s)/ Composition***	***Dosage Form***	***Strength***	***Pack Size***
1.	010786	Adrenaline Each 100ml contains:- Adrenaline … 0.1gm (1 in 1000)	Injection	1mg/ml.	25ml
2.	031476	Atrosin Each ml contains:- Atropine Sulphate…… 1mg	Injection	1mg/ml	10ml 25ml
3.	008036	Calcifort Each 100ml contains:- Dextrose……...15.00 gm Calcium borogluconate……22.10 gm Magnesium Borogluconate... 6.00 gm Calcium hypophosphite ……1.37 gm Water for injection……...100ml	Injection		100ml
4.	003118	Gluco-P Each 100ml contains:- Calcium Borogluconate…16.60 gm Boric Acid ……. ….3.40gm	Injection		650ml
5.	028534	Rimoxyn 20% LA Each ml contains:- Oxytetracycline HCL……200mg	Injection	200mg	50ml 100ml
6.	028533	Rimoxyn PVP-100 Each ml contains:- Oxytetracycline HCl……...100mg	Injection	100mg	50ml 100ml
7.	032201	Gluco-P Plus Each 100ml contains:- Calcium Gluconate……..26.6gm Boric Acid …….5.4gm	Injection		300ml 450 ml
8.	057104	Septrocin Injection Each ml contains:- Trimethoprim ……..80mg Sulfadiazine……400mg	Injection		10ml 50ml 100ml
9.	058964	Amoxyn-LA Injection Each ml contains:- Amoxicillin (as trihydrate)….150mg	Injection	150mg/ml	50ml 100ml
10.	058965	Mepracin Injection 5% Each ml contains:- Mepyramine Maleate……..50mg	Injection	50mg/ml	10ml 50ml
11.	081322	Ketoplus Each ml contains:- Ketoprofen B.P. …….. 100mg	Injection	100mg/ml	50ml
12.	084970	D-Flam Injection Each ml contains:- Aceclofenac …… 25mg	Injection	25mg/ml	50 ml
13.	084971	Difnac Injection 10mg Each ml contains:-	Injection	10mg/ml	50ml

		Meloxicam …… 10mg			
14.	084972	Phosphocare-P Injection Each ml contains:- Sodium Acid Phosphate…..400mg	Injection	400mg/ml	100ml
15.	084973	Tylo-PD Injection Each ml contains:- Tylosin Tartrate ……. 200mg	Injection	200mg/ml	100 ml
16.	028532	Evomec 0.08% Each 100ml contains :- Ivermectin……0.08gm.	Worm Drench	0.08% W/V	100ml 250ml 500ml 1000ml 5000ml
17.	031477	Fendanid Liquid Contains:- Oxfendazole……2.265 % W/V Oxyclozonide…… 6.25 % W/V	Liquid		100ml 250ml 500ml 1000ml 5000 ml
18.	028535	Fenzole 2.265% Each ml contains:- Oxfendazole……..22.65%	Worm Drench	2.265% W/V	100ml 1 Litre
19.	028536	Levozide 2.5% Each ml contains:- LevamisoleHCl……25mg	Worm Drench	2.5% W/V	100ml 250ml 500ml 1000ml
20.	057103	Septrocin Oral Suspension Each ml contains:- Trimethoprim ……..80mg Sulfadiazine ……...400mg	Suspension		50ml 200ml 1 Litre

Registration Board in its 289th meeting deferred the case for obtaining details from the firm regarding timelines for completion of renovation of Oral and Injectable veterinary sections as the already provided information does not provide details about same.

The firm now informed about their construction plans at the site. The construction of the Syrup Section (General) is almost complete and the section is ready for inspection. The construction of their veterinary section is planned as follows:

(i) Construction of Veterinary Section will start from March, 2020.

(ii) Expected to be completed within six months till August, 2020.

(iii) The installation of HVAC & machinery will be completed in next 03 months around November, 2020. The whole it is expected that the veterinary section would be ready for inspection till May, 2021.

Decision:- Registration Board deferred the case for confirmation by the firm for status of remaining registered products as their manufacturing facility will not be valid.

Case.No.17: Request of M/s Hipra Pakistan (Pvt) Ltd, Lahore for correction/amendment in shelf life of registered veterinary products

M/s. Hipra Pakistan (Pvt) Ltd, Lahore requested for correction of following details w.r.t their registered imported veterinary products as per details mentioned below;

S.No.	Reg.No.	Product Name & Composition	Details as per initial registration letter	Correction/amendments requested by the firm
1.	094468	Hipralona Enro-S Oral Solution Each ml Contains:- Enrofloxacin…….……100mg	Shelf life: 24 months Pack size: 1000ml	Shelf life: 36 months Additional Pack of: 100ml bottle

2.	094469	Hipralona Enro-I Injectable Solution Each ml Contains: Enrofloxacin…….50mg	Shelf life: 24 months	Shelf life: 36 months
3.	094466	Eficur Injectable Suspension 50mg/ml Each ml contains:- Ceftiofur as Hydrochloride…50mg	100ml vial	100ml PET bottle

Firm informed that in Form-5 and CoPPs/Free sale certificates the requested details are mentioned. However, in Form-5 the only stability studies of zone IV-A for shelf life of 36 months is available but no such details regarding shelf life is present in CoPP's/Free sale certificate.

It is pertinent to mentioned that the requested changes/amendments have been checked from SmPCs of the products available online on the official website of Spanish authority (*https://cimavet.aemps.es/cimavet/publico/home.html*).

Decision:- Registration Board decided as follow;

a. **For product at Sr.No.1, approved the correction in shelf life from 24 months to 36 months in accordance with the approval of the same in country of origin.**
b. **For product at Sr.No.2, approved the correction in shelf life from 24 months to 36 months in accordance with the approval of the same in country of origin.**
c. **For product at Sr.No.3, approved the correction/change in container closure system from "vial" to "PET bottle" in accordance with the approval/availability of the same in country of origin.**
d. **For product at Sr.No.1, deferred the firm's request for grant of additional pack size of 100ml for its previous registration status in favor of initial registration holder.**

Case.No. 18: Request of M/s. D-Maarson Pharmaceuticals, Rawat, Islamabad registration of drugs.

M/s. D-Maarson Pharmaceuticals, Islamabad has requested for registration of following veterinary products for local manufacture in their name and cancellation of same from the name of M/s. Breeze Pharma (Pvt) Ltd., Islamabad.

S. No.	Reg. No.	Name of Drug(s)/ Composition	Already Approved Pack Sizes	Remarks
1.	059107	Tenex Plus 8.75 Drench Each 100ml contains:- Levamisole……3.75%. Triclabendazole……..…5.0%. Cobalt Chloride……...0.075%. Sodium Selenite……..0.035%.	150ml 250ml 500ml 1 Liter 2.5 Liter	*Firm demanded the already approved pack sizes in favor of M/s. Breeze.*
2.	059127	Ivoron Super Injection Each ml contains: - Ivermectin……..10mg Clorsulon……..100mg	10ml 50ml 100ml	*Firm requested for grant of 100ml pack*
3.	075653	Oxytron LA Injection Each ml contains:- Oxytertracycline ….200mg	50ml 100ml	*04-05-2013* ***20-07-2019*** *Firm requested for grant of 50ml pack.*
4.	059152	Ivoron Injection Each ml contains -	10ml 50ml	*Firm requested for grant of 50ml*

		Ivermectin……..10mg	100ml	*pack.*
5.	063795	Dipyrene Plus Injection Each ml contains:- Diminazine Aceturate…..105mg Antipyrine……....131mg Vit B12…….4mg	10ml 50ml 100ml	27-10-2010 ***27-10-2015*** *Firm requested for grant of 50ml pack.*
6.	063557	Ceftron Injection Each ml contains:- Ceftiofur Sodium…….50mg	50ml 100ml	*20-05-2010* ***28-05-2015*** *Cephalosporin manufacturing facility needs to be confirmed..*
7.	059175	Cefpro Injection Each dry vial contains:- Ceftiofur Sodium…….1gm	1gm vial	*Cephalosporin manufacturing facility needs to be confirmed.*
8.	059156	Diaminac Granules for Injection Each sachet contains:- Diminazine Diaceturate…..2.36gm	2.36gm sachet	*Sachet manufacturing facility needs to be confirmed.*
9.	075674	Solodex Injection. Each ml contains:- Prednisolone (as Acetate)…7.5mg Dexmethasone (as sodium phosphate)…….....2.5mg	10ml 50ml	*04-06-2013* ***20-07-2019*** *Steroid manufacturing facility needs to be confirmed*
10.	059125	Flunix Injection Each ml contains:- Flunixin as Meglumin……..50mg	10ml 30ml 50ml	*Firm requested for grant of 100ml pack.*

M/s. D-Maarson Pharmaceuticals, Islamabad has deposited the required fee Rs. 20000 x 10 = 200,000 and submitted following supporting documents:-

i) Original NOC from M/s. Breeze Pharma (Pvt) Ltd., Islamabad.
ii) Copy of initial registration letters alongwith renewal status.
iii) Copy of Drug Manufacturing License.
iv) Undertaking.
v) GMP inspection report conducted on 06-02-2019.
vi) Applications on Form 5.

Decision: Registration Board decided as follow;

S. No.	Reg. No.	Name of Drug(s)/ Composition	Decision
1.	**059107**	**Tenex Plus 8.75 Drench** **Each 100ml contains:-** **Levamisole……3.75%.** **Triclabendazole……..…5.0%.** **Cobalt Chloride……...0.075%.** **Sodium Selenite……..0.035%.**	**Registration Board approved the registration of product " Tenex plus 8.75 Drench" in favor of M/s. D-Maarson Pharmaceuticals, Islamabad and cancel the registration of the same from the name of M/s. Breeze Pharma (Pvt) Ltd, Islamabad.**
2.	**059127**	**Ivoron Super Injection** **Each ml contains: -** **Ivermectin……..10mg** **Clorsulon……..100mg**	**Registration Board approved the registration of product "Ivoron Super Injection" in favor of M/s. D-Maarson Pharmaceuticals, Islamabad and cancel the registration of the same from the name of M/s. Breeze Pharma (Pvt) Ltd, Islamabad.** **Furthermore, the firm shall be granted pack**

			size of 100ml.
3.	**075653**	**Oxytron LA Injection** **Each ml contains:-** **Oxytertracycline ….200mg**	**Registration Board deferred the case for confirmation of renewal status of the product.**
4.	**059152**	**Ivoron Injection** **Each ml contains -** **Ivermectin……..10mg**	**Registration Board approved the registration of product "Ivoron Injection" in favor of M/s. D-Maarson Pharmaceuticals, Islamabad and cancel the registration of the same from the name of M/s. Breeze Pharma (Pvt) Ltd, Islamabad.** **Furthermore, the firm shall be granted pack size of 50ml.**
5.	**063795**	**Dipyrene Plus Injection** **Each ml contains:-** **Diminazine Aceturate…..105mg** **Antipyrine……....131mg** **Vit B12…….4mg**	**Registration Board deferred the case for following reasons;** **i. Confirmation of renewal status of the product.** **ii. Formulation is under review w.r.t the API "antipyrine"**
6.	**063557**	**Ceftron Injection** **Each ml contains:-** **Ceftiofur Sodium…….50mg**	**Registration Board deferred the case for following reasons;** **i. Confirmation of renewal status of the product.** **ii. Confirmation of Cephalosporin manufacturing facility of the firm.**
7.	**059175**	**Cefpro Injection** **Each dry vial contains:-** **Ceftiofur Sodium…….1gm**	**Registration Board deferred the case for Confirmation of Cephalosporin manufacturing facility of the firm.**
8.	**059156**	**Diaminac Granules for Injection** **Each sachet contains:-** **Diminazine Diaceturate ……....2.36gm**	**Registration Board deferred the case for confirmation of sachet manufacturing facility of the firm.**
9.	**075674**	**Solodex Injection.** **Each ml contains:-** **Prednisolone (as Acetate)…7.5mg** **Dexmethasone (as sodium phosphate)….2.5mg**	**Registration Board deferred the case for following reasons;** **i. Confirmation of renewal status of the product.** **ii. Confirmation of Steroid manufacturing facility of the firm.**
10.	**059125**	**Flunix Injection** **Each ml contains:-** **Flunixin as Meglumin……..50mg**	**Registration Board approved the registration of product "Flunix Injection" in favor of M/s. D-Maarson Pharmaceuticals, Islamabad and cancel the registration of the same from the name of M/s. Breeze Pharma (Pvt) Ltd, Islamabad.** **Furthermore, the firm shall be granted pack size of 100ml.**

Case.No.19: Request of M/s. Medinet Pharmaceuticals, Rawalpindi for Registration of their applied two products Anastrazol Varifarma Tablets 1mg and Letrozol Varifarma tablets 2.5mg.

The following two products along with other products of M/s Medinet Pharmaceuticals, Rawalpindi have been approved in M-223rd.

1.	M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Anastrozol Coated Tablets Each Tablet contains; - Anastrozole….1mg (Anticancer)	Rs. Pack of 28 tablets	2 year	Approved
2.	M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Letrozol Tablets 2.5mg Each tablet contains; - Letrozol….2.5mg (Anticancer)	28's Tablet	2 year	Approved

There is a typographic error by the respective evaluator in composition and the manufacturer of the above two products. The correct composition and manufacturer as per COPP is as follows:

Sr. NO.	**As per M-223rd**		**As per COPP**	
1.	M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Anastrozol Coated Tablets Each Tablet contains; - Anastrozole….1mg (Anticancer)	M/s. Medinet Pharmaceuticals Rawalpindi / **Manufacturer & Product License Holder** M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina	Anastrozol Varifarma Coated Tablets Each Film Coated Tablet contains; - Anastrozole….1mg (Anticancer)
2.	M/s. Medinet Pharmaceuticals Rawalpindi / M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina. **Manufactured by** M/s. Laboratorios IMA SAIC, Palpa Argentina	Letrozol Tablets 2.5mg Each tablet contains; - Letrozol….2.5mg (Anticancer)	M/s. Medinet Pharmaceuticals Rawalpindi / **Manufacturer & Product License Holder** M/s. Laboratorio Varifarma S.A Ernesto De Las Carreras Buenos Aires, Argentina	Letrozol Varifarma Tablets 2.5mg Each Film Coated Tablet contains; - Letrozol….2.5mg (Anticancer)

The case was again discussed for the change of manufacturer in 253rd meeting for M/s Medinet's other products, wherein they informed that they are not interested in the import of above two products.

Decision of 258th : Registration Board approved the grant of registrations to the below mentioned products manufactured by M/s. Laboratorio Varifarma S.A., Ernesto de las Carreas 2469 (B1643AVK) Ceccar – Buenos Aires - Republica,

Argentina, as requested by the applicant, subject to inspection of manufacturer abroad, verification of storage facilities and price fixation / calculation etc as per policy:

S.No.	Name of Drug (s) /Composition.	S.No.	Name of Drug (s) /Composition.
1.	Carboplatino Varifarma Injection 150mg	6.	Paclitaxel Varifarma Injection 150mg
2.	Carboplatino Varifarma Injection 450mg	7.	Oxaliplatino Varifarma Injection 50mg
3	Docetaxel Varifarma Injection 80mg	8.	Oxaliplatino Varifarma Injection 100mg
4.	Solvent for Docetaxel Injection 80mg	9.	Varidronico Lyophilized Powder for Injection 4mg
5.	Paclitaxel Varifarma Injection 100mg	10.	Solvent for Varidronico Lyophilized Powder for Injection 4mg

The letter written by the Reg-I section to the Panel for the foregin inspection includes the above 10 products along with the Anastrozol Varifarma Coated Tablets and Letrozol Varifarma Tablets 2.5mg. Accordingly, the panel also inspected these two products in addition to the others.

Now the firm has submitted request for the grant of registration of these 2 products.

Decision of 291st Meeting: Registration Board deferred the case for further deliberation.

Decision: Registration Board acceded the firm's request for the grant of registration of Anastrozol Varifarma Coated Tablets and Letrozol Varifarma Tablets 2.5mg as per import policy for finished product.

Case.No.20: Request of M/s OBS Pakistan (Pvt) Ltd, Karachi for Registration of Drug to Their Name.

M/s OBS Pakistan (Pvt) Ltd, Karachi has submitted an application for change of status of following registerd product from M/s ICI Pakistan Ltd, Karachi to M/s OBS Pakistan (Pvt) Ltd, Karachi. Detail of proposed product is as under: -

Product-1: Diprivan 10mg/ml Emulsion for Injection (Reg. No. 014067)		
Sr.#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	Each ml contains: - Propofol……10mg
2.	Name and address of Applicant (transferee)	M/s OBS Pakistan (Pvt) Ltd, C-14, Manghopir Road, SITE, Karachi.
3.	Name of Transferor	M/s ICI Pakistan Ltd, ICI House, 5 west Wharf, Karachi.
4.	Detail of Drug Sale License	M/s OBS Pakistan (Pvt) Ltd, Plot No.C-14, Manghopir Road, SITE, Karachi. Valid upto 26-03-2021
5.	Name and address of manufacturer	**As per approval:** M/s ICI Pharmaceuticals, U.K. **Form-5A & COPP:** **Manufacturer.** M/s Corden Pharma SPA, Viale Dell Industria 3, E Reparto via Galilei 17, Caponago MB, I-120867, Italy. **Packagers:-** M/s Astrazeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, United Kingdom.
6.	Name and address of marketing authorization holder (as per COPP)	M/s Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, D24 X586, Ireland.
7.	Name of exporting country	United Kingdom
8.	Diary No. & Date of R& I	Dy. No. 36340 Dated 01/11/2018
9.	Finished Product Specification	-

10.	Shelf life	3 Years
11.	Pack Size	20ml ampoule
12.	Remarks:- nil	
Product-2: Diprivan 10mg/ml Prefilled Syringe (Reg. No. 020716)		
S.#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	Each ml contains: - Propofol……10mg
2.	Name and address of Applicant (transferee)	M/s OBS Pakistan (Pvt) Ltd, C-14, Manghopir Road, SITE, Karachi.
3.	Name of Transferor	M/s ICI Pakistan Ltd, ICI House, 5 west Wharf, Karachi.
4.	Detail of Drug Sale License	M/s OBS Pakistan (Pvt) Ltd, Plot No.C-14, Manghopir Road, SITE, Karachi. Valid upto 26-03-2021
5.	Name and address of manufacturer	**As per approval:** M/s ICI Pharmaceuticals, U.K. **Form-5A & COPP:** **Manufacturer:** M/s Corden Pharma SPA, Viale Dell Industria 3, E Reparto via Galilei 17, Caponago MB, I-120867, Italy. **Packagers:** M/s Astrazeneca UK Limited, Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, United Kingdom.
6.	Name and address of marketing authorization holder	M/s Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, D24 X586, Ireland.
7.	Name of exporting country	United Kingdom
8.	Diary No. & Date of R& I	Dy. No. 36340 Dated 01/11/2018
9.	Finished Product Specification	-
10.	Shelf life	2 Years
11.	Pack Size	Pre filled syringe of 50ml
12.	**Remarks:-** The product is prefilled syringe and mentioned on COPP as "Diprivan, Emulsion for Injeciton", while the at point 6.5 of summary of product characteristics mentioned as: - **Nature and contents of container** a) Clear neutral glass ampoules of 20ml in boxes of 5. b) Clear neutral glass vials of 50ml and 100ml. c) Type 1 glass pre-filled syringe of 50ml.	

The firm has submitted the following documents / information for approval: -

a) Fee of Rs.200,000/- (100,000/- for each product)
b) Applications on Form-5A.
c) Original legalized CoPP.
d) Copies of registration letters with complete detail of post registration variation (change in manufacturing site) & renewal status.
e) Authority letter / sole agent letter from manufacturer for M/s OBS Pakistan Private Limited, Pakistan.
f) NOC from existing registration holder for transfer of registration (dated:23-07-2018).
g) Withdrawal of Diprivan imporatation and distribution rights of ICI Pkistan Ltd by AstraZeneca UK limited.
h) An undertaking that the provided information / documents are true / correct.

Decision: Registration Board decided as follow;

- **Approved the registration of Diprivan 10mg/ml Emulsion for Injection in the name of M/s. OBS Pakistan (Pvt) Ltd, C-14 Manghopir Road, SITE, Karachi as per policy for imported finished drug registration (in accordance with details of composition and manufacturer as per CoPP).**

- **A reference shall be sent to Costing & Pricing Division regarding MRP of the above product.**
- **Deferred the product "Diprivan 10mg/ml Prefilled Syringe" for clarification of composition as per COPP.**

Case.No.21: Request of M/s Martin Dow Limited, Karachi for Registration of Drugs to Their Name.

M/s Martin Dow Limited, Karachi has submitted an application for Registration of following already registered products from M/s Hilton Pharma (Pvt) Ltd, Karachi to their name. Detail of each proposed product is as under:

Product-1: Enflor Sachet 250mg (Reg.No.022071)		
Sr.#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	**As per approval** Enflor Sachet 250mg Each sachet contains: - Lyophilised Saccharomyces Boulardii…..282.5mg (Corresponding to 250mg of yeat per sachet (Biological) **As per COPP (France)** Saccharomyces Boulardii, strain CNCM I-745, …….282.50mg (mixture of 250mg of lyophilized yeast cells with 32.50mg of lactose)
2.	Name and address of Applicant (transferee)	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
3.	Name of Transferor	M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi
4.	Detail of Drug Sale License	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown address:** Plot No. 32, Sector 16, K.I.A, Karachi
5.	Name and address of manufacturer.	**As per approval:** N/A **As per COPP:-** Biocodex 1 avenue Blaise Pascal 60000 Beauvais-France.
6.	Name and address of product license holder (as per COPP)	Biocodex 7 avenue Gallieni, Gentilly, 94250 Gentilly, France.
7.	Name of exporting country	France
8.	Diary No. & Date of R& I	Dy. No. 14900 Dated 19/08/2019.
9.	Finished Product Specification	-
10.	Shelf life	3 Years (as per CoPP)
11.	Pack Size	10's (as per approval)
12.	**Remarks: -** • The firm has provided termination letter from M/s Hilton Pharma (Pvt) Ltd, Karachi instead of PLH of product. • The product is not freely available in the provided COPP.	
Product-2: Enflor Capsules 250mg (Reg.No.022072)		
Sr.#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	**As per approval** Enflor 250 Capsules Each capsule contains: - Lyophilised Saccharomyces Boulardii…..282.5mg (Corresponding to 250mg of yeat per sachet (Biological) **As per COPP (France)** Lyophilized Saccharomyces Boulardii, strain CNCM I-745, …….282.50mg (mixture of 250mg of lyophilized yeast cells with 32.50mg of lactose)
2.	Name and address of Applicant (transferee)	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi.
3.	Name of Transferor	M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14, Sector 15,

		Korangi Industrial Area, Karachi
4.	Detail of Drug Sale License	M/s. Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi. **Godown address:** Plot No. 32, Sector 16, K.I.A, Karachi
5.	Name and address of manufacturer.	**As per approval:** N/A **As per COPP:** Biocodex 1 avenue Blaise Pascal 60000 Beauvais-France.
6.	Name and address of product license holder (as per COPP)	Biocodex 7 avenue Gallieni, Gentilly, 94250 Gentilly, France.
7.	Name of exporting country	France
8.	Diary No. & Date of R& I	Dy. No. 14901 Dated 19/08/2019.
9.	Finished Product Specification	-
10.	Shelf life	3 Years (as per CoPP)
11.	Pack Size	10's (as per approval)
12.	**Remarks: -** • The firm has provide termination letter from M/s Hilton Pharma (Pvt) Ltd, Karachi instead of PLH of product. • The product is not freely available in the provided COPP.	

The firm has submitted the following supporting documents / information for approval of above transfer of registrations: -

a) Fee of Rs.200,000/- (100,000/- for each product)
b) Applications on Form-5F.
c) Registration letters with complete renewal status.
d) Original legalized CoPP issued by Sweden.
e) NOC for transfer of registration by M/s Hilton Pharma (Pvt) Ltd (issued on 30-0-2019).
f) Letter of authorization in the name of M/s Martin Dow ltd, Karachi by Biocodex.
g) Termination letter from M/s Hilton Pharma (Pvt) Ltd.
h) An undertaking that annexed documents is correct and true.

Decision: Registration board deferred the above 2 products for:

a) Submission of termination letter of above products from M/s Hilton Pharma (Pvt) Ltd, Karachi.
b) Submission of free sale certificates as the products are not freely available in the provided COPP.
c) Advised the evaluator to evaluate CTD of above products.

Case.No.22: Request of M/s Atco Laboratories Limited, Karachi For Change Of Manufacturing Site Of Their Registed Product.

M/s Atco Laboratories Limited, B-18, S.I.T.E. Karachi has applied for change of manufacturing site of their following already registered product as per details given below: -

S. No	Reg. No.	Name & Composition (as per initial letter) (issued on 27-11-2011)	Existing approved Site Manufacturing Site (as per approval letter) (31-03-2016)	New Proposed Site / Manufacturer (as per COPP)
1.	025299	Aggrastat Injection Each ml contains: - Tirofiban Hydrochloride Monohydrate equivalent to 0.25mg Tirofiban.	M/s Patheon Manufacturing Services LLC, Greenville, North Carolina, 27834, USA	**Manufacturer / Primary Packaging:** 1. Patheon Manufacturing Services LLC 5900 Martin Luther King Jr. Highway, Greenville, North Carolina, 27834, USA. 2. Siegfried Hameln GmbH Langes Feld 13 31789 Hameln, Germany. **Secondary Packaging:** 1. Orion Corporation, Orion Pharma Espoo Site Orionintie 1, FI 00220, Espoo Finland.

				2. Arvato Distribution Gmbh Gottlieb-Daimler-Strabe 1 33428 Harsewinkel Germany. **Product License Holder:-** Correvio (UK) Ltd, Lakeside House, 1 Furzeground Way, Stockley Park UB11 1BD Uxbridge, United Kingdom

The firm has submitted the following supporting documents: -

a) Fee of Rs.100,000/-.
b) Application on Form-5F
c) Copy of initial registration letter & Post Registration renewal trail.
d) Original & legalized COPP.
e) Legalized GMP certificate.
f) Site master file (Siegfried Hameln GmbH).
g) Undertakings that provided information are correct.

Decision: Registration Board approved the above changes in respect of registered product Aggrastat Injection (Reg.No. 025299) subject to policy for imported finished drug registration. Other terms and conditions remain the same.

Case.No.23: Request of M/s Glaxo Smith Kline Pakistan Limited, Karachi For Change Of Manufacturing Site Of Their Registed Product.

M/s Glaxo Smith Kline Pakistan Limited, Karachi has applied for change of manufacturing site of their following already registered product as per details given below: -

S. No	Reg. No.	Name & Composition (as per approval)	Existing approved Site Manufacturing Site (as per approval)	New Proposed Site / Manufacturer / MAH (as per COPP)
1.	027381	Seretide Evohaler 25/50mcg. Each actuation contains: Salmeterol Xinafoate 36.3ug Fluticasone Propionate 50ug	M/s Glaxo SmithKline Australia Pty Limited, Australia.	**Manufacturer** Glaxo Wellcome Production Zone Industrielle No.2, 23 rue Lavoisier 27000 Evreux-France. **Marketing Authorization Holder:** Laboratoire GlaxoSmithKline 23 rue Francois Jacob 92500 Rueil-Malmaison-France.
2.	027382	Seretide Evohaler 25/125mcg. Each actuation contains: Salmeterol Xinafoate 36.3ug Fluticasone Propionate 125ug	-do-	-do-
3.	027383	Seretide Evohaler 25/250mcg. Each actuation contains: Salmeterol Xinafoate 36.3ug Fluticasone Propionate 250ug	-do-	-do-

The firm has submitted the following supporting documents: -

a) Fee of Rs.300,000/- for above three products.
b) Application on Form-5A and Form-5F.
c) Copy of initial registration letter & Post Registration renewal trail.

d) Original & legalized COPP.
e) Site master file for new manufacturing site.
f) Undertakings that provided information are correct.

	Name, address of Applicant / Marketing Authorization Holder	Name: GlaxoSmithKline Pakistan Limited, Address: 35-Dockyard Road, West Wharf,Karachi 74000
	Name, address of Manufacturing site.	Name: Glaxo Wellcome Production, Address: Zone Industrielle No. 2,23, rue Lavoisier, 27000 Evreux,France
	Status of the applicant	□ Manufacturer ☑ Importer □ Is involved in none of the above (contract giver)
	Dy No. and date of submission	Dy No. 18698, : 26.09.2019
	Details of fee submitted	PKR 100,000/- x 3 =Rs. 300,000/- : 26.09.2019
	The proposed proprietary name / brand name	Seretide Evohaler 25/50ug Seretide Evohaler 25/125ug Seretide Evohaler 25/250ug
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	**Each actuation contains:** ***Seretide Evohaler 25/50mcg*** Salmeterol Xinfoate …….36.3ug Fluticasone Propionate ….50.0ug ***Seretide Evohaler 25/125mcg*** Salmeterol Xinfoate….. 36.3ug Fluticasone Propionate **...**125.0ug ***Seretide Evohaler 25/250mcg*** Salmeterol Xinfoate …..36.3ug Fluticasone Propionate …250.0ug
	Dosage form of applied drug	Inhaler
	Route of administration	Oral
	Pharmacotherapeutic Group of (API)	Adrenergics in combination with corticosteroids or other drugs, excl. Anticholinergics
	Pharmacopoeial reference	GSK Specifications
	Proposed Pack size	120 doses
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	EMA Approved
	For generic drugs (me-too status)	
	Valid drug manufacturing license/Drug Sale License	Firm has submitted Inspection Report of M/s Glaxo Wellcome Production – Evreux issued by French National Agency for Medicines and Health Products Safety.
	Evidence of approval of manufacturing facility / approved section from licensing authority	Firm has submitted GMP Certificate of M/s Glaxo Wellcome Production – Evreux issued by French National Agency for Medicines and Health Products Safety.
	Type of Application	□New Drug Product (NDP) □ Generic Drug Product (GDP) ☑ Others (Source Transfer)
	Intended use of pharmaceutical product	☑ Domestic sale □ Export sale □ Domestic and Export sales
	For imported products, please specify one of following:	☑ Finished Pharmaceutical Product Import □ Bulk Import and local repacking (Specify status of bulk)

	□ Bulk Import local repacking for Export purpose only	
Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976	Not Applicable	
List of registered products	Not Applicable	
Manufacturer's site master file and credentials (for importers)	Yes	
Identification of signature of authorized persons , Incharge Production, Quality Control & Quality Assurance of manufacturer.		Yes
Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens		Yes
Description of Batch numbering system		Not Applicable
Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).		Not Applicable
Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).		Yes
Commitments		Firm has submitted undertaking/commitments on it's letter head
Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.		Yes
Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.		Yes
Information on Prior-related Applications		Not Applicable
Electronic Review Package		Yes
QIS (Quality Information Summary)		Yes
Drug Substance related Document including following:		
a. Name and address of API manufacturer.	**Glaxo Wellcome Production,** Zone Industrielle No. 2, 23, rue Lavoisier, 27000 Evreux, France	
b. Approval of manufacturing facility of API by regulatory body of country and validity.	Yes	
c. Vendor qualification / audit is	☑ Document based ☑ Site inspection based	
d. Reason for above point (c)	Already approved vendor for other API's	
MODULE 2: OVERVIEWS & SUMMARIES		
Drug Substance	Firm has submitted overall summary of drug substance including: General Information Manufacture Characterization Control of Drug Substance	

		Reference Standards or Materials Container Closure System Stability
	Drug Product	Firm has submitted summary of drug product including: Description & Composition of Drug Product Pharmaceutical Development Manufacture Control of Excipients Control of Drug Product Reference standard or materials Container Closure System Stability
	MODULE 3: QUALITY / CMC	
	3.2.S: Drug substance	
	General Information	General information on Structure, Nomenclature, General Properties are provided
	Manufacture	Salmeterol Xinafoate is manufactured by: Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations) Cobden Street, Montrose Angus DD10 8EA, United Kingdom and/or Glaxo Wellcome Manufacturing Pte Ltd 1 Pioneer Sector 1, Jurong, Singapore 628413 Salmeterol Xinafoate is micronised by: Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations) Priory Street Ware Hertfordshire, SG12 0DJ, United Kingdom and/or Glaxo Wellcome Production Zone Industrielle No.2, 23, rue Lavoisier 27000 Evreux, France Fluticasone Propionate is manufactured by: Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations) Cobden Street Montrose Angus DD10 8EA United Kingdom and/or Glaxo Wellcome Manufacturing Pte Limited 1 Pioneer Sector 1 Jurong Singapore 628413 Fluticasone Propionate is micronised by: Glaxo Operations UK Limited (trading as Glaxo Wellcome Operations) Priory Street Ware Hertfordshire SG12 0DJ United Kingdom And/or Glaxo Wellcome Production Zone Industrielle No. 2, 23, rue Lavoisier 27000 Evreux France
	Characterization	Firm has submitted data.
	Control of drug substance	Firm has submitted data.
	Reference standards or materials	Firm has submitted data.

	Container closure system	Firm has submitted data.
	Stability	Firm has submitted data of 3 batches of Salmeterol Xinafoate and 6 batches of Micronised Salmeterol Xinafoate; 3 production scale batches of Fluticasone Propionate and 6 batches of Fluticasone Propionate (micronised).
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of Pharmaceutical development, Components of the FPP, formulation development, overages, physicochemical and biological properties.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	Firm has submitted Control of excipients, Specifications, Analytical Procedures, Validation of analytical procedures, Justification of specifications, Excipients of Human or animal origin and Novel excipients
	Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.
	Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards
	Container closure system	Inhaler can, valve, collar, actuator and dust cap.
	Stability	Firm has provided completed stability study data of 3 batches
	Comparative dissolution profile	Not Applicable
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Not Applicable
	Pharmacokinetics	Not Applicable
	Toxicology	Not Applicable
	MODULE 5: CLINICAL / EFFICACY	
	Firm has submitted Clinical data.	
Remarks of the Evaluator:		

Decision: Registration Board approved the above changes in respect of registered products Seretide Evohaler 25/50mcg (Reg.No. 027381), Seretide Evohaler 25/125mcg (Reg.No. 027382) and Seretide Evohaler 25/250mcg (Reg.No. 027383) subject to policy for imported finished drug registration. Other terms and conditions remain the same.

Case.No.24: REQUEST OF M/S BAYER PAKISTAN (PVT) LTD, KARACHI FOR DE-REGISTRATION/ CANCELLATION OF REGISTRATION REGISTERED PRODUCT.

The case was presented in 289th & 290th meeting of Registration Baord of M/s Bayer Pakistan (Pvt) Ltd, Karachi for de-registration/cancellation of registrations of following registered imported products as per details mentioned alongside.

S. No	Firm Name	Product(s) Name	Reg. No	Reason for De-Reg (stated by firm)	Alternative registered product
1.	M/S Bayer Pakistan (Pvt) Ltd, Karachi	Dopergin Tablet Each Tablet Contains: - Lisuride Hydrogen Maleate……0.2mg	009882	TEVA CZECH Republic was the single qualified source of Lisuride Hydrogen maleate worldwide & our parent company Bayer AG Germany procure this API from the same manufacturer. M/s Medipharm (Pvt) Ltd (now merged with M/s Bayer Pakistan) was getting same API from our principal Bayer AG Germany. Bayer AG has stopped the production / marketing of this product in Europe since 2013. To continue with this product in Pakistan we directly approached TEVA & based on our very less requirement of this API (i.e. less than 1kg) TEVA has shown his inability to produce API batches solely for Pakistan due to big production batch sizes.	Other product containing Lisuride Hydrogen Maleate as an active ingredient is not available in Pakistan.
2.	-do-	Qlaira Tablet, Each wallet (28 film coated tablets) contains: - Part I (2 dark yellow film coated tablets-Core) Estradiol valerate….3.000 mg. Part II (5 medium red film-coated tablets-Core) Estradiol valerate….2.000 mg Dienogest…….2.000 mg Part III (17 light yellow film-coated tablets-Core) Estradiol valerate….2.000 mg Dienogest…….3.000 mg Part IV (2 dark red film-coated tablets-Core) Estradiol valerate….1.000 mg Part V (2 white film-coated tablets-Core) None	088370	• The business of this product is not viable. • Due to delayed registration, globally our principal has taken decision to not market this product. • Therefore, we are applying for cancellation / De-registration of this product to avoid unnecessary workload of life cycle management at both ends DRAP & Company.	Qlaira contains two APIs: • Estradiol Valerate. • Dinogest (not available in pakistan). Company provided brands containing Estradiol Valerate as. Estranor, M/s Saffron Pharma. Norestra, M/s British Pharma ltd, Orgyluton, M/s Hansel Pharma, Progyluton, M/s Bayer Health care. Ovlogyn M/s Zafa.

The firm has also provided the following supporting documents:-

a. Copy of registration letter with last renewal status..
b. Justification (for de-registration/cancellation of registration).
c. An undertaking that no case is pending at any forum/court of law.

Decision of 289th meeting:

Registration Board deferred the case for confirmation of alternative registered products.

With reference to above products firm states as under: -

S. No. 1 (Dopergin Tablet),

Teva Czech republic ws the single qualified source of Lisuride Hydrogen Maleate worldwide & our parent company Bayer AG Germany procure this API from the same manufacturer. Medipharm Pvt Ltd (now merged with Bayer pakistan) was getting same API from our principal Bayer AG Germany. Bayer AG has stopped the production / marketing of this product in Europe since 2013. To continue with this product in Pakistan we directly approached TEVA & based on our very less euirment of this API (less than 1kg/year) TEVA has shown his inability to produce API batches solely for Pakistan due to big production batch sizes.

S.No.2 Qlaira Tablet

Qlaira contains two APIs:

- Estradiol Valerate.
- Dinogest (not available in pakistan).

Company provided brands containing Estradiol Valerate as.

1. Estranor, M/s Saffron Pharma.
2. Norestra, M/s British Pharma ltd,
3. Orgyluton, M/s Hansel Pharma,
4. Progyluton, M/s Bayer Health care.
5. Ovlogyn M/s Zafa.
6. Star-gest, M/s Mass Pharma

Decision of 290th meeting:

Registration Board deferred the case for confirmation/provision of alternative registered products in Pakistan.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case.No.25: Request of M/s. Amgomed, Islamabad for Registration of Drug.

The case was presented in 287th meeting of Registration Board held on 3rd & 4th January, 2019 as under:-

Registration Board in its 262nd meeting approved the following products of M/s. Amgomed, Islamabad for import from Korea as per details mentioned alongside;

S.No	Name of importer / manufacturer	Name & Composition of Drug(s)	Demanded Pack size & Price	Decision of Board
1.	M/s Amgomed, Islamabad. **Manufacturer:** M/s Dong Kook Pharmaceutical Co. Ltd. 33-19, yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea.	Diluent for Lorelin depot 3.75 mg Each ampoule (2ml) contains: D-Mannitol..100mg Sodium Carboxymethylcellulose…10mg Polysorbate 80……2mg Water for Injection…..q.s.	Free of Cost.	Approved
2.	M/s Amgomed, Islamabad. **Manufacturer:** M/s Dong Kook Pharmaceutical Co. Ltd. 33-19, yongso 2-gil, Gwanghyewon-myeon, Jincheon-gun, Chungcheongbuk-do, Republic of Korea.	Lorelin depot 3.75 mg Injection Leuprolide acetate 3.75mg Injection	As per SRO	Approved

While issuance of registration letter it has been observed the above mentioned product "Lorelin Depot 3.75mg injection" has already been granted registration in favor of M/s.

Medisure Pharma International, Karachi from the same source having registration number ***027357***.

Accordingly M/s. Amgomed, Islamabad was informed about the above stated position. The firm informed that the principle has already cancelled/terminated the sole agency agreement from the name of M/s. Medisure Pharma International, Karachi in 2013 (provided copy of that cancellation letter dated 16-03-2013) for the reasons that M/s. Medisure Pharma International, Karachi *has never imported a single vial since the time of registration i.e 2002* and *violation of conditions of agreement*.

It is pertinent to mention that the inspection of the above mentioned manufacturer has been carried out dated 21st -22nd June, 2018 by nominated panel comprised of Mr.Malik Irshad Hussain (Member Policy Board), Mr.Sayyad Hussain (Deputy Director, DRAP).

Decision of 287th meeing:-

Registration Board decided to issue show cause notice to the firm M/s. Medisure Pharma International, Karachi as to why not the registration of product *Lorelin depot 3.75 mg Injection* may not be cancelled because of the termination of their sole agency agreement by M/s. Dong Kook Pharmaceutical Co. Ltd, Korea, as reported by M/s. Amgomed, Islamabad.

Fresh Proceedings:

In the light of Registration Board decision a Show Cause Notice has been served to the firm on 21st June, 2019 but no reply has been received. Furthermore, a reminder (No.F.1-40/2007-Reg-I-Pt) through registered post has been issued on on 26th August, 2019 to the firm (C-145, K.D.A. Scheme No.1 Off Karsaz Road, Karachi) with advised to submit reply within seven days after issuance of this letter, the same has been received back with failed delivery status. Afterwards, on 18th September 2019 the reminder letter handed over to firm's representative (Mr. Atta) & till the date no reply from M/s Medisure Pharma Internatinal, Karachi has been reiceved.

Decision: Registration Board advised to issue final showcase notice to M/s Medisure Pharma International Karachi and in case of no reply, case will be considered by Registration Board.

Case.No.26: SHORTAGE OF FORANE (ISOFLURANE) LIQUID FOR INHALATION 100ML

The subject case was presented in 289th meeting of Registration Board as under: -

M/s Getz Pharma has intimated DRAP for discontinuation of their following marketed product;

S.No.	Reg. No	Name & Composition of Product
1.	011081	Forane Liquid for Inhalation 100ml (Isoflurane 99.9% w/w)

as M/s AbbVie, Malaysia has informed them that this shortage is due to an unexpected suspension of manufacture of API by AbbVie's third party manufacturing facility. M/s Getz Pharma submitted that on the basis of this reason we would no longer be able to continue the marketing of above-mentioned product.

Decision of 289th Meeting:

Registration Board deferred the case for further deliberation.

Decision of 291st Meeting: Registration Board deferred the case for further deliberation.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case.No.27: Intimation for Discontinuation of Registered / Marketed Products by M/s Getz Pharma (Pvt) Ltd, Karachi.

M/s Getz Pharma (Pvt) Ltd, Karachi has informed that they have received letter from M/s AbbVie for the discontinuation of following products form Pakistan.

S.No.	Reg. No	Name & Composition of Product
1.	027374	Sevorane Volatile Liquid for Inhalation Contains:- Sevoflurane….100% w/w.
2.	015532	Survanta (beractant) Intratracheal Suspension 8ml Each ml contains: - Total Phospholipids….25mg
3.	059025	Survanta (beractant) Intratracheal Suspension 4ml Each ml contains: - Total Phospholipids….25mg

Firm has stated that M/s AbbVie has informed that due to business reasons, they are going to close their opertions from Pakistan by December, 2019 including product withdrawal.

Decision of 291st Meeting: Registration Board deferred the case for further deliberation.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case.No.29: REQUEST OF M/S ZAM ZAM CORPORATION KARACHI FOR DE-REGISTRATION OF DRUGS.

S. No	Product Name / Reg. No.	Reason for De-Reg	Alternative registered product
1.	Fucithalmic Eye Drops Fusidic Acied 20mg/g Reg. No. 009115	**Justification from principal** The fucithalmic eye drops 10mg/g. had undergone a divestment from =Leo Pharma to Amdipharm who do not intend on maintaining this registration in Pakistan. As LEO Pharma is still the marketing authorization holder for the product in Pakistan, we have been requested to progress the license cancellation of this product.	Fusigel – M/s Sante (Pvt) Ltd, Fusitek– M/s Innvotek Pharmaceuticals. Sidic – M/s Epoch Pharmaceuticals.
2.	Innohep Inj (10,000 i.u.) Each ml contains: Tinzaparin Sodium 10,000I.U. Reg. No. 031315	Commercial reasons. No profit margin. Other alternative brands are available in Pakistan	Since, there is no alternate brand with Tinzaparin Sodium available in Pakistan. Therefore, we provided the reference of its two me-too compounds enoxaparin sodium and dalteparin sodium, available in Pakistan.
3.	Innohep Inj 2ml (20,000 i.u.) Each ml contains: Tinzaparin Sodium 20,000I.U Reg. No. 031316	-do-	-do-
4.	Innohep Inj (10,000 i.u.) 0.35ml pre-filled syringe Each ml contains: Tinzaparin Sodium 10,000 anti-Xa IU/ml Reg. No. 023629	-do-	-do-

5.	Innohep Inj (10,000 i.u.) 0.45ml pre-filled syringe Each ml contains: Tinzaparin Sodium 10,000 anti-Xa IU/ml Reg. No. 023628	-do-	-do-
6.	Innohep Inj (20,000 i.u.) 0.5ml pre-filled syringe Each ml contains: Tinzaparin Sodium 20,000 I.U. Reg. No. 031313	-do-	-do-
7.	Innohep Inj (20,000 i.u.) 0.7ml pre-filled syringe Tinzaparin Sodium 20,000 I.U. Reg. No. 031314	-do-	-do-

Renewal status of above products are valid at the time of submission of application.

Decision of 291st Meeting: Registration Board deferred the case for further deliberation.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case.No.30: REQUEST OF M/S NOVARTIS PHARMA (PAKISTAN) LTD, KARACHI FOR DE-REGISTRATION OF DRUGS.

S. No	Product Name / Reg. No.	Reason for De-Reg	Alternative registered product
1.	Hydergine Oral Solution 1mg/ml Each ml contains :- Ergoloid Mesylates 1mg (Co-dergoorine mesylate) Reg. No. 006582	Due to unavailability of the active ingredient / API (Co-degocrine mesylate) from our principals, we will no longer be able to produce and supply the said products.	Ergovas-3 1mg/ml Oral Solution. M/s Zafa Pharmaceutical Lab
2.	Hydergine ampoule Each 1ml contains :- Dihydroergotoxine Mesylates Reg. No. 001584		Not provided
3.	Hydergin Tablets 1.5mg Reg. No. 001567		Ceregin Tab 1.5mg. M/s Platinum Pharmaceutical. Ergoline Tab. 1.5mg. M/s Century Pharmaceuticals.
4.	Hydergin 4.5mg tablets Each tablet contains: -. (Co-dergoorine mesylate) Reg. No. 007132		Ceregin Tab 4.5mg. M/s Platinum Pharmaceutical. Ergoline Tab. 4.5mg. M/s Century Pharmaceuticals.

Renewals status of above products are valid at the time of submission of application.

Decision of 291st Meeting: Registration Board deferred the case for further deliberation.

Decision: Registration Board deferred for confirmation of registration and existing manufacturing status.

Case.No.31: REQUEST OF M/S GETZ PHARMA (PVT) LTD, KARACHI FOR WITHDRAWAL OF TRANSFER OF IMPORTED PRODUCTS

M/s Getz Pharma (Pvt) Ltd, Karachi has submitted an application for withdrawal of transfer of marketing authorization transfer application from M/s Abbott Labortories (Pakistan) Ltd to their name (M/s Getz Pharma (Pvt) Ltd, Karachi) due to business decision by M/s AbbVie, abroad and currently these products are not marketed in pakistan. Details of products are as

under: -

S. No.	Name of Product Licesne Holder / Manufacturer.	Name of Product / Reg. No.
1.	M/s. AbbVie Inc. 1 N Waukegan Rd, North Chicago, IL 60064, USA. (Name of manufacturer has been changed from M/s. Abbott Laboratoreis International, USA to M/s. abbVie Inc., USA. Original CoPP & GMP certificate of M/s. abbVie Inc., USA provided)	Norvir Capsule 100mg Each capsule contains:- Ritonavir …. 100mg Reg. No. 025245
Decision of 259 Meeting. Registration Board deferred the case of "Norvir Capsule" (Reg.No. 025245) for clarification of address of manufacturer in CoPP and Form-5 A **Decision of 263 Meeting** i. Cancellation of registrations of Norvir Capsule 100mg (025245) from the name of M/s. Abbott Laboratories (Pakistan) Limited, Opposite: Radio Pakistan Transmission Centre, Hyderabad Road, Karachi. ii. Registration of Norvir Capsule 100mg in the name of M/s. Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area Karachi – 74900. iii. Manufacturer and Product License Holder/Packer Of Norvir Capsule 100mg: a. Manufacturer: M/s. Catalent Pharma Solutions, LLC, Saint Petersburg, FL 33716 USA. b. Product License Holder & Labeler/Packer: M/s. AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064.		
2.	-do-	**Norvir Oral Solution** Each ml contains:- Ritonovir …. 80mg Reg. No. 025246
3.	M/s. AbbVie Inc. 1 N Waukegan Rd, North Chicago, IL 60064, USA. (Name of manufacturer has been changed from M/s. Abbott Laboratoreis International, USA to M/s. AbbVie Inc., USA. Original CoPP of USA and GMP of MHRA is provided)	**Kaletra Oral Solution** Each ml contains:- Lopinavir …. 80mg Ritonavir ….. 20mg Reg. No. 028427
Decision of 259 Meeting. Cancel the registration of "Norvir Oral Solution (Reg.No. 025246) & Kaletra Oral Solution (Reg.No. 028427)" from the name of M/s. Abbot Laboratories (Pakistan) Limited, Opposite: Radio Pakistan Transmission Centre, Hyderabad Road, Karachi and registered the same in the name of M/s. Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area Karachi – 74900 on same terms and conditions.		
4.	Product license holder: M/s. Abbvie Farmaceutica, S.L.U. Avda. de Burgos, 91 28050 Madrid , Spain. Manufacturer: (manufacturer of vial & ampoules): M/s. Takeda Pharmaceutical Company Ltd. 1-1 Doshomachi 4- chome, 540-8645 Chuo-ku, Osaka, Japan. Packaging of Finished Product: M/s. Abbott Laboratories, S.A. Avda. De Burgos, 91, 28050 Madrid Spain. CoPP expired on: Sep2015.	**Lucrin Depot 3.75mg Injection** Each vial contains:- Leuprorelin Acetate…3.75mg Reg. No. 025293
5.	Manufacturer: M/s. Hospira SPA, VIA Fosse Ardeatine, 2-20060 Liscate (MI), Italy. Market authorization Holder & Batch releaser: M/s. Abbvie S.R.L, S.R. 148 Pontina Km 52 s.n.c. 04011 Campoverde DI Aprilia (LT), Italy.	**Zemplar Injectable** Each ml contains:- Paricalcitol ……. 5mcg Reg. No. 028456
6.	Manufacturer: M/s. Takeda Nycomed As, Solbaervegen, 5- n 2409 EL Verum Norway Batch releaser and Authorization Holder: M/s. AbbVie S.R.L, S.R. 148 Pontina KM 52 s.n.c. 04011 Campoverde DI Aprilia (Latina), Italy.	**Chirocaine 2.5mg/ml Injectable** Each ml contains:- Levobupivacaine HCl as (Levobupivacaine base) .. 2.50mg Reg. No. 033118
7.	-do-	**Chirocaine 5mg/ml Injectable** Each ml contains:- Levobupivacaine HCl as (Levobupivacaine base) ……. 5mg Reg. No. 033119

8.	-do-	**Chirocaine 7.5mg/ml Injectable** Each ml contains:- Levobupivacaine HCl as (Levobupivacaine base) …. 7.5mg Reg. No 033120

Decision of 279th meeting.

a) Approved the cancellation of registration of products at Sr.No.2-5 from the name of M/s. Abbott Laboratories (Pakistan) Limited, Opposite: Radio Pakistan Transmission Centre, Hyderabad Road, Karachi.
b) Approved registration of products at Sr.No.2-5 from the name of M/s. Getz Pharma (Pvt.) Limited 29-30/27, Korangi Industrial Area Karachi as per details mentioned alongside each product (in accordance with CoPP).
c) For products at Sr.No.2-5 a reference shall be sent to Costing & Pricing Division for their comments regarding MRP of the products. d. For product at Sr.No.1 the firm shall be advised to provide valid, legalized and attested CoPP for further consideration.

M/s AbbVie Malaysia has stated the we cancelled the transfer of Marketing Authorization holder from Abbott Laboratories Pakistan Limited to Getz Pharma Pvt Limited for the above 8 products.

Decision of 291st Meeting: Registration Board deferred the case for further deliberation.

Decision: Registration Board referred the case for views of DRAP's availability committee.

Case No.32: Request for Contract Manufacturing of Registered Products of M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi.

M/s. Bosch Pharmaceuticals (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi has requested for permission of manufacturing of their following already registered drugs from **Plant-I (DML No. 000350)** to **Plant-II (DML No. 000707)** located at Plot No. 209, Sector 23, Korangi Industrial Area, Karachi on contract manufacturing basis. The details are as under;

Sr.No.	Reg. No.	Name of drug (s) with composition	Date of i. Initial Reg. ii. Renewal Status
1.	024244	Qumic Infusion 500mg/100ml Each 100ml vial contains: Levofloxacin Hemihydrate 512.46mg eq.to Levofloxacin…….500mg	i. 7-May-02 ii.13-Jun-17
2.	061073	Qumic Infusion 750mg/150ml Each vial contains: Levofloxacin as Hemihydrate……..750mg	i. 3-Dec-09 ii.2-Dec-14
3.	023020	Quinoflox Infusion 100mg/50ml Each 50ml vial contains: Ciprofloxacin Lactate eq.to Ciprofloxacin …..100mg Sodium Chloride……450mg (USP Specification)	i. 4-Mar-99 ii.3-Mar-14
4.	023021	Quinoflox Infusion 200mg/100ml Each 100ml vial contains: Ciprofloxacin Lactate eq.to Ciprofloxacin…..200mg Sodium Chloride……900mg (USP Specification)	
5.	039583	Quinoflox Infusion 400mg/200ml Each 200ml contains: Ciprofloxacin Lactate eq.to Ciprofloxacin ……400mg Sodium Chloride…….900mg (USP Specification)	i. 17-Sep-05 ii.16-Sep-15
6.	048489	Quinoflox DS Infusion 400mg/100ml Each 100ml vial contains: Ciprofloxacin Lactate eq. to Ciprofloxacin……400mg Sodium Chloride…….900mg (USP Specification)	i. 9-Feb-08 ii.8-Feb-18
7.	021506	Tariflox I.V Infusion 200mg/100ml Each vial contains: Ofloxacin USP……200mg	i. 16-May-98 ii.15-May-18
8.	047397	Izilon Infusion 400mg/250ml Each 250mg vial contains: Moxifloxacin (as HCl)……400mg (Isotonic with NaC1)	i. 7-Jan-08 ii.6-Jan-18
9.	055540	Falgan Infusion 1000mg/100ml Each 100ml contains: Paracetamol…….1000mg	i. 26-Mar-09 ii.25-Mar-14
10.	034856	Troz Infusion 500mg/100ml Each 100ml vial contains: Metronidazole……..500mg (USP Specification)	i. 8-Dec-04 ii.7-Dec-14
11.	055914	Zolrest Infusion 200mg/100ml Each 100ml vial contains: Linezolid…….200mg	i. 7-Apr-09 ii.6-Apr-14

12.	055915	Zolrest Infusion 400mg/200ml Each 200ml vial contains: Linezolid…….400mg	
13.	055916	Zolrest Infusion 600mg/300ml Each 300ml vial contains: Linezolid…….600mg	

In this regard, the firm has submitted the following documents;

i. Applications on Form-5 alongwith Fee of Rs.50,000/- for each product **(date 19-Jul-18)**
ii. Copies of initial registration & renewal status.
iii. Copy of Section Approval (Sterile Infusion General) of **Plant-II dated 14-June-11**
iv. Copy of valid DML **Plant-I (dated 16-Feb-15) & Plant-II (dated 14-Jun-16)**
v. Last inspection report of **Plant-II** (Proposed Manufacturing Site) **(Date: 12-June-18).**
vi. Undertakings.

Decision: **Registration Board acceded to request of the firm for granting contract manufacturing permission of above mentioned products by M/s Bosch Pharmaceuticals (Pvt.) Ltd, Plot No. 209, Sector 23, Korangi Industrial Area, Karachi.**

Case No.33: Request for Change of Contract Manufacturer of Registered Product of M/s Bayer Pakistan (Pvt.) Ltd, Karachi.

M/s. Bayer Pakistan (Pvt.) Ltd, Plot No.23, Sector 22, Korangi, Karachi has requested for permission of change in contract manufacturer from M/s Zafa Pharmaceuticals, Karachi to **M/s Nabiqasim Industries (Pvt) Ltd, 17/24, Korangi Industrial Area, Karachi DML No.000105 (Formulation)**. The details are as under;

Sr.No.	Reg. No.	Name of drug (s) with composition	Date of iii. Initial Reg. iv. Renewal Status	Previous Manufacturer
1.	023008	Baydal Syrup Each 5ml contains: Cetirizine Dihydrochloride…….5mg (BP Specification)	i. 29-Apr-99 ii.10-Jan-19 Change of Brand Name 10-Oct-07	M/s Zafa Pharmaceuticals, Karachi. **(Validity: 30-June-2020)**

In this regard, the firm has submitted the following documents;

i. Applications on Form-5F along-with Fee of Rs.50,000/- **(Date: 27-Jun-19)**
ii. Copies of initial registration letter & renewal status.
iii. Copy of valid DML **(dated 12-July-14)** of M/s Nabiqasim Industries, Karachi.
iv. Copy of agreement b/w M/s Bayer Pakistan (Pvt.) Ltd & M/s Nabiqasim Industries, Karachi **dated 24-April-2019.**
v. Evidence of Section approval of Liquid/Syrup of M/s Nabiqasim.
vi. Last inspection report of M/s Nabiqasim Industries **(Date: 23-July-19).**
vii. Undertakings.

Applied specification is BP while stability protocol submitted by M/s Nabiqasim Industries, Karachi is in accordance to manufacturer's specification.

Decision: **Registration Board deferred the request of firm for clarification regarding proposed specifications and stability protocol.**

Case No.34: Correction in Formulation of Drug(s) of M/s. Maxitech Pharma (Pvt.) Ltd; Karachi.

M/s. Maxitech Pharma (Pvt.) Ltd., Plot No. E-178, SITE, Karachi have requested for correction in formulation of their following already registered product. The details are as under:

Sr.#	Reg. No.	Existing name with composition / Specifications	Correction required in composition / Specification
1.	085964	**Fusimax 2% Oinment** Each gm contains:- Fusidic Acid ……..… 2% (As per *Innovator's Specification)	**Fusimax 2% Oinment** Each gm contains:- **Sodium Fusidate ……..… 2%** (As per *Innovator's Specification)

The firm has submitted the following documents.

Sr.#	Requirement as per SOP	Submission
i.	Application with required fee as per relevant SRO.	Rs.5,000/- alongwith Form-5
ii.	Copy of registration letter (DOR: 13-12-17) and last renewal status. Validity confirmed from RRR.	Submitted.
iii.	Document in support of proposed correction/ evidence of approval status by Reference Regulatory Authorities/ innovator product and/or Pharmacopeias as adopted by Registration Board.	Evidence of approval status by RRAs **(MHRA) Provided**
iv.	Undertaking that the provided information/ documents are true/ correct.	**Provided**

Decision of 19th PRVC:

The Committee deferred the case for fee of Rs.20,000/- along-with Form-5 and referred the case to Registration Board".

Remarks: Now, the firm has submitted the differential fee of Rs.20,000/- alongwith Form-5.

Decision of M-289 Meeting:

Registration Board deferred the request of firm for justification/reason of proposed change in formulation.

Updated Status :

Now, the firm has justified that Fusidic acid is insoluble in water that will incompatible in ointment formulation while sodium fusidate is water soluble and prove to be compatible in ointment as per innovator clinical study.

Decision: Registration Board deferred for confirmation of innovator's product and MRP status of both formulations.

Case No.35: Change of Pharmaceutical Form of Drug(s) of M/S. Atco Laboratories, Karachi.

M/s. Atco Laboratories Ltd; Karachi has requested for change of pharmaceutical form of following product:-

S.No.	Name of Drug(s) with existing formulation	Name of drug demanded formulation	Reg.No.	Registration history
1.	Viracure 250mg Tablet Each tablet contains:- Famciclovir …….. 250mg	Viracure 250mg Tablet Each film coated tablet contains:- Famciclovir …….. 250mg	042313	Init. Date of reg. 12-04-2006 Renewal applied **on 16-04-2016**

The firm has provided following documents:-

a. Attested copy of fee challan of Rs.5,000/- is provided.

b. Copy of letter of registration dated **12-04-2006** and copies of renewal application is provided by the firm. The RRR section has been requested for confirmation of renewal status.
c. Copy of availability in reference is provided.
d. Copy of CRF is attached.

Finished product specification is neither mentioned on initial letter of registration nor specified in the instant application. However, the formulation is non pharmacopeial.

PRVC in 3rd meeting deferred the case for presentation before Registration Board.

Decision of M-282:

Registration Board deferred the case for confirmation of renewal status.

Updated Status:

RRR Section has confirmed that the firm has submitted application on **17-March-2016** for renewal of their product Viracure 250mg Tablet (Reg. No.042313) within due date. Moreover, proposed change is as per HPRA (Ireland) approved product.

Decision: Registration Board acceded to request of the firm for correction of pharmaceutical form in line with RRA (HPRA).

Case No.36: Fixation of Source of Omeprazole for Registered Drug(s) of M/s. Sami Pharmaceuticals (Pvt.) Ltd; Karachi.

M/s Sami Pharmaceuticals (Pvt.) Ltd, F-95, Off Hub River Road, SITE, Karachi has requested for fixation of source of pellets of omeprazole for their registered drugs as per following details;

Sr.#	Reg. No.	Name of Drug(s) with Composition	Date of i. Initial Reg. & ii. Renewal Status	Proposed Manufacturer of Source of Pellets
1.	018091	TEpH 20mg Capsule Each capsule contains: Omeprazole enteric coated pellets equivalent to Omeprazole…..20mg	i. 5-Oct-95 ii. 26-Aug-15	M/s Titan Laboratories Pvt. Ltd, (705557) E-27/1, E-27/2, M.I.D.C., Mahad Village-Jite–402309, District Raigad, India.
2.	025595	TEpH 40mg Capsule Each capsule contains: Omeprazole enteric coated pellets equivalent to Omeprazole…..20mg	i. 30-Mar-00 ii. 30-Mar-15	M/s Murli Krishna Pharma Pvt. Ltd, D-98, Ranjangaon MIDC, Ranjangaon, Taluka-Shirur, Pune 412209 Maharashtra State, India.

The firm has submitted the following documents.

i. Fee of Rs.100,000/- (dated **17-July-2019 & 18-July-2019**).
ii. Copy of registration letter and last renewal status.
iii. Both real time & accelerated stability studies of finished products (pellets / granules / ready to fill bulk) conducted by manufacturer of half finished product as per conditions of zone IV-A or zone IV-B on 3 commercial scale batches
iv. Valid & legalized copies of GMP certificates of source of pellets i.e.
    a) M/s Titan Laboratories Pvt. Ltd, India **Valid till 18-October-2019**
    b) M/s Murli Krishna Pharma Pvt. Ltd, India **Valid till 3-April-2022**
v. Copies of Certificates of analysis of manufacturers.
vi. Undertakings.

Decision: Registration Board acceded to request of the firm for source fixation of omeprazole 20mg capsule and omeprazole 40mg capsule.

Case No.37: Fixation of Source of Pellets for Registered Drug(s) of M/s. Akhai Pharmaceuticals (Pvt.) Ltd; Lasbela.

M/s Akhai Pharmaceuticals (Pvt.) Ltd, Plot No.A-248 & A-256 to A-259, Hub Industrial Trading Estate, Lasbela, Balochistan has requested for fixation of source of pellets for their registered drug as per following details;

Sr.#	Reg. No.	Name of Drug(s) with Composition	Date of i. Initial Reg. & ii. Renewal Status	Proposed Manufacturer of Source of Pellets
1.	055655	Carisano SR 200mg Capsule Each capsule contains: Mebeverine (as HCl) …..200mg	i. 2-Apr-09 ii. 18-Mar-19	M/s Vision Pharmaceuticals, Plot No.22-23, Industrial Triangel, Kahuta Road, Islamabad.

The firm has submitted the following documents.

i. Fee of Rs.20,000/- (dated 2**1-May & 18-June-2019**).
ii. Copy of registration letter and last renewal status.
iii. Both real time & accelerated stability studies of finished products (pellets / granules / ready to fill bulk) conducted by manufacturer of half finished product as per conditions of zone IV-A or zone IV-B on 3 commercial scale batches.
iv. Valid & legalized copy of GMP certificate of M/s Vision Pharma **Valid till 10-Feb-2022**
v. Copies of Certificates of analysis of manufacturer of pellets.
vi. Undertaking.

Decision: Registration Board acceded to request of the firm for source fixation of Mebeverine (as HCl) capsule.

Case No.38: Addition of Route of Administration as Ear Drops of Registered Eye drops of M/s. Ophth Pharma (Pvt.) Ltd; Karachi.

M/s Ophth Pharma (Pvt.) Ltd, Karachi has requested for addition of route of administration/indication as Otic use for ophthalmic product as per following details;

Sr.#	Reg. No.	Name of Drug(s) with Composition	Date of i. Initial Reg. & ii. Renewal Status	Remarks
1.	026973	Ophth-Cil Eye Drops Each ml contains: Ciprofloxacin HCl eq. to Ciprofloxacin……..…..3mg	i. 31-May-01 ii. 16-May-16	Applied formulation in ear drops is approved in MHRA-UK.
2.	023880	Ophth-Tobra Ophthalmic solution Each ml contains: Tobramycin……..3mg	i. 3-Nov-01 ii. 7-Sep-16	Applied formulation in eye drops is approved in MHRA-UK.
3.	058367	Opmox Eye Drops Each ml contains: Moxifloxacin as HCl……..5mg	i. 27-Aug-09 ii. 13-Jun-14	Applied formulation in eye drops is approved in MHRA-UK.
4.	029119	Ophth-Tobra D Each ml contains: Tobramycin……3mg Dexamethasone…….1mg	i. 8-Feb-03 ii. 28-Nov-17	Applied formulation in eye drops is approved in MHRA-UK.

The firm has submitted the following documents.

i. Fee of Rs.5,000/- (dated **3-Dec-2018**).
ii. Copy of registration letter and last renewal status.

Decision: Registration Board deferred request of firm for confirmation of innovator's formulation with proposed route of administration (Eye/Ear use).

Case No.39: Change of Marketing Authorization/registration from M/s OBS Pakistan, Karachi to M/s AGP Limited, Karachi.

- **Previous History of Case:**

M/s OBS Pakistan Karachi was served with show cause notice as CLB in its 251st meeting held on 6th December 2017 has considered and deliberated the case of M/s Pharmatec Pakistan (Pvt.) Ltd., D-86/A, S.I.T.E, Karachi under DML No. 000024 by way of formulation (contract manufacturer) and decided to allow grant of renewal section for sterile Liquid ampoule section with the direction that Registration Board be informed about approval of sterile Liquid ampoule section only. It is pertinent to mention that hormonal products of M/s OBS Pakistan, Karachi were manufactured by M/s Pharmatec Pakistan by permission vide letter no. F.3-3/2015-Reg-II (M-249) dated 26th August, 2015, i.e., valid for 30-06-2020.

The above stated facts of the case were presented in the 275th meeting of Registration Board. Wherein, it was decided to "issue a show cause notice to M/s OBS Pakistan, Karachi for their hormonal products which were being manufactured by M/s Pharmatec Pakistan (Pvt.) Ltd., Karachi on contract basis."

Accordingly, a show cause was issued to M/s OBS Pakistan (Pvt.) Ltd., Karachi vide letter no. F.3-12/2017-Reg-II (M-275) dated 15.02.2018. Now the firm has submitted the reply which was considered in 280th meeting of registration board. The board considered the reply of the firm and decided to defer the case till decision of Central Licensing Board on application of the firm for contract manufacturing.

Sr. No.	Registration holder	Contract manufacturer	Reg. No.	Name of drug(s) & Composition	Validity of last permission
1.	OBS Pakistan Karachi	M/s Pharmatec Pakistan, Karachi	002444	**Deca – Durabolin 100mg Injection** Each ml ampoule contains:- Nandrolone Decanoate … 100mg (As per *Innovator's Specification)	30.06.2020
2.	-do-	-do-	002442	**Deca – Durabolin 25mg Injection** Each ml ampoule contains:- Nandrolone Decanoate …. 25mg (As per *Innovator's Specification)	30.06.2020
3.	-do-	-do-	002443	**Deca – Durabolin 50mg Injection** Each ml ampoule contains:- Nandrolone Decanoate …. 50mg (As per *Innovator's Specification)	30.06.2020
4.	-do-	-do-	002446	**Sustanon 250mg Injection** Each ml contains:- Testosterone Propionate …30mg Testosterone Phenylpropionate…60mg, Testosterone Insocaproate … 60mg Testosterone Decanoate 100mg (As per *Innovator's Specification)	30.06.2020

Then, the firm has submitted applications on Form-5, along with fee of Rs. 50,000/- for each product & other relevant document. M/s. OBS Pakistan (Pvt.) Ltd; and **requested to change the contract manufacturer of above product** from M/s Pharmatec Pakistan, Karachi to M/s. Geofman Pharmaceuticals, 20/23 Main Korangi Industrial Area, Karachi. The case was placed before the Registration Board in its 284th meeting and the board decided as under: -

Decision of 284th Meeting:

"Registration board deferred the case for confirmation of Liquid Injection (ampoule) Hormone Section from Licensing Division".

Now, the firm has submitted the confirmation from Licensing Division for Injectable (Hormone) Section of M/s. Geofman Pharmaceuticals, 20/23 Main Korangi Industrial Area, Karachi, vide letter No.F.2-11/85-Lic (Pt.) dated 05th March, 2019.

Moreover, the firm has also requested for transfer of Marketing Authorization/ Registration from M/s OBS Pakistan (Pvt.) Ltd, to M/s Aspin Pharma (Pvt.) Ltd, Karachi. In this regard, the firm has also submitted the following documents;

i. Fee of Rs.70,000/- for each product (05-May-2019)
ii. Toll Manufacturing agreement between M/s Aspin & M/s Geofman (02-May-2019)
iii. NOC from M/s OBS Pakistan (Pvt.) Ltd. Karachi for transferring marketing authorization to M/s Aspin Pharma (Pvt.) Ltd, Karachi.
iv. Undertaking from Aspin Pharma that above mentioned formulations are not already registered in their name.

Decision of M-289:

Registration Board acceded to firm's request for;

a) Cancellation of registration of above mentioned products from the name of M/s OBS Pakistan (Pvt.) Ltd. Karachi
b) Grant of registration of above mentioned products in the name of M/s Aspin Pharma (Pvt.) Ltd, Karachi
c) Change of contract manufacturer of above mentioned products from M/s Pharmatec Pakistan (Pvt.) Ltd., S.I.T.E, Karachi to M/s. Geofman Pharmaceuticals, 20/23 Main Korangi Industrial Area, Karachi

Updated Status:

In pursuance of decision of Registration Board in its 289th meeting, the action has not been taken yet. Now, M/s AGP Limited, Karachi requested to grant registration/ marketing authorization of above mentioned products in their name.

The firm has submitted the following documents;

i. Fee of Rs.20,000/- for each product dated 19-September-2019.
ii. NOC from M/s OBS Pvt. Ltd, Karachi for transferring marketing authorization to AGP Ltd,. Karachi.
iii. NOC from M/s Geofman for manufacturing above mentioned products for M/s AGP Ltd.
iv. Contract manufacturing agreement b/s M/s AGP & M/s Geofman Pharma dated 5-August-2019.

Decision: Registration Board deferred request of firm for submission of differential fee of Rs 30,000/- (being contract manufacturing) and submission of application in Form 5F.

Case No.40: Change of Finished Product Specification of M/s Bryon Pharmaceuticals (Pvt.) Ltd, Peshawar.

The following case of the firm was discussed in 290th meeting of Registration Board and the Board deferred the request of the firm for evaluation of difference/comparison between specifications and equipment mentioned in both pharmacopeias i.e. BP and JP.

Name of Drug with Specification & Reg. No.	Date of initial Registration	Proposed Specification	Submission/ Remarks
Mycolock 2% Cream Each gm contains: Ketoconazole……..20mg (BP Specifications) Reg. No.084240	i. 28-Apr-17	JP Specifications	➢ Fee Rs.5,000/- ➢ Undertakings <u>Remarks</u> HPLC chromatogram /analysis is performed as

			per JP. Exist in both BP and JP

Updated Status:

Now, the firm has submitted the following details;

i. Extraction of ketoconazole from Mycolock 2% cream for assay preparation is simple and easy in JP as compared to BP method.

ii. Testing under JP needs less steps than required BP.

iii. The column recommended in JP is available with us and is easily available in market as well; whereas, we could not find the column used in BP in the market.

iv. As per our understanding if somehow we are able to acquire column recommended in BP its usage in laboratories would be very limited and quite possibly will be for testing of Mycolock 2% cream exclusively.

Decision: Registration Board deferred request of the firm for submission of comparison between analytical procedures/specifications of BP and JP.

Deferred/Referred Cases from 32-PRVC

Case No.41: Correction in Composition/Registration/Pharmaceutical Form of Registered Drugs.

The following requests of the firms were considered in 32nd meeting of PRVC held on 24-September-2019 for correction in letters of their registered products as per following details;

Sr.#	Name of Product with existing composition & Registration Number	Name of Product with Correct/proposed composition	Initial Date of i. Registration ii. Renewal Application	Submitted Documents / Remarks
I	II	III	IV	V
i.	**M/s. Karachi Chemical Industries (Pvt.) Ltd, F/25, Estate Avenue, S.I.T.E., Karachi. (P.No.245–265/C) *Dy.No.15859 (R&I) dated: 27-Aug-19.***			
1.	Keyglobin Syrup Each 100ml contains: **Ferric Ammonium Citrate……..200mg** Thiamine HCl (Vit.B1)….20mg Pyrodoxine HCl (Vit.B6)..40mg Cyanocobalamin……360mcg Nicotinamide…….200mg Folic Acid……..10mg **(Reg. No.003828-Ex)**	Keyglobin Syrup Each 100ml contains: **Ferric Ammonium Citrate……..900mg** Thiamine HCl (Vit.B1) ……..20mg Pyrodoxine HCl (Vit.B6) ……...40mg Cyanocobalamin…360mcg Nicotinamide…….200mg Folic Acid…….10mg	i. 10-Dec-12	The firm had applied for the registration of the product for Export Purpose Only with Ferric Ammonium Citrate 900mg as per Form-5. However, on registration certificate the dosage of Ferric Ammonium Citrate was granted 200mg. The proposed weightage of Ferric Ammonium Citrate 900mg is also manufactured by M/s Swiss Pharmaceuticals (Pvt.) Ltd, Karachi.
ii.	**M/s. Elite Pharma (Pvt.) Ltd, P.D.H. Street, 9.5Km Sheikhupura Road, Lahore. (P.No.266–307/C) *Dy.No.15859 (R&I) dated: 19-Nov-18.***			
2.	Neurogen Injection 3ml Each 5ml contains: Thiamine Hyrochloride B1…100mg Pyridoxine Hydrochloride B6 ……100mg Cyanocobalamin ……..1000ug	Neurogen Injection 3ml Each **3ml** contains: Thiamine Hyrochloride B1…100mg Pyridoxine Hydrochloride B6 ……100mg Cyanocobalamin..1000ug	i. 19-Dec-12 1-Aug-17	➢ Fee of Rs.5,000/- ➢ Copy of Reg.letter & Renewal status. ➢ Copy of Form-5 where formulation 3ml/ ampoule is mentioned. ➢ Undertaking. **Remarks:**

	(Reg. No.001773-Ex)			The proposed dosage form i.e. 3ml ampoule is also available for local product with the firm for Neuro-S Injection (Reg.No.022238).

The chairman, Registration Board approved the requests of the firm for correction in the formulations. Further, the Chairman, Registration Board also advised to inform the Registration Board for the correction in formulation, accordingly.

Decision: Registration Board noted the information.

Case No.42: Permission for Manufacturing of Distilled Water for M/s Geofman Pharmaceuticals, Karachi .

M/s Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi is manufacturing Distilled Water for Injection (Reg. No.007909) with different pack sizes 5ml; 20ml; 10ml. Firm has also been granted permission for manufacturing of Distilled Water for Injection of pack sizes of 17ml and 8.5ml for products of M/s The Searle Pakistan Limited, Karachi.

Now, the firm requested for granting the pack size of 13ml for product i.e. Ziocin Suspension 200mg (Reg. No.008070-Ex) of M/s Martin Dow Marker Ltd, Quetta (free of cost) for export purpose only.

The firm has submitted fee of Rs.5,000/- dated 14-June-2019 for this purpose.

Decision of 32-PRVC:

The Committee referred the case to Registration Board.

Decision: Registration Board deliberated that firm may apply for grant of registration for export purpose only with requisite fee and Chairman Registration Board will approve export registration.

Case No.43: Standard Operating Procedures for Approval of Post-Registration Variations.

Registration Board in 283rd meeting considered and approved revised SOPs for processing of post registration variations. In SOP's of following post registration variations "Form-5/ Form5-A" is required:

Sr. No	Post Registration Variation wherein Form5/Form 5A is required	Description
1.	Registration of Product from One Manufacturer to another Manufacturer with Change in Manufacturing Site.	For locally manufactured products
2.	Registration of Product after Change in Name / Title of Manufacturer (Site of Manufacturing Remains the Same)	
3.	Change of Address of Manufacturing Site/Source/Marketing Authorization Holder (MAH).	For imported products
4.	Change in Shelf Life.	
5.	Registration of Product from One importer to another Importer	

Since applications on CTD format have been implemented from now and onward hence opinion is being solicited from Registration Board whether application on CTD shall be required for processing such cases or any further direction as the Board may deem appropriate.

Decision 289th and 290th Meeting of Registration Board:

The case was deferred for further deliberation.

Brief summary of Post registration variations in the light of SOP (283rd meeting)

Total post registration variations: 22
Variations in which Form-5 / Form-5.A / Form-5.D not required: 17
Variations in which Form-5 / Form-5.A / Form-5.D required: 05

Post registration variations in which Form5/Form5A/Form-5.D has been required as per SOP (283rd meeting) are mentioned below. Proposal regarding requirement of Form-5.F for disposal of such cases is prepared with remarks as under:

Sr. No	Post Registration Variation	Requirements in light of SOPs approved by Reg. Board (M-283)	Requirement of Form-F	Remarks
1.	Registration of Product from One Marketing Authorization Holder/manufacturer/Importer to another Marketing Authorization Holder/manufacturer/Importer	Form-5/Form-5.A	Yes	Since Marketing Authorization (MA) Holder change proclaim cancellation of registration from the name of previous MA holder and grant of registration in the name of new MA holder hence Form-5.F shall be required
2.	Change in Name / Title of Manufacturer/Marketing Authorization Holder of registered products (Site of Manufacturing Remains the Same)	Form-5/Form-5.D/ Form-5.A	No	Since title of manufacturer change (manufacturing site remain same) is administrative variation merely which may not incur any quality change hence Form-5.F shall not be required. The applicant shall submit application on its letter head along with documents and Fee as per SOP.
3.	Change in Shelf Life.	Form-5.A (for imported products)	No	Only stability data regarding proposed shelf life should be submitted as per approved SOP.
4.	Change of Manufacturing Site/change of contract manufacturer / change from import to local manufacturing	Form-5/Form-5.D/ Form-5.A	Yes	Since change in manufacturing site may incur change in quality parameters hence Form-5.F shall be submitted by manufacturer.

Decision of 32-PRVC:

The Committee referred the case to Registration Board.

Decision: **Registration Board deliberated the matter and approved above mentioned amendments in SOP for processing cases regarding post registration variations**.

Case No.44: Extension in Shelf Life of Registered Products of M/s Asian Continental (Pvt.) Ltd, Karachi

a) Product name: Aqueous Injection 5ml (water for injection)

Current shelf life: 2 years

Proposed shelf life: 3 years

Sr.#	Documents required (as per SOP M-283)	Information provided
1.	Application with required fee as per relevant SRO.	Date of application 06.08.2012.Fee Rs 1000/- deposited dated 06.08.2012, differential fee of Rs 4000/- dated 09.07.2013 (Duplicate dossier). Stability data and protocols forwarded for experts opinion vide letter no. F.1-34/2011-Reg-II dated 18th March, 2016 Firm resubmitted data as per SOP approved by Registration Board in 283rd meeting (Dy. No 34842 R&I DRAP dated 19.10.18)
2.	Copy of registration letter and last renewal status	Reg No. 057861 dated 28th July,2009 last renewal May 27, 2014 (Rs 10,000/-)
3.	Proposed shelf-life, justification & data of long-term stability testing (as per conditions of zone IV-A) including chromatograms for a minimum of 3 commercial scale batches or development scale batches as set by Registration Board in 276th meeting up to the proposed shelf-life.	**Long term studies** (Temp 30◦C±2◦C /RH 65%±5%) **Interval**: 3,6,9,12,18,24,36 **Testing parameters**: appearance, conductivity, oxidisable substances, particulate matter, bacterial endotoxin test and sterility **Reference USP** **Primary packaging:** Glass ampoule, USP Type-I **Batch size**: 120 Liter **Sample size:** 32 ampoules **Batch no**: C753, C816 and C826
4.	□n undertaking that□□ • No change to the primary packaging type that is in direct contact with the FPP and to the recommended conditions of storage • No change in formulation and specification either of finished product, API and excipients etc. • In case both the above conditions are involved then manufacturer will submit complete requisite information as per procedure • In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.	provided
5.	**Remarks:**	In MHRA shelf life of water for injection is mentioned as 60 months (5 years) for ampoules. Tests performed in line with USP monograph

Decision 290th RB meeting:

Registered Board deferred request of firm for evaluation of submitted data in the light of pharmacopeial reference and confirmation of tests performed during proposed shelf life period.

Updated Status:

Firm has submitted certificate of analysis/work sheet for each point of time as evidence of the performance of all the pharmaceutical tests over the period of 36 months

Decision 32-PRVC:

The Committee referred the case to Registration Board.

Decision: Registration Board acceded to request of firm for extension in shelf life of Aqueous Injection (5ml) from 2 years to 3 years.

b) Product name: Aqueous Injection 10ml (water for injection)

Current shelf life: 2 years

Proposed shelf life: 3 years

Sr.#	Documents required (as per SOP M-283)	Information provided
1.	Application with required fee as per relevant SRO.	Date of application 06.08.2012. Fee Rs 1000/- deposited dated 06.08.2012, differential fee of Rs 4000/- dated 09.07.2013 (Duplicate dossier). Stability data and protocols forwarded for experts opinion vide letter no. F.1-34/2011-Reg-II dated 18th March, 2016 Firm resubmitted data as per SOP approved by Registration Board in 283rd meeting (Dy. No 34842 R&I DRAP dated 19.10.18)
2.	Copy of registration letter and last renewal status	Reg No. 057860 dated 28th July,2009 last renewal May 27, 2014 (Rs 10,000/-)
3.	Proposed shelf-life, justification & data of long-term stability testing (as per conditions of zone IV-A) including chromatograms for a minimum of 3 commercial scale batches or development scale batches as set by Registration Board in 276th meeting up to the proposed shelf-life.	**Long term studies** (Temp 30◦C±2◦C /RH 65%±5%) **Interval**: 3,6,9,12,18,24,36 **Testing parameters**: appearance, conductivity, oxidisable substances, particulate matter, bacterial endotoxin test and sterility **Reference USP** **Primary packaging:** Glass ampoule, USP Type-I **Batch size**: 240 Liter **Sample size:** 26 ampoules **Batch no**: C754, C756 and D620
4.	An undertaking that • No change to the primary packaging type that is in direct contact with the FPP and to the recommended conditions of storage • No change in formulation and specification either of finished product, API and excipients etc. • In case both the above conditions are involved then manufacturer will submit complete requisite information as per procedure • In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately.	provided
5.	**Remarks:**	In MHRA shelf life of water for injection is mentioned as 60 months (5 years) for ampoules. Tests performed in line with USP monograph

Decision 290th RB meeting:

Registered Board deferred request of firm for evaluation of submitted data in the light of pharmacopeial reference and confirmation of tests performed during proposed shelf life period.

Updated Status:
Firm has submitted certificate of analysis / work sheet for each point of time as evidence of the performance of all the pharmaceutical tests over the period of 36 months

Decision 32-PRVC:
The Committee referred the case to Registration Board.

Decision: **Registration Board acceded to request of firm for extension in shelf life of Aqueous Injection (10 ml) from 2 years to 3 years.**

Export Facilitation Desk

Case No.45: Registration of Drug (s) of M/s Hansel Pharmaceuticals (Pvt) Ltd. Plot No.2, Pharma City, 30km, Multan Road Lahore for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	**Submitted Documents**
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5D; (Provided)
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML provided Approval of relevant section verified from Panel inspection for renewal of DML dated 15.05.2019.
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from Panel inspection for Renewal of DML dated 15.5.2019
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ color do not resemble with already registered brands in importing country.	Provided

Detail of the products is given below:

Sr.#	**Name of Drug(s) with composition**	**Generic/RRA Status**	**Diary No. date & Remarks.**
I	**II**	**III**	**IV**
1.	**Winstrol 10mg Tablet** Each tablet contains: Stanozolol…….10mg	Not Available	Dy. No.815/2019-PE&R-(EFD) 27.08.2019. Rs.50000/- dated 07.08.2019
2.	**Winstrol Depot 100mg Injection** Each ml contains: Stanozolol…….100mg	Not Available	Dy. No.816/2019-PE&R-(EFD) 27.08.2019. Rs.50000/- dated 07.08.2019
3.	**Primobolan 100mg Injection** Each ml contains: Metenolone Enanthate……..100mg	Not Available	Dy. No.817/2019-PE&R-(EFD) 27.08.2019. Rs.50000/- dated 07.08.2019

Firm has submitted purchase order from Afghanistan (Kabul).

Decision: **Registration Board deferred above mentioned products of M/s Hansel Pharmaceuticals (Pvt) Ltd. Plot No.2, Pharma City, 30km, Multan Road Lahore for evidence of approval of applied formulations in importing country.**

Case No.46: Registration of Drug (s) of M/s Scilife Pharma (Pvt) Ltd. FD-57/58-A2, Korangi Creek Industrial Park, Karachi for Export Purpose Only (On contract Manufacturing basis by M/s Focus and Rulz Islamabad.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	**Submitted Documents**
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5D; (Provided)
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML (Provided) Approval of relevant section verified from Panel inspection for renewal of DML dated 15th and 17th January 2019.
GMP Status. Copy of Inspection report/GMP certificate.	GMP certificate issued on evaluation inspection dated 17.1.2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided
Contract Manufacturing agreement between Scilife Pharma and Focus and Rulz.	Provided

Detail of the products is given below:

Sr.#	**Name of Drug(s) with composition**	**Generic/RRA Status**	**Diary No. date & Remarks.**
I	**II**	**III**	**IV**
1.	**Scimalt-FA 125mg + 0.35mg Syrup** Each 5ml contains: Iron III Hydroxide Polymaltose Complex (equivalent to Elemental Iron)……125mg Folic Acid……..0.35mg	Not Available	Dy. No.867/2019-PE&R-(EFD) 20.09.2019. Rs.50000/- dated 18.07.2019

Firm has submitted purchase order from importing country (Ghana).

Decision: Registration Board approved above mentioned product of M/s Scilife Pharma (Pvt) Ltd. FD-57/58-A2, Korangi Creek Industrial Park, Karachi for export registration on contract manufacturing basis by M/s Focus and Rulz Islamabad. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 285th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No.47: Registration of Drug (s) of M/s Star Laboratories (Pvt) Ltd.23-Km, Multan Road (Chung) Lahore for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	**Submitted Documents [Ref.F.No.26-PRVC/2019 (EFD)].**
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5; Rs.20,000/- dated 08.02.2019
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML dated 18-12-2014
GMP Status. Copy of Inspection report/GMP certificate.	GMP certificate/last inspection report issued on 05-10-2018&12-11-2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	**Neuro Plus 1gm Tablets** Eachtabletcontains: Citicoline as sodium……..….1.0 gm	**Not available**	Dy. No.359/19-EFD 26.02.2019.

The case was considered by PRVC in 26th meeting (held on 28th February, 2019)

Decision: Chairman Registration Board has deferred the request of firm for submission of evidence of applied formulation / drug already approved by DRAP (generic/me-too status) along-with registration number, brand name and name of firm. In case of new molecule, submission of application on Form 5-D along-with differential fee of Rs.30,000/-.

Firm has submitted differential fee of Rs 30,000/- (dated 26th September 2019). Since applied formulation is neither locally registered nor approved in RRA, firm has provided purchase order from importing country (Cambodia) and evidence of approval of applied formulation in importing country i.e Brainact 1000mg by Dankos Farma.

Decision: Registration Board approved above mentioned product of M/s Star Laboratories (Pvt) Ltd.23-Km, Multan Road (Chung) Lahore for export registration. Since applied formulation is neither registered for local use nor approved by any RRA (as adopted by Registration Board in 285th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of drug product.

Case No. 48: Registration of Drug(s) of M/s Ras Pharmaceutical Pvt Ltd. Qadir Pur Raan bypass Near Shalimar Petroleum 25-km Lahore Road, Multan for Export Purpose Only. (FOR VETERINARY USE)

Firm has applied for registration of drug(s) only for export purpose as per following details:

Requirements As Per SOP	Submitted Documents
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form 5D (Provided)
Copy of DML (Renewal status) along with approval of relevant sections verified by Licensing Division or inspection report for renewal of DML before 2005.	Copy of DML (Provided). Approval of relevant section verified from Licensing section letter No.F.1-46/2010-Lic dated 27.07.2015 **Remarks : Available section is Oral liquid (general antibiotic)**
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from routine GMP inspection dated 16.10.2018
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided

Detail of the product is given below:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
1.	Gasgard Oral Liquid Semi Paste Each GasGard Oral Liquid Semi Paste contains: Omeprazole…….37%	Not available	Dy.No.847/19-EFD (PE&R) dated 12-09-2019 Rs.50000/- dated 22.08.19

Firm has submitted purchase order from importing country Iraq (Kirkuk)

Decision: Registration Board deferred request of firm for availability of concerned section.

Case No. 49: Correction in specification for the product of M/s. Care Pharmaceuticals, Lahore.

M/s. Care Pharmaceuticals, Lahore has requested for correction in specification of following products as per details given below:-

Sr.#	Reg. No.	Existing Brand Name and composition	Proposed Correction	Remarks
1	069073	Domycare Suspension Each 5ml contains:- Domperidone……....5mg (B.P specification)	Domycare Suspension Each 5ml contains:- Domperidone……..5mg **(Innovator's specification)**	The official monograph of the applied formulation does not exist in any available edition of pharmacopeia.
2	069074	Citracare Syrup Each 5ml contains:- Sodium acid citrate....1.25gm (B.P specification)	Citracare Syrup Each 5ml contains:- Sodium acid citrate……....1.25gm **(Innovator's specification)**	

Firm has submitted following documents.

- Application for correction in specification with fee Rs. 5000/- (Yellow Copy) for each product dated 21.12.2018
- Copy of Registration letter 08-01-2011
- Renewal with fee Rs.10,000/- for each product dated 31.12.2015.
- Undertaking on stamp paper

Decision of 25th PRVC:-

The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer the request of M/s. care Pharmaceuticals Co. Ltd., Lahore to Registration Board.

Decision: Registration Board deferred for confirmation of specification of innovator's products.

Case No. 50: Change of Brand Name of M/s. Medwell Pharmaceuticals, Attock.

M/s. Mundipharma, Switzerland (Contract importer/distributer Ali Gohar Pharma) has made complaint that the brand name of their following registered product has close resemblance/similarity with the brand name of product of M/s. Medwell Pharmaceuticals, Attock. The details are as under:-

Sr. No.	Product name, composition and registration No. of M/s. Mundipharma, Switzerland (Contract importer/distributer Ali Gohar Pharma)	Name of the product having resemblance alongwith Composition and Registration No. of M/s. Medwell Pharmaceuticals, Attock
1.	BETADINE is the registered name of number of products including throat spray, ointment, dry powder spray, mouth wash etc. Globally Mundipharma is the original adopter, owner and registered proprietor of the Betadine trade mark which is registered in its 463roduc in more than 70 countries around the world by way of more than 290 registrations and over 100 pending applications. Similarly Betadine trademark is registered in 463roduc of Mundipharma in Pakistan with numbers 34887 for Betadine in English version & 155007 for Betadine in Urdu version.	Betadine 7.5% Scrub Each 5ml contains: Povidine-Iodine 7.5% Reg. No. 080463

Since the registration of product of M/s. Mundipharma, Switzerland (Contract importer/distributer Ali Gohar Pharma) has been granted prior to that of M/s. Medwell Pharmaceuticals, Attock, therefore, it is proposed that later may be asked to change the brand name of their product and propose alternate brand names for approval.

Decision of 5th PRVC: The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee deferred the request of M/s. Mundipharma, Switzerland for submission of registration number of their product already registered in Pakistan.

Remarks:-

Registration Number	**Brand Name**
001276	BETADINE SURGICAL SCRUB
001277	BETADINE VAGINAL PESSARIES
005123	BETADINE ONT
004450	BETADINE-ANTISEPTIC SOL
004451	BETADINE (GARGLE & MOUTH WASH)

M/s Medwell Pharmaceuticals, Attock was advised vide No. F. 14-5/2018-Reg.III (PRVC-5) dated 15-10-2018 to change the brand name due to similarity with already registered drugs. However, the firm did not respond subsequently the firm was again issued reminder for change in brand name in letter and spirit.

Decision of 29th PRVC: The Committee evaluated the case in the light of SOPs approved by the Registration Board. Chairman Registration Board, upon recommendation(s) of Committee decided to refer the case to Registration Board.

Decision: Registration Board deferred the above case for opinion of Legal Affairs Division.

Case No. 51: Contract manufacturing permission of already registered product of M/s. Horizon healthcare (Pvt) Limited, Taxila (Formerly M/s. Walt Danzay Pharmaceuticals, Taxila).

M/s. Horizon healthcare (Pvt) Limited, Taxila (Formerly M/s. Walt Danzay Pharmaceuticals, Taxila) has requested for contract manufacturing of following registered product fromM/s. Horizon healthcare (Pvt) Limited, Lahore (Formerly M/s. Wellness Pharmaceuticals Pvt Ltd Lahore) alongwith change of brand name, as per details below.

Sr.#	**Reg.No.**	**Name of product and composition**	**Proposed brand name**
1.	085358	DNL40mg Injection Each vial contains: Omeprazole (as sodium)……40mg	DITS injection Same brand name granted to omeprazole 40mg capsule

Firm has submitted following documents:-

i. Application with fee of Rs.50000/- for this purpose

ii. Copy of Registration letter.

iii. Copy of NOC for CRF.

iv. Last GMP inspection report dated 14.12.2017 (M/s. Wellness Pharmaceuticals, Lahore).

Decision of 284th Meeting:

Registration Board deferred the request of firm for submission of reason/ justification of contract manufacturing.

Justification: This name is feasible for marketing point of view as M/s Horizon Healthcare Lahore has capsule range of 20mg & 40mg registered with name of DITS capsule 20mg & 40mg respectively from M/s. Horizon Healthcare Pvt. Limited (Sundar Road), Lahore vide registration no 078759 & 078760. Moeover, M/s Horizon Healthcare Pvt. Limited (Sundar Road), Lahore does not have dry powder Injectable section.

M/s. Horizon Healthcare Pvt. Limited (Taxila) has now revised request for change of name of their registered product DNL 40mg injection to DITS Injection.

Decision: Registration Board deferred the above case for opinion of Legal Affairs Division.

Case No. 52: M/s. Focus & Rulz, Islamabad for change in specifications. 31 PRVC

The request of M/s. Focus & Rulz, Islamabad for change in specification of following product was considered in 31st meeting of PRVC and referred to the Registration Board as per details given below:-

Sr. No.	Reg. No.	Existing Brand name, composition & formulations	Proposed Brand name, composition & formulations	Date of initial registration & renewal
1	049305	Mecofer Tablet Each Tablet contains: Mecobalamin ……500mcg (F&R Specs)	Mecofer Tablet Each Tablet contains: Mecobalamin……500mcg (USP Specification)	10-07-2008 04-07-2018 Renewal is ok

Firm has submitted the following documents:

i. Fee of Rs.5,000/- (Dated:17-07-19)
ii. Copies of Registration & Renewal Status.
iii. USP monograph **(Dietary)**.
iv. Undertaking.

Decision: Registration Board deferred the above case for submission of comparative analysis of testing parameters of USP and JP.

Case No. 53: M/s. GT Pharma, Lahore (M-290)

The request of M/s. GT Pharma, Lahore for clarification/correction in specifications of their following registered product was considered in 290th meeting of the Registration Board and deferred with details below:

S. No.	Reg. No.	Name of drug(s) with formulation	Desired specifications
I	II	III	IV
1	080881	ED-3 injection 1ml Each 1ml glass ampoule contains:- Cholecalciferol (Vitamin D3)…….5mg (BP Specifications)	ED-3 injection 1ml Each 1ml glass ampoule contains:- Cholecalciferol (Vitamin D3)…….5mg (As per Innovator's Specifications)

The firm had submitted that the BP recommends the quantity of Cholecalciferol (Vitamin D3) average 0.75% w/v in Ethyl Oleate per ampoule (i.e. 7.5mg/1ml ampoule), and lable claim is 5mg of Cholecalciferol/ampoule as per registration letter. There seems some

controversy between specifications according to British Pharmacopeia and our registered product specifications in DRAP for our product ED-3 injection (Vitamin D3)……5mg/ml (BP specifications).

Documents details as per SOPs approved 283rd Registration Board Meeting:-

Sr. No.	Requirement as per SOPs	Documents submitted
1	Application with Fee Rs. 5000/-	Provided
2	Copy of registration letter dated 07-06-2016	
3	Documents in support of proposed correction	
4	Analytical reports as per monograph of FPP	Provided
5	Undertaking that : The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. No case is pending at any forum / court of law regarding this product. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. The provided information/ documents are true/ correct.	Provided

Decision of 290th Meeting:-

Registration Board deferred for further deliberation.

Decision of 286th Meeting of RB: Registration Board in its 286th meeting acceded to similar request of M/s Barrett Hodgson and M/s S. J. & G. Fazul Ellahie regarding correction in finished product specifications of Cholecalciferol 5mg/ml Injection from BP Specifications to "As per Innovator's Specifications" along with omission of "IM" (route of administration), mentioned alongside the brand name. The Board further directed that finished product specifications of all other registered products of instant formulation shall be corrected accordingly.

Decision: Registration Board deferred the above product for status of applied formulation in pharmacopeia of RRA (ANSM).

Case No. 54: Permission of change in contract manufacturer of already registered products applied by M/s Medera Pharmaceuticals, Kahuta Road, Islamabad

M/s Medera Pharmaceuticals, Kahuta Road, Islamabad has applied for contract manufacturing permission along with change in contract manufacturer from M/s Global Pharmaceuticals, Islamabad and M/s Caraway Pharmaceuticals, Islamabad to M/s Nicholas Pharmaceuticals, Islamabad for following products.

S. No.	Name of Applicant	Existing Manufacturer	New Manufacturer	Reg. No.	Name of drug(s) & Composition	Date of application, Diary No. & Form	Remarks
1	M/s Medera Pharmaceuticals, Kahuta Road, Islamabad	M/s Global Pharmaceuticals, Plot no. 204-5, Industrial Triangle Kahuta Road, Islamabad	M/s Nicholas Pharmaceuticals, Islamabad	031695	Gigantic 250mg injection IM Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone ……250mg	Dy. No. 13214 R&I 06-03-2019	Contract manufacturing valid till 30-06-2020 The product is available in

					USP Specification		USP.
2	M/s Medera Pharmaceuticals, Kahuta Road, Islamabad	M/s Global Pharmaceuticals, Kahuta Road, Islamabad	M/s Nicholas Pharmaceuticals, Islamabad	031696	Gigantic 1gm injection IV Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone ……1gm USP Specification	Dy. No. 13213 R&I 06-03-2019	
3	M/s Medera Pharmaceuticals, Kahuta Road, Islamabad	M/s Global Pharmaceuticals, Kahuta Road, Islamabad	M/s Nicholas Pharmaceuticals, Islamabad	053023	Gigantic 500mg injection IM Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone ……500mg USP Specification	Dy. No. 13215 R&I 06-03-2019	
4	M/s Medera Pharmaceuticals, Kahuta Road, Islamabad	M/s Caraway Pharmaceuticals, Islamabad	M/s Nicholas Pharmaceuticals, Islamabad	056068	Medixim 100mg suspension Each 5ml contains:- Cefixime (as trihydrate) …….100mg (USP Specifications	Dy. No. 13216 R&I 06-03-2019	Contract manufacturing valid till 30-06-2020
5	M/s Medera Pharmaceuticals, Kahuta Road, Islamabad	M/s Caraway Pharmaceuticals, Islamabad	M/s Nicholas Pharmaceuticals, Islamabad	056069	Medixim 200mg suspension Each 5ml contains:- Cefixime (as trihydrate)…200mg (USP Specifications	Dy. No. 13217 R&I 06-03-2019	
6	M/s Medera Pharmaceuticals, Kahuta Road, Islamabad	M/s Caraway Pharmaceuticals, Islamabad	M/s Nicholas Pharmaceuticals, Islamabad	056071	Medixim 400mg Capsule Each Capsule contains:- Cefixime (as trihydrate) …….400mg (USP Specifications	Dy. No. 13218 R&I 06-03-2019	

Firm has submitted following documents in this regard:

- Application/Form 5 dated 06-03-2019
- Fee of Rs.50,000/- for each product dated 05-03-2019
- Registration letters and contract manufacturing permission

- Copy of contract manufacturing agreement between M/s Medera Pharmaceuticals, Kahuta Road, Islamabad and M/s Nicholas Pharmaceuticals, Islamabad dated 26-02-2019
- Inspection report for grant of DML M/s Nicholas Pharmaceuticals, Islamabad dated 03-08-2018 concluding that panel unanimously recommended issuance of GMP certificate.
- Evidence of approval of (Capsule section Ceph, Dry suspension section Ceph, Dry powder Injectable Section Ceph, Dry powder Injectable Section Carbapenemes) verified from section approval letter (M/s Nicholas Pharmaceuticals, Islamabad).
- Total number of approved sections of M/s. Medera pharmaceuticals (Pvt.) Limited, Islamabad: 02 and total number of products already approved for contract manufacturing in the name of applicant: 10

Decision: **Registration Board approved change of contract manufacturer of products at Sr. No. 1-3 from M/s Global Pharmaceuticals, Islamabad and for products at Sr. No. 4-6 from M/s Caraway Pharmaceuticals, Islamabad to M/s Nicholas Pharmaceuticals, Islamabad.**

Case No.55: Extension in contract manufacturing approval of M/s Tread Pharma, Lahore.

Letter received from Miss Sara Mahreen (4615/2017/DRAP-AD (I) (I&E)), Assistant Director (I&E), Lahore wherein it has been stated that M/s. Harmann Pharmaceuticals, Lahore applied for issuance of clearance for import of 50-kg Nifedipine to be consume in toll manufacturing of product Anifed Retard Tablets Reg.No.014005 for M/s. Tread Pharmaceuticals, Lahore.

M/s. Tread Pharmaceuticals, Lahore for granted transfer of registration of above product from import to local contract manufacturing by M/s. Harmann Pharmaceuticals, Lahore for the period of 03 years. While going through evaluation of document provided by applicant it was found that firm has not been granted extension of toll manufacturing till date whereas firm claimed that as per contract manufacturing policy dated 07.02.2013 they has extension of contract manufacturing period. It has been requested to clarify updated/current status of M/s. Tread Pharmaceuticals, Lahore for contract manufacturing by M/s. Harmann Pharmaceuticals, Lahore.

As per available record the case under discussion has been considered and discussed in various meetings of Registration Board M-194,M-202,M-209 and M-212 in which approval of extension in contract manufacturing to M/s. Tread Pharmaceuticals, Lahore manufactured by M/s. Harmann Pharmaceuticals, Lahore for above mentioned products has not been granted due to following reasons;

i. Stoppage of manufacturing of M/s. Harmann pharma and invalid license.
ii. Submission of record for import of raw material of all products and their production and sale record.
iii. Latest report of industrialization was required thorough DDG(E&M), Lahore and states of License for Licensing section

M/s. Tread Pharma requested for allowing them uninterrupted manufacturing of their registered products below mentioned products were transfer from import to local contract manufacturing by M/s. Harmann Pharma, Lahore.

S. No.	Name of Drug(s) with composition	Reg. No.
1	Etibi Injection Each 5ml contains:- Ethambutol di-HCl….500mg	015536

2	Anifed Retard Tablets Each film coated tablet contains:- Nifidipine ……20mg	014005
3	Pentafen Injection. Each ml contains:- Pentazocine Lactate..30mg	015773
4	Forgenac Injection. Each 3ml contains:- Diclofenac Sodium…..75mg	015537

Firm stated that in year 2002 Ministry of Health in order to save foreign exchange of the country, invited and offered all imports to get transfer their imported registered drugs from import to local by way of toll manufacturing. Previously firm as importing product from Italy later on were granted permission vide latter no 15/06/2002, for transfer of registration of drug from import to local contract manufacturing. Furthermore, confirmation about the renewal status of the products from RRR section, Since firm has been submitting renewal fee via courier hence fee slips need to be verified from B&A Division.

The case was presented before Registration Board in 269th meeting which was decided as follow:

Decision of 269th meeting:

Registration Board advised to submit complete detail of the case for further deliberations.

The firm has submitted documents pertaining to products' renewal and approval status for extension of contract manufacturing from 30.06.2010 to 31.03.2013. The firm has submitted renewal fees of Rs 4000/- for each product on 12.06.2012 via courier and now firm verified challan from bank has been submitted by the firm.

Decision of 270th meeting:

Registration Board after considering documents provided by firm deliberated that firm had deposited fees of Rs. 4,000/- (dated 12.06.2012) of above products and firm needs to submit differential / remaining fees (Rs.4,000/- for each product) for extension in contract manufacturing permission till 14.06.2017. Thus the Board advised firm to deposit remaining fee. However, further extension beyond aforementioned time in contract manufacturing will be considered after application by the firm in light of existing Rule 20A of Drugs (L,R & A) Rules, 1976.

As per decision of 270th meeting firm has submitted differential fee of 4000/- for each product on 29-08-2019. Furthermore firm has submitted fee of 10,000/- for each for renewal on 07-06-2017. Now firm has submitted differential fee of 40,000/- for each on 29-08-2019.

Decision: Registration Board approved request of M/s Tread Pharma, Lahore for extension in contract manufacturing of above products till 14-06-2022.

Case No. 56: Deferred Case of Extension in Contract Manufacturing.

M/s Trison Pharmaceuticals, Sargodha had applied for extension in contract manufacturing along with change in contract manufacturer for following products from M/s Sharooq Pharmaceuticals to M/s Synchro Pharma, Lahore.

S. No.	Name of Applicant	Name of proposed Contract manufacturer	Reg. No.	Name of drug(s) & Composition	Date of application, Diary No. & Form	Date up to which contract manufacturing permission valid (Registration Board meeting in which previous approval was granted)
1.	M/s Trison Research Laboratories (Pvt) Ltd., Sargodha.	M/s Synchro Pharmaceuticals, 77-Industrial Estate Kot Lakhpat, Lahore.	045476	Penxime 100mg Dry Powder Suspension Each 5ml contains:- Cefixime (as trihydrate) …..100mg	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
2.	-do-	-do-	045477	ARK 1gm Injection Each vial contains:- Cefepime (as Hydrochloride) …1000mg	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
3.	-do-	-do-	045478	ARK 500mg Injection Each vial contains:- Cefepime (as Hydrochloride) …500mg	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
4.	-do-	-do-	045479	Jostle 250mg Injection Each vial contains:- Ceftriaxone (as Sodium) ……250mg (USP Specifications)	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
5.	-do-	-do-	045480	Jostle 500mg Injection Each vial contains:- Ceftriaxone (as Sodium) ……500mg (USP Specifications)	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
6.	-do-	-do-	045481	Jostle 1gm Injection Each vial contains:- Ceftriaxone (as Sodium) ……1000mg (USP Specifications)	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
7.	-do-	-do-	045482	Pert 250mg Injection Each vial contains:- Cefotaxime (as Sodium) …….250mg	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
8.	-do-	-do-	045483	Pert 500mg Injection Each vial contains:- Cefotaxime (as Sodium) …….500mg	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
9.	-do-	-do-	045484	Pert 1gm Injection Each vial contains:- Cefotaxime (as Sodium) …….1000mg	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010
10.	-do-	-do-	045487	Fender 2gm Injection Each vial contains:-	30-06-2015 Dy.	30-06-2010

				Cefoperazone (as Sodium) ……1000mg Sulbactum (as Sodium) ……1000mg	No.1638 Rs.50,000/	
11.	-do-	-do-	045488	Fender 1gm Injection Each vial contains:- Cefoperazone (as Sodium) ……500mg Sulbactum (as Sodium) ……500mg	30-06-2015 Dy. No.1638 Rs.50,000/	30-06-2010

The RB considered the case in M-238 and acceded to the request of the firm and extended the contract manufacturing permission till 30-06-2015 after submission of remaining fee since firm has deposited 42,000/- for each product on 15-04-2013. Due to non-deposition of fee the permission letter for extension in contract manufacturing permission was not issued to the firm.

The firm then applied for extension in contract manufacturing permission in 2015 without providing the previous contract manufacturing permission along with fee of Rs.50,000/- per product. The case was presented before Registration Board in its 254th meeting. The Registration Board decided as follows:

Registration Board deferred the above cases for evaluation in light of Rule 20-A of Drugs (L,R&A) Rules, 1976 (Contract Manufacturing, Policy).

The firm has now submitted differential fee of Rs.8000/- per product dated 17-01-2018.

M/s Synchro Pharmaceuticals have approval of Cephalosporin (Capsule, Dry Powder for Suspension and Dry Powder for Injectable) section evident from panel inspection report (dated 29.03.2016) for renewal of DML and grant of additional sections. The firm has provided copy of contract manufacturing agreement b/w M/s Synchro Pharmaceuticals, Lahore and M/s Trison Pharmaceuticals, Sargodha dated 03-02-2018.

Decision of 279th Meeting:

Registration Board deferred the request of the firm for submission of latest GMP inspection report of M/s Synchro Pharmaceuticals, Lahore which should be conducted within last one year.

Firm has submitted GMP inspection report of M/s Synchro Pharmaceuticals, Lahoredated 12-06-2019 & 04-07-2019.

Decision: **Registration Board approved the request of M/s Trison Pharmaceuticals, Sargodha for change of contract manufacturer of above products from M/s Sharooq Pharmaceuticals to M/s Synchro Pharma, Lahore alongwith extension in contract manufacturing of till 30-06-2020. Verification of fee challan may be done as per decision of 285th meeting of Registration Board.**

Case No. 57: Change of Brand Name due to resemblance with products of M/s. Atco Laboratories, Karachi.

Chairman Registration Board, in 28th meeting of PRVC, considered the request of M/s. Atco Pakistan Limited, Karachi about resemblance of brand name with products of M/s. Searle IV Solution Pvt. Limited, Lahore. Since the brand name were granted to M/s. Atco Laboratories, Karachi prior, hence M/s. Searle IV Solution Pvt. Limited, Lahore where advised to change brand name due to resemblance. Since firm did not provided alternate brand name hence Reminders also written (dated dated 12-06-2017, 25-08-2017 & 11-06-2019) but the firm has not responded yet.

S.#	Product name	Name of firm	Similar Brand
1.	Syngab ……..50mg (Reg. 048420) Syngab ……..100mg (Reg. 048421) Syngab ……..200mg (Reg. 048422) Syngab ……..75mg (Reg. 076691) Syngab ……..150mg (Reg. 076692) Syngab ……..300mg (Reg. 076693)	**M/s. Searle IV Solution Pvt. Limited, Lahore**	Spingab 75mg (Reg. no. 079723) Spingab 100mg (Reg. no. 079724) Spingab 150mg (Reg. no. 079725) Spingab 300mg (Reg. no. 079726)

Decision: Registration Board decided to write a final letter with complete details to M/s Searle IV Solution Pvt. Limited, Lahore to change the brand name of their registered product i.e. Spingab as Syngab of M/s. Atco Pakistan Limited, Karachi has been registered earlier to their product.

Case.No.58: Request of M/s Bayer Pakistan (Pvt.) Limited, Lahore for change Of Manufacturing Site.

M/s Bayer Pakistan (Pvt.) Limited, Lahore has applied for change of manufacturing site of their following already registered products as per details given below: -

Reg. No.	Name and Composition as per initial registration letter & CoPP	Current Name of manufacturing site (as per approval)	Proposed name of manufacturing site
017864	Progynova Tablets 2mg Each tablet contains: Estradiol valerate……..2mg Product shall be imported in blister form and secondary packaging and quality control release shall be carried out at M/s Medipharm (pvt.) Ltd Lahore.	**Bulk Manufacturing:** Delpharm Lille SAS Pare d'Activities Roubaix-Est 22 Rue de Toufflers CS 50070 59452 Lys-Lez-Lannoy, France. **Primary Packaging, Secondary Packaging, Final Release:** • Delpharm Lille SAS Pare d'Activities Roubaix-Est 22 Rue de Toufflers CS 50070 59452 Lys-Lez-Lannoy, France. • Bayer AG Berlin, Germany. • Bayer Weimar GmbH & Co. KG, Weimar, Germany. **Repacked By:** Bayer Pakistan (Pvt.) Ltd. Lahore. 108 Kot Lakhpat Industrial Estates, Lahore.	**Bulk Manufacturing:** • Bayer Weimar GmbH & Co. KG, Weimar, Germany. **Primary Packaging, Secondary Packaging, Final Release:** • Bayer Weimar GmbH & Co. KG, Weimar, Germany. **Repacked By:** Bayer Pakistan (Pvt.) Ltd. Lahore. 108 Kot Lakhpat Industrial Estate, Lahore. **Product License Holder: -** M/s Jenapharm GmbH & Co. KG Otto-Schott-Strasse 15 07745 Jena Germany

The firm has submitted the following supporting documents: -

a). Fee of Rs.50,000/- dated 17-07-2019.
b). Application on Form 5F
c). Copy of initial registration letter 27-9-1995
d). Renewal application with fee Rs. 20,000/- dated 25-06-2015
e). Original & legalized COPP issued German Authority.
f). Sole agency agreement not provided.
g). Letter of transfer of registration to new title not provided.

Decision: Registration Board deferred the above product for submission of Sole agency agreement and letter of transfer of registration to new title i.e. Bayer Pakistan (Pvt.) Ltd. Lahore.

RRR Section

Sr. No.	Case	Dr. Shoaib Ahmed, Deputy Director (RRR) 109	Muneeb Ahmed Cheema, Assistant Director (RRR-I) 371	Saima Hussain, Assistant Director (RRR-II) 293	Muhammad Ayub Naveed, Assistant Director (RRR-III) 429	Syed Ajwad Bukhari, Assistant Director (RRR-IV) 393	Total
Complete Cases							
1.	Local manufacturing (Human)	67	137	67	39	134	444
2.	Local manufacturing (Veterinary)	-	40	15	5	7	67
3.	Finished Import (Human)	-	02	-	-	-	02
4.	Finished Import (Veterinary)	-	-	-	-	-	-
Total Complete Cases							**513**
Incomplete Cases							
5.	Local manufacturing (Human)	42	126	200	238	123	729
6.	Local manufacturing (Veterinary)	-	16	05	16	29	66
7.	Finished Import (Human)	-	06	01	-	13	20
8.	Finished Import (Veterinary)	-	02	05	-	12	19
Total Incomplete Cases							**834**
Deferred Cases of Previous Meetings							
9.	-	-	42	-	131	75	**248**
Miscellaneous Cases Case deferred in previous meetings/ referred from other divisions/ Typo errors etc.							
10.	-	44					**44**
Total Cases of RRR-Section for 292nd Meeting of Registration Board							**1639**

COMPLETE CASES

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Macter International Limited, F-216, S.I.T.E., Karachi						
1.	23539	Viron Capsule 200mg Each tablet contains Ribavirin……..200mg	30/04/1999	Dy. No. 9190 dated 28-02-2019 10,000/-	29-04-2024	w.e.f. 30-04-2019 to 29-04-2024
2.	23540	Viron Capsule 400mg Each tablet contains Rivavirin……400mg	30/04/1999	Dy. No. 9190 dated 28-02-2019 10,000/-	29-04-2024	w.e.f. 30-04-2019 to 29-04-2024
3.	23541	Viron Syrup Each 5ml contains Rebavirin……..50mg	30/04/1999	Dy. No. 9190 dated 28-02-2019 10,000/-	29-04-2024	w.e.f. 30-04-2019 to 29-04-2024
4.	055481	Plaquin-H Tablet 200mg Each tablet contains:- Hydroxychloroquine Sulphate…200mg	28-4-2009	Dy. No. 9182 Dated 28-02-2019 10,000/-	27-04-2024	w.e.f. 28-04-2019 to 27-04-2024
5.	055754	Onden 8mg Tablet Each tablet contains:- Ondasetron HCl… 8.0mg	15-4-2009	Dy. No. 9178 28-02-2019 10,000/-	14-04-2024	w.e.f. 15-04-2019 to 14-04-2024
M/s. AGP Ltd., B-23, C Sindh Industrial Trading Estate, Karachi						
6.	055119	Poze-G 2/30Tablet Each tablet contains: Glimepiride…….2mg Pioglitazone (as HCl)……..30mg	02/03/2009	Dy. No. 4702 dated 01-02-2019 10,000/-	01-03-2024	w.e.f. 02-02-2019 to 01-02-2024
7.	055121	Xovat 5mg Tablet Each tablet contains: Rosuvastatin as Calcium……..5mg	02/03/2009	Dy. No. 4704-A dated 01-02-2019 10,000/-	01-03-2024	w.e.f. 02-03-2019 to 01-03-2024
8.	055123	Xovat 20mg Tablet Each tablet contains: Rosuvastatin as Calcium…….20mg	02/03/2009	Dy. No. 4703 dated 01-02-2019 10,000/-	01-03-2024	w.e.f. 02-03-2019 to 01-03-2024
9.	055133	Pozemet 15/500 Tablet Each tablet contains: Pioglitazone (as HCl) …15mg Metformin HCl…500mg	04/03/2009	Dy. No. 4699 dated 01-02-2019 10,000/-	03-03-2024	w.e.f. 04-03-2019 to 03-03-2024
10.	055126	Bispa 10mg Tablet Each tablet contains: Bisoprolol Fumarate……..10mg	02/03/2009	Dy. No. 4698 dated 01-02-2019 10,000/-	01-03-2024	w.e.f. 02-03-2019 to 01-03-2024
11.	055122	Xovat 10mg Tablet Each tablet contains: Rosuvastatin as Calcium…..10mg	02/03/2009	Dy. No. 4704-B dated 01-02-2019 10,000/-	01-03-2024	w.e.f. 02-03-2019 to 01-03-2024
12.	055118	Poze G 2/30Tablet Each tablet contains:- Glimepiride….2mg Pioglitazone (as HCl) …….30mg	02/03/2009	Dy. No. 4700 dated 01-02-2019 10,000/-	01-03-2024	w.e.f. 02-03-2019 to 01-03-2024
13.	055120	Poze G 4/30Tablet Each tablet contains:- Glimepiride….4mg	02/03/2009	Dy. No. 4701 dated 01-02-2019	01-03-2024	w.e.f. 02-03-2019 to 01-03-2024

		Pioglitazone (as HCl)….30mg		10,000/-		
M/s. Le Mendoza Pharmaceutical (Pvt) Ltd., Plot No. 7, Sector 23, Korangi Industrial Area, Karachi						
14.	036222	Broven Tablet Each tablet contains:- Salbutamol Sulphate… 2mg	24/02/2004 Transfer of Registration 29-03-2018	Dy. No. 7115 dated 19-02-2019 10,000/-	23-02-2024	w.e.f. 24-02-2019 to 23-02-2024
15.	036223	Transcam D.S Capsules Each capsule contains:- Tranexamic Acid ……500mg	24/02/2004 Transfer of Registration 29-03-2018	Dy. No. 7114 dated 19-02-2019 10,000/-	23-02-2024	w.e.f. 24-02-2019 to 23-02-2024
M/s. Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi						
16.	014839	Geosef Capsule 250mg Each capsule contains:- Cephradine … 250mg	24/02/1994	Dy. No. 5210 06-02-2019 10,000/-		Deferred for approval of formulation in RRA
17.	014840	Geosef Capsule 500mg Each capsule contains:- Cephradine … 500mg	24/02/1994	Dy. No. 5209 dated 06-02-2019 10,000/-	23-02-2024	w.e.f. 24-02-2019 to 23-02-2024
M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd., Karachi						
18.	023560	Orbatol Eye Drops contains:- Dexamethasone …0.1%w/v Neomycin Sulphate eq. to neomycin…3500i.u/ml Polymyxin B Sulphate …6000i.u/ml	11/05/1999	Dy. No. 7160 dated 19-02-2019 10,000/-	10-05-2024	w.e.f. 11-05-2019 to 10-05-2024
19.	023562	Orbaleph Eye Drops contains:- Prednisolone Acetate …0.25%w/v Sodium Sulphacetamide…10%w/v	11/05/1999	Dy. No. 7100 dated 19-02-2019 10,000/-	10-05-2024	w.e.f. 11-05-2019 to 10-05-2024
M/s. WelMark Pharmaceuticals, Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar						
20.	056088	Betamark 20mg Tablet Each tablet contains: Piroxicam as Beta Cyclodextrin…20mg	19/02/2009	Dy. No.7136 dated 19-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
21.	056087	Lumale 140mg Tablets Each tablet contains: Artemether…….20mg Lumifantrine……120mg	19/02/2009	Dy. No.7136 dated 19-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
M/s. Akson Pharmaceuticals (Pvt) Ltd., Plot No. 9B-1 & 2 Sector D-1 Old Industrial Estate Mirpur Azad Kashmir						
22.	023741	Jaycil Capsules Each Capsule contains:- Cefadroxil Monohydrate...500mg	15/09/2001 Brand name change 21-02-2004	Dy. No.6616 dated 14-02-2019 10,000/-	20-02-2024	Deferred for confirmation of manufacturing facility from Licensing Division
23.	023742	Jaycil Suspension Each 5ml contains:- Cefadroxil Monohydrate...125mg	15/09/2001 Brand name change 21-02-2004	Dy. No.6614 dated 14-02-2019 10,000/-	20-02-2024	-do-
24.	032156	Atrotil Tablets Each tablet contains:- Diphenoxylate HCl	19-02-2004	Dy. No.6613 14-02-2019 10,000/-	18-02-2024	-do-

		….2.5mg Atropine Sulphate ….25mcg				
25.	023743	Jaycil Suspension Each 5ml contains:- Cefadroxil Monohydrate...250mg	15/09/2001 Brand name change 21-02-2004	Dy. No.6615 dated 14-02-2019 10,000/-	20-02-2024	-do-
26.	032157	Hemitose Syrup Each 5ml contains:- Iron III Hydroxide Polymaltose complex 187.5mg (eq. to Elemental Iron...50mg	19-02-2004	Dy. No.6612 dated 14-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
M/s. Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road, Landhi, Karachi						
27.	022481	Epival CR 500mg Tablets Each tablet contains:- Valproic Acid (as Divalproex sodium)…500mg	19/03/1999	Dy. No.6618 dated 14-02-2019 10,000/-	18-03-2024	w.e.f. 19-03-2019 to 18-03-2024
28.	023349	Epival IV Injection Each 5 ml contains:- Valproic Acid (as Valproate sodium)…500mg	19/03/1999	Dy. No.6618 dated 14-02-2019 10,000/-	18-03-2024	w.e.f. 19-03-2019 to 18-03-2024
29.	015015	Vancomycin Injection Each vial contains:- Vancomycin Hcl eq. to 500mg Vancomycin	05/03/1994	Dy. No.6618 dated 14-02-2019 10,000/-	04-03-2024	w.e.f. 05-03-2019 to 04-03-2024
30.	015016	Vancomycin Injection Each vial contains:- Vancomycin Hcl eq. to 1gm Vancomycin	05/03/1994	Dy. No.6618 dated 14-02-2019 10,000/-	04-03-2024	w.e.f. 05-03-2019 to 04-03-2024
31.	015017	Hytrin 5mg Tablets Each tablet contains:- Terazosin HCl eq. to 5mg Terazosin	05/03/1994	Dy. No.6618 dated 14-02-2019 10,000/-	04-03-2024	w.e.f. 05-03-2019 to 04-03-2024
32.	015018	Hytrin 10mg Tablets Each tablet contains:- Terazosin HCl eq. to 10mg Terazosin	05/03/1994	Dy. No.6618 dated 14-02-2019 10,000/-	04-03-2024	w.e.f. 05-03-2019 to 04-03-2024
M/s. Genome Pharmaceuticals (Pvt) Ltd., Plot No.16/1 Phase No. IV Industrial Estate Hattar Distt Haripur						
33.	78430	Parinom CR 12.5 Tablet Each controlled release tablet contains: Paroxetine Hydrochloride Hemihydrate ≡Paroxetine … 12.5mg	12/02/2014	Dy. No.5213 dated 06-02-2019 10,000/-	11-02-2024	w.e.f. 12-02-2019 to 11-02-2024
34.	78431	Omnat 20 Tablet Each enteric coated tablet contains:- Omeprazole Magnesium ≡Omeprazole … 20mg	12/02/2014	Dy. No.5213 dated 06-02-2019 10,000/-	11-02-2024	w.e.f. 12-02-2019 to 11-02-2024
35.	56076	Topilep 50 Tablet Each tablet contains:- Topiramate…. 50mg	18/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024

36.	56077	Topilep 25 Tablet Each tablet contains:- Topiramate…. 25mg	18/02/2009	Dy. No.5213 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024
37.	56078	Demantin 10 Tablet Each tablet contains:- Memantine HCl….. 10mg	18/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024
38.	56079	Rosut 20 Tablet Each tablet contains:- Rosuvastatin (as Calcium)… 20mg	18/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024
39.	56080	Rosut 5 Tablet Each tablet contains:- Rosuvastatin (as Calcium)… 5mg	18/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024
40.	56081	Rosut 10 Tablet Each tablet contains:- Rosuvastatin (as Calcium)… 10mg	18/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024
41.	56082	Hapotin Tablet Each tablet contains:- Adefovir Dipivoxil……...10mg	18/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024
42.	56083	Metoxim Tablet Each tablet contains:- Moxifloxacin (as HCl)… 400mg	18/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	17-02-2024	w.e.f. 18-02-2019 to 17-02-2024
43.	56089	Telrom 400mg Tablet Each tablet contains:- Telithromycin…..400mg	19/02/2009	Dy. No.5213 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
44.	56090	Histogen 8mg Tablet Each tablet contains:- Betahistine Dihydrochloride… 8mg	19/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
45.	56091	Paracem Tablet Each tablet contains:- Paracetamol… 450mg Orphenadrine Citrate… 35mg	19/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
46.	56092	Histogen 16mg Tablet Each tablet contains:- Betahistine Dihydrochloride… 16mg	19/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
47.	56093	Zolimit Tablet Each tablet contains:- Zolmitriptan… 2.5mg	19/02/2009	Dy. No.5213 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
48.	56094	Juline Tablet Each tablet contains:- Selegiline HCl… 5mg	19/02/2009	Dy. No.5213 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
49.	56095	Doxinom 100 Capsule Each capsule contains:- Doxycycline (as Hyclate)…100mg	19/02/2009	Dy. No.5213 dated 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
50.	56096	Meflogen Tablet Each tablet contains:- Mefloquine HCl… 250mg	19/02/2009	Dy. No.5213 06-02-2019 10,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
51.	56097	Dycloxan 100 SR Tablet Each sustained release	19/02/2009	Dy. No.5213 dated	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024

		tablet contains Diclofenac Sodium..100mg		06-02-2019 10,000/-		
52.	56098	Dycnom 50 Capsule Each capsule contains:- Diclofenac Sodium (Pellets)… 50mgs	19/02/2009	Dy. No.5213 dated 06-02-2019 20,000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
53.	56099	Dycnom SR 100 Capsule Each capsule contains:- Diclofenac Sodium (Pellets)… 100mg	19/02/2009	Dy. No.5213 dated 06-02-2019 20,000/-	18-02-2024	Deferred for confirmation of approval of Source of Pellets.
M/s. Vega Pharmaceuticals (Pvt) Ltd., 30-Km Multan Road Lahore						
54.	77114	Loteflam 0.5% Eye Drops Each ml contains:- LoteprednolEtabonate ……..5mg	19/05/2014	Dy. No.6824 dated 15-02-2019 10,000/-	18-05-2024	w.e.f. 19-05-2019 to 18-05-2024
55.	77115	Veflox-D Eye Drops Each ml contains:- Ofloxacin……3mg Dexamehthasone….1mg	19/05/2014	Dy. No.6824 dated 15-02-2019 10,000/-	18-05-2024	w.e.f. 19-05-2019 to 18-05-2024
56.	77193	Eyemox-D Eye Drops Each ml contains:- Moxifloxacin HCl eq. to Moxifloxacin…….5mg Dexamethasone Sodium Phosphate eq. to Dexamethasone Phosphate……..1mg	26/05/2014	Dy. No.6823 dated 15-02-2019 10,000/-	25-05-2024	w.e.f. 26-05-2019 to 25-04-2024
M/s. Medisure Laboratories Pakistan (Pvt) Ltd., A-115 S.I.T.E, Super Highway, Karachi						
57.	32261	Longtel Tablets 100mg Each tablet contains:- Lamotrigine…….100mg	25/02/2004	Dy. No.4959 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
58.	32262	Ziptan Tablets Each tablet contains: Zolmitriptan …….2.5mg	25/02/2004	Dy. No.4959 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
59.	32263	Nyer Tablets Each tablet contains:- Tizanidine HCl eq. to Tizanidine…….2mg	25/02/2004	Dy. No.4959 dated 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
60.	32265	Tulurik Tablets Each tablet contains:- Valsartan ……160mg	25/02/2004	Dy. No.4959 dated 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
61.	32266	Venice Tablets Each tablet contains:- Venlafaxine HCl…..37.50mg	25/02/2004	Dy. No.4959 dated 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
62.	32269	Venice Xr Capsules 75mg Each capsule contains:- Venlafaxine HCl…75mg	25/02/2004	Dy. No.4959 15-02-2019 10,000/-	24-02-2024	Deferred for confirmation of approval of Source of Pellets.
63.	32270	Malprate–D Tablets 250mg Each tablet contains:- Divalproex Sodium eq. To Valproic Acid 250mg	25/02/2004	Dy. No.4959 dated 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
64.	32271	Malprate –D Tablets 500mg Each tablet contains :-	25/02/2004	Dy. No.4959 dated 15-02-2019	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024

		Divalproex Sodium eq. To ValproicAcid.....500mg		10,000/-		
65.	32267	Astat Tablets 10mg Each tablet contains:- Atorvastatin Calcium eq. to Atorvastqatin …..10mg	25/02/2004	Dy. No.4959 dated 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
66.	32268	Astat Tablets 20mg Each tablet contains:- Atorvastatin Calcium eq. to Atorvastqatin …..20mg	25/02/2004	Dy. No.4959 dated 15-02-2019 10,000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
67.	1147-EX	Axadol Plus Tablet each tablet contains Paracetamol... 500mg Caffeine ... 65MG Chloropheniramine maleate…2mg	02/02/2009	Dy. No.4959 dated 15-02-2019 10,000/-		Differential fee is required as application is submitted after due date but within sixty days.

INCOMPLETE CASES

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Remarks
M/s. Macter International Limited, F-216, S.I.T.E., Karachi						
68.	055842	Maxima 200mg tablet Each tablet contains Cefixime (as trihydrate) ….200mg	28/04/2009	Dy. No.9181 dated 28-02-2019 10,000/-		
69.	055752	Mac-Mether Plus Each tablet contains Artemether……..20mgLume fantrine…….120mg	15/04/2009	Dy. No.9179 dated 28-02-2019 10,000/-		
70.	055845	Heptrol 10mg Tablet Each tablet contains Adefovir Dipivoxil……...10mg	28/04/2009	Dy. No.9180 dated 28-02-2019 10,000/-		
Shortcomings: Following shortcomings were communicated vide letter dated: 19-09-2019 ➢ Evidence of last renewal required. ➢ Copy of brand name change letter required. ➢ Approval status of products in Reference Drug Agencies ➢ Section approval letter issued by Licensing Division						
M/s. Davis Pharmaceutical Laboratories, Plot 121, Industrial Triangle Kahuta Road, Islamabad						
	032088	Opza Capsule Each capsule contains:- Omeprazole (coated pellets) 225mg eq. to Omeprazole……20mg	09/02/2004	Dy. No.5705 dated 08-02-2019 20,000/-		
Shortcomings: Following shortcomings were communicated vide letter dated: 19-09-2019 ➢ Original legalized lasted GMP certificate is copy required.						
M/s. Helicon Pharmaceutek Pakistan (Pvt) Ltd., Model Town Road, Faisalabad						
71.	032146	Slide Tablets Each tablet contains:- Nimesulide..... 100mg	19/02/2004	Dy. No.5706 dated 08-02-2019 10,000/-		
Shortcomings: Following shortcomings were communicated vide letter dated: 19-09-2019 ➢ Evidence of last renewal required. ➢ Attested copy of valid Drug Manufacturing License. ➢ Section approval letter issued by Licensing Division ➢ Original legalized lasted GMP certificate is copy required.						

M/s. Espoir Pharmaceutical, Plot No. TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim-uz-Zaman Siddiqui off. University Road, Karachi						
72.	076258	Haito 5mg/5ml Syrup Each 5ml contains:- Domperidone maleate eq to Domperidone…...5 mg	13/2/2014	Dy. No.4950 dated 04-02-2019 10,000/-		
Shortcomings: Following shortcomings were communicated vide letter dated: 19-09-2019 ➢ Attested copy of valid Drug Manufacturing License. ➢ Original legalized lasted GMP certificate is copy required						
M/s. Popular Chemical Works (Pvt) Ltd., 9-Km Sheikhupura Road, Lahore						
73.	32259	Obexil Tablets 20mg Each tablet contains:- Paroxetine HCl …….20mg	25/02/2004	Dy. No.4952 04-02-2019 10,000/-		
74.	32256	Mincole 10mg Tablets Each tablet contains:- Simvastatin …..10mg	25/02/2004	Dy. No.4953 04-02-2019 10,000/-		
75.	32255	Savelox Tablets 250mg Each tablet contains:- Levofloxacin (as hemihydrate).. ..250mg	25/02/2004	Dy. No.4954 dated 04-02-2019 10,000/-		
76.	32258	Mincole 40mg Tablets Each tablet contains:- Simvastatin …..40mg	25/02/2004	Dy. No.4955 04-02-2019 10,000/-		
77.	32257	Mincole 20mg Tablets Each tablet contains:- Simvastatin …..20mg	25/02/2004	Dy. No.4956 04-02-2019 10,000/-		
Shortcomings:- Following shortcomings were communicated vide letter dated: 19-09-2019 ➢ Initial Registration letter required. ➢ Attested copy of valid Drug Manufacturing License. ➢ Original legalized lasted GMP certificate is copy required.						
M/s. Pakistan Pharmaceutical Products (Pvt) Ltd., D/122, S.I.T.E. Karachi						
78.	4856	Theoron Capsules Each Capsule Contains:- Theophylline …150mg Guaifenesin….90mg	06/02/1980	Dy. No.4957 dated 04-02-2019 10,000/-		
79.	4857	Theoron Syrup Each 15ml contains Theophylline …150mg Guaifenesin …90mg	06/02/1980	Dy. No.4957 dated 04-02-2019 10,000/-		
Shortcomings:- Following shortcomings were communicated vide letter dated: 19-09-2019 ➢ Transfer of Registration to current site copy required ➢ Approval status of products in Reference Drug Agencies ➢ Attested copy of valid Drug Manufacturing License ➢ Original legalized lasted GMP certificate is copy required.						
M/s. Elko Organization (Pvt) Ltd., Plot No 27 & 28, Sector 12-B, North Karachi, Industrial Area Karachi						
80.	55128	Seasol 5mg Tablet Each tablet contains: Montelukast (as Sodium) .....……..5mg	04/03/2009	Dy. No.7701 dated 21-02-2019 10,000/-		
81.	55129	Seasol 10mg Tablet Each tablet contains: Montelukast (as Sodium)……..10mg	04/03/2009	Dy. No.7701 dated 21-02-2019 10,000/-		

82.	55130	Ronate 10mg Tablet Each tablet contains: Alendronate (as Sodium)……..10mg	04/03/2009	Dy. No.7701 dated 21-02-2019 10,000/-		
83.	55131	Ronate –OW Tablet Each tablet contains: Alendronate (as Sodium)……..70mg	04/03/2009	Dy. No.7701 dated 21-02-2019 10,000/-		
84.	55132	Dinerve 500mcg Tablet Each tablet contains: Mecobalamin…..500mcg	04/03/2009	Dy. No.7701 21-02-2019 10,000/-		
85.	39210	Elfar 100mg Tablets Each tablet contains: Sparfloxacin….100mg	04/03/2009 Brand name change 04-03-2009	Dy. No.7701 dated 21-02-2019 10,000/-		
Shortcomings: Following shortcomings were communicated vide letter dated: 24-09-2019 ➢ Approval status of products in Reference Drug Agencies. ➢ Evidence of last renewal required. ➢ Last Inspection Report ➢ Attested copy of valid Drug Manufacturing License. ➢ Section approval letter issued by Licensing Division ➢ An undertaking that the applied products have never been de-registered **(on Stamp Paper)**. ➢ An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws **(on Stamp Paper)**.						
M/s. CKD Pharmaceuticals Pakistan (Pvt) Ltd., 50/28 Korangi Industrial Area Karachi						
86.	017621	CekamolPaed Suspension	06-12-1995	Dy. No.5207 dated 06-02-2019 10,000/-		
Shortcomings:- Following shortcomings were communicated vide letter dated: 24-09-2019 ➢ Copy of initial registration letter required ➢ Copy of valid Drug Manufacturing License required.						
M/s. Alkemy Pharmaceutical Laboratories (Pvt) Ltd., P-9 S.I.T.E., Hyderabad						
87.	022996	Kemyclox Suspension Each 5ml contains:- Amoxycillin Trihydrate eq. to Amoxycillin base… 125mg	30-01-1999	Dy. No.5208 dated 06-02-2019 10,000/-		
Shortcomings: Following shortcomings were communicated vide letter dated: 24-09-2019 ➢ Copy of valid Drug Manufacturing License. ➢ Evidence of last renewal required. ➢ Section approval letter issued by Licensing Division. ➢ Latest GMP certificate is copy required. ➢ Brief detail of last batch manufactured ➢ Differential fee as the renewal application is submitted after due date.						
M/s. Pulse Pharmaceuticals (Pvt) Ltd., Mozay Badoke, Raiwind Road (Sua Asil Road), Lahore						
88.	046715	Gutsy 20mg Tablet Each tablet contains:- Esomeprazole … 20mg	20-07-2007 Brand name change 15-12-2007	Dy. No.7112 dated 19-02-2019 20,000/-		
89.	046714	Gutsy 40mg Tablet Each tablet contains:- Esomeprazole … 40mg	20-07-2007 Brand name change 15-12-2007	Dy. No.7113 dated 19-02-2019 20,000/-		
90.	069217	Water for injection Each ampoule contains:- Water for injection	26-03-2011	Dy. No.7111 19-02-2019 20,000/-		

Shortcomings: Following shortcomings were communicated vide letter dated: 24-09-2019

- Evidence of last renewal required (as submitted document shows that application is received after expiry of registration).

M/s. Shaigan Pharmaceutical (Pvt) Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi

91.	054490	Esso-40 Injection IV Each vial contains:- Esomeprazole Sodium eq. to Esomeprazole…40mg	31-03-2009	Dy. No.5212 dated 06-02-2019 10,000/-		
92.	054491	Antimin D Tablet Each tablet contains:- Desloratadine… 5mg	31-03-2009	Dy. No.5212 06-02-2019 10,000/-		
93.	054492	Glykin 500mg Injection Each vial contains:- Amikacin as Sulphate…500mg	31-03-2009	Dy. No.5212 06-02-2019 10,000/-		
94.	054493	Glykin 250mg Injection Each vial contains:- Amikacin as Sulphate. 250mg	31-03-2009	Dy. No.5212 06-02-2019 10,000/-		
95.	054494	Glykin 100mg Injection Each vial contains:- Amikacin as Sulphate. 100mg	31-03-2009	Dy. No.5212 06-02-2019 10,000/-		
96.	054495	Iroton-F Chewable Tablet Each tablet contains:- Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron … 100mg Folic Acid …. 0.35mg	31-03-2009	Dy. No.5212 dated 06-02-2019 10,000/-		

Shortcomings: Following shortcomings were communicated vide letter dated: 24-09-2019

- Copy GMP certificate required.

M/s. Indus Pharma (Pvt) Ltd., Plot No. 26, 27, 63, 64, 65, 66 & 67, Sector 27, Korangi Industrial Area Karachi

97.	53492	Nixpro 40mg Capsule Each Capsule Contains: Pantoprazole (as Sodium) Susquihydrate Pellets 40mg	10/01/2009	Dy. No.6617 dated 14-02-2019 10,000/-		
98.	53493	Dyclo GR-50 Capsule Each Capsule Contains: Diclofenac Sodium Enteric Coated Pellets ……. …50mg (USP Specifications)	10/01/2009	Dy. No.6617 dated 14-02-2019 10,000/-		
99.	36589	Xed 500mg Capsules Each capsule contains : Tranexamic Acid……500mg	24/01/2004	Dy. No.6617 dated 14-02-2019 10,000/-		
100.	14584	cimetamat (injection) Each ml contains:- Cimetidine…100mg	24/02/1994	Dy. No.6617 dated 14-02-2019 10,000/-		

Shortcomings:-

Following shortcomings were communicated vide letter dated: 24-09-2019

- Undertaking on Stamp paper required.
- Imported Pellets fee required for year (2014)
- Imported Pellets fee required for year (2019)
- An undertaking that the applied products have never been de-registered **(on Stamp Paper)**.
- An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws **(on Stamp Paper)**.
- Source fixation letter required

- Last Inspection report required

M/s. Better Traders International, 24-Z/E Saif Ullah Shaheed Road, Madina Town, Faisalabad

101.	14562	KeproTylo-Dox Extra W/S each 500g contains Tylosin tartrate…50gm Doxycycline HCl…100gm	22/02/1994	Dy. No.6610 dated 14-02-2019 20,000/-		
102.	14563	Kepro Gentaject 10% Injection each ml contains Gentamycine sulphate eq. to 100mg Gentamycine base.	22/02/1994	Dy. No.6611 dated 14-02-2019 20,000/-		

Shortcomings:-

Following shortcomings were communicated vide letter dated: 24-09-2019

- Drug Sale License as per WHO format required.
- Copy GMP Certificate required.
- COPP required.

M/s. Venus Pharma, 23 Km Multan Road Lahore

103.	015111	Viocin Injection Each ml contains:- Lincomycin HCl eq. to 300mg Lincomycin Base	05-03-1994	Dy. No.6822 dated 15-02-2019 10,000/-		

Shortcomings: Following shortcomings were communicated vide letter dated: 25-09-2019

- Evidence of last renewal required.
- Copy of valid Drug Manufacturing License.
- Section approval letter issued by Licensing Division
- Original legalized latest GMP certificate copy required.
- An undertaking that the applied products have never been de-registered (on Stamp Paper).
- An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws (on Stamp Paper).

M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, Islamabad

104.	056339	Fenum SR 100mg Capsule Each capsule contains:- Diclofenac Sodium (as enteric coated Pellets)…100mg	25/03/2009	Dy. No.6821 dated 15-02-2019 10,000/-		

Shortcomings: Following shortcomings were communicated vide letter dated: 25-09-2019

- Evidence of last renewal required.
- Original legalized latest GMP certificate copy required.
- Imported Pellets differential fee required.
- Source of Pellets letter required.
- An undertaking that the applied products have never been de-registered **(on Stamp Paper)**.
- An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws **(on Stamp Paper)**.

M/s. Pharmacare Laboratories (Pvt) Ltd., 129/1 Industrial Estate Kot Lakhpat, Lahore

105.	14852	Bactacin Tablets EACH TABLET CONTAINS:- Ofloxacin...200mg	24/02/1994	Dy. No.6826 dated 15-02-2019 10,000/-		
106.	14853	Pharmic Forte Tablets Each tablet contains: Mefenamic acid…500mg	24/02/1994	Dy. No.6825 15-02-2019 10,000/-		

Shortcomings:-

Following shortcomings were communicated vide letter dated: 25-09-2019

- Evidence of last renewal required.
- Section approval letter issued by Licensing Division
- Original legalized latest GMP certificate copy required.
- Valid Drug Sale License is required.
- An undertaking that the applied products have never been de-registered **(on Stamp Paper)**.

➢ An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws **(on Stamp Paper)**.						
M/s. Spencer & Company (Pvt) Ltd., D-105 S.I.T.E., Karachi						
107.	15057	Spencidine Solution Contains: Povidone Iodine… 10 %	28/02/1994	Dy. No.6829 15-02-2019 10,000/-		
108.	15058	Spencidine Gargle Contains: Povidone Iodine… 1% w/v	28/02/1994	Dy. No.6827 15-02-2019 10,000/-		
109.	15059	Spencidine Surgical Scrub Contains:- Povidone Iodine… 7.5 % w/v	28/02/1994	Dy. No.6828 15-02-2019 10,000/-		
Shortcomings: Following shortcomings were communicated vide letter dated: 25-09-2019 ➢ Evidence of last renewal required. ➢ Copy of valid Drug Manufacturing License. ➢ Section approval letter issued by Licensing Division ➢ Original legalized latest GMP certificate copy required ➢ Brief detail of last batch manufactured						

Assistant Director (RRR-I)

COMPLETE CASES

Local Manufacturing Human

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Decision
M/s. Mediate Pharmaceuticals (Pvt) Ltd., Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi					
110.	077460	Dispride 50 mg dispersible tablet Each dispersible tablet contains: Levosulpiride….50mg	14-10-2013	Dy. No. 33685 dated 10-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
111.	077461	Alendrowin 70 mg Tablets Each film coated tablet contains: Alendronate Sodium…..70 mg	14-10-2013	Dy. No. 33685 dated 10-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
112.	078406	Fentolit-100 mg SR Capsules Each prolonged-release capsule contains Diclofenac Sodium Prolonged Release Pellets ≡ Diclofenac…….100 mg	25-11-2013	Dy. No. 33685 dated 10-10-2018 20000/-	Deferred for confirmation of approval of source of pellets
113.	76109	Tramorhage 250mg Capsule Each capsule contains: Tranexemic acid.....250mg	24/10/2013	Dy. No. 33439 dated 08-10-2018 10000/-	w.e.f. 24-10-2018 to 23-10-2023
114.	76110	Tramorhage 500mg Capsule Each capsule contains: Tranexemic acid…….500mg	24/10/2013	Dy. No. 33438 dated 08-10-2018 10000/-	w.e.f. 24-10-2018 to 23-10-2023
115.	76111	Medi-IS Injection 20mg/ml Injection Each ml contains: Iron sucrose complex eq. to Elemental Iron……20mg	24/10/2013	Dy. No. 33440 dated 08-10-2018 10000/-	w.e.f. 24-10-2018 to 23-10-2023
M/s. Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi					
116.	004412	Mefenamic Acid Tablet 250mg Each Tablet Contains Mefenamic Acid…250mg	22-11-1978	Dy. No. 32696 dated 1-10-2018 10000/-	w.e.f. 22-11-2018 to 21-11-2023
117.	10004	DEXAMEDRON INJ Each ml Contains Dexamethasone Sodium	29-10-1988	Dy. No. 32695 dated 1-10-2018 10000/-	Deferred for confirmation of manufacturing

		Phosphate eq. to Dexamethasone Phosphate…4MG			facility.
M/s. BJ Pharmaceuticals, Mandialai Stop, Bhattianwala Road, 18-Km Lahore-Sheikhupura Road, Lahore					
118.	76956	Chlorpheniramine maleate Tablets Each tablet contains:- Chlorpheniramine (as maleate)….4mg	17-09-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 17-09-2018 to 16-09-2023
119.	76992	Bellfen 200mg Tablet Each Tablet Contains Ibuprofen…200mg	03-10-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 03-10-2018 to 02-10-2023
120.	76993	Jexin 500mg Tablet Each Tablet Contains Ciprofloxacin (as HCl)…500mg	03-10-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 03-10-2018 to 02-10-2023
121.	76994	Jexin 250mg Tablet Each Tablet Contains Ciprofloxacin (as HCl)…250mg	03-10-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 03-10-2018 to 02-10-2023
122.	76995	Onec-50mg Tablet Each Tablet Contains Diclofenac Sodium…50mg	03-10-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 03-10-2018 to 02-10-2023
123.	76996	Letec 500mg Tablet Each Tablet Contains Levofloxacin (as Hemihydrate)…500mg	03-10-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 03-10-2018 to 02-10-2023
124.	76997	Letec 250mg Tablet Each Tablet Contains Levofloxacin (as Hemihydrate)…250mg	03-10-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 03-10-2018 to 02-10-2023
125.	76998	BJ-Lyte ORS Sachet Each Sachet Contains Sodium Chloride…2.6gm Sodium Citrate…2.9gm Potassium Chloride…1.5gm Dextrose Anhydrous…13.5gm	03-10-2013	Dy. No. 32698 dated 1-10-2018 10000/-	w.e.f. 03-10-2018 to 02-10-2023
M/s. Wilshire Laboratories (Pvt) Ltd ., 124/1 Industrial Estate Kot Lakhpat Lahore					
126.	052673	Felpine 5mg Tablets Each tablet contains:- Felodipine…..…..5mg	21-10-2008	Dy. No. 33629 dated 10-10-2018 10000/-	w.e.f. 21-10-2018 to 20-10-2023
127.	052674	Felpine 10mg Tablets Each tablet contains:- Felodipine…..10mg	21-10-2008	Dy. No. 33629 dated 10-10-2018 10000/-	w.e.f. 21-10-2018 to 20-10-2023
M/s. Shazeb Pharmaceutical Industries Ltd., Hazara Trunk Road, Sarai Gadaee, Distt: Haripur					
128.	77458	Zeesol-5% I.V Infusion Each 100 ml contains: Dextrose Anhyrous……..5 gm	11-10-2013	Dy. No. 33624 dated 10-10-2018 10000/-	w.e.f. 11-10-2018 to 10-10-2023
129.	77459	Zeesol-NS O.9% I.V Solution Each 100 ml contains: Sodium chloride…….0.9 gm	11-10-2013	Dy. No. 33625 dated 10-10-2018 10000/-	w.e.f. 11-10-2018 to 10-10-2023
M/s. Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi					
130.	53279	Claritek XL Tablet Each tablet contains: Clarithromycin..…500mg (USP Specifications)	02-12-2008	Dy. No. 33876 dated 12-10-2018 10000/-	w.e.f. 02-12-2018 to 01-12-2023
131.	53413	Salbo Respirator Solution Each ml Contains Salbutamol (as Sulphate)…5mg	23-12-2008	Dy. No. 33873 dated 12-10-2018 10000/-	w.e.f. 23-12-2018 to 22-12-2023
132.	53326	Zoliget Tablets Each tablet contains:	04-12-2008	Dy. No. 33874 dated 12-10-	w.e.f. 04-12-2018 to 03-12-2023

		Pioglitazone (as HCl)…..15mg Glimepiride……2mg		2018 10000/-	
133.	53369	Celbexx Plus 400mg Capsule Each Capsule Contains: Celecoxib……...400mg	16-12-2008	Dy. No. 33875 dated 12-10- 2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
M/s. Medisure Laboratories Pakistan (Pvt) Ltd., A-115 S.I.T.E, Super Highway, Karachi					
134.	1126- EX	Aztrix Caps Each capsule contains Azithromycin as dihydrate. 250mg	19-12-2008	Dy. No. 33631 dated 10-10- 2018 10000/-	w.e.f. 19-12-2018 to 18-12-2023
135.	4306- EX	Cioxine Tab 750mg Each film coated tablet contains Ciprofloxacin HCI USP eq. to Ciprofloxacin …. 750mg	07-10-2013	Dy. No. 33631 dated 10-10- 2018 10000/-	w.e.f. 07-10-2018 to 06-10-2023
136.	4307- EX	Pantum Tab 40mg Each Enteric Coated Tablet Contains:- Pantoprazole sodium Sesquihydrate eq. to Pantoprazole ……40mg	07-10-2013	Dy. No. 33631 dated 10-10- 2018 10000/-	w.e.f. 07-10-2018 to 06-10-2023
137.	4244- EX	Rahmacin Tab 500mg Each film coated tablet contains Clarithromycin USP …. 500mg	07-10-2013	Dy. No. 33631 dated 10-10- 2018 10000/-	w.e.f. 07-10-2018 to 06-10-2023
138.	76124	Ibupril 300mg Tablet Each tablet contains:- Dexibuprofen…..300 mg	25/10/2013	Dy. No. 33631 dated 10-10- 2018 10000/-	w.e.f. 25-10-2018 to 24-10-2023
139.	76125	Ibupril 400mg Tablet Each tablet contains:- Dexibuprofen…….....400 mg	25/10/2013	Dy. No. 33631 dated 10-10- 2018 10000/-	w.e.f. 25-10-2018 to 24-10-2023
M/s. Barrett Hodgson Pakistan (Pvt) Ltd., F/423, S.I.T.E., Karachi					
140.	76121	PioBar Plus 15mg/850mg Tablet Each tablet contains:- Pioglitazone ……15 mg Metformin Hydrochloride ……...850 mg	25/10/2013	Dy. No. 33287 dated 08-10- 2018 10000/-	w.e.f. 25-10-2018 to 24-10-2023
141.	30950	Diabold 3mg Tablets Each tablet contains:- Glimepride……..3mg	17-10-2003	Dy. No. 33286 dated 08-10- 2018 10000/-	w.e.f. 17-10-2018 to 16-10-2023
142.	30962	Cefbeck 125mg Suspension Each 5ml contains:- Cephradine Micronised ….125mg	17-10-2003	Dy. No. 33290 dated 08-10- 2018 10000/-	w.e.f. 17-10-2018 to 16-10-2023
143.	30963	Cefbeck 250mg Suspension Each 5ml contains:- Cephradine Micronised ….250mg	17-10-2003	Dy. No. 33291 dated 08-10- 2018 10000/-	w.e.f. 17-10-2018 to 16-10-2023
144.	30964	Zoran Injection 50mg /2ml Each 2ml contains:- Ranitidine HCl eq. to Ranitidine……50mg	17-10-2003	Dy. No. 33295 dated 08-10- 2018 10000/-	Deferred for further deliberation for NDMA impurity
145.	30965	Zoran Tablets 150mg Each tablets contains:- Ranitidine HCl eq. to Ranitidine……150mg	17-10-2003	Dy. No. 33297 dated 08-10- 2018 10000/-	Deferred for further deliberation for NDMA impurity
146.	30966	Zoran D.S Tablets 300mg Each tablets contains:- Ranitidine HCl eq. to Ranitidine……300mg	17-10-2003	Dy. No. 33298 dated 08-10- 2018 10000/-	Deferred for further deliberation for NDMA impurity
147.	30967	Zoran Suspension 75mg Each 5ml contains:- Ranitidine HCl eq. to	17-10-2003	Dy. No. 33296 dated 08-10- 2018 10000/-	Deferred for further deliberation for NDMA

		Ranitidine……75mg			impurity
148.	30971	Opticef Suspension Each 5ml contains:- Cefpodoxime Proxetil eq. to Cefpodoxime …….40mg	17-10-2003	Dy. No. 33288 08-10-2018 10000/-	w.e.f. 17-10-2018 to 16-10-2023
149.	30981	Megaklar Tablets 250mg Each tablet contains:- Clarithromycin …….250mg	17-10-2003	Dy. No. 33292 08-10-2018 10000/-	w.e.f. 17-10-2018 to 16-10-2023
150.	30982	Megaklar Tablets 500mg Each tablet contains:- Clarithromycin …….500mg	17-10-2003	Dy. No. 33293 08-10-2018 10000/-	w.e.f. 17-10-2018 to 16-10-2023
M/s. Sami Pharmaceuticals (Pvt) Ltd., F-95, Off Hub River Road, S.I.T.E., Karachi					
151.	22422	Oxidil Injection IV 1gm Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone…1gm	05-12-1998	Dy. No. 33299 08-10-2018 10000/-	w.e.f. 05-12-2018 to 04-12-2023
152.	22421	Oxidil Injection IV 500mg Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone…500mg	05-12-1998	Dy. No. 33299 08-10-2018 10000/-	w.e.f. 05-12-2018 to 04-12-2023
153.	22582	Diclorep 50mg Tablet Each sugar coated tablet contains: Diclofenac Potassium MS…50mg	14-12-1998	Dy. No. 33299 08-10-2018 10000/-	w.e.f. 14-12-2018 to 13-12-2023
154.	22415	Caricef 100mg/5ml Suspension Each 5ml contains: Cefixime Trihydrate eq. to Cefixime…100mg	31-12-1998	Dy. No. 33299 08-10-2018 10000/-	w.e.f. 31-12-2018 to 30-12-2023
155.	22416	Caricef 400mg Capsule Each capsule contains: Cefixime Trihydrate eq. to Cefixime…400mg	31-12-1998	Dy. No. 33299 08-10-2018 10000/-	w.e.f. 31-12-2018 to 30-12-2023
156.	23073	Oxidil 250mg IM Injection Each Vial Conatins:- Ceftriaxone as sodium… 250 mg, 2 ml Lidocaine 1 %	30-01-1999	Dy. No. 36080 31-10-2018 10000/-	w.e.f. 30-01-2019 to 29-01-2024
157.	23072	Painial 1% Injection Each 100 ml contains:- Lidocaine HCl… 1 gm	30-01-1999	Dy. No. 36080 31-10-2018 10000/-	w.e.f. 30-01-2019 to 29-01-2024
158.	15063	Levijon Syrup Each 5 ml contains:- Ornithine Aspartate… 300 mg, Nicotinamide… 24 mg, Riboflavin… 0.765 mg	27-02-1994	Dy. No. 36080 31-10-2018 10000/-	w.e.f. 27-02-2019 to 26-02-2024
M/s. Ferozsons Laboratories Ltd., Amangarh Nowshehra, Khyber Pakhtunkhwa					
159.	77484	Valiant-M Tablets 50mg/850mg Each film coated tablet contains Vildagliptin…….50mg Metformin HCl…..850mg	31-10-2013	Dy. No. 33715 11-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
160.	77485	Valiant-M Tablets 50mg/1000mg Each film coated tablet contains Vildagliptin…….50mg Metformin HCl….1000mg	31-10-2013	Dy. No. 33715 11-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
M/s. Safe Pharmaceuticals (Pvt) Ltd., Plot No C-I-20 & 21 Sector 6-B, North Karachi Industrial Area, Karachi					
161.	76101	Roxisafe 300mg Tablet Each tablet contains:- Roxithromycin ……300mg	22-10-2013	Dy. No. 33862 11-10-2018 10000/-	w.e.f. 22-10-2018 to 21-10-2023
162.	76102	Amlovastan 5/80 Tablet	22-10-2013	Dy. No. 33862	w.e.f. 22-10-2018

		Each tablet contains:- Vasartan …….…80mg Amlodipine as Besylate…5mg		11-10-2018 10000/-	to 21-10-2023
163.	76103	Amlovastan 5/160 Tablet Each tablet contains:- Vasartan ..……..160mg Amlodipine as Besylate……5mg	22-10-2013	Dy. No. 33862 11-10-2018 10000/-	w.e.f. 22-10-2018 to 21-10-2023
164.	76104	Amlovastan 10/160 Tablet Each tablet contains:- Vasartan …….160mg Amlodipine as Besylate……10mg	22-10-2013	Dy. No. 33862 11-10-2018 10000/-	w.e.f. 22-10-2018 to 21-10-2023
M/s. Platinum Pharmaceuticals (Pvt) Ltd., A-20, North Westren Industries Zone, Bin Qasim, Karachi					
165.	53046	Levotam 500mg Tablets Each film coated tablet contains: Levetiracetam……500mg	03-11-2008	Dy. No. 33523 9-10-2018 10000/-	w.e.f. 03-11-2018 to 02-11-2023
166.	53047	Erdos 150mg Capsules Each Capsule Contains: Erdosteine…..150mg	03-11-2008	Dy. No. 33523 dated 9-10-2018 10000/-	w.e.f. 03-11-2018 to 02-11-2023
167.	53048	Erdos 175mg Suspension Each 5ml contains: Erdosteine…….175mg	03-11-2008	Dy. No. 33523 dated 9-10-2018 10000/-	w.e.f. 03-11-2018 to 02-11-2023
168.	53049	Zipra 20mg Capsule Each Capsule Contains: Ziprasidone (as Hydrochloride Monohydrate)…..20mg	03-11-2008	Dy. No. 33523 dated 9-10-2018 10000/-	w.e.f. 03-11-2018 to 02-11-2023
169.	53050	Zipra 40mg Capsule Each Capsule Contains: Ziprasidone (as Hydrochloride Monohydrate)…..40mg	03-11-2008	Dy. No. 33523 dated 9-10-2018 10000/-	w.e.f. 03-11-2018 to 02-11-2023
170.	31859	Ossogin Tablet Each Film Coated Tablet Contains Ossein Mineral Complex i.e. Hydroxyapatite compound 830mg eq. to Calcium…….177.6mg Phosphorus……..82.2mg Residual mineral Salt….24.9mg Colagen……..224mg Other proteins……66.4mg Trace Elements (F, Mg, Fe, Zn, Cu, Ni)	14-11-2003	Dy. No. 33523 dated 9-10-2018 10000/-	w.e.f. 14-11-2018 to 13-11-2023
171.	31858	Ossogin Suspension Each 5ml contains:- Ossein hydroxyapatite compound (anhydrous) 250mg eq. to Calcium…….53.5mg Phosphorus……..24.8mg Residual mineral Salt….7.5mg Collegan……..67.5mg Other proteins……20mg	14-11-2003	Dy. No. 33523 dated 9-10-2018 10000/-	w.e.f. 14-11-2018 to 13-11-2023
172.	53129	Levotam 250mg Tablets Each tablet contains: Levetiracetam……250mg	24-11-2008	Dy. No. 33523 dated 9-10-2018 10000/-	w.e.f. 24-11-2018 to 23-11-2023
M/s. Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road Islamabad					
173.	31252	Levonic –250 Tablets Each tablet contains:- Levofloxacin Hemihydrate eq. to Levofloxacin…….250mg	27-10-2003	Dy. No. 33879 12-10-2018 10000/-	w.e.f. 27-10-2018 to 26-10-2023

174.	31253	Levonic –500 Tablets Each tablet contains:- Levofloxacin Hemihydrate eq. to Levofloxacin ….500mg	27-10-2003	Dy. No. 33879 dated 12-10-2018 10000/-	w.e.f. 27-10-2018 to 26-10-2023
175.	31254	Paraflox-250mg Tablets Each tablet contains:- Ciprofloxacin HCL eq. to Ciprofloxacin……250mg	27-10-2003	Dy. No. 33879 dated 12-10-2018 10000/-	w.e.f. 27-10-2018 to 26-10-2023
176.	31255	Paraflox -500mg Tablets Each tablet contains:- Ciprofloxacin HCL eq. to Ciprofloxacin…..500mg	27-10-2003	Dy. No. 33879 dated 12-10-2018 10000/-	w.e.f. 27-10-2018 to 26-10-2023
177.	52728	Morvella Tablet Each Tablet contains:- Artemether……20mg Lumefantrine……120mg	25-10-2008 Change of brand name dated: 26-11-2008	Dy. No. 33879 dated 12-10-2018 10000/-	w.e.f. 25-10-2018 to 24-10-2023
178.	52729	Morvella DS Tablet Each Tablet contains;- Artemether……40mg Lumefantrine……240mg	25-10-2008 Change of brand name dated: 26-11-2008	Dy. No. 33879 12-10-2018 10000/-	w.e.f. 25-10-2018 to 24-10-2023
179.	52727	Ronset SR Tablets. Each Tablet contains:- Diclofenac Potassium……100mg. (B.P Specs)	25-10-2008	Dy. No. 33879 12-10-2018 10000/-	Deferred for clarification that the registration of product was granted with condition that you will submit comparative dissolution profile with innovator before marketing. Copy of approval of comparative dissolution profile is required.
M/s. Focus & Rulz Pharmaceuticals (Pvt) Ltd., Plot No. 44 Industrial Triangle, Kahuta Road Islamabad					
180.	75500	Lectom Oral Solution Each ml contains:- Levetiracetam BP…….100mg	22-10-2013	Dy. No. 34025 12-10-2018 10000/-	w.e.f. 22-10-2018 to 21-10-2023
M/s. Indus Pharma (Pvt) Ltd., Plot No. 26, 27, 63, 64, 65, 66 & 67, Sector 27, Korangi Industrial Area, Karachi					
181.	14461	Metoclon Syrup 5mg/5ml Each 5ml Contains Metoclopramide (HCl) 5mg	14-10-1993	Dy. No. 33877 12-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
182.	14462	Allervil Syrup 15mg/5ml Each 5ml Contains Pheniramine Maleate…15mg	14-10-1993	Dy. No. 33877 12-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
183.	76107	Dyclo Plus 2ml Injection IM Each 2ml contains:- Diclofenac Sodium ……..75 mg Lignocaine Hydrochloride..20mg	24-10-2013	Dy. No. 33877 12-10-2018 10000/-	w.e.f. 24-10-2018 to 23-10-2023
M/s. Macter International (Pvt) Ltd., F-216, S.I.T.E., Karachi					
184.	22819	Ramol Inj IM/IV 50mg Each ml contains Tramadol HCI …. 50mg	21-12-1998	Dy. No. 35335 24-10-2018 10000/-	w.e.f. 21-12-2018 to 20-12-2023
185.	22823	Buphain Inj IM/IV 10mg Each ml contains	21-12-1998	Dy. No. 35335 24-10-2018	w.e.f. 21-12-2018 to 20-12-2023

		Nalbuphine HCI …. 10mg		10000/-	
186.	22824	Buphain Inj IM/IV 20mg Each ml contains Nalbuphine HCI …. 20mg	21-12-1998	Dy. No. 35335 24-10-2018 10000/-	w.e.f. 21-12-2018 to 20-12-2023
M/s. Elite Pharma (Pvt) Ltd., 9.5-Km Sheikhupura Road, Lahore					
187.	31150	Asmacaine Inj IM Each ml contains:- Paracetamol...150mg Lignocaine Hcl …10mg	06-12-2003	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 06-12-2018 to 05-12-2023
188.	53712	Rocelite Injection 250mg I.V Each Vial Contains:- Ceftriaxone (as Sodium)…250mg (USP Specifaction)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
189.	53713	Rocelite Injection 500mg IV Each Vial Contains:- Ceftriaxone (as Sodium)..500mg (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
190.	53714	Rocelite Injection 1gm IV Each Vial Contains:- Ceftriaxone (as Sodium.....1gm (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
191.	53715	Faraxime Injection 250mg Each Vial Contains:- Cefotaxime (as Sodium) ..250mg (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
192.	53716	Faraxime Injection 500mg Each Vial Contains:- Cefotaxime (as Sodium) ..500mg (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
193.	53717	Faraxime Injection 1gm Each Vial Contains:- Cefotaxime (as Sodium) …1gm (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
194.	53719	Dimicef Injection 500mg Each Vial Contains:- Ceftazidime (as Pentahydrate) Sterile ……..500mg (USP Specs)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
195.	53720	Dimicef Injection 1gm Each Vial Contains:- Ceftazidime (as Pentahydrate) Sterile ……..1gm (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
196.	53737	Mavecef Injection 500mg Each Vial Contains:- Cephradine (Sterile) ……..500mg (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
197.	53710	Pendiscab Cream. Each gm Contains: Permethrin……5%w/w. (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
198.	53711	Scabizene Cream. Each gm Contains: Gamma Benzene Hexa Chloride…….1%w/w	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	Deferred for confirmation of formulation in RRA.
199.	53729	Elixime Dry Suspension 100mg Each 5ml contains: Cefixime (as Trihydrate) ..100mg	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023

		(USP Specification)			
200.	53730	Eliximе Dry Suspension 200mg Each 5ml contains: Cefixime (as Trihydrate) ..200mg (USP Specification)	16-12-2008	Dy. No. 35333 24-10-2018 10000/-	w.e.f. 16-12-2018 to 15-12-2023
M/s. AGP (Pvt) Ltd., B-23, Sindh Industrial Trading Estate, Karachi					
201.	15227	Neophylline 100mg S.R Tab Each sustained release Tablet contains: Theophylline Monohydrate as Anhydrous …. 300mg	22-06-1994 Change of brand name dated 18-12-2003	Dy. No. 34598 18-10-2018 10000/-	w.e.f. 18-12-2018 to 17-12-2023
202.	15228	Neophylline 200mg S.R Tab Each Tablet contains: Theophylline Monohydrate as Anhydrous …. 200mg	22-06-1994 Change of brand name dated 18-12-2003	Dy. No. 34600 18-10-2018 10000/-	w.e.f. 18-12-2018 to 17-12-2023
203.	15229	Neophylline 300mg S.R Tab Each Tablet contains: Theophylline Monohydrate as Anhydrous …. 300mg	22-06-1994 Change of brand name dated 18-12-2003	Dy. No. 34599 18-10-2018 10000/-	w.e.f. 18-12-2018 to 17-12-2023
204.	16417	Nebcin Injection 20mg Each vial contains Tobramycin Sulphate …. 20mg	21-11-1994	Dy. No. 34595 18-10-2018 10000/-	Deferred for further evaluation with reference to post registration variation
205.	39254	Nebcin Injection 10Mg Each ampoule contains: Tobramycin Sulphate eq.to Tobramycin base….10mg	31-05-2005	Dy. No. 34594 18-10-2018 10000/-	Deferred for further evaluation with reference to post registration variation
206.	53385	Floxigem Tablet Each tablet contains: Gemifloxacin (as Mesylate Sesquihydrate)..320mgs)	18-12-2008	Dy. No. 34593 18-10-2018 10000/-	w.e.f. 18-12-2018 to 17-12-2023
207.	53386	Tinasil Cream Each gram contains: Terbinafine (as HCl)……..10gm	18-12-2008	Dy. No. 34597 18-10-2018 10000/-	w.e.f. 18-12-2018 to 17-12-2023
208.	53387	Tinasil 125mg Tablet Each tablet contains: Terbinafine (as HCl)...125gm	18-12-2008	Dy. No. 34596 18-10-2018 10000/-	w.e.f. 18-12-2018 to 17-12-2023
M/s. Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road, Landhi, Karachi					
209.	14730	Vidaylin-L Syrup Each 5ml Contains Vitamin A…0.9mg (3000 Units) Vitamin D…10mcg (400 Units) Vitamin B1…1.5mg Vitamin B2…1.2mg Vitamin B6…1mg Vitamin B12…3mcg Vitamin C…50mg Nicotinamide…10mg Choline…5mg Inositol…5mg Lysine Mono-HCl…300mg	24-11-1993 Change of brand name dated 16-02-1994	Dy. No. 34239 15-10-2018 10000/-	w.e.f. 24-11-2018 to 23-11-2023
M/s. Lowitt Pharma (Pvt) Ltd., Plot No. 24, Industrial Estate, Hayatabad, Peshawar					
210.	4313-	Lomoxy 125mg Dispersible	31-10-2013	Dy. No. 34245	w.e.f. 31-10-2018

	EX	Tablet Each Dispersible Tablet Contains Amoxicilline Trihydrate eq. to Amoxycillin…125mg		dated 15-10-2018 10000/-	to 30-10-2023
211.	4314-EX	Lomoxy 250mg Dispersible Tablet Each Dispersible Tablet Contains Amoxicilline Trihydrate eq. to Amoxycillin…250mg	31-10-2013	Dy. No. 34245 dated 15-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
212.	4315-EX	Zolmit 5mg Tablet Each Film Coated Tablet Contains Zolmitriptan…5mg	31-10-2013	Dy. No. 34245 dated 15-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
213.	4316-EX	Zolmit 2.5mg Tablet Each Film Coated Tablet Contains Zolmitriptan…2.5mg	31-10-2013	Dy. No. 34245 dated 15-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
214.	4317-EX	Liberal 300mg Tablet Each Film Coated Tablet Contains Irbesartan…300mg	31-10-2013	Dy. No. 34245 dated 15-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
215.	4318-EX	Liberal 150mg Tablet Each Film Coated Tablet Contains Irbesartan…150mg	31-10-2013	Dy. No. 34245 dated 15-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
216.	4376-EX	Lomoxy 500mg Dispersible Tablet Each Dispersible Tablet Contains Amoxicilline Trihydrate eq. to Amoxycillin…500mg	25-11-2013	Dy. No. 34245 dated 15-10-2018 10000/-	w.e.f. 25-11-2018 to 24-11-2023
217.	4387-EX	Femcef 200mg Capsule Each Capsule Contains Cefixime Trihydrate eq. to Cefixime…200mg	13-01-2014	Dy. No. 34245 dated 15-10-2018 10000/-	w.e.f. 13-01-2019 to 12-01-2024
M/s. Global Pharmaceuticals, Plot No 204-205, Industrial Triangle Kahota Road, Islamabad					
218.	24794	Angiopril Tablets. Each tablet contains: Enalapril Maleate.....5mg	19-06-1999 Transfer of registration: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
219.	30006	Fevonor Injection IM Each 2ml contains:- Paracetamol…300mg Lignocaine HCl…..20mg	17-02-2003 Transfer of registration: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
220.	28147	Lincolide 600mg Injection Each 2ml contains:- Lincomycin (as Lincomycin HCl)…….600mg	01-07-2002 Transfer of registration 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
221.	28146	Lincolide 300mg Injection Each 2ml contains:- Lincomycin (as Lincomycin HCl)…….300mg	01-07-2002 Transfer of registration 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
222.	48327	Fucilan Tablets. Each tablet contains: Sodium Fucidate...250mg.	24-01-2008	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
223.	30033	Mobix 15mg Tablets Each tablet contains: Meloxicam……15mg	21-02-2003 Transfer of registration: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
224.	30032	Mobix 7.5mg Tablets Each tablet contains: Meloxicam……7.5mg	21-02-2003 Transfer of registration: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023

225.	26983	Water For Injection Sterile Water For Injection Contains:- Sterile Water for Injection	01-06-2001 Transfer of registration dated: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
226.	28148	Zinorox 250mg Injection Each vial contains:- Cefuroxime (as Cefuroxime Sodium)…..250mg	19-07-2002 Transfer of registration dated: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
227.	28149	Zinorox 750mg Injection Each vial contains:- Cefuroxime (as Cefuroxime Sodium)…..750mg	19-07-2002 Transfer of registration 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
228.	26981	Tinearin Cream Each 100gm contains:- Miconazole (Nitrate)….2gm	16-06-2001 Transfer of registration dated: 18-11-2003 Change of brand name 10-03-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
229.	024745	Prosta Tablet Each tablet contains: Ibuprofen…600mg	18-05-1999 Transfer of registration dated: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
230.	024750	Protole Capsules Each capsule contains: Omerprazole…..20mg Source of pellets: M/s Titan Laboratories (Pvt) Limited Plot No. E27/1 & E27/2 MIDC Mahad Village Jite Ralgad India.	18-05-1999 Transfer of registration 18-11-2003 Change of brand name dated: 03-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	Deferred for submission of Differential Fee.
M/s. Hoover Pharmaceuticals (Pvt) Ltd., Plot No.16, Zain Park Industrial Area, Saggain By Pass Road, Lahore					
231.	77036	Kilpain Gel Each gel contains:- Piroxicam…0.5% w/w	27-11-2013	Dy. No. 33596 dated 10-10-2018 10000/-	w.e.f. 27-11-2018 to 26-11-2023
232.	77038	Arocaine Gel 2% Each gel contains:- Lignocaine HCl…2% w/w	27-11-2013	Dy. No. 33597 dated 10-10-2018 10000/-	w.e.f. 27-11-2018 to 26-11-2023
233.	77022	Emevid Tablets 200mg Each tablet contains:- Ofloxacin…200mg	18-11-2013	Dy. No. 33598 dated 10-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
234.	77023	Emevid Tablets 400mg Each tablet contains:- Ofloxacin…400mg	18-11-2013	Dy. No. 33599 dated 10-10-2018 10000/-	w.e.f. 18-11-2018 to 17-11-2023
M/s. Medicraft Pharmaceuticals (Pvt) Ltd., 126-B Industrial Estate Hayatabad, Peshawar					
235.	4319-EX	Cefporup 40mg D/S Each 5ml contains Cefpodoxime Proxetil eq. to Cefpodoxime …. 40mg	31-10-2013	Dy. No. 34623 dated 18-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
236.	4320-EX	Azilancin 200mg D/S Each 5ml contains Azithromycin Dihydrate eq. to Azithromycin …. 200mg	31-10-2013	Dy. No. 34623 dated 18-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023

237.	4322-EX	Nesta Oral Drops Each 5ml contains Cefpodoxime Proxetil eq. to Cefpodoxime …. 40mg	31-10-2013	Dy. No. 34623 dated 18-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
238.	4323-EX	Kalvits 120ml Syp Each ml contains Nystatin …. 20mg	31-10-2013	Dy. No. 34623 18-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
239.	4324-EX	Pezot-V 50ml Syp Each 5ml contains Calcium Lactate Gluconate . 40mg Vitamin D3 …. 100 I.U Vitamin B2 …. 1mg Vitamin C …. 50mg Vitamin B12 …. 10mcg Vitamin B1 …. 1mg Pyridoxine HCI …. 0.5mg Dexpanthenol …. 2mg Vitamin E …. 1mg	31-10-2013	Dy. No. 34623 dated 18-10-2018 10000/-	w.e.f. 31-10-2018 to 30-10-2023
M/s Martin Dow Marker, 7-Jail Road, Quetta					
240.	00723	Polybion Forte Injection Each 2ml contains: Vitamin B1 (Thiamine HCl) USP…10mg Riboflavin 5-Phosphate Sodium USP…4mg Vitamin B6 (Pyridoxine HCl) USP…4mg Vitamin B12 (Cyanocobalamin) USP…8mcg Dexpanthenol USP…6mg Nicotinamide USP…40mg	30-11-1976 Transfer of Registration dated: 03-03-2008	Dy. No. 6606 21-02-2018 10,000/-	Deferred for confirmation of transfer of registration.
241.	018718	Pcam Gel 0.5% Contains: Piroxicam USP…0.5% w/w	13-05-1997 Transfer of Registration 03-03-2008	Dy. No. 6601 dated: 21-02-2018 10,000/-	-do-
242.	026854	Lodopin 5mg Tablet Each film coated tablet contain: Amlodipine Besylate eq. to Amlodipine…5mg	12-05-2001 Change of Brand Name 22-01-2002 Transfer of Registration 03-03-2008	Dy. No. 6559 dated: 21-02-2018 10,000/-	-do-
243.	026853	Lodopin 2.5mg Tablet Each film coated tablet contain: Amlodipine Besylate eq. to Amlodipine…2.5mg	12-05-2001 Change of Brand Name 22-01-2002 Transfer of Registration 03-03-2008	Dy. No. 6558 dated: 21-02-2018 10,000/-	-do-
244.	018048	Pcam 20mg Injection Each ml contains: Piroxicam USP…2mg	13-05-1997 Transfer of Registration dated: 03-03-2008	Dy. No. 6604 dated: 21-02-2018 10,000/-	-do-
245.	006473	Refobacin Injection 80mg Each 2ml contains: Gentamicin sulfate USP equivalent to Gentamicin …….80mg	11-07-1982 Transfer of Registration 03-03-2008	Dy. No. 6617 dated: 21-02-2018 10,000/-	-do-

246.	018033	Optifam Tablet 40mg Each film coated tablet contains: Famotidine … 40mg	05-10-1995 Change of Brand Name dated: 04-05-1996 Transfer of Registration dated: 03-03-2008	Dy. No. 6597 dated: 21-02-2018 10,000/-	-do-

Local Veterinary

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Remarks
M/s. Baariq Pharmaceuticals, Plot No.600, Sundar Industrial Estate, Sundar Raiwind Road, Lahore					
247.	75783	Furosebar Water Soluble Powder Each 1000gm contains: Furosemide……...20gm Potassium chloride….4gm Calcium carbonate...45gm Magnesium sulphate..1gm	12-11-2013	Dy. No. 34562 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
248.	75784	Colibar Oral Liquid Each 1000ml Contains: Colistin Sulphate.2,000,000,000 IU	12-11-2013	Dy. No. 34563 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
249.	75785	Zoleriq 10% Oral Drench Each ml Oral Drench Contains Albendazole……100mg	12-11-2013	Dy. No. 34564 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
250.	75786	Oxfendaox Plus Oral Drench Each ml contains: Oxyclozanide …..62.50mg Oxfendazole ……22.65mg Cobalt sulphate…..1.67mg Sodium selenite….0.50mg	12-11-2013	Dy. No. 34566 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
251.	75787	Zolesel-CS Oral Drench Each ml contains: Albendazole……...50mg Cobalt sulphate…..3.82mg Sodium selenite….0.35mg	12-11-2013	Dy. No. 34565 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
252.	75788	Levoxbar-Plus Drench Each ml contains: Levamisole HCl…...15mg Cobalt sulphate…..1.67mg Oxyclozanide……30mg Sodium selenite….0.50mg	12-11-2013	Dy. No. 34568 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
253.	75789	Levacob-SS Oral Drench Each ml contains: Levamisole HCl…...15mg Cobalt sulphate…..3.82mg Sodium selenite….0.50mg	12-11-2013	Dy. No. 34567 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
254.	75790	Amantadox-T Water Soluble Powder Each 1000 gm Powder Contains Tylosin tartrate…....100gm Doxycyline HCl…..200gm Amantadine HCl…….45gm	12-11-2013	Dy. No. 34561 dated 18-10-2018 10000/-	Deferred for clarification from concerned section regarding Amantadine containing formulation

255.	75791	Colibect Water Soluble Powder Each 100gm powder contains: Colistin Sulphate...500,000,000 IU	12-11-2013	Dy. No. 34561 dated 18-10-2018 10000/-	w.e.f. 12-11-2018 to 11-11-2023
M/s. Selmore Pharmaceuticals (Pvt) Ltd., 36 Km Multan Road Lahore					
256.	49615	LEVASEL–15 POWDER Each gm Contains: LEVAMISOLE HCL….. 150MG.	14-10-2008	Dy. No. 33718 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
257.	49616	COLISEL-50 POWDER. Each gm Contains: COLISTINE SULPHATE 5,000,000 IU.	18-10-2008	Dy. No. 33723 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
258.	49617	ETHOPROL POWDER Each gm Contains: AMPORLIUM HCL ….. 200MG. ETHOPABATE…… 20MG.	18-10-2008	Dy. No. 33723 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
259.	49618	LINCOTIN POWDER. Each gm Contains: LINCOMYCIN AS HCL 33.3%. SPECTINOMYCIN AS SULPHATE 66.7%.	18-10-2008	Dy. No. 33723 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
260.	49619	SPIRACHLOR POWDER. Each gm Contains: SPIRAMYCIN ADIPATE 25MG. CHLORTETRACYCLINE HCL 75MG.	14-10-2018	Dy. No. 33720 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
261.	49620	ALBENSEL 20 POWDER. Each gm Contains: ALBENDAZOLE 200MG.	14-10-2018	Dy. No. 33720 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
262.	49621	RINOSEL POWDER. Each gm Contains: HEXAMETHYLENE TETRAMINE 955MG. RIBOFLAVIN 10MG. CALCIUM PANTOTHENATE 5MG. NICOTINAMIDE 25MG.	14-10-2018	Dy. No. 33720 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
263.	49622	VITOZYME POWDER. Each gm Contains: LYSOZYME 22.0%. VITAMIN E 50 SD 0.5%.	18-10-2008	Dy. No. 33724 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
264.	49623	COXIVIT POWDER. EACH 500GM CONTAINS 2,4, DIAMINO-5, VERATRYLPYRIMIDINE 25GM. SULPHABENZPYRAZINE 100GM. VITAMIN A 1.250 MIU. MENADIONE SULPHITE SODIUM (VITAMIN K3) 2.50GM.	18-10-2008	Dy. No. 33724 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
265.	49624	SELZAIN DRENCH Each ml contains: OXYCLOZANIDE 30MG. LEVAMISOLE 15MG. COBALT SULPHATE 0.382MG.	18-10-2008 Change of brand name dated: 19-01-2010	Dy. No. 33724 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
266.	49625	NICLOZOLE DRENCH Each ml contains:	14-10-2008	Dy. No. 33727 dated 11-10-	w.e.f. 14-10-2018 to 13-10-2023

		NICLOSAMIDE 75MG. OXYBENDAZOLE 10MG.		2018 10000/-	
267.	49626	CLOMISOL DRENCH. Each ml contains: LEVAMISOLE HCL…..100MG. CLOSANTEL…….100MG.	14-10-2008	Dy. No. 33727 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
268.	49627	TRIVERFEN DRENCH. Each ml contains: TRICLABENDAZOLE 50MG. IVERMECTIN …… 1MG. FENBENDAZOLE 50MG.	14-10-2008	Dy. No. 33727 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
269.	49628	LINCOSPIRA SOLUTION. Each ml contains: SPIRAMYCIN ADIPATE 12.5% W/V. LINCOMYCIN HCL 7.5% W/V.	14-10-2008	Dy. No. 33727 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
270.	49629	SUPERTONE SOLUTION. Each ml contains: VITAMIN E 200MG. SORBITOL 50MG. CHOLINE CHLORIDE 50MG. SELENIUM 2.3MG. ZINC….. 4MG	14-10-2008	Dy. No. 33721 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
271.	49630	HEPACARE SOLUTION Each ml contains: L-CARNITINE …… 50MG. BETAIN …… 20MG. INOSITOL …….7MG. CHOLINE CHLORIDE 100MG. SORBITOL 200MG. MAGNESIUM SULPHATE 10MG.	14-10-2008	Dy. No. 33721 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
272.	49631	SELCINA SOLUTION. Each ml contains: CENOXINE……. 75MG. SULFAMETHOXIPYRIDAZINE 75MG. SULFAMETHAZINE 50MG. TRIMETHOPRIM 25MG	14-10-2008	Dy. No. 33721 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
273.	49632	DARVINOX SOLUTION. Each ml contains: DIAVERIDINE 0.6% W/V. SULPHAQUINOXALINE 2.56% W/V.	18-10-2008	Dy. No. 33725 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
274.	49633	DARVINOX PLUS SOLUTION. Each ml contains: SULFAQUINOXALINE 80MG. SULFADIMETHOXINE 20MG. DIAVERIDINE 20MG.	18-10-2008	Dy. No. 33725 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
275.	49634	ENROXSEL 20 ORAL SOLUTION. Each ml contains: ENROFLOXACIN 200MG.	18-10-2008	Dy. No. 33725 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
276.	49635	VITAL-3 INJECTION. Each ml contains: VITAMIN A (RETINYL PALMITATE) 80,000 IU. VITAMIN D3 (COLICALCOFEROL) 40,000 IU. VITAMIN E (DL-U-	18-10-2008	Dy. No. 33725 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023

		TOCOPHEROL ACETATE) 20MG.			
277.	49636	TYGENT INJECTION. Each ml contains: TYLOSIN TARTRATE 100MG. GENTAMICIN …… 50MG.	14-10-2008	Dy. No. 33722 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
278.	49637	IVOSANTEL INJECTION. Each ml contains: IVERMECTIN…… 10MG. CLOSANTEL ……. 125MG.	14-10-2008	Dy. No. 33722 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
279.	49638	QUINA-CS INJECTION. Each Vial Conatins:- QUINAPYRAMINE SULPHATE 1.5GM. QUINAPYRAMINE CHLORIDE 1.0GM.	14-10-2008	Dy. No. 33722 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
280.	49640	ENROXSEL-10 INJECTION. Each ml contains: ENROFLOXACIN……. 100MG.	18-10-2008	Dy. No. 33726 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
281.	49641	CLOMISOLE INJECTION Each ml contains: CLOSANTEL …….. 50MG. LEVAMISOLE……75MG.	18-10-2008	Dy. No. 33726 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
282.	49642	SOLOMIN INJECTION. Each ml contains: PREDNISOLONE ……. 10MG. CHLORPHENIRAMINE MALEATE 4MG.	18-10-2008	Dy. No. 33726 dated 11-10-2018 10000/-	Deffered for confirmation of segregated facility
283.	49643	MELOXI-10 INJECTION. Each ml contains: MELOXICAM …… 10MG.	18-10-2008	Dy. No. 33726 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
284.	49646	VITAJECT INJECTION. Each ml contains: VITAMIN A (RETINYL PALMITATE) 80,000IU. VITAMIN D3 (COLICALCOFEROL) 40,000IU. VITAMIN E (DL-U-TEOCOPHEROL ACETATE) 20MG. VITAMIN B1 …….. 2.5MG. VITAMIN B6 …. 1.25MG. VITAMIN B12 … 30MCG.	18-10-2008	Dy. No. 33717 dated 11-10-2018 10000/-	w.e.f. 18-10-2018 to 17-10-2023
285.	49647	NEFLOX SOLUTION. Each 100 ml contains: FLORFENICOL USP 23GM.	14-10-2008	Dy. No. 33719 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023
286.	49648	NEFLOX INJECTION. Each 100 ml contains: FLORFENICOL USP 30GM.	14-10-2008	Dy. No. 33719 dated 11-10-2018 10000/-	w.e.f. 14-10-2018 to 13-10-2023

Decision: Registration Board granted the renewal to aforementioned drugs as mentioned in last column above.

Finished Import (Human)

Sr. No	Reg. No.	Manufacturer	Brand Name & Composition	Initial date of registration	Date of application (R&I) Fee submitted	Remarks
M/s Allied Distributors Akhai Arcade 1st Floor, 103K Block-2 PECHS Shahra-e-Quaideen Karachi						
287.	021969	M/s Myungmoon Pharmaceutical,Co., Ltd., 26 Jeyakgongdan 2-gil Hyangnam – eup Hwaseong-si Gyeonggi-do-Republic of Korea	CEREBOLIN 250mg/2ml Injection Each 2ml contains: Citicoline……250mg	08-12-1998	Dy. No. 35412 dated 25-10-201820000/-	Legalized CoPP vide No. 2018-DI-1577 dated 03-07-2018 issued by Ministry of Food and Drug Safety has been submitted.
288.	021970	M/s Myungmoon Pharmaceutical,Co., Ltd., 26 Jeyakgongdan 2-gil Hyangnam – eup Hwaseong-si Gyeonggi-do-Republic of Korea	CEREBOLIN 500/2ml Injection Each 2ml contains: Citicoline……500mg	08-12-1998	04-12-201820000/-	Legalized CoPP vide No. 2018-DI-2335 dated 16-10 -2018 issued by Ministry of Food and Drug Safety has been submitted.
Decision: application	**Registration Board acceded to the request of the firm and confirms the receipt of renewal of above products subject to prevailing Import Policy for Finished Drugs.**					

INCOMPETE CASES

Local Manufacturing (Human)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Remarks
M/s. Pakistan Pharmaceutical Products (Pvt) Ltd., D/122, S.I.T.E. Karachi					
289.	6983	ULCEDINE 400MG TAB Each tablet contains: Cimetidine ……400mg	09-10-1983	Dy. No. 32589 dated 1-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019 ➢ Latest GMP Inspection report.
290.	14313	Neclof Tablet 100mg (S/R) Each S/R Tablet Contains Diclofenac Sodium…100mg	05-10-1993	Dy. No. 32589 dated 1-10-2018 10000/-	
M/s. Caylex Pharmaceuticals (Pvt) Ltd., 27-Km Mian Raiwind Road, Lahore					
291.	029125	Calotren Cream Contains Clotrimazole…1%	20-01-2003	Dy. No. 32592 dated 1-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 02nd September, 2019 ➢ The copy of registration letter indicates the permission of toll manufacturing from M/s Mass Pharma Lahore for period of three years. Approval of manufacturing at your premises is required.

					➢ Evidence of submission of last renewal i.e. 2013 ➢ Moreover the application under consideration is also submitted after due date of renewal i.e. 19-01-2018. Differential fee as SRO 1005 (I) / 2017 needs to be submitted. ➢ Valid DLM. ➢ Section approval letter issued by Licensing Division. ➢ Brief report of last batch manufactured. ➢ Latest GMP report in compliance to report dated: 20-10-2017. ➢ The above inspection report submitted indicates that the firm didn't possess dedicated manufacturing facility for Cephalosporin products. The production was also stopped in said facility. Latest status is required.
292.	029126	Betasporin Cream Contains Betamethasone Dipropionate…0.05%	20-01-2003	Dy. No. 32592 dated 1-10-2018 10000/-	-do-
293.	029127	Germi Cream Contains Gentamycin Sulphate…0.3%	20-01-2003	Dy. No. 32592 dated 1-10-2018 10000/-	-do-
294.	029128	Cayzon 0.25gm Injection Each Vial Contains Ceftazidime (as Pentahydrate)…0.25gm	20-01-2003	Dy. No. 32592 dated 1-10-2018 10000/-	-do-
295.	029129	Cayzon 0.5gm Injection Each Vial Contains Ceftazidime (as Pentahydrate)…0.5gm	20-01-2003	Dy. No. 32592 dated 1-10-2018 10000/-	-do-
296.	029130	Cayzon 1gm Injection Each Vial Contains Ceftazidime (as Pentahydrate)…1gm	20-01-2003	Dy. No. 32592 dated 1-10-2018 10000/-	-do-
M/s. Albro Pharmaceutical (Pvt) Ltd., 340-S, Industrial Area, Kot Lakhpat, Lahore					
297.	004378	Torant Expectorant Each 5ml Contains Chlorpheniramine Maleate ……..2mg, Ephedrine HCl…. 7mg, Ammonium Chloride ……...100mg, Sodium Citrate …..60mg, Terpin Hydrate ……5mg, Menthol ……1mg,	19-09-1978	Dy. No. 32587 dated 1-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 02nd September, 2019 ➢ Differential fee is required as application for the renewal of 2013 was submitted after due date. ➢ Details of last batch manufactured. ➢ Product composition is not mentioned on the initial registration letter, approval of composition if any. ➢ Latest GMP inspection report. ➢ Approval of formulation in

					reference drug agencies. ➢ Copy of approval of last quota allocation. ➢ Brief report of last batch manufactured.
M/s. Hansel Pharmaceuticals (Pvt) Ltd., Plot No. 2, Pharma City, 30-Km Multan Road, Lahore					
298.	76979	Taricin Eye Drops Each ml of solution contains:- Ofloxacin…3mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 02nd September, 2019 ➢ Differential fee is required as application is submitted after due date but within sixty days. ➢ Latest GMP inspection report. ➢ Brief details of last batch manufactured ➢ Section approval letter issued by Licensing Division ➢ Valid DML.
299.	76980	Q-Mox Eye Drops Each ml of solution contains:- Moxifloxacin HCl eq. to Moxifloxacin…5mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-
300.	76981	Timodor Eye Drops Each ml contains:- Timolol maleate eq. to Timolol…5mg Dorzolamide HCl eq. to Dorzolamide…20mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-
301.	76982	Poly Tears Eye Drops Each ml of ophthalmic solution contains:- Polyethylene Glycol 400…4mg Propylene Glycol…3mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-
302.	76983	Eyepat 0.2% Eye Drops Each ml contains:- Olopatadine HCl eq. to Olopatadine …2mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-
303.	76984	Ternafine Cream Each gram contains:- Terbinafine (as HCl) ……10mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-
304.	76985	Fungtel Cream Each gram contains:- Clotrimazole …10mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-
305.	76986	Futril Cream Each gram contains:- Fusidic Acid …20mg	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-
306.	76987	Painnil Gel Each 100 g Gel contains:- Diclofenac Di-ethyl amine …1.16g (eq. to Diclofenac Sodium…1g)	01-10-2013	Dy. No. 32699 dated 1-10-2018 10000/-	-do-

M/s. Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar					
307.	77488	Olpine 10 mg Tablets Each tablet contains: Olanzapine Citrate ≡ Olanzapine……10 mg	11-11-2013	Dy. No. 32594 dated 1-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 02nd September, 2019: ➢ Latest GMP inspection report
M/s. Medisure Laboratories Pakistan (Pvt) Ltd., A-115 S.I.T.E, Super Highway, Karachi					
308.	4242-EX	Rahmacin Dry Suspension 125mg Each 5ml contains Clarithromycin as dihydrate …. 125mg	07-10-2013	Dy. No. 33631 dated 10-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 3rd September, 2019: ➢ Source of granules for Rahmacin Dry Suspension 125mg and 250mg and in case of imported the differential fee thereof. ➢ Evidence of approval of formulation of Citide 1mg Tablet in reference drug agencies. ➢ Differential fee for Quopine Tablet 100mg & 200mg and Moment Tablet 10mg as application is submitted after due date but within sixty days.
309.	4243-EX	Rahmacin Dry Susp 250mg Each 5ml contains Clarithromycin as dihydrate …. 250mg	07-10-2013	Dy. No. 33631 dated 10-10-2018 10000/-	-do-
310.	76123	Citide 1mg Tablet Each tablet contains:- Cinitapride as acid Tartrate.1 mg	25/10/2013	Dy. No. 33631 dated 10-10-2018 10000/-	-do-
311.	50773	Quopine Tablet Each tablet contains: Quetiapine (as fumarate) …100mg	07-10-2008	Dy. No. 33631 dated 10-10-2018 10000/-	-do-
312.	50774	Quopine Tablet Each tablet contains: Quetiapine (as fumerate) ...200mg	07-10-2008	Dy. No. 33631 dated 10-10-2018 10000/-	-do-
313.	50775	Moment 10mg Tab Each film coated tablet contains: Memantine HCl…..10mg	07-10-2008	Dy. No. 33631 dated 10-10-2018 10000/-	-do-
M/s. WelMark Pharmaceuticals, Plot No. 122, Block-B, Phase-V, Industrial Estate, Hattar					
314.	52708	Elzed 20mg Capsule Each capsule contains:- Omeprazole pellets eq. to Omeprazole …20mg M/s Murli Krishna Pharma Pvt Limited, Shop No. 08 Pearl Building Powai Vihar Complex Powai India.	21-10-2008	Dy. No. 33630 dated 10-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 3rd September, 2019: ➢ Section approval letter issued by Licensing Division. ➢ Latest GMP inspection report. ➢ Evidence of submission of last renewal for Gentamark 20mg Injection ➢ Approval of change of brand name for Topmark 50mg & 100mg Tablets ➢ Approval of change of brand name for Topmark 50 and 100mg

					Tablet. ➢ Differential fee for imported pellets.
315.	52709	Brince 20mg Capsule Each capsule contains:- Esomeprazole pellets eq.to Esomeprazole …...20mg	21-10-2008	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
316.	77462	Carbawel 200 mg Tablets Each tablet contains: Carbamazepine…200 mg	23-10-2013	Dy.33630 dated 10-10-2018 10000/-	-do-
317.	77463	Topmark 50mg Tablets Each film coated tablet contains: Topiramate…….50 mg	23-10-2013	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
318.	77464	Topmark 100mg Tablets Each film coated tablet contains: Topiramate…….100 mg	23-10-2013	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
319.	77465	Schizolan 10 mg Tablets Each film coated tablet contains: Olanzapine Citrate ≡ Olanzapine……..10 mg	23-10-2013	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
320.	77466	Seizoram 250 mg Tablets Each film coated tablet contains Levetiracetam…250 mg	23-10-2013	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
321.	77467	Seizoram 500 mg Tablets Each film coated tablet contains: Levetiracetam…500 mg	23-10-2013	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
322.	77468	Lupin 50 mg Tablets Each film coated tablet contains: Lamotrigine…….50 mg	23-10-2013	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
323.	77469	Lupin 100 mg Tablets Each film coated tablet contains: Lamotrigine….100 mg	23-10-2013	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
324.	52847	Gentamark 20mg Injection Each 2ml Contains: Gentamycin……20mg (BP Specs)	22-11-2008	Dy. No. 33630 dated 10-10-2018 10000/-	-do-
M/s. Aims Pharmaceuticals, Plot No.291 Industrial Triangle Kahuta Road Islamabad					
325.	52643	Cefaim 400mg Capsules Each capsule contains:- Cefixime…….400mg (USP Specs)	13-10-2008	Dy. No. 33528 dated 10-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 3rd September, 2019: ➢ Evidence of submission of last renewal i.e. 2013. ➢ Section approval letter issued by Licensing Division.
326.	52646	Cef-P Injection Each Vial Contains:- Cefepime as …..1.0gm (USP Specs)	13-10-2008	Dy. No. 33626 dated 10-10-2018 10000/-	

327.	52649	Cefaim D Suspension Each 5ml contains:- Cefixime…….100mg (USP Specs)	13-10-2008	Dy. No. 33527 dated 10-10-2018 10000/-	
M/s Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi					
328.	53115	Ognis-D Tablet Each film coated tablet contains: Vitamin D…… 400 IU Ossein Mineral Complex…830mg* corresponding to: Calcium…….177.6 mg Phosphorus… 82.2 mg Residual Mineral Salts 24.9 mg Collagen……..224 mg Other Proteins…….66.4 mg Trace elements F, Mg, Fe, Zn, Cu, Ni * Corresponding to approx. 440mg Hydroxyapatite	11-11-2008 Correction of registration letter dated: 26-06-2009	Dy. No. 34970 dated 22-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 3rd September, 2019: ➢ Evidence of approval of formulation in reference drug agencies. ➢ Details of manufacturer of API along with certificate of analysis of latest batch of API imported.
329.	53116	Ognis-D Suspension Each 5ml contains: Vitamin D…….. 400 IU Ossein Mineral Complex…250mg corresponding to: Calcium……. 53.5 mg Phosphorus…… 24.8 mg Residual Mineral Salts...7.5 mg Collagen……..67.5 mg Other Proteins….20 mg Trace elements F, Mg, Fe, Zn, Cu, Ni	11-11-2008	Dy. No. 34970 dated 22-10-2018 10000/-	-do-
330.	53117	Ognis 400mg/5ml Suspension Each 5ml contains: Ossein Mineral Complex…400mg Corresponding to: Calcium……..85.59mg* Phosphorus…….39.61 mg Residual Mineral Salts……12mg Collagen…..107.95mg Other Proteins……32mg Trace Elements F, Mg, Fe, Zn, Cu, Ni *Corresponding to approx. Hydroxyapatite..212mg	11-11-2008	Dy. No. 34970 dated 22-10-2018 10000/-	-do-
M/s. Spencer & Company (Pvt) Ltd., Formerly: Spencer & Co. (Pakistan) Ltd., D-105, S.I.T.E., Karachi					
331.	30857	Lostaz 50mg Tablets Each tablet contains:- Cilostazol…….50mg	12-08-2003	Dy. No. 33441 dated 08-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019: ➢ Evidence of submission of last

					renewal i.e. 2013 ➢ Latest GMP inspection report ➢ Section approval letter issued by Licensing Divison ➢ Valid DML. ➢ Approval of last quota allocation of Ephedrine HCl for Spensid Cough Syrup ➢ Details of last batch manufactured. ➢ Evidence of approval of formulation in reference drug agencies.
332.	30858	Lostaz 100mg Tablets Each tablet contains:- Cilostazol…….100mg	12-08-2003	Dy. No. 33442 dated 08-10-2018 20000/-	
333.	4482	NEO-FERILEX SYP Each 4ml Contains: Iron Choline Citrate ……0.2gm, L-Lysine Mono-HCl ….25mg, Cyanocobalamin …5mcg, Folic Acid ….5mg, Thiamine HCl …2mg, Riboflavin ….0.5mg, Nicotinamide …15mg, Pyridoxine HCl ..0.25mg, Di-Pantothenyl Alcohol…..2mg	30-10-1978	Dy. No. 34242 dated 15-10-2018 10000/-	-do-
334.	53033	Polygard Infusion Each 100 ml contains: Ciprofloxacin Lactate eq. to Ciprofloxacin .200mg	29-10-2008	Dy. No. 34241 dated 15-10-2018 10000/-	-do-
335.	14715	Spensid Cough Syrup Each 5ml Contains Dextromethorphan HBr…10mg Chlorpheniramine Maleate…2mg Ephedrine HCl…7mg	24-11-1993	Dy. No. 34240 dated 15-10-2018 10000/-	-do-
M/s. Welwrd Pharmaceuticals, Plot No 3 Block–A Phase-I-II Industrial Estate Hattar					
336.	052629	Welmadol Injection Each 2ml contains:- Tramadol HCl…...100mg	11-10-2008	Dy. No. 33632 dated 10-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 04th September, 2019: ➢ Latest GMP inspection report ➢ Evidence of submission of last renewal
M/s. Barrett Hodgson Pakistan (Pvt) Ltd., F/423, S.I.T.E., Karachi					
337.	30970	Opticef Tablets 100mg Each tablet contains:- Cefpodoxime Proxetil eq. to Cefpodoxime …….100mg	17-10-2003	Dy. No. 33289 dated 08-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019: ➢ Approval of manufacturing facility for Dry Powder Injections and Cephalosporin Tablets

338.	30983	Megaklar I.V Injection Each vial contains:- Clarithromycin Lactobionate eq. to Clarithromycin….500mg	17-10-2003	Dy. No. 33294 dated 08-10-2018 10000/-	
M/s. Biogen Pharma, 8-Km, Chakbeli Road, Rawat Rawalpindi					
339.	75491	Alendrogen 70mg Tablet Each Tablet Contains: Alendronate (as Sodium)…70mg	11-10-2013	Dy. No. 33301 dated 08-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 04th September, 2019: ➢ Latest GMP inspection re[port ➢ Evidence of approval pof formulation for Melif-D Tablets
340.	75492	Dexipro 400mg Tablet Each Film Coated Tablet Contains: Dexibuprofen…400mg	11-10-2013	Dy. No. 33301 dated 08-10-2018 10000/-	-do-
341.	75493	Melif-D Tablet Each Tablet Contains: Melitracen (HCl)…10mg Flupenthixol (HCl and Decanoate)…0.5mg	11-10-2013	Dy. No. 33301 dated 08-10-2018 10000/-	-do-
M/s. Lisko Pakistan (Pvt) Ltd., L-10/D Block 21 Federal B Industrial Area Karachi.					
342.	004508	LYSOL LIQUID Each 100ml Contains Cresol…50ml Sodium Hydroxide…5gm Cotton Seed Oil…30ml	20-11-1978	Dy. No. 33860 dated 11-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 04th September, 2019: ➢ Evidence of approval of formulation in reference drug agencies .
343.	004425	MULTIMIN MULTIVITAMIN PEAD DROPS Each 0.6ml Contains VITAMIN A 6000Units VITAMIN D 1000Units Vitamin B1…1mg Vitamin B2…1mg Vitamin B6…1mg Nicotinamide…10mg Calcium D Pentothenate…2mg Ascorbic Acid…50mg	22-11-1978	Dy. No. 33859 dated 11-10-2018 10000/-	-do-
M/s. Venus Pharma, 23 Km Multan Road Lahore					
344.	49755	XYLEX 2% + AD INJECTION. Each ml contains: LIGNOCAINE HCH (B.P) 2% W/V. ADRENALINE 0.0005% W/V.	23-10-2008	Dy. No. 33858 dated 11-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 11th September, 2019: ➢ Evidence of approval of formulation in reference drug agencies. ➢ Evidence of submission of last renewal ➢ Valid DML ➢ Section approval letter issued by Licensing Division ➢ Details of last batch manufactured
345.	49756	VITAMIN B COMPLEX INJECTION. Each ml contains:	23-10-2008	Dy. No. 33858 dated 11-10-2018	-do-

		THIAMIN HCL 5MG. RIBOFLAVIN SODIUM PHOSPHATE 2.5MG. PYRIODOXINE HCL 2.5MG. NICOTINAMIDE 37.5MG.		10000/-	
346.	31295	Vepressor Injection Each ml Ampoule Contains Ephedrine (As Sulphate)…50mg	22-10-2003	Dy. No. 33857 dated 11-10-2018 10000/-	-do-
M/s. Mass Pharma (Pvt) Ltd., 17 Km Ferozpur Road Lahore					
347.	30859	Celicob Capsule 200mg Each capsule contains:- Celecoxib……..200mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 11th September, 2019: ➢ Latest GMP inspection report ➢ Source of pellets Itranex Capsule 100mg and in case of imported pellets the differential fee thereof. ➢ Approval of manufacturing facility for the steroidal injectable formulations. ➢ Approval of section / manufacturing facility for the Topical solutions
348.	30860	Seroless Tablet 20mg Each tablet contains:- Paroxetine (as HCl)…20mg	16-08-2003 Change of brand name 18-05-2011	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
349.	30865	Synalar C Ointment Contains:- Fluocinolone Acetonide…0.025%w/w Clioquinol……3.0%w/w	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
350.	30866	Synalar C Cream Contains:- Fluocinolone Acetonide……0.025%w/wClioquinol…3.0%w/w	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
351.	30870	Tretinex Cream Contains:- Tretinoin……..0.05%	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
352.	30875	Aerius Tablets 10mg Each tablet contains:- Ebastine…….10mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
353.	30876	Dinaphin Injection 500mg Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone…..500mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
354.	30877	Itranex Capsule 100mg Each capsule contains:- Itraconazole……..100mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-

355.	30880	Probase Tablets 5mg Each tablet contains:- Bisoprolol Fumarate …..5mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
356.	30881	Probase Tablets 10mg Each tablet contains:- Bisoprolol Fumarate…….10mg	16-08-2003	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
357.	26126	Triton Injection 40mg Each ml Contains Triamcinolone Acetonide…40mg	11-09-2000 Re-registration dated: 22-08-2008	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
358.	51159	Procon Tablets 10mg. Each enteric coated tablet contains:- Rabeprazole Sodium……..10mg.	01-09-2008	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
359.	51160	Procon Tablets 20mg. Each Enteric Coated Tablet Contains:- Rabeprazole Sodium …..20mg	01-09-2008	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
360.	52469	Hyseke Solution Each Bottle Contains Ketoconazole ..... 2% w/v	13-09-2008	Dy. No. 33728 dated 11-10-2018 20000/-	-do-
M/s. Alkemy Pharmaceutical Laboratories (Pvt) Ltd., P-9 SITE Hyderabad.					
361.	50328	Pantacool 40mg Tablet Each tablet contains:- Pantoprazole (as Sesequihydrate)…40mg	30-07-2008	Dy. No. 33709 dated 11-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 11th September, 2019: ➢ Differential fee needs to be submitted under SRO 1005 (I)/ 2017 as application of renewal is submitted after due date. ➢ Description of all applied tablet dosage forms. ➢ Evidence of approval of formulation for Sonomycin Dry syrup ➢ Latest GMP inspection report ➢ Section approval letter issued by Licensing Division ➢ Valid DML ➢ Evidence of submission of last renewal ➢ Source of pellets for Omzole Capsules and in case of imported pellets differential fee thereof.
362.	50329	Levofam 250mg Tablet Each tablet contains:- Levofloxacin (as hemihydrate)…250mg	30-07-2008	Dy. No. 33708 dated 11-10-2018 10000/-	-do-
363.	50330	Kemipan Plus Tablet Each tablet contains:- Diclofenac Potassium……75mg	30-07-2008	Dy. No. 33707 dated 11-10-2018 10000/-	-do-

364.	50331	Tarithrocid 250mg Tablet Each tablet contains:- Clarithromycin….250mg	30-07-2008	Dy. No. 33705 dated 11-10-2018 10000/-	-do-
365.	50332	Tarithrocid 500mg Tablet Each tablet contains:- Clarithromycin…500mg	30-07-2008	Dy. No. 33706 dated 11-10-2018 10000/-	-do-
366.	50333	Kemyceph Suspension Each 5ml contains:- Cephradine…….250mg	30-07-2008	Dy. No. 33713 dated 11-10-2018 10000/-	-do-
367.	50335	FB-Said Tablet Each tablet contains:- Flurbiprofen……..100mg	30-07-2008	Dy. No. 33710 dated 11-10-2018 10000/-	-do-
368.	50336	Zaridine Tablet Each tablet contains:- Loratadine……..10mg	30-07-2008	Dy. No. 33712 dated 11-10-2018 10000/-	-do-
369.	50338	Biodine Tablet Each tablet contains:- Ranitidine (as HCl) …..150mg	30-07-2008	Dy. No. 33711 dated 11-10-2018 10000/-	-do-
370.	30842	Sonomycin Dry Syrup Each 5ml contains:- Fosfomycin……..250mg	04-08-2003	Dy. No. 33704 dated 11-10-2018 20000/-	-do-
371.	30841	Omcool Capsule 20mg Each capsule contains:- Omeprazole USP…..20mg	04-08-2003 Change of brand name dated: 12-07-2007	Dy. No. 33714 dated 11-10-2018 20000/-	-do-
M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Plot No. A-127 SITE Super Highway Karachi.					
372.	014081	Ultec 150mg Tablet Each Tablet Contains 167.4mg Ranitidine HCl eq. to 150mg Ranitidine	26-10-1993	Dy. No. 33861 dated 11-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 11th September, 2019: ➢ Approval of Change of name of manufacturer from M/s Alina Combine Pakistan (Pvt) Karachi to M/s Alina Combine Pharmaceutical (Pvt) Ltd Karachi. ➢ Approval of transfer of registration from M/s Alina Combine Pakistan (Pvt) Karachi to M/s Alina Combine Pharmaceutical (Pvt) Ltd Karachi ➢ Evidence of submission of last renewal i.e. 2013. ➢ Latest GMP inspection report.
373.	014082	Ultec 300mg Tablet Each Tablet Contains Ranitidine HCl eq. to 300mg Ranitidine	26-10-1993	Dy. No. 33861 dated 11-10-2018 10000/-	-do-
M/s. Lahore Pharma, 9-Km Sheikhupura Road Lahore					
374.	14438	Cetrimide Solution Contains:- Cetrimide…15gm	14-10-1993	Dy. No. 33871 dated 12-10-2018	Letter of following shortcomings was issue to the firm vide letter dated 13th September, 2019:

		Chlorohexidine…1.5gm		10000/-	➢ Latest GMP inspection report. ➢ Valid DML. ➢ Section approval letter issued by licensing division. ➢ Brief details of last batch manufactured
375.	14439	Chloroxylenol Solution EACH 1000ML CONTAINS: Chloroxylenol…50gm	14-10-1993	Dy. No. 33871 dated 12-10-2018 10000/-	-do-
M/s. Nawabsons Laboratories (Pvt) Ltd., Jia Bagga off Raiwind Road Lahore					
376.	14334	Nobstan Tablet Each Tablet Contains Mefnamic Acid…250mg	14-10-1993	Dy. No. 33878 dated 12-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 13th September, 2019: ➢ Evidence of submission of renewal of 2013. ➢ Latest GMP inspection report. ➢ Description of all applied tablet dosage form.
377.	14335	Metronidazole Tablet 200mg Each Tablet Contains Metronidazole…200mg	14-10-1993	Dy. No. 33878 dated 12-10-2018 10000/-	-do-
378.	14336	Metronidazole Tablet 400mg Each Tablet Contains Metronidazole…400mg	14-10-1993	Dy. No. 33878 dated 12-10-2018 10000/-	-do-
379.	14337	Ibuprofen Tablet 200mg Each Tablet Contains Ibuprofen…200mg	14-10-1993	Dy. No. 33878 dated 12-10-2018 10000/-	-do-
380.	14338	Ibuprofen Tablet 400mg Each Tablet Contains Ibuprofen…400mg	14-10-1993	Dy. 33878 12-10-2018 10000/-	-do-
381.	14339	Ibuprofen Suspension 90ml Each 5ml Contains Ibuprofen…100mg	14-10-1993	Dy. No. 33878 dated 12-10-2018 10000/-	-do-
M/s. Nawal Pharmaceuticals, Plot No. 11-A Punjab Small Industrial Estate, Taxila					
382.	75750	Bella Raft Oral Powder Each 100gm Contains: Furosemide…2gm Belladonna Extract.0.2gm	22-10-2013	Dy. No. 34026 dated 12-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 16th September, 2019: ➢ Latest GMP inspection report.
M/s. Macter International (Pvt) Ltd., F-216, S.I.T.E., Karachi					
383.	22825	Midolam Inj 1mg Each ml contains Midazolam as HCI …. 1mg	21-12-1998	Dy. No. 35335 dated 24-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019: ➢ Approval manufacturing facility for psychotropic Injectable products
M/s. Reckitt Benckiser Pakistan Ltd., F-18 S.I.T.E Karachi					
384.	000484	Disprol Suspension Each 5ml contains: PARACETAMOL 120MG,	19-04-1976 Change of brand name & formulation 28-10-1991	Dy. No. 35329 dated 24-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 16th September, 2019: ➢ Copy of initial registration letter of Disprol Suspension & Polycrol

			Change of title dated: 21-12-2000 Transfer of registration from contract to own facility: 06-11-2008		Forte Gel
385.	000487	POLYCROL Forte Gel Each 5ml contains: Simethicone …. 125mg Magnesium Oxide B.P ……70mg Aluminum Hydroxide B.P as Aluminum Oxide …. 200mg	19-04-1976 Transfer of registration from contract to own facility: 06-11-2008	Dy. No. 35330 dated 24-10-2018 10000/-	-do-
M/s. Harmann Pharmaceutical Laboratories (Pvt) Ltd., P.O. Chung, 16-Km Multan Road, Lahore					
386.	003933	LYSOBEX SYP Each 30ml Contains Thiamine HCl…..25mg Pyridoxine HCl……6mg Riboflavin 5-Phosphate……10mg Cyanocobalamin.50mcg Calcium Pantothenate …...15mg Lysine Monohydrochloride …200mg Ascorbic acid……450mg Inositol…..30mg Nicotinamide…..108mg	30-10-1988	Dy. No. 35331 dated 24-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 17th September, 2019: ➢ Valid DML. ➢ Evidence of submission of renewal of 2013. ➢ Approval of formulation in reference drug agencies. ➢ Section approval letter issued by Licensing Division. ➢ Latest GMP inspection report.
M/s. Pharmix Laboratories (Pvt) Ltd. , 21-Km Ferozepur Road, Lahore					
387.	001840 -EX	Kwantadin Tab 10mg Each tablet contains Loratadine USP …. 10mg	02-09-2013	Dy. No. 36070 dated 31-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 19th September, 2019: ➢ Registration Letter and evidence of renewal submitted is of Lorate Tablets (022371) instead of Kwantadin Tablets.
M/s. Sami Pharmaceuticals (Pvt) Ltd., F-95, Off Hub River Road, S.I.T.E., Karachi					
388.	76174	Sitip 1mg Tablet Each tablet contains:- Cinitapride acid tartrate eq. to cinitapride.. ……..… 1mg	29/1/2014	Dy. No. 36080 dated 31-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 19th September, 2019: ➢ Evidence of submission of last renewal for Sitip 1mg Tablet ➢ Approval of manufacturing facility for penicillin oral syrup/ suspension.
389.	15062	Moxypen DS Syrup Each 5 ml contains:- Amoxicillin trihydrate eq. to 250 mg Amoxicillin base	27-02-1994	Dy. No. 36080 dated 31-10-2018 10000/-	-do-

M/s. The Schazoo Pharmaceutical Laboratories (Pvt) Ltd., Kalalwala Stop, 20-Km Lahore-Jaranwala Road, District Sheikhupura					
390.	077030	Arify Tablets 15mg Each film coated tablet contains:- Aripiprazole….15mg	20-11-2013	Dy. No. 36081 dated 31-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019: ➢ Latest GMP inspection report.
391.	077031	Arify Tablets 10mg Each film coated tablet contains:- Aripiprazole…..10mg	20-11-2013	Dy. No. 36081 dated 31-10-2018 10000/-	-do-
M/s. Cherwel Pharmaceuticals (Pvt) Ltd., Plot No. 20, Phase-IV, Industrial Estate, Hattar					
392.	52702	Cherose Capsules. Each Capsule contains:- Iron III Hydroxy Polymaltose complex eq. to elemental Iron..100mg	21-10-2008	Dy. No. 33601 dated 10-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019: ➢ Latest GMP inspection report ➢ Valid DML.
M/s. P.D.H Pharmaceuticals (Pvt) Ltd., 19-Km Ferozepur Road, Lahore					
393.	14442	Hypnotil Capsule 15mg Each Capsule Contains Temazepam…….15mg	14-10-1993	Dy. No. 33600 dated 10-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019: ➢ Transfer of registration from Punjab Drug House 42 Nicholson Road Lahore to PDH Pharmaceuticals Pvt Limited 19-Km Ferozepur Road, Lahore. ➢ Approval of psychotropic capsule section by Licensing Division. ➢ Brief details of last batch manufactured along with quota allocation approval by Controlled Drugs Division. ➢ Latest GMP inspection report.
394.	14443	Hypnotil Capsule 30mg Each Capsule Contains Temazepam……30mg	14-10-1993	Dy. No. 33600 dated 10-10-2018 10000/-	-do-
395.	22378	Corinor Tablet 5mg Each Tablet Contains Amlodipine Besylate……5mg	19-10-1998	Dy. No. 33600 dated 10-10-2018 10000/-	-do-
396.	22379	Corinor Tablet 10mg Each Tablet Contains Amlodipine Besylate…….10mg	19-10-1998	Dy. No. 33600 dated 10-10-2018 10000/-	-do-
M/s. Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi					
397.	53280	Lanic Injection Each ml contains: Triamcinolone Acetonide..…40.0mg (USP Specifications)	02-12-2008	Dy. No. 33872 dated 12-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 16th September, 2019: ➢ Approval of manufacturing facility for injectable steroids as required under Schedule B (1) (5.2) of Drug (LR&A) Rules 1976from Licensing Division.
M/s. Jawa Pharmaceuticals (Pvt) Ltd., 112/10 Quaid-e-Azam Industrial Estate, Kot Lakhpat Lahore					
398.	52775	P-Lock Tablets 400mg. Each tablet contains: Pefloxacin as Mesylate…….400mg.	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 23rd September, 2019: ➢ Differential fee is required as the

		(B.P Specs)			renewal of 2013 was submitted after due date but within sixty days. ➢ Evidence of submission of renewal for Mfor Tablets 500mg
399.	52776	J-Rox Tablets 150mg. Each tablet contains: Roxithromycin..150mg.	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
400.	52777	Typdex Tablets 500mg. Each tablet contains: Nalidixic Acid..500mg (USP Specs)	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
401.	52778	Fanoxin Tablets 120mg. Each tablet contains: Fexofenadine HCl……120mg.	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
402.	52779	Fanoxin Tablets 60mg Each tablet contains: Fexofenadine HCl……60mg.	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
403.	52780	Jperidon Tablets 10mg Each tablet contains: Domperidone …..10mg (BP Specs)	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
404.	52781	Cholein Tablets 20mg. Each tablet contains: Atorvastatin…..20mg	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
405.	52782	Cholein Tablets 10mg. Each tablet contains: Atorvastatin ……..10mg.	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
406.	52783	Jasartan Tablets 50mg. Each tablet contains: Losartan Potassium……...50mg .	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
407.	52784	Mfor Tablets 500mg. Each tablet contains: Metformin HCl…500mg (BP Specs)	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
408.	52785	Mntazole -DS Tablets Each tablet contains: Metronidazole…..400mg Diloxanide Furoate ..500mg (B.P Specs)	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
409.	52786	Mntazole Tablets Each tablet contains: Metronidazole .200mg. Diloxanide Furoate ……..250mg (B.P Specs)	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-
410.	52787	Zenzol Tablets Each tablet contains: Mebendazole.100mg. (USP Specs)	10-11-2008	Dy. No. 34624 dated 18-10-2018 10000/-	-do-

M/s. Global Pharmaceuticals, Plot No 204-205, Industrial Triangle Kahota Road, Islamabad					
411.	29501	Coasacort Ointment Each gm Contains: Strong CoalTar Solution..30mg Hydrocortisone.10mg Salicylic Acid…..30mg	01-09-2002 Transfer of registration dated: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	➢ Approval of formulation in RRA.
412.	30031	Doudcer-Nil Caps Each capsule contains:- Lansoprazole……30mg	21-02-2003 Transfer of registration dated: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	➢ Copy of approval of change of brand name from Nevazole to Doudecer Nil Capsules does not bear the date of issuance of letter. ➢ Renewal letter dated 20-07-2009 indicates the brand name Nevazole capsules however the brand name was changed in 2007. ➢ Source of pellets.
413.	052250	Opepzole 40mg IV Injection Each vial contains: Omeprazole sodium eq. to Omeprazole…..40mg Manufactured by: M/s Habrin Pharmaceutical Group Bioengineering Co., Ltd China.	05-11-2008	Dy. No. 34569 dated 18-10-2018 10000/-	➢ You have submitted Form-5B for local manufacturing however the product is registered as Finished import from China. In case the product has been transferred from import to local manufacturing then approval of same is required. ➢ Valid legalized CoPP/ FSC and GMP ➢ DRAP attested last import invoice. ➢ Differential fee applicable in case of finished import.
414.	017488	Tobicon Capsules Each capsule contains: Sodium Chondroitin Sulphate…..100mg Thiamine HCl…..20mg Retinol Palmitate….2500IU Ribofavin ….5mg Hydrocholine tartrate…..25mg	05-07-1995 Transfer of registration dated: 18-11-2003	Dy. No. 34569 dated 18-10-2018 10000/-	➢ Evidence of approval of formulation in RRA.

Decision: Registraion Board deferred the above products for rectification of shortcomings as mentioned in last column above.

Local (Veterinary)

Sr. No.	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Remarks
M/s. Prix Pharmaceutica (Pvt) Ltd., 5-Pharmacity, 30-Km, Multan Road, Lahore					
415.	49517	HEPAPRI ORAL SOLUTION Each 100 ml contains: DL-METHIONINE…5GM L-LYSINE MONOHYDROCHLORIDE…10GM CHOLINE CHLORIDE…19GM VITAMIN B12….1MG SORBITOL…..10GM	26-11-2008	Dy. No. 32593 dated 1-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 4th September, 2019: ➢ Latest GMP inspection report ➢ Section approval letter issued by Licensing Division.

416.	49530	DOXIMAC-C WATER SOLUBLE POWDER Each gm Contains: COLISTIN SULPHATE BP…25,00,000IU, TYLOSIN (AS TARTRATE)BP 100MG DOXYCYCLINE (AS HYCALTE) BP…100MG BROMHEXINE (AS HYDROCHLORIDE) BP 5MG	26-11-2008	Dy. No. 32593 dated 1-10-2018 10000/-	-do-
417.	75780	PRI-DIMIDINE 33.3% INJECTION Each ml injection contains:- SULPHADIMIDINE SODIUM…….333.3MG	05-11-2003	Dy. No. 32593 dated 1-10-2018 10000/-	-do-
418.	75781	PRI-DOLOCAM 7.5 INJECTION Each ml contains: MELOXICAM…...…7.5MG	05-11-2003	Dy. No. 32593 dated 1-10-2018 10000/-	-do-
419.	75782	PRI-DEFLAME 5 INJECTION Each ML INJECTION contains FLUNIXIN MEGLUMINE……..50MG	05-11-2003	Dy. No. 32593 dated 1-10-2018 10000/-	-do-
M/s. D-Marson Pharmaceuticals, Plot No. 17, SS-2, RCCI, Rawat, Rawalpindi					
420.	75742	FLUSH B POWDER Each 100gm Contains: FUROSEMIDE……..2gm BELLADONNA EXTRACT...0.2gm	22-10-2013	Dy. No. 34027 dated 12-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 16th September, 2019: ➢ Latest GMP inspection report.
421.	75743	RIZ ZAN PLUS SUSPENSION Each 100 ml contains: OXYCLOZANIDE…….….3.0 G LEVAMISOLE HCL …..…1.5G COBALT SULPHATE …0.382%	22-10-2013 Change of brand name dated: 10-06-2014	Dy. No. 34027 dated 12-10-2018 10000/-	-do-
422.	75744	ALBENMARS SUSPENSION Each 100 ml contains: ALBENDAZOLE……....2.5 G SODIUM SELENITE ....0.035% COBALT CHLORIDE …0.075%	22-10-2013	Dy. No. 34027 dated 12-10-2018 10000/-	-do-
423.	75745	LEVAMARS SUSPENSION Each 100 ml contains: LEVAMISOLE HCL ……1.5%	22-10-2013	Dy. No. 34027 dated 12-10-2018 10000/-	-do-
424.	75746	TOLMARS LIQUID EACH 1000ML CONTAINS: TOLTRAZURIL ……...25G VITAMIN K3 ……...…3G	22-10-2013	Dy. No. 34027 dated 12-10-2018 10000/-	-do-
425.	75747	FENMARS SUSPENSION Each ml contains: OXFENDAZOLE ….. 22.65MG	22-10-2013	Dy. No. 34027 dated 12-10-2018 10000/-	-do-
426.	75748	COL-PLUS ORAL LIQUID Each 100 ml contains: FLORFENICOL…...… 20GM	22-10-2013	Dy.# 34027 12-10-2018 10000/-	-do-

427.	75749	MAXEN LIQUID. Each 100 ml contains: ENROFLOXACIN …….....20GM COLISTIN SULPHATE…50 MIU	22-10-2013	Dy. No. 34027 dated 12-10-2018 10000/-	-do-
M/s. Univet Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi					
428.	049799	Coxban Powder Each 100gm Contains: SODIUM SULPHAQUINOXALINE.20G SODIUM SULPHADIMIDINE….8.25MG DIAVERIDINE…4.0G VITAMIN A….280,000IU VITAMIN K3….0.200G	17-12-2008 Change of brand name dated: 16-05-2013	Dy. No. 35332 dated 24-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 17th September, 2019: ➢ Latest GMP inspection report.
429.	049800	ECBRO POWDER Each 100GM POWDER contains ERTHROMYCIN BASE (AS THIOCYANATE)…..5GMCOLICOLISTIN SULPHATE…5,000,000 IU BROMHEXINE HYDROCHLORIDE.0.375G	17-12-2008	Dy. No. 35332 dated 24-10-2018 10000/-	-do-
M/s. Symans Pharmaceuticals (Pvt) Ltd., 10-Km Sheikhupura Road, Lahore					
430.	29700	Cholipol Powder Each 1000gm contains: CHOLINE CHLORIDE … 500GM. DL-METHIONINE …… 40GM. L-LYSINE ……. 40GM.	15-10-2018	Dy. No. 34233 dated 15-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 20th September, 2019: ➢ Latest GMP inspection report. ➢ Section approval letter issued by Licensing Division ➢ Valid DML. ➢ Brief details of last batch manufactured.

Decision: Registraion Board deferred the above products for rectification of shortcomings as mentioned in last column above.

Finished Import (Human)

Sr. No	Reg. No.	Manufacturer	Brand Name & Composition	Initial date of registration	Date of application (R&I) Fee submitted	Remarks
M/s Lundbeck Pakistan (Pvt) Ltd., 40 T/4 Blessing Street Block-6 P.E.C.H.S., Karachi						
431.	028467	M/s H. Lundbeck A/S Denmark	Cipralex 10mg Tablets. Each tablet contains: Escitalopram Oxalate 12.77mg ~Escitalopram 10mg.	06-08-2003 Re-registration dated: 22-10-2008	Dy. No. 32588 1-10-2018 20000/-	➢ Valid legalized CoPP issued by Danish Medicines Agnecy vide No. 2019010913 dated 09-01-2019, Export License Holder (Name and Address): M/s H. Lundbeck A/S

						Ottiliavej 9, 2500 Valby, Denmark
M/s. Novartis Pharma (Pakistan) Limited, 15-West Wharf, Karachi						
432.	052235	M/s Lek Pharmaceuticals d.d. Slovenia	Lozal 40mg Powder for Infusion. Each vial of powder for solution for infusion contains: Omeprazole sodium eq. to 40mg Omeprazole.	22-10-2008	Dy. No. 33623 dated 10-10-2018 10000/-	Letter of following shortcomings was issue to the firm vide letter dated 3rd September, 2019: ➢ Copy of valid DSL. ➢ Valid legalized CoPP/ FSC and GMP ➢ Last DRAP attested import invoice.
M/s. Drug's Inn, 1-I, Park View Plaza, Sector F-10 Markaz, Islamabad						
433.	21939	M/s Chengdu Second Pharmaceutical Factory China Exported by M/s Shanghai Pharmaceutical Co., Ltd China	ZACIN TABLETS 250MG Each tablet contains: CIPROFLOXACIN HCL 250MG	15-10-1998	Dy. No. 33550 dated 9-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 13thSeptember, 2019: ➢ Valid legalized CoPP/ FSC & GMP.
M/s. Shaheen Agency, P.No.GK-3/13, Adamji Dawood Road, Karachi						
434.	014602	M/s Egis Pharmaceutical Budapest Hungary	GRANDAXIN TABLETS Each tablet contains: TOFIZOPAM 50MG	04-11-1993	Dy. No. 35328 dated 24-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 17thSeptember, 2019: ➢ Evidence of submission of renewal of 2013 having endorsement of receiving in DRAP. ➢ Valid legalized CoPP/ FSC and GMP
M/s. Al Habib Pharmaceuticals, 81-B Block B, S.M.C.H.S, Karachi						
435.	21955	M/s Korea United Pharm Inc., Korea	UCETAM CAPSULES 400MG Each Capsule Contains: PIRACETAM 400MG	31-10-1998	Dy. No. 36086 dated 31-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 17thSeptember, 2019: ➢ Address of Importer mentioned on DSL varies with address on transfer of registration. Approval letter for address as per DSL is required. ➢ Valid legalized CoPP/ FSC and GMP ➢ DRAP attested invoice of last imported batch.
436.	21956		UCETAM TABLETS 800MG Each tablet contains: PIRACETAM 800MG	31-10-1998	Dy. No. 36086 dated 31-10-2018 20000/-	-do-

Decision: Registraion Board deferred the above products for rectification of shortcomings as mentioned in last column above.

Imported (Veterinary)

Sr. No	Reg. No.	Manufacturer	Brand Name & Composition	Initial date of registration	Date of application (R&I) Fee submitted	Remarks
M/s. Prix Pharmaceutica (Pvt) Ltd., 26-Abbot Road, District Lahore						
437.	12989	M/s Fatro SPA Italy	OXTRA LA (INJECTABLE SOL.) Each tablet contains:- OXYTETRACYCLINE DIHYDRATE 20gm	02-12-1993	Dy. No. 34237 15-10-2018 20000/-	Letter of following shortcomings was issue to the firm vide letter dated 04th September, 2019: ➢ Valid legalized CoPP/ FSC & GMP
438.	22175	M/s Farvet Laboratories B.V. Netherland	Vitamin AD3E Injection Each ml Contains Retinyl Palmitate 80,000 IU Cholecalciferol 40,000IU A-Tocopherol Acetate 20mg	04-12-1998	Dy. No. 34238 dated 15-10-2018 20000/-	-do-

Decision: Registraion Board deferred the above products for rectification of shortcomings as mentioned in last column above.

DEFERRED CASES

Sr. No	Reg. No.	Brand Name &Composition	Initial date of Registration	Date of application (R&I) Fee submitted	Decision in previous meetings	Decision
M/s. MeDLey Pharmaceuticals, 41-A, P.S.I.E. JhangBahtar Road, WahCantt. Rawalpindi						
439.	075453	Le-Ride 100mg Capsule Each Capsule Contains: Levosulpiride.100mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	Registration Board in its 289th meeting deferred the case for following: Latest GMP report is not submitted. Valid DML is not submitted.	w.e.f. 22-07-2018 to 21-07-2023
440.	075454	Arte-M Capsule 20/120 Each Capsule Contains: Artemether…20mg Lumefantrine…120mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
441.	075455	Arte-M Capsule 40/240 Each Capsule Contains: Artemether…40mg Lumefantrine…240mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
442.	075456	Z-Cin 250mg Capsule Each Capsule Contains:	22-07-2013	Dy. No. 25587 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023

		Azithromycin Dihydrate…250mg				
443.	075457	Mexo120mg Capsule Each Capsule Contains: Fexofenadine…120mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
444.	075458	MecoCap 500mcg Capsule Each Capsule Contains: Mecobalamin.500mcg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	Deferred for confirmation of formulation in RRA.
445.	075459	Meroxi 20mg Capsule Each Capsule Contains: Piroxicam as Beta-Cyclodextrin…20mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
446.	075460	Medifos 500mg Capsule Each Capsule Contains: Fosfomycin Calcium eq. to Fosfomycin …500mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
447.	075461	Maltoley Syrup Each ml Contains: Iron III Hydroxide Polymaltose Complex…100mg Folic Acid…0.35mg Sugar Free Syrup	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
448.	075462	Letose Syrup Each 5ml Contains: Iron III Hydroxide Polymaltose Complex…50mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
449.	075463	Medfir 10mg Tablet Each Tablet Contains: Adefovir Dipivoxil…10mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
450.	075464	Medcavir 0.5mg Tablet Each Tablet Contains: Entecavir as Monohydrate…0.5mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
451.	075465	T-Poxi 20mg Tablet Each Film Coated Tablet Contains: Paroxitine (as HCl)…20mg	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
452.	075466	Ice 30 Capsule Each Capsule Contains: Lansoprazole (Pellets)…30mg Source : M/s Vision Pharmaceuticals Islamabad.	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023

453.	075467	Olx 20mg Capsule Each Capsule Contains: Omeprazole (Pellets) …20mg Source : M/s Vision Pharmaceuticals Islamabad.	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
454.	075468	D-Lox 40mg Capsule Each Capsule Contains: Duloxetine as HCl (Pellets) …40mg Source : M/s Vision Pharmaceuticals Islamabad.	22-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 22-07-2018 to 21-07-2023
455.	075469	Kanamed 1gm Injection Each 4ml Ampoule Contains: Kanamycin Sulphate eq. to Kanamycin Base…1000mg	25-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 25-07-2018 to 24-07-2023
456.	075472	Medka 100mg Injection Each Vial Contains: Amikacin (as Sulphate)…100mg	31-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 31-07-2018 to 30-07-2023
457.	075473	Medka 250mg Injection Each Vial Contains: Amikacin (as Sulphate)…250mg	31-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 31-07-2018 to 30-07-2023
458.	075474	Medka 500mg Injection Each Vial Contains: Amikacin (as Sulphate)…500mg	31-07-2013	Dy. No. 25587 dated 23-07-2018 10000/-	-do-	w.e.f. 31-07-2018 to 30-07-2023
M/s. Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E, Super Highway, Karachi						
459.	076193	Trankilium 250mg Injection Each 5ml contain: Tranexamic Acid…250mg	29-01-2014	Dy. No. 44594 dated 31-12-2018 10000/-	Deferred for in 291st meeting of RB for Evidence of approval of formulation in reference agencies.	w.e.f. 29-01-2019 to 28-01-2024
460.	076194	Trankilium 500mg Injection Each 5ml contain: Tranexamic Acid…500mg	29-01-2014	Dy. No. 44594 dated 31-12-2018 10000/-	Deferred for in 291st meeting of RB for Evidence of approval of formulation in reference agencies.	w.e.f. 29-01-2019 to 28-01-2024
461.	076147	Suregine Oral Solution Each ml contain: Co-	06-01-2014	Dy. No. 44594 dated 31-12-2018 10000/-	Deferred for in 291st meeting of RB for	Deferred of confirmation of formulation in

		degrocrinemesylate……1mg			Evidence of approval of formulation in reference agencies.	RRA.
462.	032033	Clarocin Granules Each 5ml contain: Clarithromycin ….125mg	17-01-2004	Dy. No. 44594 dated 31-12-2018 10000/-	Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Approval of source of granule and in case of imported granules the differential fee thereof.	Deferred for approval of granules from M/s Surge Laboratories Pvt Limited Sheikhupura.
463.	076160	Colistat Powder for injection Each vial contain: Colistimethate sodium……1million I.U	09-01-2014	Dy. No. 44594 dated 31-12-2018 10000/-	Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Clarification of formulation as the formulation approved in the reference agencies is lyophilized powder however the inspection report doesn't indicate the availability of lyophilizer. Brief details of last batch manufactured.	Deferred of Clarification of formulation as the formulation approved in the reference agencies is lyophilized powder however the inspection report doesn't provide the availability of lyophilizer.
464.	031747	Sulvo Tablet 25mg Each Tablet Contain: Levosulpiride….25mg	13-11-2003	Dy. No. 42662 dated 13-12-2018 10000/-	Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Differential fee required as renewal application is submitted after due date.	Deferred of submission of differential fee.

					Section approval letter issued by Licensing Division.	
M/s. Paramount Pharmaceuticals, 36-Industrial Triangle, Kahuta Road, Islamabad						
465.	050285	Respimet Syrup. Each 1ml contains: Ketotifen as Fumarate…0.2mg.	28-07-2008	Dy. No. 25824 dated 26-07-2018 10000/-	Deferred in 289th meeting for approval status of tablet section by CLB	w.e.f. 28-07-2018 to 27-07-2023
466.	050286	Silicur Tablets. Each tablet contains: Silymarin….200mg.	28-07-2008	Dy. No. 25824 dated 26-07-2018 10000/-		Deferred for confirmation of formulation in RRA.
467.	050287	Sycon Tablet 3mg. Each film coated Tablet contains: Risperidone…3mg	28-07-2008	Dy. No. 25824 26-07-2018 10000/-		Deferred for confirmation of tablet (general section) as reported in inspection report
468.	050288	Sycon Tablets 4mg. Each film coated Tablet contains: Risperidone……4mg	28-07-2008	Dy. No. 25824 dated 26-07-2018 10000/-		Deferred for confirmation of tablet (general section) as reported in inspection report
469.	050986	Polymat Syrup Each 15ml contains: Iron Protein Succinylate……...800 mg (eq to 40mg elemental iron)	12-08-2008	Dy. No. 25824 dated 26-07-2018 10000/-		w.e.f. 12-08-2018 to 11-08-2023
M/s Tabros Pharma (Pvt) Ltd, L-20/B, Sector-22, F.B. Industrial Area, Karachi						
470.	014343	Hemsamic Capsule 250mg Each Capsule Contains: Tranexamic Acid…250mg	14-10-1993	Dy. No. 25525 dated 23-07-2018 10000/-	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 1-3-2019 which has not yet been responded by the firm and accordingly deferred in 289th meeting of RB.	w.e.f. 14-10-2018 to 13-10-2023
471.	014344	Hemsamic Capsule 500mg Each Capsule Contains Tranexamic Acid …500mg	14-10-1993	Dy. No. 25525 dated 23-07-2018 10000/-	-do-	w.e.f. 14-10-2018 to 13-10-2023
472.	014345	Hemsamic Injection 250mg/5ml Each 5ml Contains: Tranexamic Acid…250mg	14-10-1993	Dy. No. 25525 dated 23-07-2018 10000/-	-do-	w.e.f. 14-10-2018 to 13-10-2023
M/s. English Pharmaceutical Industries, Link Kattar Bund Road, ThokarNiazBaig, Multan Road, Lahore						
473.	022926	Cartac 50mg tablet Each tablet contains: Atenolol ..50mg	19-12-1998	Dy. No. 42569 dated 13-12-2018 10000/-	Deferred for following in 291st meeting of RB:	Deferred for confirmation of renewal of tablet

					a) Latest GMP inspection report As per letter dated 09-03-2015 regarding renewal of DML, your Tablet section (General) was not renewed, therefore clarification in this respect is needed c) Evidence of approval of formulation on reference drug agencies for products at Sr. No. 269&270	(general) section from licensing division.
474.	022927	Cartac 100mg tablet Each tablet contains: Atenolol…...100mg	19-12-1998	Dy. No. 42569 dated 13-12-2018 10000/-	-do-	Deferred for confirmation of renewal of tablet (general) section from licensing division.
475.	022928	Ardi-75 Tablet Each tablet contains: Diclofenac Sodium 75mg	19-12-1998	Dy. No. 42569 dated 13-12-2018 10000/-		Deferred for confirmation of renewal of tablet (general) section from licensing division and formulation in RRA
476.	022929	Ornivit Syrup Each 5ml contains: L-Ornithine L-Aspartate 300mg Nictinamide.24mg Riboflavin-5 phosphate Sodium 0.76mg	19-12-1998 Change of brand name dated 31-10-2001	Dy. No. 42569 dated 13-12-2018 10000/-	-do-	Deferred for confirmation of formulation in RRA.
477.	022930	Cezen Tablets Each tablet contains: Cetrizine Dihydrochloride 10mg	19-12-1998	Dy. No. 42569 dated 13-12-2018 10000/-	-do-	Deferred for confirmation of renewal of tablet (general) section from licensing division
478.	022931	F-100 Tablet Each tablet contains: Flurbiprofen 100mg	19-12-1998 Change of brand name dated 06-07-1999	Dy. No. 42569 dated 13-12-2018 10000/-	-do-	Deferred for confirmation of renewal of tablet (general) section from Licensing Division

Decision: Registration considered the renewal cases of above products and decision mentioned in the last column of above table.

Imported Finished Drugs

Sr. No	Reg. No.	Manufacturer	Brand Name &Composition	Initial date of Registration	Date of application (R&I) Fee submitted	Decision in previous meetings
M/s Medisure Laboratories Pakistan Pvt Limited Karachi						
479.	028462	M/s Shin Poong Pharmaceuticals Co., Ltd Seoul Korea.	Hyal Prefilled Injection Each ml contain: Sodium hyaluronate…10mg	16-07-2003	Dy. No. 42662 dated 13-12-2018 10000/-	Deferred for the rectification of following shortcoming in 291st meeting of RB: i. Approval of formulation in reference drug agencies. ii. Evidence of submission of last renewal. ii. Differential fee as per SRO 1005 (I)/ 2017. v. Valid legalized CoPP/ FSC and GMP v. Last DRAP attested import invoice. vi. Valid Drug Sale License
480.	014004	M/s RemedicaAhmon Street Limassol Cyprus	Trizoline 400mg Tablet Each Tablet contain: Norfloxacin USP….400mg	21-07-1993	Dy. No. 42662 dated 13-12-2018 20000/-	Deferred for the rectification of following shortcoming in 291st meeting of RB: i. Approval of formulation in reference drug agencies. ii. Evidence of submission of last renewal. ii. Differential fee as per SRO 1005 (I)/ 2017. v. Valid legalized CoPP/ FSC and GMP v. Last DRAP attested import invoice. vi. Valid Drug Sale License.

Reply of the firm: The firm informed that they are no longer interested in the in the above products and same may kindly be deregistered.

Decision: Keeping in view the reply of firm Registration Board de-registered the above mentioned products in the name of M/s. Medisure Laboratories Pakistan Pvt Limited Karachi

COMPLETE CASES

Local Manufacturing (Human)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Pharmatec Pakistan (Pvt) Ltd., D-86/A S.I.T.E., Karachi						
481.	004096 -EX	Baby Zinc Syrup Each 5ml contains Elemental Zinc as Zinc Gluconate …. 10mg	21-03-2013	Dy. No. 7935 dated 01-03-2018 10,000/-/-	20-03-2023	w.e.f. 21-03-2018 to 20-03-2023
482.	004094 -EX	Fludol EX Expectorant Syrup Each 5ml contains Ammonium Chloride …. 100mg Phenylephrine HCI …. 5mg Guaifensin …. 50mg Chlorpheniramine Maleate …. 2mg	21-03-2013	Dy. No. 7935 dated 01-03-2018 10,000/-/-	-do-	w.e.f. 21-03-2018 to 20-03-2023
483.	004095 -EX	Polycid Plus Tablet Each chewable tablet contains Aluminium Hydroxide …. 200mg Magnesium Hydroxide …. 200mg Chlorpheniramine Maleate …. 2mg	21-03-2013	Dy. No. 7935 dated 01-03-2018 10,000/-/-	-do-	w.e.f. 21-03-2018 to 20-03-2023
484.	004047 -EX	Simecon Tablet Each film coated tablet contains Aluminium Hydroxide …. 200mg Magnesium Hydroxide …. 200mg Simethicone …. 25mg	12-03-2013	Dy. No. 7935 dated 01-03-2018 10,000/-/-	11-03-2023	w.e.f. 12-03-2018 to 11-03-2023
485.	004046 -EX	Simecon Suspension Each 5ml contains Aluminium Hydroxide …. 215mg Magnesium Hydroxide …. 80mg Simethicone …. 25mg	12-03-2013	Dy. No. 7935 dated 01-03-2018 10,000/-/-	-do-	w.e.f. 12-03-2018 to 11-03-2023
M/s. Noa Hemis Pharmaceuticals, Plot No. 154, Sector 23, Korangi Industrial Area, Karachi						
486.	048592	Kurida Tablet Each tablet contains Artemether …. 20mg Lumefantrine …. 120mg	06-05-2008	Dy. No. 9261 dated 13-03-2018 10,000/-	05-05-2023	w.e.f. 06-05-2018 to 05-05-2023
487.	048593	Ricoda-10 Tablet Each tablet contains Rosuvastatin as Calcium …. 10mg	08-05-2008	Dy. No. 9261 dated 13-03-2018 10,000/-	07-05-2023	w.e.f. 08-05-2018 to 07-05-2023
488.	048594	Ricoda-20 Tablet Each tablet contains Rosuvastatin as Calcium …. 20mg	08-05-2008	Dy. No. 9261 dated 13-03-2018 10,000/-	-do-	-do-
489.	048595	Bianchi 5mg Tablet Each tablet contains Levocetirizine …. 5mg	08-05-2008	Dy.# 9261 13-03-2018 10,000/-	-do-	-do-

M/s. Sante (Pvt) Ltd., A/97 S.I.T.E Super Highway, Karachi						
490.	075809	Nepac 0.1% Ophthalmic Suspension Each ml contains Nepafenac …. 1mg	01-04-2013	Dy. No. 11440 dated 28-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
491.	075810	2blink Eye Drops Each ml contains Polyethylene Glycol 400 …. 4mg Propylene Glycol …. 3mg	01-04-2013	Dy. No. 11440 dated 28-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
492.	075811	Ristases Ophthalmic Emulsion Each ml contains Cyclosporine …. 0.5mg	01-04-2013	Dy. No. 11440 dated 28-03-2018 10,000/-/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13 - 14, Sector 15, Korangi Industrial Area, Karachi						
493.	075940	Qusel XR 400mg Tablet Each extended release tablet contains Quetiapine Fumarate eq. to Quetiapine …. 400mg	29-05-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	28-05-2023	w.e.f. 29-05-2018 to 28-05-2023
494.	075941	Ranagin XR 1g Tablet Each extended release tablet contains Ranolazine …. 1000mg	29-05-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	-do-	w.e.f. 29-05-2018 to 28-05-2023
495.	075942	Ranagin XR 500mg Tablet Each extended release tablet contains Ranolazine …. 500mg	29-05-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	-do-	w.e.f. 29-05-2018 to 28-05-2023
M/s. Ferozsons Laboratories Ltd., Amangarh Nowshehra, Khyber Pakhtunkhwa						
496.	076806	Valiant Tablet Each tablet contains Vildagliptin …. 50mg	04-04-2013	Dy. No. dated 22-03-2018 10,000/-	03-04-2023	w.e.f. 04-04-2018 to 03-04-2023
M/s. Adamjee Pharmaceuticals (Pvt) Ltd., Plot No. 39, Sector 15, Korangi Industrial Area, Karachi						
497.	030261	Hapicit Tablet Each tablet contains Citalopram …. 20mg	26-04-2003	Dy. No. 10786 dated 22-03-2018 10,000/-	25-04-2023	w.e.f. 26-04-2018 to 25-04-2023
498.	075830	Artine DS 80/480 Tablet Each tablet contains Artemether …. 80mg Lumefantrine …. 480mg	03-04-2013	Dy. No. 10786 dated 22-03-2018 10,000/-	02-04-2023	w.e.f. 03-04-2018 to 02-04-2023
M/s. Helix Pharma (Pvt) Ltd., A-56, S.I.T.E., Karachi						
499.	048552	Tycef DS Suspension Each 5ml contains Cefixime Trihydrate eq. to Cefixime …. 200mg	20-03-2008	Dy. No. 10201 dated 19-03-2018 10,000/-	19-03-2023	w.e.f. 20-03-2018 to 19-03-2023
500.	048553	Tycef Capsules 200mg Each capsule contains Cefixime Trihydrate eq. to Cefixime …. 200mg	20-03-2008	Dy. No. 10201 dated 19-03-2018 10,000/-	19-03-2023	w.e.f. 20-03-2018 to 19-03-2023
M/s. Indus Pharma (Pvt) Ltd., Plot No. 26, 27, 63, 64, 65, 66 & 67, Sector 27, Korangi Industrial Area Karachi						
501.	008422	Atrosol Injection 1ml Each ml contains Atropine Sulphate …. 1mg	25-04-1988 Change of brand name 16-12-1997	Dy. No. 9260 dated 12-03-2018 10,000/-	24-04-2023	w.e.f. 25-04-2018 to 24-04-2023

502.	008515	Vitacompon Injection Each ml contains: Vitamin B1…10mg Vitamin B2…2mg Vitamin B6…5mg Nicotinamide…75mg Calcium Pantothenate…5mg	21-04-1988	Dy. No. 9260 dated 12-03-2018 10,000/-		Deferred for confirmation of formulation in RRA.
M/s. High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi						
503.	073882	Kert 8mg Tablet Each tablet contains Betahistine Dihydrochloride …. 8mg	01-04-2013	Dy. No. 9130 dated 12-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
504.	073883	Kert 16mg Tablet Each tablet contains Betahistine Dihydrochloride …. 16mg	01-04-2013	Dy. No. 9130 dated 12-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
505.	073884	Rement 20mg Tablet Each tablet contains Memantine HCI …. 20mg	01-04-2013	Dy. No. 9130 dated 12-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
506.	073885	Rement 10mg Tablet Each tablet contains Memantine HCI …. 10mg	01-04-2013	Dy. No. 9130 dated 12-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
507.	073886	Ufrim 20mg Tablet Each tablet contains Escitalopram …. 20mg	01-04-2013	Dy. No. 9130 dated 12-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
508.	073887	Lcyn 750 Tablet Each tablet contains Levofloxacin …. 750mg	01-04-2013	Dy. No. 9130 dated 12-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
509.	073888	Cint 1mg Tablet Each tablet contains Cinitapride Hydrogen tartrate eq. to Cinitapride …. 1mg	01-04-2013	Dy. No. 9130 dated 12-03-2018 10,000/-	31-03-2023	w.e.f. 01-04-2018 to 31-03-2023
M/s. Bosch Pharmaceuticals Pvt. Ltd. Plot no.209,Sector 23,Korangi Industrial Area, Karachi						
510.	075845	Norash Cream Each gm contains Benzalkonium Chloride …. 1mg Zinc Oxide …. 85mg	10-04-2013	Dy. No. 9133 dated 12-03-2018 10,000/-	09-04-2023	w.e.f. 10-4-2018 to 09-04-2023
511.	075846	Clim 1% Cream Each gm contains Clotrimazole …. 10mg	10-04-2013	Dy. No. 9133 dated 12-03-2018 10,000/-	09-04-2023	w.e.f. 10-4-2018 to 09-04-2023
M/s. Standpharm Pakistan (Pvt) Ltd., 20-Km Ferozepur Road, Lahore						
512.	074381	Bludol DS Suspension Each 5ml contains Ibuprofen …. 200mg	03-04-2013	Dy. No. 9964 dated 16-03-2018 10,000/-	02-04-2023	w.e.f. 03-4-2018 to 02-04-2023
513.	074384	Levra 250mg Tablet Each tablet contains Levetiracetam …. 250mg	03-04-2013	Dy. No. 9964 dated 16-03-2018 10,000/-	02-04-2023	w.e.f. 03-4-2018 to 02-04-2023

514.	074385	Levra 750mg Tablet Each tablet contains Levetiracetam …. 750mg	03-04-2013	Dy. No. 9964 dated 16-03-2018 10,000/-	02-04-2023	w.e.f. 03-4-2018 to 02-04-2023
515.	074386	Levra 1000mg Tablet Each tablet contains Levetiracetam …. 1000mg	03-04-2013	Dy. No. 9964 dated 16-03-2018 10,000/-	02-04-2023	w.e.f. 03-4-2018 to 02-04-2023
M/s. PharmEvo (Pvt) Ltd., A-29, North Western Industrial Zone Bin Qasim, Karachi						
516.	073818	Ramipace-D 10/12mg Tablet Each tablet contains Ramipril …. 10mg Hydrochlorothiazide …. 12.5mg	15-03-2013	Dy. No. 7950 dated 01-03-2018 10,000/-	14-03-2023	w.e.f. 15-3-2018 to 14-03-2023
517.	073854	Woncef 1g Injection Each vial contains Cefoperazone as Sodium …. 500mg Sulbactam as Sodium …. 500mg	27-03-2013	Dy. No. 7949 dated 01-03-2018 10,000/-	26-03-2023	w.e.f. 27-3-2018 to26-03-2023
518.	073853	Woncef 2g Injection Each vial contains Cefoperazone as Sodium …. 1g Sulbactam as Sodium …. 1g	27-03-2013	Dy. No. 7949 dated 01-03-2018 10,000/-	26-03-2023	w.e.f. 27-03-2018 to26-03-2023
519.	048560	Epik 200mg Tablet Each film coated tablet contains Topiramate …. 200mg	31-03-2008	Dy. No. 7947 dated 01-03-2018 10,000/-	30-03-2023	w.e.f. 31-03-2018 to 30-03-2023
520.	048561	Epik 100mg Tablet Each film coated tablet contains Topiramate …. 100mg	31-03-2008	Dy. No. 7946 dated 01-03-2018 10,000/-	30-03-2023	w.e.f. 31-03-2018 to 30-03-2023
521.	000858 -EX	Evorox 500mg Tablet Each tablet contains Cefuroxime Axetil D.C Grade (AT 60.00% Potency) 833.32mg eq. to ….. 500mg	11-03-2008	Dy. No. 7948 dated 01-03-2018 10,000/-	10-03-2023	w.e.f. 11-03-2018 to 10-03-2023
522.	004056 -EX	Trixafin 250mg I.M. inection Each vial contains Ceftriaxone Sodium …. 250mg	12-03-2013	Dy. No. 7932 dated 02-03-2018 10,000/-	11-03-2023	w.e.f. 12-03-2018 to 11-03-2023
523.	004057 -EX	Trixafin 500mg I.M. injection Each vial contains Ceftriaxone Sodium …. 500mg	12-03-2013	Dy. No. 7932 dated 02-03-2018 10,000/-	11-03-2023	w.e.f. 12-03-2018 to 11-03-2023
524.	004058 -EX	Trixafin 1g I.M. injection Each vial contains Ceftriaxone Sodium …. 1g	12-03-2013	Dy. No. 7932 dated 02-03-2018 10,000/-	11-03-2023	w.e.f. 12-03-2018 to 11-03-2023
525.	004059 -EX	Trixafin 250mg I.V. injection Each vial contains Ceftriaxone Sodium …. 250mg	12-03-2013	Dy. No. 7932 dated 02-03-2018 10,000/-	11-03-2023	w.e.f. 12-03-2018 to 11-03-2023

526.	004060 -EX	Trixafin 500mg I.V. injection Each vial contains Ceftriaxone Sodium …. 500mg	12-03-2013	Dy. No. 7932 dated 02-03-2018 10,000/-	11-03-2023	w.e.f. 12-03-2018 to 11-03-2023
527.	004061 -EX	Trixafin 1g I.V. injection Each vial contains Ceftriaxone Sodium …. 1g	12-03-2013	Dy. No. 7932 dated 02-03-2018 10,000/-	11-03-2023	w.e.f. 12-3-2018 to 11-03-2023
M/s. Macter International (Pvt) Ltd., F-216 S.I.T.E., Karachi						
528.	029788	Enzo 0.25mg Tablet Each tablet contains Alprazolam …. 0.25mg	11-03-2003	Dy. No. 8453 dated 06-03-2018 10,000/-		Deferred for confirmation of pshycotropic tablet section from the firm.
529.	029789	Enzo 0.5mg Tablet Each tablet contains Alprazolam …. 0.5mg	11-03-2003	Dy. No. 8453 dated 06-03-2018 10,000/-		Deferred for confirmation of pshycotropic tablet section from firm
530.	029790	Enzo 1mg Tablet Each tablet contains Alprazolam …. 1mg	11-03-2003	Dy. No. 8453 dated 06-03-2018 10,000/-		Deferred for confirmation of pshycotropic tablet section from firm.
531.	029794	Viron 600mg Capsule Each capsule contains Ribavirin …. 600mg	11-03-2003	Dy. No. 8453 dated 06-03-2018 10,000/-	10-03-2023	w.e.f. 11-03-2018 to 10-03-2023
532.	029791	Ultima 250mg Tablet Each tablet contains Clarithromycin …. 250mg	10-03-2003	Dy. No. 8454 dated 06-03-2018 10,000/-	09-03-2023	w.e.f. 10-03-2018 to 09-03-2023
533.	029792	Ultima 500mg Tablet Each tablet contains Clarithromycin …. 500mg	10-03-2003	Dy. No. 8454 dated 06-03-2018 10,000/-	09-03-2023	w.e.f. 10-03-2018 to 09-03-2023
M/s. Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi						
534.	000937 -EX	Getpanto Tablet 40mg Each enteric coated tablet contains Pantoprazole as Sodium Sesquihydrate ….. 40mg	10-05-2008	Dy. No. 8750 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023
535.	000938 -EX	Getmoxy Tablet 400mg Each film coated tablet contains Moxifloxacin as HCI …. 400mg	10-05-2008	Dy. No. 8750 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023
536.	000939 -EX	Amloget Tablet 5mg Each tablet contains Amlodipine Besylate …. 5mg	10-05-2008	Dy. No. 8754 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023
537.	000940 -EX	Amloget Tablet 10mg Each tablet contains Amlodipine Besylate …. 10mg	10-05-2008	Dy. No. 8754 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023

538.	000892 -EX	Palquine Tablet 200mg Each film coated tablet contains Hydroxychloroquine Sulphate …. 200mg	03-04-2008	Dy. No. 8753 dated 08-03-2018 10,000/-	02-04-2023	w.e.f. 03-04-2018 to 02-04-2023
539.	000935 -EX	Azoget Oral Suspension 200mg/5ml Each 5ml contains Azithromycin as Dihydrate …. 200mg	10-05-2008	Dy. No. 8756 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023
540.	000936 -EX	Azoget Oral Suspension 100mg/5ml Each 5ml contains Azithromycin as Dihydrate …. 100mg	10-05-2008	Dy. No. 8756 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023
541.	004103 -EX	Avestalo Tablet 5mg Each film coated tablet contains Escitalopram as Oxalate …. 5mg	04-04-2013	Dy. No. 8758 dated 08-03-2018 10,000/-	03-04-2023	w.e.f. 04-04-2018 to 03-04-2023
542.	004104 -EX	Avestalo Tablet 10mg Each film coated tablet contains Escitalopram as Oxalate …. 10mg	04-04-2013	Dy. No. 8758 dated 08-03-2018 10,000/-	03-04-2023	w.e.f. 04-04-2018 to 03-04-2023
543.	004105 -EX	Avestalo Tablet 15mg Each film coated tablet contains Escitalopram as Oxalate …. 15mg	04-04-2013	Dy. No. 8758 dated 08-03-2018 10,000/-	03-04-2023	w.e.f. 04-04-2018 to 03-04-2023
544.	004106 -EX	Avestalo Tablet 20mg Each film coated tablet contains Escitalopram as Oxalate …. 20mg	04-04-2013	Dy. No. 8758 dated 08-03-2018 10,000/-	03-04-2023	w.e.f. 04-04-2018 to 03-04-2023
545.	000933 -EX	Pigolite Plus Tablet 15mg/500mg Each film coated tablet contains Pioglitazone as HCI... 15mg Metformin as HCI.. 500mg	10-05-2008	Dy. No. 8755 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023
546.	000934 -EX	Pigolite Plus Tablet 15mg/850mg Each film coated tablet contains Pioglitazone as HCI …. 15mg Metformin as HCI …. 850mg	10-05-2008	Dy. No. 8755 dated 08-03-2018 10,000/-	09-05-2023	w.e.f. 10-05-2018 to 09-05-2023
M/s. Martin Dow Ltd., Plot No. 37, Sector 19, Korangi Industrial Area, Karachi						
547.	004375 -EX	Unipan Tablet Each Enteric Coated Tablet Contains:- Pantoprazole as Sodium Sesquihydrate USP . 40mg	25-11-2013	Dy. No. 34592 dated 18-10-2018 10000/-	24-11-2023	w.e.f. 25-11-2018 to 24-11-2023

Decision: Registration Board considered the case of above products and decision mentioned in the last column of above table.

Local Manufacturing (Vet)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13 - 14, Sector 15, Korangi Industrial Area, Karachi						
548.	074072	Neurozoc Injection Each 100ml contains Novaminsulfon …. 100mg Etilefrin …. 0.5mg Calcium Gluconate …. 250mg Magnesium Gluconate …. 25mg Sodium Salicylate …. 17.5mg Nicotinamide …. 0.75mg Caffeine …. 25mg Boric Acid …. 25mg	09-05-2013	Dy. No. 11675 dated 30-03-2018 10,000/-		Deferred for confirmation of status of Novaminsulfon containing formuations from concerned section.
549.	004563	Tribrissen Injection 48% Contains Trimethoprim (Vet) …. 8% w/v Sulphadiazine (Vet) …. 40% w/v	Transfer of registration dated 11-06-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	10-06-2023	w.e.f. 11-06-2018 to 10-06-2023
550.	004832	Tribrissen Oral Suspension Contains Trimethoprim (Vet) …. 8% w/v Sulphadiazine (Vet) …. 40% w/v	Transfer of registration dated 11-06-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	10-06-2023	w.e.f. 11-06-2018 to 10-06-2023
551.	004831	Darvisul Liquid Contains Diaveridine (Vet) …. 0.64% w/v Sulphaquinoxaline (Vet) …. 2.56% w/v	Transfer of registration dated 11-06-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	10-06-2023	w.e.f. 11-06-2018 to 10-06-2023
552.	025745	Oxanid Liquid Each ml contains Oxfendazole …. 22.65mg Oxyclozanide …. 62.50mg	Transfer of registration dated 11-06-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	10-06-2023	w.e.f. 11-06-2018 to 10-06-2023
553.	005127	Oxafax Liquid Each ml contains Oxfendazole ….. 22.65mg	11-06-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	10-06-2023	w.e.f. 11-06-2018 to 10-06-2023
554.	008687	Triquin Granules Contains Trimethoprim …. 4.62% Sulphaquinoxaline …. 15.02%	11-06-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	10-06-2023	w.e.f. 11-06-2018 to 10-06-2023
555.	007371	Vitasol Super Powder Each 100gm contains Vitamin A. 2,000,000 I.U Vitamin D. 400,000 I.U Vitamin E …. 160 I.U Vitamin K …. 900mg Vitamin B1 …. 125mg Vitamin B2 …. 2000mg Vitamin B6 …. 600mg	11-06-2013	Dy. No. 11675 dated 30-03-2018 10,000/-	10-06-2023	w.e.f. 11-06-2018 to 10-06-2023

		Vitamin B12…. 3000mcg Vitamin C …. 1000mg Folic Acid.... 200mg Nicotinamide..10,000mg Calcium Pantothenate.... 3000mg				
M/s. Nawan Laboratories (Pvt) Ltd., 136, Sector 15, Korangi Industrial Area, Karachi						
556.	014104	Albazol-S Bolus Each bolus contains: Albendazole…152mg	01-08-1993 Transfer of registration 31-03-1998	Dy. No. 8771 08-03-2018 10,000/-	30-03-2023	w.e.f. 31-03-2018 to 30-03-2023
557.	022146	Nephravit Oral Powder Each 100gm Contains: Methenamine ..65gm, Vitamin B-1….800mg, Vitamin B-2….920mg, Vitamin K-3….200mg	05-11-1998	Dy. No. 34756 dated 18-10-2018 10000/-	04-11-2023	w.e.f. 05-11-2018 to 04-11-2023
558.	022148	Penbiotic Injection Each Vial Contains:- Benzyl Penicillin 500,000 I.U. Procaine Penicillin 1,500,000 I.U. Streptomycin Sulphate 5gm	05-11-1998	Dy. No. 34755 dated 18-10-2018 10000/-	04-11-2023	Deferred for confirmation of penicillin section
559.	022149	Lincowan Forte Premix Powder Each Kg Powder Contains Lincomycin Hcl 110gm	05-11-1998	Dy. No. 34757 dated 18-10-2018 10000/-	04-11-2023	w.e.f. 05-11-2018 to 04-11-2023
560.	022151	Olandox Powder Each Kg Contains: - Olaquindox 100gm	05-11-1998	Dy. No. 34758 dated 18-10-2018 10000/-	04-11-2023	w.e.f. 05-11-2018 to 04-11-2023
561.	022152	Colisan Injection Each 100 ml contains: Colistin Sulphate Eq To 20MIU Colistin Base	05-11-1998	Dy. No. 34754 dated 18-10-2018 10000/-	04-11-2023	w.e.f. 05-11-2018 to 04-11-2023
562.	022153	Nawagon Powder Each Kg Contains: - Dimethylester Phosphonic Acid (Trichlorphon)985gm	05-11-1998	Dy. No. 34759 dated 18-10-2018 10000/-	04-11-2023	w.e.f. 05-11-2018 to 04-11-2023

Decision: Registration Board considered the cases of above products and decisions are mentioned in last column of above table.

Local Manufacturing (Human)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Remarks (if any)
M/s. Pharmix Laboratories (Pvt) Ltd. , 21-Km Ferozepur Road, Lahore						
563.	053784	Alide Capsule 500mg Each capsule contains Azithromycin as Dihydrate …. 500mg	16-12-2008	Dy. No. 8605 dated 07-03-2018 10,000/-		
Shortcomings Following shortcoming has been observed: ➢ Evidence of last renewal is required						
M/s. Amros Pharmaceuticals, A-96 S.I.T.E., North Karachi						
564.	004051 -EX	Mediquin Tablet Each tablet contains Quinine Sulphate …. 300mg	12-03-2013	Dy. No. 8452 dated 06-03-2018 10,000/-		
565.	004052 -EX	Haemoforte Syrup Each 100ml contains Ferric Ammonium Citrate …. 1g Folic Acid …. 11mg Pyridoxine HCI …. 48mg Thiamine HCI …. 24mg Nicotinamide …. 220mg	12-03-2013	Dy. No. 8452 dated 06-03-2018 10,000/-		
566.	004053 -EX	Regogent Eye/Ear Drops Each 10ml contains Gentamycin Sulphate eq. to Gentamycin Base …. 0.3% w/v	12-03-2013	Dy. No. 8452 dated 06-03-2018 10,000/-		
567.	004054 -EX	Regozone Tablet Each tablet contains Dexamethasone …. 0.5mg	12-03-2013	Dy. No. 8452 dated 06-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Latest cGMP inspection letter required. ➢ Section approval letter issued by licensing division is required for confirmation of steroidal (tablet) section.						
M/s. Sante (Pvt) Ltd., A/97 S.I.T.E Super Highway, Karachi						
568.	075812	Softeal 0.3% Eye Drops Each ml contains Hydroxypropylmethyl Cellulose …. 3mg	01-04-2013	Dy. No. 11440 dated 28-03-2018 10,000/-/-		
Shortcomings: Following shortcoming has been observed: ➢ Approval status of product in Reference Regulatory Agency is required.						
M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13 - 14, Sector 15, Korangi Industrial Area, Karachi						
569.	001000 -EX	Tramin 250mg Capsule Each capsule contains Tranexamic Acid …. 250mg	28-06-2008	Dy. No. 11675 dated 30-03-2018 10,000/-		

570.	000997 -EX	Tramin 250mg Injection Each 5ml contains Tranexamic Acid …. 250mg	28-06-2008	Dy. No. 11675 dated 30-03-2018 10,000/-		
571.	009730	Transamin Capsule 500mg Each capsule contains Tranexamic Acid …. 500mg	21-04-1988	Dy. No. 11675 dated 30-03-2018 10,000/-		
572.	000999 -EX	Tramin 500mg Capsule Each capsule contains Tranexamic Acid …. 500mg	28-06-2008	Dy. No. 11675 dated 30-03-2018 10,000/-		
573.	009816	Anapaz Drops Each ml contains Hyoscyamine Sulphate …. 0.125mg	23-05-1988 Change of brand name dated	Dy. No. 11675 dated 30-03-2018 10,000/-		
574.	001000 -EX	Tramin 250mg Capsule Each capsule contains Tranexamic Acid …. 250mg	28-06-2008	Dy. No. 11675 dated 30-03-2018 10,000/-		
575.	010103	Disal Powder Each sachet contains Sodium Chloride …. 3.5g Potassium chloride. 1.5g Sodium Bicarbonate. 2.5g Dextrose Anhydrous.. 20g Flavour Banana, Strawberry, Lime, Mango and Orange.	27-05-1988	Dy. No. 11675 dated 30-03-2018 10,000/-		
576.	000998 -EX	Tramin Injection 500mg Each 5ml contains Tranexamic Acid. 500mg	28-06-2008	Dy.#11675 30-03-2018 10,000/-		
577.	021667	Amovac 10mg Tablet Each tablet contains Amlodipine Besylate …. 10mg	20-05-1998	Dy. No. 11675 dated 30-03-2018 10,000/-		
578.	021668	Eknit Tablet Each tablet contains Scenidazole …. 500mg	20-05-1998	Dy. No. 11675 dated 30-03-2018 10,000/-		
579.	022071	Enflor Sachet 250mg Each sachet contains Lyophilised Saccharomyces Boulardii 282.5mg corresponding to …. 250mg of yeast	17-06-1998	Dy. No. 11675 dated 30-03-2018 10,000/-		
580.	022072	Enflor Capsule 250mg Each capsule contains Lyophilised Saccharomyces Boulardii 282.5mg corresponding to …. 250mg of yeast (Biological)	17-06-1998	Dy. No. 11675 dated 30-03-2018 10,000/-		The Central Licensing Board vide letter date 11-04-2018 considered and approved the grant of amendment / expension to the firm in partial modification of their letter dated 04-12-2014 for sachet probiotics. The Borad further requrested that

						the Drug Registration Board may decide the matter in the light of the decision of the DRAP Policy Board.
581.	021874	Stimol Oral Liquid Each 100ml contains Citrulline Maleate (50% Citrulline Maleate Solution) …. 10g	20-06-1998	Dy. No. 11675 dated 30-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Differential fee required for regularization of renewal of year 2013 in the light of SRO 1117/2012.Renewal of year 2013 was submitted on 27-08-2012 with fee of Rs.4000/-. ➢ Detail of manufacturing facility of Lyophilized Saccharomyces Boulardii is required. ➢ Approval status of product in RRA is required.						
M/s. Epla Laboratories (Pvt) Ltd., D-12, Estate Avenue, S.I.T.E. Karachi						
582.	003912	Eplacin Tablet Each tablet contains Aspirin …. 200mg Paracetamol …. 200mg	03-05-1978	Dy. No. 9128 dated 12-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Transfer of registration of product in the name of M/s. Epla Laboratories is required. ➢ Approval status of product in RRA						
M/s. Wilson's Pharmaceuticals, Plot No. 387-388, Sector I-9, Industrial Area, Islamabad						
583.	075373	Stay-H Tablet Each film coated tablet contains: Aliskirin …. 300mg Hydrochlorothiazide …. 12.5mg	17-04-2013	Dy. No. 11429 dated 28-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Detail of chemical composition of Aliskirin is required as it is in the form of Aliskirin Hemifumarate in reference regulatory agencies.						
M/s. Ferozsons Laboratories Ltd., Amangarh Nowshehra, Khyber Pakhtunkhwa						
584.	021203	Helicure Contains: Clarithromycin Tablet 250mg Omeprazole enteric coated pellets eq. to Omeprazole capsule …. 20mg Metronidazole Tablet…. 400mg	25-04-1998	Dy. No. 10794 dated 22-03-2018 10,000/-		Approval status of formulation in RRA
585.	021204	Genesis Tablet Each tablet contains: Finasteride …. 1mg	25-04-1998	Dy. No. 10795 dated 22-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Approval status of formulation in RRA is required. ➢ Section approval letter issued by Licensing Division for product being steroidal dosage form.						
M/s. Regent Laboratories, C-20, S.I.T.E., Super Highway, Karachi						
586.	030102	Roral Syrup Each 5ml contains Loratadine …. 5mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		

	030103	Roral Tablet Each tablet contains Loratadine …. 10mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
587.	030106	Cipronet 250mg Tablet Each tablet contains Ciprofloxacin …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
588.	030107	Cipronet 500mg Tablet Each tablet contains Ciprofloxacin …. 500mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
589.	030108	Revonil 250mg Tablet Each tablet contains Levofloxacin as Hemihydrate …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
590.	030109	Revonil 500mg Tablet Each tablet contains Levofloxacin as Hemihydrate …. 500mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
591.	030110	Azelide 250mg Tablets Each tablet contains Azithromycin as Dihydrate …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
592.	030111	Azelide 200mg Suspension Each 5ml contains Azithromycin …. 200mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
593.	030112	Remoxy 250mg Capsule Each capsule contains AmoxycillinTrihydrate eq. to Amoxycillin Base …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
594.	030113	Remoxy 500mg Capsule Each capsule contains AmoxycillinTrihydrate eq. to Amoxycillin Base …. 500mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
595.	030114	Remoxy 125mg Suspension Each 5ml contains AmoxycillinTrihydrate eq. to Amoxycillin Base …. 125mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
596.	030115	Remoxy 250mg Suspension Each 5ml contains AmoxycillinTrihydrate eq. to Amoxycillin Base …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
597.	030116	Pencil 250mg Capsule Each capsule contains Ampicillin Trihydrate eq. to Ampicillin …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
598.	030117	Pencil 500mg Capsule Each capsule contains Ampicillin Trihydrate eq. to Ampicillin …. 500mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		

599.	030118	Pencil 125mg Suspension Each 5ml contains Ampicillin Trihydrate eq. to Ampicillin …. 125mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
600.	030119	Recard 150mg Tablet Each enteric coated tablet contains Aspirin …. 150mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
601.	030120	Rentolin 2mg Tablet Each tablet contains Salbutamol Sulphate eq. to Salbutamol …. 2mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
602.	030122	Rentolin Syrup Each 5ml contains Salbutamol Sulphate eq. to Salbutamol …. 2mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
603.	030123	Recid Tablet Each tablet contains Famotidine …. 40mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
604.	030124	Recid Syrup Each 5ml contains Famotidine …. 10mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
605.	030125	Regopyrin 50mg Tablet Each tablet contains Diclofenac Potassium …. 50mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
606.	030128	Regoclox Suspension Each 5ml contains Ampicillin Trihydrate eq. to Ampicillin …. 125mg Cloxacillin Sodium eq. to Cloxacillin base …. 125mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
607.	030129	Megodine Tablet Each tablet contains Metronidazole …. 250mg Di-Iodohydroxyquinoline …. 325mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
608.	030130	Megodine Suspension Each 5ml contains Metronidazole Benzoate … 321.6mg Di-Iodohydroxyquinoline …. 200mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
609.	030131	Mycef 100mg Suspension Each 5ml contains Cefixime Trihydrate …. 100mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
610.	030132	Mycef 400mg Capsule Each capsule contains Cefixime Trihydrate …. 400mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
611.	030133	Prodral 10mg Tablet Each tablet contains Propranolol as HCI …. 10mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		

612.	030134	Prodral 40mg Tablet Each tablet contains Propranolol as HCI …. 40mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
613.	030135	Doprine 5mg Tablet Each tablet contains Amlodipine Besylate …. 5mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
614.	030136	Doprine 10mg Tablet Each tablet contains Amlodipine Besylate …. 10mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
615.	030137	Pril 5mg Tablet Each tablet contains Enalapril Maleate …. 5mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
616.	030138	Pril 10mg Tablet Each tablet contains Enalapril Maleate …. 10mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
617.	030139	Colexib 100mg Tablet Each tablet contains Celecoxib …. 100mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
618.	030140	Colexib 200mg Tablet Each tablet contains Celecoxib …. 200mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
619.	030141	Rusort 50mg Tablet Each tablet contains Losartan Potassium …. 50mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
620.	030142	Monorid 20mg Tablet Each tablet contains Isosorbide Mononitrate …. 20mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
621.	030143	Monorid 40mg Tablets Each tablet contains Isosorbide Mononitrate …. 40mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
622.	030144	Racor 10mg Tablet Each tablet contains Simvastatin …. 10mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
623.	030145	Racor 20mg Tablet Each tablet contains Simvastatin …. 20mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
624.	030148	Ompizol 20mg Capsule Each capsule contains Omeprazole …. 20mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
625.	030149	Napxen 250mg Tablet Each tablet contains Naproxen …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
626.	030150	Napxen 500mg Tablet Each tablet contains	20-03-2003	Dy. No. 10215 dated		

		Naproxen …. 500mg		19-03-2018 10,000/-		
627.	030151	Orphadine Tablet Each tablet contains Orphenradine Citrate …. 35mg Paracetamol …. 450mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
628.	030152	Randazol Tablet Each tablet contains Albendazole …. 200mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
629.	030153	Randazol Suspension Each 5ml contains Albendazole …. 100mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
630.	030154	Pancare Tablet Each tablet contains Piroxicam …. 20mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
631.	030155	Rivid 200mg Tablet Each tablet contains Ofloxacin …. 200mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
632.	030156	Looslac Syrup Each 5ml contains Lactulose …. 3.35g	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
633.	030158	Pheno Tablet Each tablet contains Phenobarbitone …. 30mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
634.	030159	Benovate-In Cream Contains Betamethasone as Valerate …. 0.1% neomycin Sulphate. 0.5%	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
635.	030160	Kanarod-N Cream Contains Dexamethasone …. 0.1% Neomycin Sulphate …. 0.5%	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
636.	030161	Regofax Skin Ointment Each gm contains Polymyxin B Sulphate …. 10,000 Units Bacitracin Zinc …. 500 Units	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
637.	030162	Pancare Gel Each 100gm contains Piroxicam …. 500mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
638.	030163	Regofenac Gel Each 100gm contains Diclofenac Diethylamonium Salt 1.16g eq. to Diclofenac Sodium …. 1g	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		

639.	030164	Wellcef 125mg Suspension Each 5ml contains Cephradine …. 125mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
640.	030165	Wellcef 250mg Suspension Each 5ml contains Cephradine …. 250mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
641.	030166	Wellcef 500mg Capsule Each capsule contains Cephradine …. 500mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
642.	030167	Tencid 100mg Tablet Each tablet contains Flurbiprofen …. 100mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
643.	030168	Hylin-Plus Syrup Each 5ml contains Aminophyline …. 32mg Diphenhydramine HCI …. 8mg Ammonium Chloride …. 30mg Menthol …. 0.98mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
644.	030169	Amonil Syrup Each 5ml contains Ammonium Chloride …. 100mg Sodium Citrate …. 58mg Chlorpheniramine Maleate …. 2mg Menthol …. 1mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
645.	030171	Alumico Suspension Each 5ml contains Aluminium Hydroxide …. 215mg Magnesium Hydroxide …. 80mg Simethicone …. 25mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
646.	030172	Resil Tablet Each tablet contains Magnesium Tricyclate …. 250mg Dried Aluminium Hydroxide …. 120mg Peppermint oil …. 03ml	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
647.	030173	Resil Suspension Each 5ml contains Magnesium Hydroxide …. 80mg Aluminium Hydroxide …. 215mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
648.	030174	Protozol 200mg Tablet Each tablet contains Metronidazole …. 200mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
649.	030175	Protozol 400mg Tablet Each tablet contains Metronidazole …. 400mg	20-03-2003	Dy. No. 10215 dated 19-03-2018		

				10,000/-		
650.	030178	Citrolyte Syrup Each 5ml contains Sodium Acid Citrate …. 1.25g	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
651.	030179	Regocof Cough Syrup Each 5ml contains Ammonium Chloride …. 100mg Sodium Citrate …. 60mg Chlorpheniramine Maleate …. 2mg Ephedrine HCI …. 7mg Menthol …. 1mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
652.	030180	Carminative Mixture Each 100ml contains Soda Bi-Carbonate …. 5mg Tr.Card Co …. 6.5ml Spirit Ammonia Aromatic …. 6.5ml Tr. Zingiberis Forte..0.4ml Aqua Menthapip…. 4.8ml	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
653.	030183	Regofid DM Cough Tablet Each tablet contains Triprolidine HCI …. 1.25mg Pseudoephedrine HCI …. 30mg Dextromethorphan HBr …. 10mg	20-03-2003	Dy. No. 10215 dated 19-03-2018 10,000/-		
654.	030176	Paracetamol Compound Tablet Each tablet contains Paracetamol …. 75mg Aspirin …. 300mg Caffeine …. 10mg	21-03-2003	Dy. No. 10214 dated 19-03-2018 10,000/-		
655.	030177	Hylin Tablet Each tablet contains Aminophylline …. 100mg	21-03-2003	Dy. No. 10214 dated 19-03-2018 10,000/-		

Shortcomings:

Following shortcoming has been observed:

- Evidence of submission of last renewal required
- Latest cGMP report required
- Section approval letter issued by Licensing Division is required
- Both Undertaking as per approved SOP is required.
- Valid DML required
- Approval status of formulation in RRA
- Source fixation letter required for pellets of Omeprazole and in case of imported pellets prescribed fee required for renewal of year 2013 &2018.
- Source fixation letter of bulk importer of Lactulose related to Looslac Syrup and prescribed fee required for regularization of renewal of year 2013 & 2018.

M/s. Delux Chemical Industries, Plot No. 26-A1 Landhi Karachi						
656.	048573	Mega-III Syrup Each 5ml contains Iron III Hydroxide Polymaltose complex 400mg eq. to Elemental Iron …. 50mg	29-04-2008	Dy. No. 8221 dated 05-03-2018 10,000/-		
657.	030190	Kidcold Syrup Each 5ml contains Paracetamol …. 80mg Pseudoephedrine HCI …. 15mg Chlorpheniramine Maleate …. 1mg	12-03-2003	Dy. No. 8221 dated 05-03-2018 10,000/-		
658.	030076	Deemac Suspension Each 5ml contains Mefenamic Acid …. 50mg	12-03-2003	Dy. No. 8221 dated 05-03-2018 10,000/-		
659.	013944	Deemac Tablet Each tablet contains Mefenamic Acid …. 250mg	16-01-1993	Dy. No. 9132 dated 12-03-2018 20,000/-		
660.	013945	Deefol Tablet Each tablet contains Folic Acid …. 5mg	16-01-1993	Dy.. 9132 12-03-2018 10,000/-		
661.	013946	Deepol Tablet Each tablet contains Paracetamol …. 500mg	16-01-1993	Dy. 9132 12-03-2018 10,000/-		
662.	013947	Deemine Tablet 4mg Each tablet contains Chlorpheniramine Maleate …. 4mg	16-01-1993	Dy. No. 9132 dated 12-03-2018 10,000/-		
663.	013948	Deerin Tablet Each tablet contains Aspirin …. 300mg	16-01-1993	Dy.9132 . 12-03-2018 10,000/-		
664.	013950	Deeoxine Capsule Each capsule contains Oxytetracycline HCI …. 250mg	16-01-1993	Dy. No. 9132 dated 12-03-2018 10,000/-		
665.	013951	Deemycin Skin Ointment Contains Neomycin Sulphate …. 0.5%	16-01-1993	Dy. No. 9132 dated 12-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Evidence of submission of last renewal required ➢ Latest CGMP report required ➢ Section approval letter issued by Licensing Division is required ➢ Both Undertaking as per approved SOP is required. ➢ Valid DML required ➢ Approval status of formulation in RRA						
M/s. Standpharm Pakistan (Pvt) Ltd., 20-Km Ferozepur Road, Lahore						
666.	018659	Bludol Suspension Each 5ml contains Ibuprofen …. 100mg	06-02-1996	Dy. No. 9964 dated 16-03-2018 10,000/-		Clarification required regarding the renewal application submitted in 2018, according to the initial registration date renewal is due on 05-02-2016.

						Evidence of any post registration variation Evidence of renewal of year 2013.
667.	018655	Coldrex Syrup Each 15ml contains Paracetamol …. 325mg Dextromethorphan HBr …. 10mg Chlorpheniramine Maleate …. 1mg	23-01-1996 Change of formulation dated 08-08-2001	Dy. No. 9964 dated 16-03-2018 10,000/-		Clarification required regarding the renewal application submitted in 2018, according to the initial registration date renewal is due on 05-02-2016. Evidence of any post registration variation Evidence of renewal of year 2013.
668.	074382	Viloc Suspension 250mg Each 5ml contains Ciprofloxacin as HCI …. 250mg	03-04-2013	Dy. No. 9964 dated 16-03-2018 10,000/-		Firm is advised to comply the decision of 290th meeting of registration board regarding Manufacturing Requirement of Diluent for Ciprofloxacin Dry Powder Suspension before further processing the renewal of product.
669.	074383	Viloc Suspension 125mg Each 5ml contains Ciprofloxacin as HCI …. 125mg	03-04-2013	Dy. No. 9964 dated 16-03-2018 10,000/-		Firm is advised to comply the decision of 290th meeting of registration board regarding Manufacturing Requirement of Diluent for Ciprofloxacin Dry Powder Suspension before further processing the renewal of product
M/s. Humayun International Pharma (Pvt) Ltd., 20-Km Satiana Road, Faisalabad						
670.	074325	Pakvit Injection 5mg Each ml contains Cholecalciferol…5mg	05-04-2013	Dy. No. dated 22-03-2018 10,000/-		

Shortcomings: Following shortcoming has been observed:

- An undertaking that the applied products have never been de-registered.
- An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy/misinformation is detected / observed the firm/company will be held responsible as per relevant laws.
- Attested copy of valid Drug Manufacturing License.
- Attested copy of last inspection report conducted by DRAP.
- Approval of the section / manufacturing facility (by Central Licensing Board).
- Brief report of last manufactured batch.
- Any post registration variation since grant of registration
- Approval status of products in Reference Drug Agencies.

M/s. Elko Organization (Pvt) Ltd., Plot No 27 & 28, Sector 12-B, North Karachi, Industrial Area Karachi						
671.	030034	Elkopheniramine Tablet Each tablet contains Chlorpheniramine	24-03-2003	Dy. No. 11057 dated 26-03-2018		

		Maleate …. 4mg		10,000/-		
672.	030035	Elfolic Tablet Each tablet contains Folic Acid …. 5mg	24-03-2003	Dy. No. 11057 dated 26-03-2018 10,000/-		
673.	030036	Elkofur Tablet Each tablet contains Furazolidone …. 100mg	24-03-2003	Dy. No. 11057 dated 26-03-2018 10,000/-		
674.	008750	Dextrose 4.3% + Sodium Chloride 0.18% w/v Infusion Each 100ml contains Dextrose …. 4.3% Sodium Chloride …. 0.18% w/v	30-03-1998	Dy. No. 11057 dated 26-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Renewal application was submitted late but within sixty days prescribed fee required. ➢ An undertaking that the applied products have never been de-registered. ➢ An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. ➢ Approval of the section / manufacturing facility (by Central Licensing Board). ➢ Brief report of last manufactured batch. ➢ Any post registration variation since grant of registration ➢ Approval status of products in Reference Drug Agencies.						
M/s. Medicraft Pharmaceuticals (Pvt) Ltd., 126-B Industrial Estate Hayatabad, Peshawar						
675.	028988	Clafax Tablet 250mg Each tablet contains Clarithromycin …. 250mg	26-03-2003	Dy. No. 8592 dated 07-03-2018 10,000/-		
676.	028989	Clafax Tablet 500mg Each tablet contains Clarithromycin …. 500mg	26-03-2003	Dy. No. 8592 dated 07-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Renewal of year 2013 has been submitted late but within sixty days prescribed fee required for regularization. ➢ Latest GMP inspection report required. ➢ An undertaking that the applied products have never been de-registered. ➢ An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. ➢ Approval of the section / manufacturing facility (by Central Licensing Board). ➢ Brief report of last manufactured batch.						
M/s. Shaigan Pharmaceutical (Pvt) Ltd., 14-Km Adyala Road, Post Office Dahgal, Rawalpindi						
677.	057267	Remet-5 Tablet Each tablet contains Ramipril …. 5mg	04-04-2009	Dy. No. 8058 02-03-2018 10,000/-		
678.	057268	Remet-2.5 Tablet Each tablet contains Ramipril …. 2.5mg	04-04-2009	Dy. No. 8058 dated 02-03-2018 10,000/-		
679.	057269	Remet-1.25 Tablet Each tablet contains Ramipril …. 1.25mg	04-04-2009	Dy. No. 8058 dated 02-03-2018 10,000/-		
680.	049130	Mionex Tablet 400mg Each tablet contains	03-04-2008	Dy. No. 8058 dated 02-03-		

		Moxifloxacin as HCI …. 400mg		2018 10,000/-		
681.	049131	Fertab Tablet Each tablet contains Clomiphene Citrate …. 50mg	03-04-2008	Dy. No. 8058 dated 02-03-2018 10,000/-		
682.	049137	Cefdin Dry Suspension 125mg Each 5ml contains Cefdinir …. 125mg	03-04-2008	Dy. No. 8059 dated 02-03-2018 10,000/-		
683.	049138	Cefdin Dry Suspension 250mg Each 5ml contains Cefdinir …. 250mg	03-04-2008	Dy. No. 8059 dated 02-03-2018 10,000/-		
684.	049139	Cefdin Capsule Each capsule contains Cefdinir …. 300mg	03-04-2008	Dy. No. 8059 dated 02-03-2018 10,000/-		
685.	049140	Tepride Tablet Each tablet contains Itopride HCI …. 50mg	03-04-2008	Dy. No. 8059 dated 02-03-2018 10,000/-		
686.	049187	Tenocin Tablet Each tablet contains Minocycline as HCI …. 100mg	05-05-2008	Dy. No. 8059 dated 02-03-2018 10,000/-		
687.	057270	Dilgem Tablet 1mg Each tablet contains Glimepiride …. 1mg	04-04-2009	Dy. No. 8060 02-03-2018 10,000/-		
688.	057273	Dilgem Tablet 2mg Each tablet contains Glimepiride …. 2mg	04-04-2009	Dy. No. 8060 dated 02-03-2018 10,000/-		
689.	057272	Dilgem Tablet 3mg Each tablet contains Glimepiride …. 3mg	04-04-2009	Dy. No. 8060 dated 02-03-2018 10,000/-		
690.	057271	Dilgem Tablet 4mg Each tablet contains Glimepiride …. 4mg	04-04-2009	Dy. No. 8060 dated 02-03-2018 10,000/-		
691.	057274	Dilgem Plus Tablet Each tablet contains Glimepiride …. 1mg Metformin HCI …. 500mg	04-04-2009	Dy. No. 8060 dated 02-03-2018 10,000/-		Show cause notice has been issued to the formulation by the concerned section.
692.	057275	Gluzon Tablet 15mg Each tablet contains Pioglitazone as HCI …. 15mg	04-04-2009	Dy. No. 8061 dated 02-03-2018 10,000/-		
693.	057276	Gluzon Tablet 30mg Each tablet contains Pioglitazone as HCI …. 30mg	04-04-2009	Dy. No. 8061 dated 02-03-2018 10,000/-		
694.	057277	Gluzon Plus Tablet Each tablet contains Pioglitazone as HCI …. 15mg Metformin as HCI …. 500mg	04-04-2009	Dy. No. 8061 dated 02-03-2018 10,000/-		
695.	049151	Ecad Tablet	09-04-2008	Dy. No. 8061		

		Each tablet contains Elemental Calcium.400mg Vitamin D …. 100 I.U.		dated 02-03-2018 10,000/-		
696.	049152	Gezlin Tablet Each tablet contains Gemifloxacin as Mesylate …. 320mg	09-04-2008	Dy. No. 8061 dated 02-03-2018 10,000/-		

Shortcomings: Following shortcoming has been observed:

- Latest GMP inspection report required.
- An undertaking that the applied products have never been de-registered.
- An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws.
- Approval of the section / manufacturing facility (by Central Licensing Board).
- Brief report of last manufactured batch.

M/s. English Pharmaceutical Industries, Link Katarband Road, Thokar Niaz Baig, Multan Road, Lahore

697.	074332	Biotic-P 1.20 M.I.U. Injection Each vial contains Penicillin G Benzathine …. 1.20 M.I.U.	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
698.	074333	Biotic-P 0.60 M.I.U. Injection Each vial contains Penicillin G Benzathine …. 0.60 M.I.U.	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
699.	074334	Enmox 250mg Injection Each vial contains Amoxicillin Sodium eq. to Amoxicillin …. 250mg	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
700.	074335	Zyncillin 500mg Injection Each vial contains Ampicillin Sodium eq. to Ampicillin …. 500mg	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
701.	074336	Zyncillin 250mg Injection Each vial contains Ampicillin Sodium eq. to Ampicillin …. 250mg	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
702.	074337	Ampitan 750mg Injection Each vial contains Ampicillin Sodium eq. to Ampicillin …. 500mg Sulbactam Sodium eq. to Sulbactam …. 250mg	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
703.	074338	Chroncef 2g Injection Each ml contains Ceftriaxone as Sodium …. 2g	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
704.	074339	Cefi 2g Injection Each ml contains Cefepime HCI with L-Arginine eq. to Cefepime …. 2g	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		
705.	074340	Xim DS Suspension Each 5ml contains Cefixime as Trihydrate …. 200mg	26-03-2013	Dy. No. 11061 dated 26-03-2018 10,000/-		

Shortcomings: Following shortcoming has been observed:

- Renewal application has been submitted late but within sixty days prescribed fee required.

M/s. Macter International (Pvt) Ltd., F-216 S.I.T.E., Karachi

706.	029793	Ultima 125mg Suspension Each 5ml contains Clarithromycin ... 125mg	10-03-2003	Dy. No. 8454 dated 06-03-2018 10,000/-		
707.	029786	Maxima 400mg Capsules Each capsule contain Cefixime …. 400mg	10-03-2003	Dy. No. 8454 dated 06-03-2018 10,000/-		
708.	029787	Maxima 100mg Suspension Each capsule contains Cefixime …. 100mg	10-03-2003	Dy. No. 8454 dated 06-03-2018 10,000/-		

Shortcomings: Following shortcoming has been observed:

- Clarification required regarding the source of granules of Clarithromycin and in case of imported source differential fee required for regularization of renewal of year 2013 &2018.
- Approval of the section / manufacturing facility of cephalosporin (by Central Licensing Board).

M/s. Getz Pharma (Pvt) Ltd., Plot No. 29-30, Sector 27, Korangi Industrial Area Karachi

709.	022019	Ceftazid 250mg Injection Each vial contains Ceftazidime Pentahydrate, Sterile …. 29.5mg Import in Bulk from M/s. LG Chemical Ltd. Chun Buk-Do, Korea and repack locally	20-05-1998	Dy. No. 8757 dated 08-03-2018 20,000/-		
710.	022020	Ceftazid 500mg Injection Each vial contains Ceftazidime Pentahydrate, Sterile …. 59mg Import in Bulk from M/s. LG Chemical Ltd. Chun Buk-Do,Korea and repack locally	20-05-1998	Dy. No. 8757 dated 08-03-2018 20,000/-		
711.	022021	Ceftazid 1g Injection Each vial contains Ceftazidime Pentahydrate, Sterile …. 118mg Import in Bulk from M/s. LG Chemical Ltd. Chun Buk-Do,Korea **and repack locally**	20-05-1998	Dy. No. 8757 dated 08-03-2018 20,000/-		
712.	075970	Titro Powder for Inhalation 18mcg Each capsule contains Tiotropium Bromide Monohydrate eq. to Tiotropium …. 18mcg	30-05-2013	Dy. No. 8751 dated 08-03-2018 10,000/-		

Shortcomings: Following shortcoming has been observed:

- Detail required, either the primary packaging, secondary packaging and quality release of product are done locally or product is imported in finished form.
- Free sale status of product in market.
- Original legalized valid COPP is required.
- Original legalized valid GMP certificate is required as copy is submitted.
- Latest DRAP attested invoice.
- Prescribed fee required for regularization of renewal of year 2013 as the products are imported in bulk and locally repack.
- Clarification regarding the manufacturing facility of Dry Powder for inhalation, in the light of decision of

290th meeting of Registration Board.

M/s. Pakistan Pharmaceutical Products (Pvt) Ltd., D/122, S.I.T.E. Karachi

713.	003493	Cloramidina Eye Ointment Each 10gm contains Chloramphenicol …. 1% w/w	13-03-1978 Change of brand name dated 29-06-1982	Dy. No. 8222 dated 05-03-2018 10,000/-		
714.	003489	Cloramidina Ear Drops Each 100ml contains Chloramphenicol …. 1g	13-03-1978 Change of brand name 29-06-1982	Dy. No. 8222 dated 05-03-2018 10,000/-		
715.	003495	Cloramidina Eye Drops Each 100ml contains Chloramphenicol …. 0.5g	13-03-1978 Change of brand name 29-06-1982	Dy. No. 8222 dated 05-03-2018 10,000/-		
716.	003491	Sa Cit Syrup Each 5ml contains Sodium Acid Citrate …. 1.25g	13-03-1978 Change of brand name 07-01-1986	Dy. No. 8222 dated 05-03-2018 10,000/-		

Shortcomings: Following shortcoming has been observed:

- Latest GMP inspection report required.
- An undertaking that the applied products have never been de-registered.
- An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws.
- Approval of the section / manufacturing facility (by Central Licensing Board).
- Brief report of last manufactured batch.
- Copy of Valid DML.

M/s. Espoir Pharmaceuticals PCSIR KLC, PCSIR Laboratories Complex, Shahrah-e-Dr. Salim-Uz-Zaman Siddiqui off University Road, Karachi

717.	073821	Enfys Capsule 20mg Each capsule contains Esomeprazole as Magnesium Trihydrate enteric coated pellets eq. to Esomeprazole …. 20mg Pellets will be purchased in bulk from M/s.Vision Pharmaceuticals	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
718.	073822	Enfys Capsule 40mg Each capsule contains Esomeprazole as Magnesium Trihydrate enteric coated pellets eq. to Esomeprazole…. 40mg Pellets will be purchased in bulk from M/s.Vision Pharmaceuticals	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
719.	073819	Refuge Capsule 20mg Each capsule contains Omeprazole enteric coated pellets eq. to Omeprazole …. 20mg Pellets will be purchased in bulk from M/s.Vision Pharmaceuticals	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		

720.	073820	Refuge Capsule 40mg Each capsule contains Omeprazole enteric coated pellets eq. to Omeprazole …. 40mg Pellets will be purchased in bulk from M/s.Vision Pharmaceuticals	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
721.	073823	Pdif Capsule 40mg Each enteric coated tab contains Pantoprazole Sodium Sesquihydrate eq. to Pantoprazole …. 40mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
722.	073824	Invicta 300mg Tablet Each tablet contains Dexibuprofen …. 300mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
723.	073825	Titlis 80/480 Tablet Each film coated tablet contains Artemether …. 80mg Lumefantrine …. 480mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
724.	073826	Titlis 20/120 Tablet Each film coated tablet contains Artemether …. 20mg Lumefantrine …. 120mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
725.	073827	invicta 400mg Tablet Each tablet contains Dexibuprofen …. 400mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
726.	073828	Titlis 40/240 Tablet Each film coated tablet contains Artemether …. 40mg Lumefantrine …. 240mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
727.	073829	RH-12 Sachet Each sachet contains Sodium Chloride …. 2.6g Tri Sodium Citrate..2.9g Potassium Chloride. 1.5g Glucose Anhydrous..13.5g	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
728.	073830	Wilten 100mg Dry Powder Suspension Each 5ml contains Nitazoxanide …. 100mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
729.	073831	Letob 125mg/5ml Dry Powder Suspension Each 5ml contains Levofloxacin Hemihydrate eq. to Levofloxacin …. 125mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
730.	073832	Letob 250mg/5ml Dry Powder Suspension Each 5ml contains Levofloxacin Hemihydrate eq. to Levofloxacin …. 250mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
731.	073833	Zimaze 20mg/5ml	21-03-2013	Dy. No. 10801		

		Each 5ml contains Zinc Sulphate Monohydrate eq. to Elemental Zinc …. 20mg		dated 22-03-2018 10,000/-		
732.	073834	Ijs Syrup Each 5ml contains Iron III Hydroxide Polymaltose complex eq. to Elemental Iron …. 50mg Folic Acid …. 0.35mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
733.	073835	Invicta 100mg/5ml Syrup Each 5ml contains Dexibuprofen …. 100mg	21-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
734.	073847	Painflex 20mg Capsule Each capsule contains Piroxicam as Beta Cyclodextrin 191.2mg eq. to Piroxicam …. 20mg	27-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
735.	073848	Xclent 400mg Tablet Each tablet contains Moxifloxacin as HCl….. 400mg	27-03-2013	Dy. No. 10801 dated 22-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Renewal application of year 2018 has been receive late but within sixty days prescribed fee required. ➢ Latest GMP inspection report required. ➢ Approval of the section / manufacturing facility (by Central Licensing Board).- ➢ Brief report of last manufactured batch. ➢ Copy of Valid DML.						
M/s. S.J & G. Fazul Ellahie (Pvt) Ltd., E/46, S.I.T.E., Karachi						
736.	075829	Despar MR Capsule Each capsule contains: Mebeverine HCl extended release pellets eq. to Mebeverine HCl …. 200mg Pellets are imported in bulk from R.A. Chem Pharma Ltd. Plot No. A-19/C, Road No.18, IDA, Nacharam, Hyderabad, India	03-04-2013	Dy. No. 8935 dated 09-03-2018 10,000/ -		
737.	004059	Rexaplex Injection Contains: Vitamin B complex	03-05-1978 Change of brand name 11-04-1982	Dy. No. 8935 dated 09-03-2018 10,000/-		
738.	004060	Vitamin B Compound Forte Injection Contains: Vitamin B compound Forte	03-05-1978	Dy. No. 8935 dated 09-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Prescribed fee required as the pellets are imported from India. ➢ You have submitted the master formulation of product in which Riboflavin -5Sodium Phosphate, Pyridoxine HCl, Nicotinamide and Dexpanthenol is use as an excipient. Justification is required to use these as an excipient and define their role as an inactive in this formulation. ➢ Define the role of Sodium Formaldehyde Sulfoxylate in the formulation.- ➢ Further complete Form 5-B is required as incomplete form has been submitted along with dossier.						

➢ You have submitted the master formulation of product in which Pyridoxine HCl, Cyanocobalamin is used as an excipient. Justification is required to use these as an excipient and define their role as an inactive in the formulation.						
M/s. Zanctok Pharmaceutical Laboratories, F/5 S.I.T.E., Hyderabad						
739.	021601	Zantazil Suspension Each 10ml contains Aluminium Hydroxide Gel …. 400mg Magnesium Hydroxide …. 400mg	20-05-1998	Dy. No. 10530 dated 21-03-2018 10,000/-		-
740.	021602	Zalomycetin Suspension Each 5ml contains Chloramphenicol Palmitate eq. to Chloramphenicol Base …. 125mg	20-05-1998	Dy. No. 10530 dated 21-03-2018 10,000/-		
741.	021603	ZeoplexSyp Each 15ml contains Thiamine HCI …. 3mg Riboflavin …. 3mg Pyridoxine HCI …. 2mg Nicotinamide …. 23mg	20-05-1998	Dy. No. 10530 dated 21-03-2018 10,000/-		
Shortcoming letter has been issued on 15-10-2018; reminder is communicated to the firm dated 19-09-2019.						
Mediate Pharmaceutical (Pvt) Ltd., Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi						
742.	044104	Hilixophin 250mg Dry Powder Injection Each Vial Contains:- Ceftriaxone (as Ceftriaxone Sodium) …..250mg	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008 Change of brand name dated 04-12-2017	Dy. No. 34611 dated 18-10-2018 10000/-		
743.	044105	Hilixophin 500mg Dry Powder Injection Each Vial Contains:- Ceftriaxone (as Ceftriaxone Sodium) …..500mg	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008 Change of brand name dated 04-12-2017	Dy. No. 34612 dated 18-10-2018 10000/-		
744.	044106	Hilixophin 1g Dry Powder Injection Each Vial Contains:- Ceftriaxone (as Ceftriaxone Sodium) …..1g	Transfer of registration from contract manufacturing to own facility 15-11-2008 Change of brand name 04-12-2017	Dy. No. 34613 dated 18-10-2018 10000/-		
745.	044107	Hitaxime 250mg Dry Powder Injection Each Vial Contains:-	Transfer of registration from contract	Dy. No. 34614 dated 18-10-2018 10000/-		

		Cefotaxime (as Cefotaxime Sodium) …..250mg	manufacturing to own facility Dated 15-11-2008 Change of brand name dated 04-12-2017			
746.	044108	Hitaxime 500mg Dry Powder Injection Each Vial Contains:- Cefotaxime (as Cefotaxime Sodium) …..500mg (Cephalosporin)	Transfer of registration from contract manufacturing to own facility 15-11-2008 Change of brand name 04-12-2017	Dy. No. 34615 dated 18-10-2018 10000/-		
747.	044109	Hitaxime1g Dry Powder Injection Each Vial Contains:- Cefotaxime (as Cefotaxime Sodium) …..1g	Transfer of registration from contract manufacturing to own facility 15-11-2008 Change of brand name 04-12-2017	Dy. No. 34616 dated 18-10-2018 10000/-		
748.	044110	Mediroxime 250mg Dry Powder Injection Each Vial Contains:- Cefuroxime(as Sodium)	Transfer of registration from contract manufacturing to own facility 15-11-2008	Dy. No. 34620 dated 18-10-2018 10000/-		
749.	044111	Mediroxime 750mg Dry Powder Injection Each Vial Contains:- Cefuroxime (as Sodium) …..750mg	Transfer of registration from contract manufacturing to own facility 15-11-2008	Dy. No. 34621 dated 18-10-2018 10000/-		
750.	044112	Mediroxime 1.5g Dry Powder Injection Each Vial Contains:- Cefuroxime (as Sodium) …..1.5g	Transfer of registration from contract manufacturing to own facility 15-11-2008	Dy. No. 34622 dated 18-10-2018 10000/-		
751.	044113	Hitazidime 250mg Injection Each vial contains: Ceftazidime……250mg	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008 Change of brand name 04-12-2017	Dy. No. 34608 dated 18-10-2018 10000/-		
752.	044114	Hitazidime 500mg Injection Each vial contains: Ceftazidime……500mg	Transfer of registration from contract manufacturing to own facility	Dy. No. 34609 dated 18-10-2018 10000/-		

			Dated 15-11-2008 Change of brand name 04-12-2017			
753.	044115	Hitazidime 1g Injection Each vial contains: Ceftazidime……1g	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008 Change of brand name 04-12-2017	Dy. No. 34610 dated 18-10-2018 10000/-		
754.	045297	CS-Sumbest 1gm Dry Powder Injections Each Vial Contains:- Cefoperazone (as Sodium)..500mg Sulbactam(as Sodium)… 500mg	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008 Change of brand name 13-02-2018	Dy. No. 34606 dated 18-10-2018 10000/-		
755.	045298	CS-Sumbest 2gm Dry Powder Injections Each Vial Contains:- Cefoperazone (as Sodium)..1000mg Sulbactam(as Sodium)…1000mg	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008 Change of brand name dated 13-02-2018	Dy. No. 34607 dated 18-10-2018 10000/-		
756.	045299	Opimed 500mg Dry Powder Injections Each Vial Contains:- Cefpirome……500mg	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008	Dy. No. 34604 dated 18-10-2018 10000/-		
757.	045300	Opimed 1g Dry Powder Injections Each Vial Contains:- Cefpirome……1g	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008	Dy. No. 34605 dated 18-10-2018 10000/-		
758.	045301	Inzolir 250mg Dry Powder Injections Each Vial Contains:- Cefazolin (as Sodium)…250mg	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008	Dy. No. 34617 dated 18-10-2018 10000/-		
759.	045302	Inzolir 500mg Dry Powder Injections	Transfer of registration	Dy. No. 34618 dated 18-10-		

		Each Vial Contains:- Cefazolin (as Sodium)…500mg	from contract manufacturing to own facility Dated 15-11-2008	2018 10000/-		
760.	045303	Inzolir 1g Dry Powder Injections Each Vial Contains:- Cefazolin (as Sodium)…1g	Transfer of registration from contract manufacturing to own facility Dated 15-11-2008	Dy. No. 34619 dated 18-10-2018 10000/-		
Shortcomings: Following shortcoming has been observed: ➢ Initial registration letter required ➢ Clarification required regarding the address of firm on change of brand name letter dated 04-12-2017, address mentioned on said letter is Sector C-14, Manghopir Road, SITE Karachi. While address on DML is Sector-24 Korangi Industrial Area Karachi.						
M/s. Hamaz Pharmaceuticals (Pvt) Ltd., 13-Km, Bosan Road, Lutfabad, Multan						
761.	076988	Nixin Suspension 125mg Each 5ml contains: Ciprofloxacin HCI eq. to Ciprofloxacin …. 125mg	02-10-2013	Dy. No. 34591 dated 18-10-2018 20000/-		
762.	076989	Nixin Suspension 250mg Each 5ml contains: Ciprofloxacin HCI eq. to Ciprofloxacin …. 250mg	02-10-2013	Dy. No. 34591 dated 18-10-2018 20000/-		
Shortcomings: Following shortcoming has been observed: ➢ Firm is advised to comply with the decision of 290th meeting of registration board regarding Manufacturing Requirement of Diluents for Ciprofloxacin Dry Powder Suspension before further processing the renewal of product. ➢ Valid DML required.						

Decision: Registrtaion Board deferred the cases of above products for completion of shortcoming mentioned above.

Finished Import (Veterinary)

Sr. No	Reg. No.	Manufacturer	Brand Name, Composition	Initial date of Reg.	Date of application (R&I) Fee submitted CoPP details	Renewal validity	Remarks
M/s. Poul Med Enterprises, 9 Amber Estate Building Baloch Colony, Shahra-e-Faisal, Karachi							
763.	021230	M/s Chemifarma S.P. Italy	Trimetoprim 40 Sulfadimetossina 200 Oral Solution Each liter contains Trimethoprim …. 40g Sulphamethoxazole …. 200g	11-05-1998	Dy. No. 11504 dated 29-03-2018 20,000/-		
Shortcomings: Letter of shortcoming has been communicated to the firm dated 03-09-2019,details are as under: ➢ Drug Sale License (DSL) ➢ Free sale status of product in market. ➢ Original legalized valid COPP is required. ➢ Original legalized valid GMP certificate is required as copy is submitted. ➢ Latest DRAP attested invoice. ➢ Both undertaking as per SOP.							
M/s. ICI Pakistan Ltd.,5-West Wharf Road, Karachi							
764.	017113	M/s. Help Limited Athens, Greece	Systamex 200mg Bolus Each Bolus contains Oxfendazole 200mg	28-05-1995 Change of principal name dated 28-03-1998	Dy. No. 10800 dated 22-03-2018 20,000/-		
765.	028590	M/s. Norbrook Laboratories Limited, Northern Ireland	Tricure Injection Each ml contains Flunixin as Meglumine …. 50mg	19-04-2003 (Two years import, After two-year period product will be automatically shifted in toll manufacturing)	Dy. No. 10799 dated 22-03-2018 20,000/-		
766.	020134	M/s. Schering-Plough Animal Health Corporation, UK	Spectrazole (Milking Cow Intra-Mammary) Infusion Each single dose syringe contains Cefuroxime as Sodium Salt. 250mg	Change of principal name dated 28-03-1998	Dy. No. 10793 dated 22-03-2018 20,000/-		
767.	017112	M/s. Schering-Plough Animal Health Corporation, UK	Zaquilan Bolus Each Bolus contains Baquiloprim …. 0.8g Sulphadimidine …. 7.2g	28-05-1995 Change of principal name dated 28-03-1998	Dy. No. 10798 dated 22-03-2018 20,000/-		
Shortcomings: Letter of shortcoming has been communicated to the firm dated 17-10-2018, and reminder was given on 13-09-2019 Details are as under: ➢ Drug Sale License (DSL) ➢ Free sale status of product in market. ➢ Original legalized valid COPP is required. ➢ Original legalized valid GMP certificate is required as copy is submitted.							

- Latest DRAP attested invoice.
- Both undertaking as per SOP
- Initial registration letter required for product at sr.no.270
- Post registration variation letter required regarding toll manufacturing for product at sr.no.269

Decision: Registrtaion Board deferred the cases of above products for completion of shortcoming mentioned above.

Local Manufacturing Veterinary

	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Remarks (if any)
M/s. Delux Chemical Industries, Plot No. 26-A1 Landhi Karachi						
768.	029640	Reocin-TD Each 100gm contains Tylosin Tartrate …. 20g Doxycycline HCI …40g	19-03-2003	Dy. No. 8221 dated 05-03-2018 10,000/-		
769.	029626	Acipin Powder Each kg contains Procaine Pencillin. 12g Streptomycin Sulphate …. 36g Zinc Bacitracin …. 52g	04-03-2003	Dy. No. 8056 dated 02-03-2018 10,000/-		
770.	029627	Normic Powder Each gm contains Oxytetracycline HCI …. 300mg Neomycin Sulphate …. 150mg Chlormaphenicol …. 300mg	04-03-2003	Dy. No. 8056 dated 02-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Renewal of year 2013 has been submitted late but within sixty days prescribed fee required for regularization. ➢ Approval of the section / manufacturing facility of (by Central Licensing Board ➢ Attested copy of valid Drug Manufacturing License. ➢ Attested copy of last inspection report conducted by DRAP. ➢ Both undertaking required as per approved SOP.						
M/s. Elko Organization (Pvt) Ltd., Plot No 27 & 28, Sector 12-B, North Karachi, Industrial Area Karachi						
771.	029631	Flumeg Injection Each ml contains Flunixin Melamine …. 50mg	22-03-2003	Dy. No. 11057 26-03-2018 10,000/-		
772.	029656	Brics Injection Each vial contains Ceftiofur Sodium …. 1g	24-03-2003	Dy.11057 26-03-2018 10,000/-		
Shortcomings: Following shortcoming has been observed: ➢ Renewal application was submitted late but within 60 days prescribed fee required. ➢ Evidence of submission of last renewal ➢ Latest GMP inspection report ➢ Detail of post registration variation (if any) ➢ Both undertakings (as per SOP) ➢ Section approval letter issued by Licensing Division.						

Decision: Registrtaion Board deferred the cases of above products for completion of shortcoming mentioned above.

Finished Import (Human)

Sr. No	Reg. No.	Manufacturer	Brand Name, Composition	Initial date of Registration	Date of application (R&I) Fee submitted CoPP details	Renewal validity	Decision
M/s. Atco Pharma International (Pvt) Ltd., , B-18, S.I.T.E., Karachi							
773.	021230	M/s. Fresenius Kabi Oncology Limited, India	Diluent for Bemocin 15 Units Injection Each ampoule contains Sterile Water for Injection USP 5.0ml	17-04-2008 Change of Manufacturer name 06-04-2010	Dy. No. 11039 dated 26-03-2018 20,000/-		
Shortcomings: Letter of shortcoming has been communicated to the firm dated 13-09-2019,details are as under: ➢ Original legalized valid COPP is required. ➢ Original legalized valid GMP certificate is required							

Decision: Registrtaion Board deferred the cases of above products for completion of shortcoming mentioned above.

Assistant Director (RRR-III)

COMPLETE CASES

Local Manufacturing (Veterinary)

Sr. No	Reg. No.	Brand Name, Composition& Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Nawan Laboratories Ltd, 136 Sector 15 Korangi Industrial Area Karachi. (VET)						
774.	054000	Colimox Powder Each gm contains Amoxicillin Sodium (Base) … 100mg Colistin Sulphate … 500,000IU	31/3/2009	Dy.No.2833 Dated.22/01/2019 Rs.10000	30-03-2024	Deferred for confirmation of penicillin section
775.	053998	VIM-SEL Injection Each ml contains:- Alpha Tocopheryl Acetate (vitamin E)... 50mg Sodium Selenite ……..0.50mg	31/3/2009	Dy.No.2835 Dated.22/01/2019 Rs.10000	30-03-2024	w.e.f. 31-3-2019 to 30-03-2024
776.	053999	VIM-SEL Oral Injection Each ml contains:- Alpha Tocopheryl Acetate (vitamin E)... 100mg Sodium Selenite…2mg	31/3/2009	Dy.No.2834 Dated.22/01/2019 Rs.10000	30-03-2024	w.e.f. 31-3-2019 to 30-03-2024
777.	053997	Neo-Strep Pen Injection Each ml contains:-	31/3/2009	Dy.No.2836 Dated.22/01/2019 Rs.10000	30-03-2024	Deferred for confirmation of penicillin section

		Streptomycin Sulphate … 160mg Procaine Penicillin … 200mg				
778.	022728	Enroject Intramammary Sterile Injectablet Suspension Each 4gm contains:- Enrofloxacin … 300mg	03/03/1999	Dy.No.2837 Dated.22/01/2019 Rs.10000	30-03-2024	w.e.f. 03-03-2019 to 02-03-2024

Decision: Registration Board considered the case of above products and validity is given in the last column of above table.

Local Manufacturing (Human)

Sr. No	Reg. No.	Brand Name, Composition& Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Remarks
M/s. Genix Pharma Pvt Ltd,44-45/B Korangi Creek Raod Karachi						
779.	055029	Telrom Tablet 400mg Each tablet contains Telithromycin…400mg	22/01/2009	Dy.No.39015 Dated.27/11/2018 Rs.10000	21-01-2024	w.e.f. 22-01-2019 to 21-01-2024
780.	076165	RBC Oral Drops 50mg Each ml contains Iron (III) hydroxide polymaltose complex eq to elemental iron..50mg	29/01/2014	Dy.No.39015 Dated.27/11/2018 Rs.10000	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
M/s. The Searle company limited,F-319 SITE Karachi.						
781.	077039	Vals 80mg Tablet Each tablet contains Valsartan……80mg	27/11/2013	Dy.No.38335 Dated.29/11/2018 Rs.20000	26-11-2023	w.e.f. 27-11-2018 to 26-11-2023
782.	077040	Co-Vals 80mg/12.5mg Each tablet contains Valsartan……80mg Hydrochlorothiazide …….12.5mg	27/11/2013	Dy.No.38335 Dated.29/11/2018 Rs.20000	26-11-2023	w.e.f. 27-11-2018 to 26-11-2023
783.	077041	Co-Vals 160mg/25mg Each tablet contains Valsartan…160mg Hydrochlorothiazide …….25mg	27/11/2013	Dy.No.38335 Dated.29/11/2018 Rs.20000	26-11-2023	w.e.f. 27-11-2018 to 26-11-2023
784.	077042	Co-Vals 160mg/12.5mg Each tablet contains Valsartan…160mg Hydrochlorothiazide …….12.5mg	27/11/2013	Dy.No.38335 Dated.29/11/2018 Rs.20000	26-11-2023	w.e.f. 27-11-2018 to 26-11-2023
M/s. Medicraft Pharmaceuticals,126-B Industrial Estate Hayatabad, Peshawar.						
785.	053000	Dicloking SR Tablet Each tablet contains Diclofenac sodium …..100mg	2/12/2008	Dy.No.39333 Dated.29/11/2018 Rs.10000	01-12-2023	w.e.f. 02-12-2018 to 01-12-2023
786.	052900	Ventomed G Expectorent Each 5ml contains Salbutamol as sulphate……..1mg Guaiphenesin……50mg	2/12/2008	Dy.No.39333 Dated.29/11/2018 Rs.10000	01-12-2023	w.e.f. 02-12-2018 to 01-12-2023
M/s. Ferozsons Laboratories Limited,Amangarh Nowshehra						
787.	022871	Xolox Capsule 100mg Each capsule contains	16/12/1998	Dy.No.39334 Dated.29/11/2018	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023

		Ribavirin USP….100mg		Rs.10000		
788.	022872	Xolox Capsule 200mg Each capsule contains Ribavirin USP….200mg	16/12/1998	Dy.No.39334 Dated.29/11/2018 Rs.10000	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
789.	022873	Xolox Capsule 400mg Each capsule contains Ribavirin USP….400mg	16/12/1998	Dy.No.39334 Dated.29/11/2018 Rs.10000	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
M/s. Platinum Pharmaceuticals (Pvt) Ltd, A/20 North Westren Industries Zone Bin Qasim Karachi.						
790.	053444	Misppros 100mcg Tablet Each tablet contains Misoprostal 100mcg	25/12/2008	Dy.No.39331 Dated.29/11/2018 Rs.10000	24-12-2023	w.e.f. 25-12-2018 to 24-12-2023
791.	053445	Misppros 200mcg Tablet Each tablet contains Misoprostal 200mcg	25/12/2008	Dy.No.39331 Dated.29/11/2018 Rs.10000	24-12-2023	w.e.f. 25-12-2018 to 24-12-2023
M/s. Sanofi Aventis Pakistan Limited,Plot No.23 Sector 22, Korangi Industrial Area Karachi						
792.	076156	Claforan 2.0g Injection Each vial contains Cefotaxime as sodium…….2gm	7/1/2014	Dy.No.39541 Dated.30/11/2018 Rs.10000	06-01-2024	w.e.f. 07-01-2019 to 06-01-2024
M/s. Irza Pharma, 10.2-Km Lahore Sheikhupura Road P.O Kot Abdul Malik District Sheikhupura.						
793.	76991	Denum-S Tablet Each Tablet Contains Diclofenac Sodium.75mg	02/10/2013	Dy. No.32035 Dated 25/09/2018 Rs.10000/-	01-10-2023	W.e.f. 02-10-2018 to 01-10-2023
M/s. Life Pharmaceutical Company, 24-III Industrial Estate Multan.						
794.	1847-EX	Estra 50mg Tablet Each Tablet Contains Sertraline (as HCl).50mg	17/09/2013	Dy. No.30945 Dated 25/09/2018 Rs.10000/-	16-09-2023	w.e.f. 17-09-2018 to 16-09-2023
795.	1846-EX	ES-Pram 10mg Tablet Each Tablet Contains Escitalopram (as Oxalate) …..10mg	17/09/2013	Dy. No.30946 Dated 13/09/2018 Rs.10000/-	16-09-2023	w.e.f. 17-09-2018 to 16-09-2023
M/s Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore.						
796.	14348	**Xamig Capsule 250mg** Each Capsule Contains Tranexamic Acid…250mg	14/10/1993	Dy. No. 31721 24-09-2018 10,000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
797.	14349	**Xamig Capsule 500mg** Each Capsule Contains Tranexamic Acid.500mg	14/10/1993	Dy. No. 31721 dated 24-09-2018 10,000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
M/s. Bloom Pharmaceutical (Pvt) Ltd, Plot No. 30 Phase I & II Industrial Estate Hattar.						
798.	032089	Austagent Cream Each gm contains Betamethasone Dipropionate … 0.64mg Gentamicin Sulphate .. 1.7mg	13/1/2004	Dy.No.1405 11/01/2019 Rs.10000	12-01-2024	w.e.f. 13-01-2019 to 12-01-2024
799.	032090	Mezine Tablet 200mg Each tablet contains:- Carbarnazepine …200mg	13/1/2004	Dy.No.1405 11/01/2019 Rs.10000	12-01-2024	w.e.f. 13-01-2019 to 12-01-2024
M/s. Pacific Pharmaceutical (Pvt) Ltd, 30-Km Multan Road Lahore.						
800.	060791	Benicol Syrup Each 5ml contains:- Diphenhydramine HCl … 10mg Ammonium Chloride … 100mg	15/1/2009	Dy.No.1406 11/01/2019 Rs.10000	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
801.	060792	Uric Low Tablet Each film coated Tablet	15/1/2009	Dy.No.1406 11/01/2019	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024

		contains:- Allopurinol … 100mg		Rs.10000		
M/s. Rock Pharmaceutical Lab.Plot No. 134-B 135-B Nowshera Industrial Estate, Risalpur						
802.	04381-Ex	Pyribol Liquid Each 5ml contains:- Pyritinol Dihydrochloride monohydrate Pyritinol … 80.5mg	13/01/2014	Dy.No.1275 10/01/2019 Rs.10000	12-01-2024	w.e.f. 13-01-2019 to 12-01-2024
803.	04384-Ex	Cal-M Vit Syrup Each 5ml contains:- Calcium Lactate Gluconate … 40mg Vitamin A … 1200IU Vitamin D3 (Cholecalciferol)..100IU Vitamin B1 (Thiamine Hydrochloride) …1mg Vitamin B2 (Riboflavin 5-Sodium Phosphate)..1mg Vitamin B6 (Pyridoxine Hydrochloride) … 0.5mg Nicotinamide … 5mg Dexpanthenol ... 2mg Vitamin C (Ascorbic Acid) ... 50mg Vitamin E (-Tocopheryl Acetate).1mg	13/01/2014	Dy.No.1275 10/01/2019 Rs.10000	12-01-2024	w.e.f. 13-01-2019 to 12-01-2024
M/s. Servier Research & Pharmceutical, 9 Km Sheikhupura Road Lahore.						
804.	032260	Coversyl Tablet Each tablet contains:- Perinodopril as tert-butylamine salt USAN (Perindoprilerbumin).8mg	25/2/2004	Dy.No.1572 14/01/2019 Rs.10000	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
M/s. Barett Hodgson Pakistan (Pvt) Ltd, F/423 SITE Karachi.						
805.	023533	Febrol DS Suspension Each 5ml cotains:- Paracetamol… 250mg	01/05/1999	Dy.No.1578 14/01/2019 Rs.10000		w.e.f. 01-05-2019 to 30-04-2024
M/s. Noa Hemis Pharmaceutical, Plot No. 154 Sector 23 Korangi Industrial Area Karachi.						
806.	055550	Noaryl 4mg Tablet Each tablet contains:- Glimepiride … 4mg	30/03/2009	Dy.No.1113 .09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
807.	055551	Catril 10mg Tablet Each tablet contains:- Atorvastatin (as Calcium Trihydrate) … 10mg	30/03/2009	Dy.No.1113 .09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
808.	055552	Catril 20mg Tablet Each tablet contains:- Atorvastatin (as Calcium Trihydrate) … 20mg	30/03/2009	Dy.No.1113 .09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
809.	055553	Catril 40mg Tablet Each tablet contains:- Atorvastatin (as Calcium Trihydrate) … 30mg	30/03/2009	Dy.No.1113 .09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
810.	055554	Ezava 20mg Tablet Each tablet contains:- Leflunomide … 20mg	30/03/2009	Dy.No.1113 09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
811.	055555	Monaka 4mg Sachet Each Sachet contains:-	30/03/2009	Dy.No.1113 09/01/2019		w.e.f. 30-03-2019 to 29-03-2024

		Montelukast (as Sodium) … 4mg		Rs.10000		
812.	055556	Voxam 600mg Tablet Each tablet contains:- Linezolid … 600mg	30/03/2009	Dy.No.1113 09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
813.	055557	Zeorox 320mg Tablet Each tablet contains:- Gemifloxacin as Mesylate … 320mg	30/03/2009	Dy.No.1113 .09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
814.	055558	Obemax-D Tablet Each tablet contains:- Alendronic Acid (as Sodium Alendronate) … 70mg Cholecaciferol. 0.0712mg	30/03/2009	Dy.No.1113 .09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
815.	055559	Amante-PF Tablet Each tablet contains:- Ethambutol … 275mg Rifampicin … 150mg Isoniazid … 75mg Pyrizinamide … 400mg	30/03/2009	Dy.No.1113 .09/01/2019 Rs.10000		w.e.f. 30-03-2019 to 29-03-2024
M/s. Atco Laboratories, B-18 S.I.T.E Karachi.						
816.	055094	Addfer-F Tablet Each chewable tablet contains:- Iron (III) Hydroxide Polymaltose Complex eq. to elemental Iron..100mg Folic Acid … 0.35mg	2/23/2009	Dy.No.1973 .16/01/2019 Rs.10000		w.e.f. 23-2-2019 to 22-2-2024
817.	015051	Gempid-600 Tablet Each tablet contains:- Gemfibrozil … 600mg	2/27/1994	Dy.No.1973 16/01/2019 Rs.10000		w.e.f. 27-2-2019 to 26-2-2019

Decision: Registration Board considered the case of above products and validity is given in the last column of above table.

DEFERRED CASES

Local manufacturing

Sr. No	Reg. No.	Brand Name, Composition& Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Remarks
M/s. Hilton Pharma, Plot 13 & 14, Sector 15, Korangi Industrial Area, Karachi.						
818.	031436	**Mycocid injection** Each ml contains: Tylosin (as tylosin tartrate) 200mg.	03-10-2003	Dy. No. 2935 dated 28-09-2019	02-10-2023	w.e.f 03-10-2018 to 02-10-2023
819.	031437	**Unigen injection** Each ml contains: Gentamicin sulphate equivalent to 100mg gentamicin base.	03-10-2003	Dy. No. 2935 dated 28-09-2019	02-10-2023	w.e.f 03-10-2018 to 02-10-2023
820.	031440	**Pronide plus suspension** Each ml contains: Oxfendazole 22.65mg. Oxyclozanide 62.5mg. Selenium (as sodium selenate) 0.5mg. Cobalt (as cobalt sulphate) 1.67mg.	03-10-2003	Dy. No. 2935 dated 28-09-2019	02-10-2023	w.e.f 03-10-2018 to 02-10-2023

M/s. Helix Pharma, A/56, S.I.T.E., Monghopir Road, Karachi						
821.	53014	Hidilol 6.25mg Tablets Each film coated tablet contains Carvedilol……6.25mg	16/10/2008	Dy.No.32220 dated 26.09.2018 Rs.10000/-	15-10-2023	w.e.f. 16-10-2018 to 15-10-2023
822.	53012	Lowseiz 25mg Tablets Each film coated tablet contains Topiramate….25mg	16/10/2008	Dy.No.32220 dated 26.09.2018 Rs.10000/-	15-10-2023	w.e.f. 16-10-2018 to 15-10-2023
823.	53013	Lowseiz 50mg Tablets Each film coated tablet contains Topiramate….50mg	16/10/2008	Dy.No.32220 dated 26.09.2018 Rs.10000/-	15-10-2023	w.e.f. 16-10-2018 to 15-10-2023
824.	76128	Nurosa 200mg Tablet Each film coated tablet contains:- Lacosamide…….200 mg	29/10/2013	Dy.No.32220 dated 26.09.2018 Rs.10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
825.	76129	Nurosa 100mg Tablet Each film coated tablet contains:- Lacosamide…….100 mg	29/10/2013	Dy.No.32220 dated 26.09.2018 Rs.10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
826.	76130	Nurosa 50mg Tablet Each film coated tablet contains:- Lacosamide……..50 mg	29/10/2013	Dy.No.32220 dated 26.09.2018 Rs.10000/-	28-10-2023	w.e.f. 29-10-2018 to 28-10-2023
M/s. Semos Pharmaceuticals Pvt. Limited, Plot No. 11, Sector 12-A, North Karachi industrial Area, Karachi						
827.	14377	Mefalgic Tablet Each Tablet Contains Mefenamic Acid…250mg	14/10/1993	Dy.No.32221 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
828.	14379	Pyrol Suspension Each 5ml Contains Paracetamol…120mg	14/10/1993	Dy.No.32221 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
829.	14381	Semotox Tablet Each Tablet Contains Attapulgite…500mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		Deferred for proof of availability in Reference regulatory authority
830.	14382	Semo-C Tablet Each Tablet Contains Ascorbic Acid…100mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		Deferred for proof of availability in Reference regulatory authority
831.	14385	Semo-Rex Ointment Contains Iodine…4% w/w Methyl Salicylate…5% w/w	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		Deferred for proof of availability in Reference regulatory authority
832.	14387	Semoquine Tablet Each Tablet Contains Amodiaquine…150mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
833.	14389	Semorfen Suspension Each 5ml Contains Ibuprofen…100mg	14/10/1993	Dy.No.32221 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
834.	14390	Semozol Tablet Each Tablet Contains Trimethoprim…80mg Sulphamethoxazole..400mg	14/10/1993	Dy.No.32221 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023

835.	14391	Semozol Suspension Each 5ml Contains Sulphamethoxazole..200mg Trimethoprim…40mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
836.	14393	Neocin Skin Ointment Each gm Contains Neomycin Sulphate…5mg	14/10/1993	Dy.No.32221 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
837.	14395	Semocof Syrup Each 5ml Contains Ammonium Chloride…100mg Chlorpheniramine Maleate…2mg Ephedrine HCl…7mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
838.	14386	Semodazol Tablet 400mg Each Tablet Contains Metronidazole…400mg	27/12/1993	Dy.No.32221 26.09.2018 Rs.10000/-	13-10-2023	w.e.f. 14-10-2018 to 13-10-2023
M/s. Searle Company Limited, F-319, S.I.T.E, Karachi						
839.	053340	Alpent 20mg Injection Each 2ml contains Flupentixol Decanoate….20mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
840.	053341	Alpent 100mg Injection Each ml contains Flupentixol Decanoate.100mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
841.	053342	Atrium Injection 10mg Each ml contains Atracurium Besylate….10mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
842.	053338	Defnac 75mg/3ml Injection Each 3ml contains Diclofenac sodium…….75mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
843.	053344	Relispa 40mg/2ml Injection Each 2ml contains Drotaverine HCl…40mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
844.	053327	Rotec-50mg Tablet Each tablet contains Diclofenac sodum…50mg, Misoprostol 200mcg	4/12/2008	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	03-12-2023	w.e.f. 04-12-2019 to 03-12-2024
845.	076184	Ropion 100mg Tablets Each tablet contains Bupropion HCl…100mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
846.	076185	Ropin SR 150mg Tablet Each sustained lealease tablet contains Bupropion HCl…..150mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
847.	076186	Ropin SR 300mg Tablet Each sustained lealease tablet contains Bupropion HCl …..300mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
848.	076187	Olesta-AM 5/20mg Tablet Each film coated tablet contains Amlodipine as besylate ….5mg, Olmesartan Medoxomil	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024

		…..20mg				
849.	076188	Olesta-AM 5/40mg Tablet Each film coated tablet contains Amlodipine as besylate ….5mg, Olmesartan Medoxomil…….40mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
850.	076189	Olesta-AM 10/20mg Tablet Each film coated tablet contains Amlodipine as besylate….10mg, Olmesartan Medoxomil20mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
851.	076190	Olesta-AM 10/40mg Tablet Each film coated tablet contains Amlodipine as besylate….10mg, Olmesartan Medoxomil40mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
852.	076191	Beslol 2.5mg Tablet Each film coated tablet contains Bisoprolol Fumarate….2.5mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
853.	076192	Beslol 10mg Tablet Each film coated tablet contains Bisoprolol Fumarate….10mg	29/01/2014	Dy.No. 38099 dated 19.11.2018 Rs.10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
M/s. Epla Laboratories, D-12, Estate Evenue, S.I.T.E, Karachi, 75700						
854.	22048	**Mecol Injection** Each ml Contains Mecobalamin…500mcg imported in bulk vials from Panbiotic Taiwan and repacked locally.	10/09/1998	Dy.No.29395 dated 03.09.2018 Rs.20000/-		Deferred for rectification of following shortcomings:- Embassy Attested CoPP/ FSC Attested GMP Certificate. (firm has no dedicated repacking area and using the general packing area).
855.	76082	**Pregrose-F Tablet** Each chewable Tablet contains:- Iron (lll) Hydroide polymaltose complex eq. to Elemental Iron……....100 mg polymaltose complex) Folic Acid……..……0.35 mg	26/09/2013	Dy.No.32050 dated 26.09.2018 Rs.10000/-		Deferred for rectification of following shortcomings:- differential Fee for late submiision of renewal application
856.	76083	**Pregrose Syrup** Each 5ml contains:- Iron (lll) Hydroide polymaltose complex eq. to	26/09/2013	Dy.No.32049 dated 26.09.2018 Rs.10000/-		

		Elemental Iron……..50 mg				
857.	76084	**Ulcez 20mg Tablet** Each enteric coated tablet contains:- Esomeprazole as Magnesium Trihydrate ……..…….20 mg	26/09/2013	Dy.No.32051 dated 26.09.2018 Rs.10000/-		
M/s. Zafa Pharmaceuticals Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi						
858.	007154	Furatop Cream 0.2% Contains Nitrofurazone USP/ BP.0.2%w/w	25/02/1984	Dy.No. 37979 dated 16.11.2018 Rs.10000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
859.	006926	Naptrol 250mg Tablet Each tablet contains Naproxen B.P……..250mg	25/02/1984	Dy.No. 37977 dated 16.11.2018 Rs.10000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
860.	007153	Furatop Powder Contains Nitrofurazone USP/BP.0.2%w/w	25/02/1984	Dy.No. 37978 dated 16.11.2018 Rs.10000/-	24-02-2024	w.e.f. 25-02-2019 to 24-02-2024
M/s Friends Pharma Pvt. Limited,31-Km, Ferozpur Road, **Lahore.**						
861.	076960	**Friendine Injection** Each ampoule contains:- Ranitidine (as HCl) ….. 25 mg (B.P. Specs)	30-09-2013	Dy. No. 32557 dated 28-09-2018 10,000/-	29-09-2023	Deferred for rectification of following shortcomings. ➢ Please provide Notarized copy of approval of change of brand name.
862.	052842	Nomilex Tablets 0.5mg Each tablet contains Alprazolam.0.5mg	22/11/2008	Dy.No. 38002 19.11.2018 Rs.10000/-	21-11-2023	w.e.f. 22-11-2018 to 21-11-2023
863.	052843	Tanil Tablet 3mg Each tablet contains Bromazepam...3mg	22/11/2008	Dy.No. 38002 19.11.2018 Rs.10000/-	21-11-2023	w.e.f. 22-11-2018 to 21-11-2023
M/s. Vetcon Pharmaceutical Pvt. Ltd, Plot No. 7-10 B, Industrial Estate, Bhimbar, AJK.						
864.	031499	**Levacon-50 Liquid Solution.** Each ml contains: levamisole hydrochloride 500mg.	06-10-2003	Dy. No. 32313 27-09-2018 10,000/-	05-10-2023	Deferred for rectification of following Shortcomings Approval of steroidal injectable section Firm has provided following documents but not duly notarized. last submitted renewal application along with fee or renewal certificate. Receipt of application for renewal of Drug Manufacturing
865.	031500	**Oxfendacon Liquid Suspension.** Each ml contains: Oxfendazole 22.65mg.	06-10-2003	Dy. No. 32313 dated 27-09-2018 10,000/-	05-10-2023	
866.	031501	**Clozacon Liquid Suspension.** Each ml contains: Oxyclozanide 34mg.	06-10-2003	Dy. No. 32313 dated 27-09-2018 10,000/-	05-10-2023	
867.	031502	**Ivercon-10 Injection** Each ml contains: Ivermectin 10mg.	06-10-2003	Dy. No. 32313 dated 27-09-2018 10,000/-	05-10-2023	
868.	031503	**Predcon-D Injection.** Each ml contains: Prednisolone acetate 7.5mg.	06-10-2003	Dy. No. 32313 dated 27-09-2018	05-10-2023	

		Dexamethasone sodium phosphate 2.5mg.		10,000/-		License. registration letter for confirmation of brand name and strength. DRAP's approval for qualified staff or attested copy of application submitted in DRAP.
869.	031504	**Gentacon-100 Injection.** Each ml contains: Gentamicin Sulphate (As Base) 100mg	06-10-2003	Dy. No. 32313 dated 27-09-2018 10,000/-	05-10-2023	
870.	031505	**Albacon-10% Liquid Suspension.** Each ml contains: Albendazole 100mg	06-10-2003	Dy. No. 32313 dated 27-09-2018 10,000/-	05-10-2023	
M/s Amros Pharmaceuticals, A-96, S.I.T.E. North Karachi.						
871.	031192	**Amdik Tablets 50mg** Each tablet contains;- Diclofenac Potassium…50mg	30-09-2003	Dy.No. 31603 dated 19-9-2018 10,000/-		Deferred in 290th meeting of DRB. Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 17-06-2019 firm has provided shortcoming. However, Notarized copy of Registration letter of Amroton Syrup is not provided. Firm has submitted differential fee of Rs. 10,000/- for late submisstion of application for Amroton Syrup on 26-06-2019. However, copy is provided which is not notarized.
872.	031193	**Amrofec Tablet 50mg** Each tablet contains;- Diclofenac Sodium….50mg	30-09-2003	Dy.No. 31603 dated 19-9-2018 10,000/-		
873.	022565	**Amroton Syrup** Each 100ml contains:- Ferric Ammonium Citrate…900mg Folic Acid…10mg Vitamin B1…20mg Vitamin B6…40mg Nicotinamide…20mg Vitamin B12..360mcg D-Panthenol…33mg	28-11-1998	Dy.No. 31602 dated 19-9-2018 10,000/-		
M/s. Indus Pharma (Pvt) Ltd, Plot No. 65, Sector 27, Korangi Industrial Area, Karachi						
874.	004339 -Ex	Bioran Injection Each 3ml contains Diclofenac Sodium..75mg	25/11/2013	Dy.No. 38475 23.11.2018 Rs.10000/-		Deferred for rectification of following. Shortcoming:- undertakings provided is not signed.
875.	000037 -Ex	Erythrocin Granules 125mg/5ml Each 5ml contains Erythromycin as (Erythromycin Ethyl succinate)…….125mg	05-12-2013	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
876.	053450	Indomal Tablet 20mg+120mg Each tablet contains Ondaserton (as HCL)..4mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
877.	053451	Indomal Tablet 40mg+240mg Each tablet contains Artemether……..40mg, Lumefantrine……..240mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
878.	014823	Oflox Tablet 200mg	5/12/1993	Dy.No. 38475		

		Each tablet contains Ofloxacin……..200mg		23.11.2018 Rs.10000/-		
879.	053448	Onseron 4mg Tablet Each tablet contains Ondaserton (as HCL)…….4mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
880.	053449	Onseron 8mg Tablet Each tablet contains Ondaserton (as HCL)…….8mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
881.	053452	Onseron Injection 2ml Each 2ml contains Ondaserton (as HCl) …….4mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
M/s. Genix Pharma Pvt Limited, 44-45-B, Korangi Creek Road, Karachi						
882.	53388	Dimis 50/200 Tablet Each tablet contains: "Diclofenac Sodium..50mg Misoprostol ….200mcg (BP Specifications)"	18/12/2008	Dy.No.29396 dated 03.09.2018 Rs.10000/-		Deferred for clarification required for availability of Tablet in Tablet compression machine.
M/s Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore.						
883.	000033 -EX	Acetazolamide 500mg Tablet Each Tablet Contains Acetazolamide……500mg	13/10/1998	Dy. No. 31721 dated 24-09-2018 10,000/-	12-10-2023	Board deferred the cases and directed the Firm to proceed change of address from Reg-II section of PE&R Division before confirmation of renewal.
884.	000031 -EX	Xamig Tablet 500mg Each Tablet Contains Tranexamic Acid…500mg	13/10/1998	Dy. No. 31721 dated 24-09-2018 10,000/-	12-10-2023	
885.	000032 -EX	Rifampicin 500mg Capsule Each Capsule Contains Rifampicine 500mg	13/10/1998	Dy. No. 31721 dated 24-09-2018 10,000/-	12-10-2023	
886.	4496	Hi-Togan Drops (For Ear) Contains Benzocaine…1% Phenazone…5% Glycerin qs to 100%"	30/10/1978	Dy. No. 31721 dated 24-09-2018 10,000/-	29-10-2023	
M/s Harmann Pharmaceutical Laboratories Pvt. Limited, P.O Chung, 16 Km, Multan Road, Lahore.						
887.	003612	Diazepam 2mg Tablet Each Tablet Contains Diazepam…2mg	14-09-1988	Dy. No. 31387 dated 17-09-2018 10,000/-	13-09-2023	Deferred for confirmation of psychotropic section
888.	003664	Diazepam 5mg Tab Each Tablet Contains:- Diazepam 5mg,	14-09-1988	Dy. No. 31387 dated 17-09-2018 10,000/-	13-09-2023	
889.	003665	Paracetamol 500mg Tab Each Tablet Contains:- Paracetamol 500mg,	14-09-1988	Dy. No. 31387 dated 17-09-2018 10,000/-	13-09-2023	w.e.f 14-09-2018 to 13-09-2023
890.	003666	Paracetamol 120mg Elixer Each 5ml Contains Paracetamol 120mg,	14-09-1988	Dy. No. 31387 dated 17-09-2018 10,000/-	13-09-2023	w.e.f 14-09-2018 to 13-09-2023
891.	003932	**Vitonol Syrup** Each 15ml Contains:- Nicotinamide..23mg Riboflavin…3mg Thiamine Hcl 3mg Pyridoxine Hcl 2mg	14-09-1988	Dy. No. 31387 dated 17-09-2018 10,000/-	13-09-2023	w.e.f 14-09-2018 to 13-09-2023
M/s. English Pharmaceuticals, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore						

892.	052921	Ironone Syrup Each 5ml contains Iron Polysaccharide Complex 217.4mg equivalent to elemental Iron…..100mg	26/11/2008 Change of brand name from Engfer syrup on 12-12-2017	Dy.No. 37992 dated 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
893.	052922	Enxamin 250mg Capsule Each capsule contains Tranexamic Acid…250mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
894.	052923	Enxamin 500mg Capsule Each capsule contains Tranexamic Acid…500mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
895.	052924	Enxamin 250mg Injection Each 5ml contains Tranexamic Acid…250mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
896.	052925	Enxamin 500mg Injection Each 5ml contains Tranexamic Acid…500mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
897.	052926	Etar 10mg Tablet Each tablet contains Atorvastatin Calcium (Trihydrate) equivalent to Atorvastatin ……...10mg	26/11/2008	Dy.No. 37992 dated 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
898.	052927	Etar 10mg Tablet Each tablet contains Atorvastatin Calcium (Trihydrate) equivalent to Atorvastatin ……..20mg	26/11/2008	Dy.No. 37992 dated 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
899.	052928	Medex 20mg tablet Each tablet contains Piroxicam Beta cyclodextrin eq. to Piroxicam…20mg	26/11/2008	Dy.No. 37992 dated 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
900.	001875 -Ex	Amborox 150mg Tablet Each tablet contains Roxithromycin USP…..150mg	20/11/2013	Dy.No. 37992 dated 16.11.2018 Rs.10000/-	19-11-2023	w.e.f. 20-11-2018 to 19-11-2023
901.	001876 -EX	Hoxidal 200mg Tablet Each film coated tablet contains Ofloxacin…200mg	20/11/2013	Dy.No. 37992 dated 16.11.2018 Rs.10000/-	19-11-2023	w.e.f. 20-11-2018 to 19-11-2023
902.	077034	Jeta 15mg Tablet Each tablet contains Mirtazapin.15mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
903.	077035	Jeta 30mg Tablet Each tablet contains Mirtazapin.30mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-	25-11-2023	w.e.f. 26-11-2018 to 25-11-2023
904.	014707	Enmol Cough Syrup Each 5ml contains Amonium Chloride 100mg, Ephedrine HCl…….7mg, Chlorpheniramine Maleate…….2mg	24/11/1993	Dy.No. 37992 16.11.2018 Rs.10000/-	23-11-2023	w.e.f. 24-11-2018 to 23-11-2023
M/s OBS Pakistan Pvt. Limited, C-14, Mangopir Road, S.I.T.E,Karachi						
905.	076116	C-Yalta 20mg Capsule Each capsule contains:- Duloxetine HCl enteric coated pellets eq. to	25-10-2013	Dy.No. 32302 dated 27-09-2018 10,000/-	24-10-2023	Deferred for confirmation of source of pellets

		Duloxetine ..20 mg				
906.	076117	C-Yalta 60mg Capsule Each capsule contains:- Duloxetine HCl enteric coated pellets eq. to Duloxetine ..60 mg	25-10-2013	Dy.No. 32308 dated 27-09-2018 10,000/-	24-10-2023	Deferred for confirmation of source of pellets
907.	076118	C-Yalta 30mg Capsule Each capsule contains:- Duloxetine HCl enteric coated pellets eq. to Duloxetine ....30 mg	25-10-2013	Dy.No. 32306 27-09-2018 10,000/-	24-10-2023	Deferred for confirmation of source of pellets
M/s Sanna Laboratories, 1019-B, Punjab Small Industrial Estate, Sargodha Road, Faisalabad.						
908.	031441	Senrox-10 Injection Each ml contains: Enrofloxacin HCl …100mg (as base).	10-04-2003	Dy. No. 32248 27-09-2018 10,000/-	09-04-2023	w.e.f. 10-04-2018 to 09-04-2023
909.	031442	Scs-20 Injection Each ml contains: Colistin sulphate 20 MIU.	10-04-2003	Dy. No. 32248 27-09-2018 10,000/-	09-04-2023	w.e.f. 10-04-2018 to 09-04-2023
910.	031443	Flumesan-50 Oral Solution. Each 100 ml contains: Flumequine.. 50gm.	10-04-2003	Dy. No. 32248 27-09-2018 10,000/-	09-04-2023	w.e.f. 10-04-2018 to 09-04-2023
911.	031444	Gentamisan-50 Injection. Each ml contains: Gentamycin sulphate equivalent to 50mg gentamycin base.	10-04-2003	Dy. No. 32248 27-09-2018 10,000/-	09-04-2023	w.e.f. 10-04-2018 to 09-04-2023
912.	031445	Cpm-100 External Spray Each 100 ml contains: Cypermethrin 10gm.	10-04-2003	Dy. No. 32248 27-09-2018 10,000/-	09-04-2023	w.e.f. 10-04-2018 to 09-04-2023
913.	031446	Coxicide W/S Powder Each 100gm Contains: Sulphadimidine sodium 22.5gm. Diaverdine HCl 2.65gm. Vitamin k3 2.05mg.	10-04-2003	Dy. No. 32248 27-09-2018 10,000/-	09-04-2023	w.e.f. 10-04-2018 to 09-04-2023
914.	031447	Exact Injection Each gm Contains: Ceftiofur Sodium 1000mg	04-10-2003	Dy. No. 32246 27-09-2018 10,000/-	03-10-2023	Deferred for confirmation of cephalosporin section
915.	031486	Resbro-300 W/S Oral Powder. Each gm Contains: Doxycycline HCl 200mg. Tylosine tartrate 100mg. Bromhexine HCl 2.5mg.	04-10-2003	Dy. No. 32247 dated 27-09-2018 10,000/-	03-10-2023	w.e.f. 04-10-2018 to 03-10-2023
916.	031487	Santrifon-100 W/S Powder. Each gm Contains: Dimethylester of (2,2,2,-trichloro-1-hydroxyethyl) phosphonic acid (trichlorophon 980mg. Silicon dioxide 20mg.	04-10-2003	Dy. No. 32247 dated 27-09-2018 10,000/-	03-10-2023	w.e.f. 04-10-2018 to 03-10-2023
917.	031488	Sanamisol 30 Oral Solution. Each ml contains: Levamisole HCl 30% W/V.	04-10-2003	Dy. No. 32247 dated 27-09-2018 10,000/-	03-10-2023	w.e.f. 04-10-2018 to 03-10-2023
918.	031489	Slectromin Forte W/S Oral	04-10-2003	Dy. No. 32245	03-10-2023	w.e.f. 04-10-2018

		Powder. Each 100gm Contains: Vitamin A …2,025,000 IU. Vitamin D3 …1,850,000 Iu. Vitamin E ..5,500 Iu. Vitamin K3 5,000mg. Riboflavin1,110mg. Calcium-D-Panthothenate ……10,200mg. Folic Acid….850mg. Thiamine HCl 4,150mg. Potassium Chloride 4,000mg. Vitamin B12 20mcg. Sodium …1,000mg. Chloride… 2,000mg. Biotin…… 100mg. Vitamin C 1750mg.		dated 27-09-2018 10,000/-		to 03-10-2023
M/s Kohinoor Industries, 159-160, Small Industrial Estate, Sahiwal.						
919.	076947	Safenol Liquid Contains Parachlorometaxylenol …1.44% Terpineol…..1.8%	09-07-2013	Dy. No. 29554 dated 04-09-2018 20,000/-	08-07-2023	Deferred for proof of availability in reference regulatory authority.
M/s. AkhaiPharmaceuticals Pvt. Limited, Plot No. A-248 & A-256 to A-259, Hub Industrial Trading Estate, Lasbela, Balochistan.						
920.	050780	Zertigo 8mg Tablet Each tablet contains: Betahistine (as 2HCl) …….8mg	09-10-2008	Dy. No. 31861 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
921.	050781	Zertigo 16mg Tablet Each tablet contains:Betahistine (as 2HCl) …….16mg	09-10-2008	Dy. No. 31862 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
922.	050782	Tanedor 5mg Tablet Each tablet contains: Risedronate (as Sodium)….5mg	09-10-2008	Dy. No. 31863 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
923.	050783	Tanedor 35mg Tablet Each tablet contains: Risedronate (as Sodium)….35mg	09-10-2008	Dy. No. 31864 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
924.	050784	Sulpy 25mg Tablet Each tablet contains: Levosulpiride.25mg	09-10-2008	Dy. No. 31865 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
925.	050785	Sulpy 50mg Tablet Each tablet contains: Levosulpiride...50mg	09-10-2008	Dy. No. 31866 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
926.	050786	Lefid 10mg Tablet Each tablet contains: Leflunomide 10mg	09-10-2008 Change of brand name 29-12-2009.	Dy. No. 31867 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
927.	050787	Lefid 20mg Tablet Each tablet contains: Leflunomide.20mg	09-10-2008 Change of brand name 29-12-2009	Dy. No. 31868 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
928.	050788	Aclova 800mg Tablet	09-10-2008	Dy. No. 31860	08-10-2023	w.e.f. 09-10-2018

		Each tablet contains: Acyclovir..800mg		dated 24-09-2018 10,000/-		to 08-10-2023
929.	050789	Rnofer 20/120mg Tablet Each tablet contains: Artemether……20mgLumefantrine.120mg	09-10-2008	Dy. No. 31871 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
930.	050790	Rnofer 40/240mg Tablet Each tablet contains: Artemether.....40mgLumefantrine 240mg	09-10-2008	Dy. No. 31872 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
931.	050791	Togal 25mg Tablet Each tablet contains: Quetiapine (as Fumarate)…25mg	09-10-2008	Dy. No. 31869 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
932.	050792	Togal 100mg Tablet Each tablet contains: Quetiapine (as Fumarate)……..100mg	09-10-2008	Dy. No. 31870 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
933.	050793	Zonacin Capsule Each Capsule Contains: Azithromycin 250mg	09-10-2008	Dy. No. 31859 dated 24-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
934.	50794	Sycozip 20mg Capsule Each Capsule Contains: Ziprasidone (as HCl)..20mg	09/10/2008	Dy.No. 32042 dated 25-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
935.	50795	Sycozip 40mg Capsule Each Capsule Contains: Ziprasidone (as HCl)..40mg	09/10/2008	Dy. No. 32043 dated 25-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
936.	50796	Benlon Syrup Each 5ml contains: Piracetam……1gm (BP Specification)	09/10/2008	Dy.No. 32037 dated 25-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
937.	50797	Sursyp Syrup Each 5ml contains: Cetirizine Dihydrochloride 5mg	09/10/2008	Dy.No. 32041 dated 25-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
938.	50798	Akicol Syrup Each 5ml contains: Simeticone….50mg Dicyclomine…..5mg	09/10/2008	Dy. No. 32038 dated 25-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
939.	50799	Ronymose Syrup Each 5ml contains: Iron (III) Hydroxide Polymaltose Complex eq. to Elemental Iron 50mg	09/10/2008	Dy.No. 32040 dated 25-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
940.	50800	Enalbin Syrup Each 5ml contains: Ibuprofen….100mg	09/10/2008	Dy. No. 32039 dated 25-09-2018 10,000/-	08-10-2023	w.e.f. 09-10-2018 to 08-10-2023
M/s Neutro Pharmaceuticals Pvt. Limited,9.5 km, Sheikhupura Road, Lahore						
941.	052600	B-Fusid Cream Each gm Contains:- Fusidic Acid…….20mg Betamethasone (as valarate).10mg	29-09-2008	Dy.No. 32309 dated 27-09-2018 10,000/-	28-09-2023	w.e.f. 29-09-2018 to 28-09-2023
942.	052601	Benate Cream Each gm Contains:- Betamethasone Dipropionate 0.05%	29-09-2008	Dy.No. 32309 dated 27-09-2018 10,000/-	28-09-2023	w.e.f. 29-09-2018 to 28-09-2023
M/s Opal Laboratories Pvt. Limited LC-41, L.I.T.E, Landhi Karachi						

943.	031270	Revloc Plus Tablet Each tablet contains Amlodipine Besylate..5mg, Hydrochlorothiazide.12.5mg	3/12/2003	Dy.No. 37639 dated 13.11.2018 Rs.10000/-	02-12-2023	w.e.f. 03-12-2018 to 02-12-2023
944.	053372	Malther DS Tablet Each tablet contains Artemether…40mg Lumefantrine….240mg	17/12/2008	Dy.No. 37639 dated 13.11.2018 Rs.10000/-	16-12-2023	w.e.f. 17-12-2018 to16-12-2023
M/s. Mediate Pharmaceuticals (Pvt) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi						
945.	053244	Water for Injection Each 5ml contains water for injection	1/12/2008	Dy.No. 38484 23.11.2018 Rs.10000/-	30-11-2023	w.e.f. 01-12-2018 to 30-11-2023
946.	053241	Lignocaine 2% Injection Each 10ml contains Lignocaine HCl……20mg	1/12/2008	Dy.No. 38485 23.11.2018 Rs.10000/-	30-11-2023	w.e.f. 01-12-2018 to 30-11-2023
947.	053240	Tramorhage 500mg Injection Each 5ml contains Tranexamic Acid….500mg	1/12/2008	Dy.No. 38486 23.11.2018 Rs.10000/-	30-11-2023	w.e.f. 01-12-2018 to 30-11-2023
948.	053237	Medifenac 75mg Injection Each 3ml contains Diclofenac Sodium…75mg	1/12/2008	Dy.No. 38487 23.11.2018 Rs.10000/-	30-11-2023	w.e.f. 01-12-2018 to 30-11-2023

Decision: Registration Board considered the case of above products and decision is given in the last column of above table.

IN-COMPLETE CASES

Sr. No	Reg. No.	Brand Name, Composition& Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Remarks
M/s. Medipak Limited, Plot No 132 Industrial Estate Kot Lakhpat Lahore. Lahore						
949.	022594	Haes Steril 3% Intravenous infusion Each 1 litre contains Poly(0-2 Hydroxyethyl) starch= 60.0g Molar Substition 0.40-0.55 (MS) Average Molecular weight Mv 200,000) Sodium chlorid...9.0g (Osmolarity = 309 mosm/1) Water for injection to = 1000ml	7/12/1998	Dy.No.38526 23/11/2018 Rs.10000		Shortcoming communicated on 16-09-2019 no reply received yet. ➢ Notarized copy of valid Drug Manufacturing License along with letter of approved sections.in case of renewal, notarized copy of receipt of application for renewal of licence along with fee challan. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division.
950.	022583	Ciprofena Eye Drops Each ml contains Ciprofloxacin HCl eq to.ciprofloxacin…….3mg	7/12/1998	Dy.No.38527 Dated.23/11/2018 Rs.10000		
951.	014778	Medical BES Blance Electrolyte Ophthalmic irrigation solution Each 100ml contains:- Sodium chloride……0.64gm, Potassium	6/12/1993	Dy.No.38528 Dated.23/11/2018 Rs.10000		

		chloride…0.75gm, Calcium chloride…..0.048gm, Magnesium chloride……0.003gm, Sodium Aetate….0.39gm, Sodium citrate….0.17gm				➢ Notarized Copy of Last Renewal Application Receipt along with Fee challan. ➢ Notarized copy of registration letter for confirmation of brand name. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Proof of availability of these medicines in reference regulatory authority.
M/s. Epla Laboratoies (Pvt) Ltd, D-12 Estate Avenue S.I.T.E Karachi						
952.	014770	Ciprocide-500 Tablet Each tablet contains Ciprofloxacin HCl eq to…..500mg Ciprofloxacin.	6/12/1993	Dy.No.39010 Dated.27/11/ 2018 Rs.10000		Shortcoming communicated on 16-09-2019 no reply received yet. ➢ Application on prescribed Form 5B along with enclosures duly signed by Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level. In case of authorized person, authority letter shall be submitted along with application. Please note that Prescribed form 5-
953.	014769	Ciprocide-250 Tablet Each tablet contains Ciprofloxacin HCl eq to…..500mg Ciprofloxacin.	6/12/1993	Dy.No.39009 Dated.27/11/ 2018 Rs.10000		

						B should not be printed on company's letterhead. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized copy of approval of Change of Technical Staff.
M/s. Danas Pharmaceuticals (Pvt) Ltd,Plot No .312-Industrial Triangle Kahuta Road Islamabad.						
954.	053610	Cyclodan Capsule 50mg Each capsule contains Diclofenac sodium as pellets…50mg	4/12/2008	Dy.No.38785 Dated.26/11/2018 Rs.10000		Shortcoming communicated on 16-09-2019 no reply received yet. ➢ Notarized copy of valid Drug Manufacturing License along with letter of approved sections.in case of renewal, notarized copy of receipt of application for renewal of licence along with fee challan. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized Copy of Last Renewal Application Receipt along with Fee challan. ➢ Notarized copy of registration letter for confirmation of brand name.
955.	053611	Danpep Capsule 40mg Each capsule contains Pantoprazole Sodium Sesquihydrate eq. to Pantoprazole…….40mg	4/12/2008	Dy.No.38785 Dated.26/11/2018 Rs.10000		
956.	053612	Rumide Tablet 20mg Each film coated tablet contains Leflunomide……..20mg	4/12/2008	Dy.No.38785 Dated.26/11/2018 Rs.10000		
957.	054591	Cyclodan SR capsule 100mg Each capsule contains Diclofenac sodium (pellets)….100mg	23/12/2008	Dy.No.38785 Dated.26/11/2018 Rs.10000		
958.	054592	Cyclofen SR Tablets 100mg Each tablet contains Diclofenac sodium…..100mg	23/12/2008	Dy.No.38785 26/11/2018 Rs.10000		
959.	054593	Vendep XR Tablet 75mg Each capsule contains Venlafaxine as HCl…….75mg	23/12/2008	Dy.No.38785 26/11/2018 Rs.10000		
M/s. Elite Pharma (Pvt) Ltd, 9.5 Km, Sheikhupura Road, Lahore						
960.	053733	Mavecef Cap.250mg Each 5ml contains Cephradine….250mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		Shortcoming communicated on 16-09-2019 no reply received yet. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division. ➢ Notarized Copy of Last Renewal
961.	053734	Mavecef Cap.500mg Each capsule contains Cephradine….500mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		
962.	053735	Mavecef Dry susp 125mg Each 5ml contains Cephradine….125mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		
963.	053736	Mavecef Dry susp 250mg Each 5ml contains Cephradine….250mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		
964.	053721	Elexin Dry Suspension 125mg Each 5ml contains Cephalexin……..125mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		

965.	053722	Elexin Dry Suspension 250mg Each 5ml contains Cephalexin……..250mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		Application Receipt along with Fee challan. ➢ Notarized copy of registration letter for confirmation of brand name. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Proof of availability of these medicines in reference regulatory authority. ➢ Notarized copy of approval of section for manufacturing of these drugs.
966.	053725	Eliclor Dry Suspension 125mg Each 5ml contains Cefaclor (as monohydrate) …125mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		
967.	053726	Eliclor Dry Suspension 250mg Each 5ml contains Cefaclor (as monohydrate)…250mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		
968.	053718	Cefulite Injection 750mg Each vial contains:- Cefuroxime (as Sodium) Sterile… 750 mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		
969.	053731	Droxilite Dry Susp 125mg Each 5ml contains Cefadroxil (as monohydrate).125mg	16/12/2008	Dy.No.38782 26/11/2018 Rs.10000		
M/s. Alina Pharmaceuticals, Plot No. A-127 SITE Super Highway Karachi.						
970.	052348	C-Pyrine Injection Each ml contains Methampyrone….200mg, Aminopyrine……50mg, Caffeine…..20mg, Chlorpheniramine Maleate…….2mg	29/11/2008	Dy.No.38836 27/11/2018 Rs.10000		Shortcoming communicated on 16-09-2019 no reply received yet. ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License ➢ Notarized copy of last inspection report conducted by DRAP. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted
971.	052349	Vitamin-SA Injection Each ml contains Vitamin E……70mg, Vitamin B1……20mg, Vitamin B12…..0.1mg, Sodium selenite…0.5mg, Adenosine 5 monophosphate….5mg	29/11/2008	Dy.No.38836 27/11/2018 Rs.10000		
972.	052350	Toldimfos Injection Each ml contains Toldimfos sodium.100mg	29/11/2008	Dy.No.38836 27/11/2018 Rs.10000		
973.	052351	D-Methrin Solution Each ml contains Deltamethrin…..25mg	29/11/2008	Dy.No.38836 27/11/2018 Rs.10000		
974.	052352	Almee oral Solution Each ml contains Ivermectin……..10mg	29/11/2008	Dy.No.38837 27/11/2018 Rs.10000		
975.	052353	Ciprolina 10% Injection Each ml contains	29/11/2008	Dy.No.38837 27/11/2018		

		Ciprofloxacin…100mg		Rs.10000		documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch. ➢ Proof of availability of product in reference regulatory authority. ➢ Notarized copy of Approval of section for manufacturing of these products.
976.	052354	Chlorphen-P Injection Each ml contains Chlorpheniramine maleate…..4mg, prednisolone…….10mg	29/11/2008	Dy.No.38837 27/11/2018 Rs.10000		
977.	052355	S-Vit E Injection Each ml contains Vitamin E(Acetate)…..25mg, Selenium……2.2mg	29/11/2008	Dy.No.38837 27/11/2018 Rs.10000		
978.	052333	Norlin Injection Each ml contains Norfloxacin……..100mg Lincomycin Hydrochloride……113.38mg eq to Lincomycin base…..100mg Amantadine Hydrochloride 49.6mg eq to Amantadine base ……40mg	29/11/2008	Dy.No.38840 27/11/2018 Rs.10000		
979.	052334	Trichlor W.S. Powder Each gm contains:- Trichlorfon……980mg	29/11/2008	Dy.No.38840 27/11/2018 Rs.10000		
980.	052335	Clomix Plus Injection Each ml contains Cloxacillin sodium 136.25mg eq to cloxacillin base……125mg Amoxicillin trihydrate 143.75mg eq to Amoxicillin base…….125mg	29/11/2008	Dy.No.38840 27/11/2018 Rs.10000		
981.	052360	Analasone-C Injection Each ml contains Analgin……220mg Vitamin C……..20mg Dexamethasone…..96mg	29/11/2008	Dy.No.38839 27/11/2018 Rs.10000		
982.	052361	Vit-B Complex Each ml contains Vitamin B1…..0.2gm Vitamin B6…0.06gm Vitamin B12…0.40gm	29/11/2008	Dy.No.38839 27/11/2018 Rs.10000		
983.	052362	Multi vit injection Each ml contains Vitamin A Palmitate……5MIU Vitamin D…….2.5MIU Vitamin E……2000IU Vitamin B1…..0.2gm Vitamin B6……0.0gm Vitamin B12……0.4gm Nicotinamide…..0.06gm	29/11/2008	Dy.No.38839 27/11/2018 Rs.10000		
984.	052363	S-Prim Injection Each ml contains Sulphamethoxypyridazine	29/11/2008	Dy.No.38839 27/11/2018 Rs.10000		

		……200mg Trimethoprim……40mg				
985.	052356	Ascorlina Injection Each ml contains Ascorbic acid……10mg	29/11/2008	Dy.No.38838 27/11/2018 Rs.10000		
986.	052357	B.Hexine Injection Each ml contains Bromexine HCl…….3mg	29/11/2008	Dy.No.38838 27/11/2018 Rs.10000		
987.	052358	Alverm Injection Each ml contains levamisol HCl……75mg	29/11/2008	Dy.No.38838 27/11/2018 Rs.10000		
988.	052359	Anagin-C Injection Each ml contains Analgin……220mg Vitamin C……..20mg	29/11/2008	Dy.No.38838 27/11/2018 Rs.10000		
989.	052340	Licocin C W.s Powder Each kg contains Lincomycin HCl..100gm Colistin sulfate…800MIU	29/11/2008	Dy.No.38842 .27/11/2018 Rs.10000		
990.	052341	Calbor Injection Each ml contains Calcium Gluconate …...266mg Boric Acid……..54mg	29/11/2008	Dy.No.38842 27/11/2018 Rs.10000		
991.	052342	Nicofloxin Injection Each ml contains Norfloxacin…100mg Nicotinic Acid…..40mg	29/11/2008	Dy.No.38842 27/11/2018 Rs.10000		
992.	052343	Estropur Injection Each ml contains Cloprostenol Sodium…..263mg	29/11/2008	Dy.No.38842 27/11/2018 Rs.10000		
993.	052344	Enflox Plus Powder Each gm contains:- Enrofloxacin…..100mg Colistin sulfate…35mg Amantdine HCl…..40mg	29/11/2008	Dy.No.38841 27/11/2018 Rs.10000		
994.	052345	Enflox-C Oral Suolution Each ml contains Enrofloxacin……100mg Colistin sulfate…..48MIU	29/11/2008	Dy.No.38841 27/11/2018 Rs.10000		
995.	052346	Vitamin ADE Injection Each ml contains Vitamin A…80000 IU Vitamin D3…40000 IU Vitamin E……..20mg	29/11/2008	Dy.No.38841 27/11/2018 Rs.10000		
996.	052347	K.N.Dex Injection Each ml contains Kanamycin Sulfate..50mg Neomycin sulfate.50mg Colistin Sulfate10000IU Dexamethasone sodium Phosphate…….0.5mg	29/11/2008	Dy.No.38841 27/11/2018 Rs.10000		
997.	052337	Iverzole-F Suspension Each liter contains Triclabendazole….5mg Ivermectin…….1gm Fenbendazole……5gm	29/11/2008	Dy.No.39039 28/11/2018 Rs.10000		

998.	052338	Levazole suspension Each liter contains Triclabnedazole…5gm Levamisole HCl..3.75gm Albendazole……..10gm	29/11/2008	Dy.No.39039 Dated.28/11/ 2018 Rs.10000		
999.	052339	Strepto-Pen Inectable solution Each ml contains Procaine pencillin..200mg streptomycin sulfate…..250mg	29/11/2008	Dy.No.39039 Dated.28/11/ 2018 Rs.10000		
M/s. Nawan Laboratories (Pvt) Ltd,136 Sector 15 Korangi Industrial Area Karachi.						
1000.	014524	Nawazan Suspension Contains Levamisole hydrochloride…1.5%w/v, Oxyclozanide…3.0% w/v	7/12/1993 Transferred from M/s EPla Pharmaceuticals on 31-12-1998. Change of brand name from levazan to nawazan 24-07-2000	Dy.No 38844 dated 26/11/2018 Rs. 10000		Shortcoming communicated on 16-09-2019 no reply received yet. Please Clarify the difference in dosage from description as initial registration states Drench and in change of brand name suspension is written.
M/s. Care Pharmaceuticals,8-Km Thokar Raiwind Road Lahore.						
1001.	077044	Hysospas syrup Each 5ml contains Hysosine N-Butyl Bromide…..5mg	5/12/2013	Dy.No.39202 Dated.27/11/ 2018 Rs.10000		Please provide proof of availability in Reference regulatory Authority.
1002.	077045	Metocare Oral Drops Each 5ml contains Metoclopramide HCl eq to Metoclopramide….5mg	5/12/2013	Dy.No.39202 Dated.27/11/ 2018 Rs.10000		
M/s. Glitz Pharma, Plot No 265 Industrial Triangle Kahuta Road Islamabad.						
1003.	054724	Ziglit Syrup Each 5ml contains Elemental zinc (as zinc sulphate monohydrate)…….20mg	31/12/2008	Dy.No.39205 Dated.28/11/ 2018 Rs.10000		Shortcoming communicated on 16-09-2019 no reply received yet.
1004.	077698	Osilex-D Tablet Each film coated tablet contains Ossein Mineral complex..830mg eq to calcium…177.60mg Phosphorous…82.20mg Residual mineral salts…..24.80mg collagen...……224mg Other Proteins…88.4mg Trace elements F1,Mg,Fe,Nim Cu corresponding to Approx…….440mg Hydroxyapatitie Vitamin D.....400IU	10/12/2013	Dy.No.38206 Dated.28/11/ 2018 Rs.10000		➢ Please provide proof of availability in reference regulatory Authority. ➢ Please confirm the availability of Atomic Absorption for testing of these products.
1005.	077699	Osilex-D Suspension	10/12/2013	Dy.No.38206		

		Each ml contains Vitamin D…….400IU Ossein mineral complex I,e Hydroxyaoatite compound (Anhydrous)..250mg Eq to calcium….53.50mg Phosphorous…..24.80mg Residual Mineral salt……7.50mg collagen……8750mg other protein…….20mg Trace element…..Fi, Mg, Zn, Fe, Ni, Cu corresponding to approx.....132.53mg hydroxyapatite		Dated.28/11/ 2018 Rs.10000		
1006.	077700	Osilex-D Suspension Each 5ml contains Vitamin D…….400IU Ossein mineral complex I,e Hydroxyaoatite compound (Anhydrous).400mg Eq to calcium….85.59mg Phosphorous…..39.61mg Residual Mineral salt……12mg collagen…107.95mg other protein…….32mg Trace element…..Fi, Mg, Zn, Fe, Ni, Cu corresponding to approx.....212mg hydroxyapatite	10/12/2013	Dy.No.38206 Dated.28/11/ 2018 Rs.10000		
M/s. Kohinoor Industries, 159-160/B Small Industrial Estate Sahiwal						
1007.	022436	Prodine Solution Each 100ml contains:- 10% w/v Providone iodine USP eq.to. available iodine (1.0% w/v)	14/12/1998 Change of formulation 20-07-2006	Dy.No.39329 Dated.29/11/ 2018 Rs.10000		Shortcoming communicated on 16-09-2019 no reply received yet. ➢ Last renewal was applied after due date. Differential fee required. ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ An undertaking on stamp paper that

						the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch. ➢ Proof of availability of product in reference regulatory authority. ➢ Notarized copy of Approval of section for manufacturing of these products.
M/s. Bosch Pharmaceuticals, 221 Bosch House Sector 23 Korangi industrial Area Karachi.						
1008.	015112	Boschtamol Tablet Each tablet contains Paracetamol BP….500mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		Shortcoming communicated on 16-09-2019 ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that
1009.	015113	Boshtan tablet Each tablet contains Mefenamic Acif BP……..250mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1010.	015114	Boschofen Tablet 200mg Each tablet contains Ibuprofen BP…..200mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1011.	015115	Boschofen Tablet 400mg Each tablet contains Ibuprofen BP…..400mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1012.	015118	Ulceloc tablet 200mg Each tablet contains Cimetidine ….200mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1013.	015119	Ulceloc tablet 400mg Each tablet contains Cimetidine…….400mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1014.	015120	Nulcer Tablet 150mg Each tablet contains Ranitidine (as HCl)……..150mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1015.	015121	Norocin Tablet 400mg	3/3/1994	Dy.No.39043		

		Each tablet contains Norfloxacin USP...400mg		28/11/2018 Rs.10000		submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch. ➢ Proof of availability of product in reference regulatory authority. ➢ Notarized copy of Approval of section for manufacturing of these products
1016.	015122	Omezol capsule 20mg Each capsule contains Omeprazole……20mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1017.	015123	Cefrinex Capsule 250mg Each capsule contains Cephradine…..250mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1018.	015124	Cefrinex Capsule 500mg Each capsule contains Cephradine……..500mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1019.	015125	Cefrinex Suspension 125mg/5ml Each 5ml contains Cephradine…..125mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1020.	015126	Cefrinex Suspension 125mg/5ml Each 5ml contains Cephradine……..250mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1021.	015127	Cefrinex vial 250mg Each vial contains Cephradine…..250mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1022.	015128	Cefrinex vial 500mg Each vial contains Cephradine…..500mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1023.	015129	Cefrinex vial 1000mg Each vial contains Cephradine…..1000mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1024.	015130	Cefotax Inj 250mg Each vial contains Cefotaxime sodium……250mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1025.	015131	Cefotax Inj 1000mg Each vial contains Cefotaxime sodium ……1000mg	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1026.	015132	Dexamex Eye Drops 0.1% w/v Each ml contains Dexamethasone doidum phosphate eq to 1mg dexamethasone	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1027.	015133	Water for injection 1ml,2ml,3ml,5ml &10ml Sterile distilled water for injection	3/3/1994	Dy.No.39043 28/11/2018 Rs.10000		
1028.	023015	Dolo-K 50mg Each tablet contains Diclofenic potassium …….50mg	4/3/1999	Dy.No.39043 28/11/2018 Rs.10000		
1029.	023020	Quinflox Infusion 100mg Each vial contains Ciprofloxacin….100mg	4/3/1999	Dy.No.39043 28/11/2018 Rs.10000		
1030.	023021	Quinflox Infusion 200mg Each vial contains Ciprofloxacin….200mg	4/3/1999	Dy.No.39043 28/11/2018 Rs.10000		
1031.	023018	Lorefect 10mg Tablet	28/06/1999	Dy.No.39043		

		Each tablet contains loratadine…10mg		28/11/2018 Rs.10000		
1032.	055017	Zezot 500mg Injection Each vial contains Azithromycin (as Dihydrate)…500mg	16/01/2009	Dy.No.39043 28/11/2018 Rs.10000		
1033.	055018	Q-Pro 30mg Injection Each vial contains Lansoprazole30mg	16/01/2009	Dy.No.39043 28/11/2018 Rs.10000		
1034.	055540	Falgan 1gm/100ml infusion Each 100ml contains:- Paracetamol…..1000mg	26/03/2009	Dy.No.39043 28/11/2018 Rs.10000		
1035.	055541	Batro 10mg Tablet Each tablet contains Bambuterol HCl…10mg	26/03/2009	Dy.No.39043 28/11/2018 Rs.10000		
1036.	055542	Batro 20mg Tablet Each tablet contains Bambuterol HCl…20mg	26/03/2009	Dy.No.39043 28/11/2018 Rs.10000		
1037.	055638	Bvir 0.5mg Tablet Each tablet contains Entecavir……0.5mg	2/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1038.	055639	Bvir 1mg Tablet Each tablet contains Entecavir…..1mg	2/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1039.	055909	Demtrat 10mg Tablet Each tablet contains Zolpidem Tartrate..10mg	7/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1040.	055910	Etidron 200mg Tablet Each tablet contains Etidronate Disodium ……200mg	7/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1041.	055911	Octorin 0.1mg Tablet Each tablet contains Desmopressin Aetate……0.1mg	7/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1042.	055912	Octorin 0.2mg Tablet Each tablet contains Desmopressin Aetate……0.2mg	7/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1043.	055913	Cefxone 2gm Injection Each vial contains Ceftriaxone (as Sodium)……..2gm	7/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1044.	055314	Zolrest 200mg/100ml Infusion Each 100ml contains:- Linzezolid….200mg	7/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1045.	055915	Zolrest 400mg/200ml Infusion Each 200ml contains Linzezolid400mg	7/4/2009	Dy.No.39043 28/11/2018 Rs..10000		
1046.	055916	Zolrest 600mg/300ml Infusion Each 200ml contains Linzezolid….600mg	7/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1047.	055850	Zion 150mg Tablet	28/04/2009	Dy.No.39043		

		Each tablet contains Bupropion HCl…150mg		28/11/2018 Rs.10000		
1048.	055851	Proart 50/200 Tablet Each tablet contains Diclofenac sodium (In eneric coated core)…..50mg Misoprostol…200mcg	28/04/2009	Dy.No.39043 28/11/2018 Rs.10000		
1049.	000221-EX	Baxidyme 1gm Injection Each vial contains Ceftazidime (as pentahydrate)….1000mg	8/6/2004	Dy.No.39043 28/11/2018 Rs.10000		
1050.	001192-EX	Fixcef 400mg Capsule Each capsule contains Cefixime…..400mg	1/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1051.	001193-EX	Diflan 75mg/3ml Injection Each 3ml contains Diclofenac sodium (Bromide free)…..75mg	1/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1052.	001194-EX	Clovax 75mg Tablet Each film coated tablet contains Clopidogrel (as Bisulphate) 78.76mg eq to clopidogrel…75mg	1/4/2009	Dy.No.39043 28/11/2018 Rs.10000		
1053.	002157-EX	Cefxone-S 375mg Injection Each vial contains Ceftriaxone (as Sodium)…..250mg Sulbactam as doium…….125mg	26/06/2009	Dy.No.39043 28/11/2018 Rs.10000		
1054.	002158-EX	Cefxone-S 750mg Injection Each vial contains Ceftriaxone (as Sodium)…..500mg Sulbactam as doium…….250mg	26/06/2009	Dy.No.39043 28/11/2018 Rs.10000		
1055.	002159-EX	Cefxone-S 1500mg Injection Each vial contains Ceftriaxone (as Sodium)……..1g Sulbactam as doium …….500mg	26/06/2009	Dy.No.39043 28/11/2018 Rs.10000		
M/s. Axis Pharmaceuticals,3-B Value Addition City 1.5 Km Khurrianwala – Sahanwala Road Faisalabad.						
1056.	077074	Megrofen Suspension Each 5ml contains Ibuprofen…100mg	18/12/2013	Dy.No.39328 28/11/2018 Rs.10000		Shortcoming communicated on 17-09-2019. Reply yet not received. ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of
1057.	077073	Magnicon Oral Suspension Each 5ml contains Aluminium hydroxide…215mg, Nmagnesium Hydroxide….80mg	18/12/2013	Dy.No.39327 28/11/2018 Rs.10000		

		Simethicone 25mg				valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch. ➢ Proof of availability of product in reference regulatory authority. ➢ Notarized copy of Approval of section for manufacturing of these products.
1058.	077075	Amclomide Syrup Each 5ml contains Metoclopramide (as Hcl)…..5mg	18/12/2013	Dy.No.39326 28/11/2018 Rs.10000		
1059.	077066	Genifer-F- Syrup Each 5ml contains Iron (III) hydroxide polymaltose complex eq to elemental iron..50mg	18/12/2013	Dy.No.39325 28/11/2018 Rs.10000		
1060.	077068	Ceridal Syrup Each 5ml contains Cetirizine Di Hydrochloride …5mg	18/12/2013	Dy.No.39324 28/11/2018 Rs.10000		
1061.	077069	Dypin Oral Suspension Each 5ml contains Domperidone……5mg	18/12/2013	Dy.No.39323 28/11/2018 Rs.10000		
1062.	077072	Deltalin Syrup Each 5ml contains Ammonium chloride……..30mg Aminophylline……32mg Diphenhdramine HCl ……..8mg Menthol…0.98mg	18/12/2013	Dy.No.39322 28/11/2018 Rs.10000		
M/s. Zanctok Pharmaceutical Laboratories, F/5 SITE Hyderabad.						
1063.	022586	Zalovit Syrup Each 30ml contains Vitamin A….14000IU Vitamin D…….1400IU Vitamin B1……..2.8mg Nicotinamide….28.4mg Vitamin C…….82.2mg	16/12/1998	Dy.No.39542 Dated.30/11/ 2018 Rs.10000		Shortcoming communicated on 17-09-2019. Reply yet not received. ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Proof of availability of product in
1064.	022587	Zufen Suspension Each 5ml contains Ibuprofen BP……100mg	16/12/1998	Dy.No.39542 30/11/2018 Rs.10000		
1065.	022588	Zyfuron Suspension Each 5ml contains Furazolidone……25mg	16/12/1998	Dy.No.39542 30/11/2018 Rs.10000		

						reference regulatory authority
M/s. Epharm Laboratories, A-40, Road No. 1, S.I.T.E. Super Highway Industrial Area, North Karachi						
1066.	075826	Eptrim M 20/120mg Tablet Each tablet contains Artemether……..20mg, Lumefantrine…..120mg	3/4/2013	Dy.No.39545 30/11/2018 Rs.90000		Shortcoming communicated on 17-09-2019. Reply yet not received. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Notarized copy of registration letter for confirmation of brand name. ➢ Detail of last manufactured batch. ➢ Proof of availability of product in reference regulatory authority. ➢ Notarized copy of Approval of section for manufacturing of these products.
1067.	075827	Eptrim M 40/120mg Tablet Each tablet contains Artemether…..40mg, Lumefantrine…..240mg	3/4/2013	Dy.No.39545 30/11/2018 Rs.90000		
1068.	075828	Eptrim M 80/480mg Tablet Each tablet contains Artemether……..80mg, Lumefantrine…..480mg	3/4/2013	Dy.No.39545 30/11/2018 Rs.90000		
1069.	076485	Eptrim 20mg Injection Each ml contains Artemether….20mg	24/06/2013	Dy.No.39545 30/11/2018 Rs.70000		
1070.	076486	Eptrim 40mg Injection Each ml contains Artemether….40mg	24/06/2013	Dy.No.39545 30/11/2018 Rs.70000		
1071.	076487	Eptrim 80mg Injection Each ml contains Artemether….80mg	24/06/2013	Dy.No.39545 30/11/2018 Rs.70000		
M/s. Shawan Pharmaceuticals, Plot No. 37 Road NS-1 National Industrial Zone Rawat Rawalpindi						
1072.	052671	Shawbal Capsule Each capsule contains Mecobalamin…...500mcg	20/10/2008	Dy.No.39543 30/11/2018 Rs.20000		Shortcoming communicated on 17-09-2019. Reply yet not

1073.	052672	Xegtin Capsule Each capsule contains Piroxicam as beta cyclodextrin …..20mg	20/10/2008	Dy.No.39543 30/11/2018 Rs.20000		received.

Shortcomings:-

- Notarized copy of valid Drug Manufacturing License.
- Notarized copy of last inspection report conducted by DRAP.
- An undertaking on stamp paper that the applied products has never been de-registered duly notarized.
- An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized.
- Notarized copy of registration letter for confirmation of brand name.
- Detail of last manufactured batch.
- Proof of availability of product in reference regulatory authority.
- Notarized copy of Approval of section for manufacturing of these products.
- Xegtin Capsule name is hand written without signature of issuing authority, please clarify?

M/s. Martin Dow Limited, F-126 SITE Karachi.

1074.	076142	Cal One-D Suspension Each 5ml contains Vitamin D…….400IU Ossein Mineral complex…..400mg Corresponding to Calcium….85.59mg Phosphorous…39.61mg Residual Mineral Salt……..12mg Collagen 107.95mg other proteins…….32mg Trace elements F1, Mg, Zn, Fe, Ni, Cu,) corresponding to Approximate 212mg hydroxyapatite.	27/12/2013	Dy.No.39540 Dated.30/11/ 2018 Rs.10000		Shortcoming communicated on 17-09-2019. Reply yet not received. Proof of availability of product in reference regulatory authority. Please clarify and justify manufacturing of Stronsha Sachet 2 gm as no sachet section is approved in letter for approval of amendments/ regularization of sections.
1075.	076141	Salvaj-DS 30mg/180mg Dry powder suspension Each 5ml contains Artemether……..30mg Lumefantrine……180mg	16/12/2013	Dy.No.39539 30/11/2018 Rs.10000		
1076.	076140	Stronsha Sachet 2gm Each sachet contains Storntium renelate….2gm	16/12/2013	Dy.No.39538 30/11/2018 Rs.10000		

M/s. Fassgen Pharmaceuticals, Plot No. 67/1 Block-A Phase-III Industrial Estate Hattar.

1077.	053504	Artegen 140mg Each tablet contains Artemether…….20mg Lumefantrine…120mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		Shortcoming communicated on 17-09-2019. Reply yet not received. ➢ Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level. In
1078.	053505	Atregen 280 Each tablet contains Artemether……..40mg Lumefantrine……240mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1079.	053506	Cebect 250 Each tablet contains Ciprofloxacin HCl eq.to Ciprofloxacin…250mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1080.	053507	Ceftagen 250mg Inj Each vial contains Ceftazidime as	3/12/2008	Dy.No39544 30/11/2018 Rs.10000		

		Sodium…….250mg				case ofauthorized person, authority letter shall be submitted along with application. Form-5B should not be printed on company letterhead. ➢ Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of approval of sections for manufacturing of said drugs. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized copy of registration letter for confirmation of brand name and strength. ➢ Notarized copy of any change in particulars of registration of these products. ➢ An undertaking on stamp paper that the applied products have never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy /
1081.	053508	Cefigen 500mg Inj Each vial contains Cefipime…….500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1082.	053509	Cefrafass 1.0 inj Each vial contains Cephradine with L-Arginine...1.0gm	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1083.	053510	Cefrafass 500 inj Each vial contains Cephradine with L-Arginine...500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1084.	053511	Ceftagen 1.0 Inj Each vial contains Ceftazidime……1gm	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1085.	053512	Ceftagen 500 inj Each vial contains Ceftazidime…500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1086.	053513	Dezatax 1.0 inj Each vial contains Cefotaxime as Sodium ……..…1gm	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1087.	053514	Dezatax 500 inj Each vial contains Cefotaxime Sodium eq. to Cefotaxime…..500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1088.	053515	Dezatax 250 inj Each vial contains Cefotaxime Sodium eq. to Cefotaxime ……250mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1089.	053516	Fabstin 10 Each tablet contains Ebastine ……10mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1090.	053517	Famycin capsule 500mg Each capsule contains Azithromycin as Dihydrate…..500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1091.	053518	Fasidex Tablet 20mg Each tablet contains Piroxicam B Cyclodextrin ……20mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1092.	053519	Fasmont Tablet 5mg Each tablet contains Montelukast as Sodium ……..5mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1093.	053520	Faspirome 1g Inje Each vial contains Cefpirome as Sulphate eq.to Cefpirome…..1gm	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1094.	053521	Cefigen 1 inj Each vial contains Cefepime ……..1gm	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1095.	053522	Faspirome 500mg Inj Each vial contains Cefpirome as Sulphate ……..500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1096.	053523	Fastrixone 1.0 Inj Each vial contains	3/12/2008	Dy.No.39544 30/11/2018		

		Ceftriaxone as Sodium …….1gm		Rs.10000		misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Proof of availability of product in reference regulatory authority.
1097.	053524	Fastrixone 250 Inj Each vial contains Ceftriaxone Sodium eq.to Ceftriaxone….250mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1098.	053525	Fastrixone 500 Inj Each vial contains Ceftriaxone as Sodium……..500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1099.	053526	Fasxime 100 susp Each 5ml contains Cefixime……..100mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1100.	053527	Fasxime 200 DS susp Each 5ml contains Cefixime……..200mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1101.	053528	Fasxime 400 Cap Each capsule contains Cefixime……400mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1102.	053529	Fasxime 200 Cap Each capsule contains Cefixime……200mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1103.	053530	Ironex Tablet 100mg Each tablet contains Iron polymaltose complex equivalent to elemental Iron…..100mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1104.	053531	Kanagen Tablet 200mg Each tablet contains Ketoconazole….200mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1105.	053532	Levotar 500 Each tablet contains Levofloxacin Hemihydrate eq. to Levofloxacin…500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1106.	053533	Mecobon Tablet 0.5mg Each tablet contains Mecobalamine..500mcg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1107.	053536	Sulbacef 1.0 Inj Each vial contains Cefoperazone Sodium eq. to Cefoperazone..500mg Sulbactum……500mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1108.	053537	Sulbacef 2.0 Inj Each vial contains Cefoperazone Sodium eq. to Cefoperazone..1000mg Sulbactum…..1000mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1109.	053538	Sulpride 25 Each tablet contains Levosulpride…25mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1110.	053539	Sulpride 50 Each tablet contains Levosulpiride…….50mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		
1111.	053540	Levotar 250 Each tablet contains Levofloxacin as Hemihydrate….250mg	3/12/2008	Dy.No.39544 30/11/2018 Rs.10000		

1112.	053630	Mepragen 20 cap Each capsule contains Omperazole Pelelts……..20mg	5/12/2008	Dy.No.39544 30/11/2018 Rs.20000		
1113.	053631	Essofas 20 Caps Each capsule contains Esomeprazole Pellets ……20mg	5/12/2008	Dy.No.39544 30/11/2018 Rs.20000		
1114.	053632	Essofas 40 Caps Each capsule contains Esomeprazole Pellets ……40mg	5/12/2008	Dy.No.39544 30/11/2018 Rs.20000		
1115.	053633	Mepragen 40 cap Each capsule contains Omeprazole Pelelts……40mg	5/12/2008	Dy.No.39544 30/11/2018 Rs.20000		
M/s. Novartis Pharma (Pakistan),15-West Wharf Dockyard Road Karachi.						
1116.	024660	Annuva Tablet Each Tablet Contains 46.50 Diclofenac Free Acid eq. to 50mg of Diclofenac Salt	13/05/2002 Change of brand name from Voltral-D on 20-10-2008	Dy. No.31919 25/09/2018 Rs.10000/-		Shortcoming communicated on 17-09-2019. Reply yet not received.

Shortcomings:-

- Notarized copy of last submitted renewal application along with fee or renewal certificate.
- Notarized copy of valid Drug Manufacturing License.
- Notarized copy of last inspection report conducted by DRAP.
- An undertaking on stamp paper that the applied products has never been de-registered duly notarized.
- An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized.
- Detail of last manufactured batch.
- Proof of availability of product in reference regulatory authority.
- In address of manufacturer, M/s GSK OTC Pvt. Ltd is mentioned. Please Clarify?
- Notarized copy of registration letter for confirmation of brand name and strength.
- Notarized copy of any change in particulars of registration of these products.

M/s. Pharmedic Laboratories Pvt. Ltd, 16 Km Multan Road Lahore.						
1117.	052634	Plaxinol-50mg Injection Each vial contains:- Oxaliplatin……50mg.	13/10/2008	Dy. No.31916 25/09/2018 Rs.10000/-		Shortcoming communicated on 17-09-2019. Reply yet not received.
1118.	006923	Diaben 500mg Tab Each Tablet Contains:- Metformin Hcl…..500mg	10/10/1983	Dy. No.31917 25/09/2018 Rs.10000/-		

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- Proof of availability of product in reference regulatory authority.
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- Notarized copy of any change in particulars of registration of these products.

M/s. English Pharmaceuticals Industries, Indus Link Katarband Road Thokar Niaz Beg, Multan Road Lahore.						
1119.	001857-EX	Ketanov-EP Tablet Each Film Coated Tablet Contains Ketorolac Trometamol…10mg	19/09/2013	Dy. No.30949 Dated 13/09/2018 Rs.10000/-		Shortcoming communicated on 19-09-2019. Reply yet not received. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ Detail of last manufactured batch.
1120.	001858-EX	Ketanov-EP Injection Each ml Contains Ketorolac Trometamol…30mg	19/09/2013	Dy. No.30949 13/09/2018 Rs.10000/-		
1121.	001859-EX	Inzagi 250mg Dry Suspension Each 5ml Contains Fosfomycin…250mg	19/09/2013	Dy. No.30949 13/09/2018 Rs.10000/-		
1122.	001860-EX	Inzagi 500mg Capsule Each Capsule Contains Fosfomycin…500mg	19/09/2013	Dy. No.30949 13/09/2018 Rs.10000/-		
1123.	001861-EX	E-SPA Injection Each Ampoule (4ml) Contains"Phloroglucinol Hydrate…40mg Trimethylphloroglucinol …0.04mg"	19/09/2013	Dy. No.30949 13/09/2018 Rs.10000/-		
1124.	001862-EX	Ecam Capsule 20mg Each Capsule Contains Piroxicam…20mg	19/09/2013	Dy. No.30949 13/09/2018 Rs.10000/-		
1125.	1863-EX	Loprid 75mg Tablet Each Film Coated Tablet Contains Clopidogrel Hydrogen Sulfate eq. to 75mg Clopidogrel	03/10/2013	Dy. No.30949 Dated 13/09/2018 Rs.10000/-		
M/s. Lahore Chemical & Pharmaceutical Works, 137-Shahrah-e-Moulana Jalal Ud din Roomi Lahore.						
1126.	14431	Riacen Cream Contains Piroxicam…1%w/w	14/10/1993	Dy. No.2874 26/09/2018 Rs.10000/-		Shortcoming communicated on 1-09-2019. Reply yet not received.
1127.	14432	Fluibron Syrup Each 100ml contains:- Ambroxol HCl…300mg	14/10/1993	Dy. No.2874 26/09/2018 Rs.10000/-		
1128.	14433	Fluibron Tablet Each Tablet Contains Ambroxol HCl…30mg	14/10/1993	Dy. No.2874 26/09/2018 Rs.10000/-		

Shortcomings:-

- Notarized copy of last submitted renewal application along with fee or renewal certificate.
- Notarized copy of valid Drug Manufacturing License.
- Notarized copy of last inspection report conducted by DRAP.
- An undertaking on stamp paper that the applied products has never been de-registered duly notarized.
- An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized.
- Detail of last manufactured batch.
- Proof of availability of product in reference regulatory authority.
- Notarized copy of registration letter for confirmation of brand name and strength.

M/s. Aims Pharmaceutical, Plot No.291 Industrial Triangle Kahuta Road Islamabad. (VET)						
1129.	054804	Roxaim 20mg Capsule Each capsule contains:- Piroxicam … 20mg	1/14/2009	Dy.No.1396 11/01/2019 Rs.10000		Shortcoming communicated on 19-09-2019. No reply received yet. ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized copy of registration letter for confirmation of brand name and strength. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch. ➢ Proof of availability of product in reference regulatory authority
1130.	054802	Alexicam 15mg Tablet Each tablet contains:- Meloxicam … 15mg	1/14/2009	Dy.No.1398 11/01/2019 Rs.10000		
1131.	054801	Moxiaim 400mg Tablet Each tablet contains:- Moxifloxacin (as HCl) … 400mg	1/14/2009	Dy.No.1400 11/01/2019 Rs.10000		
1132.	054800	Amidic 50mg tablet Each tablet contains:- Diclofenac Sodium … 50mg	1/14/2009	Dy.No.1395 11/01/2019 Rs.10000		
1133.	054803	Dexpir 20mg tablet Each tablet contains:- Piroxicam -beta-cyclodextrin 191.2mg eq. to Piroxicam … 20mg	1/14/2009	Dy.No.1397 11/01/2019 Rs.10000		
1134.	054806	Aimpram 10mg tablet Each tablet contains:- Escitalopram (as Oxalate) … 10mg	1/14/2009	Dy.No.1394 11/01/2019 Rs.10000		
1135.	054805	Lotdis 5mg Tablet Each tablet contains:- Desloratidine … 20mg	1/14/2009	Dy.No.1395 11/01/2019 Rs.10000		
M/s. Zakfas Pharmaceutical (Pvt) Ltd, 12-Km Bosan Road Lutafabad Multan (vet)						
1136.	057077	Albentex Oral Suspension Each 100ml contains:- Albendazole 2.5mg	4/3/2009	Dy.No.2839 Dated.22/01/2019 Rs.10000		Shortcoming communicated on 19-09-2019. No reply received yet. ➢ Notarized copy

1137.	057068	Oxfoban Suspension Each ml contains:- Oxfendazole.22.65mg	4/3/2009	Dy.No.2839 22/01/2019 Rs.10000		of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized copy of registration letter for confirmation of brand name and strength. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch. ➢ Proof of availability of product in reference regulatory authority.
1138.	057073	Coliran-60 Injection Each 100 ml contains:- Colistin Sulphate … 60MIU	4/3/2009	Dy.No.2839 22/01/2019 Rs.10000		
1139.	057071	Enras -20 Injection Each ml contains:- Enrofloxacin… 20mg	4/3/2009	Dy.No.2839 22/01/2019 Rs.10000		
1140.	057072	CD Raas Powder Each kg contains:- Tylosin Tartrate … 100gm Doxycycline Hyclate … 200gm Colistin Sulphate … 50gm Bromhexine HCl … 5gm	4/3/2009	Dy.No.2839 22/01/2019 Rs.10000		
1141.	057074	Coli Raas Powder Each gm contains Colistin Sulphate … 600,000IU	4/3/2009	Dy.No.2839 22/01/2019 Rs.10000		
1142.	057076	O.C Raas Plus Powder Each kg contains:- Oxytetracycline HCl … 100gm Colistin Sulphate …80000000IU Vitamin A … 2100000IU Vitamin D3…420,000IU Vitamin E…. 6500mg Vitamin K3… 750mg Vitamin B2… 300mg Vitamin B12… 8300mcg Nicotinic Acid … 15000mg Calcium Pantothenate … 6000mg	4/3/2009	Dy.No.2839 22/01/2019 Rs.10000		
1143.	057078	Broncofas Powder Each kg contains:- Tylosin Tartrate … 100gm Doxycycline Hyclate … 200gm Colistin Sulphate … 500MIU Phenylbutazone … 12gm Bromhexine HCl … 5gm	4/3/2009	Dy.No.2839 22/01/2019 Rs.10000		
1144.	048156	Tylozak Plus Powder Each kg contains:- Tylosin Tartrate …	7/2/2008	Dy.No.2839 22/01/2019 Rs.10000		

		25gm Furaltadone … 75gm Colistin Sulphate .. 300MIU				
M/s. Indus Pharma (Pvt) Ltd, Plot No. 26, 27, 63, 64, 65, 66 & 67 Sector 27 Korangi Industrial Area Karachi.						
1145.	053489	Cidpro 20mg Capsule Each capsule contains:- Omeprazole enteric coated pellets… 20mg	10/01/2009	Dy.No.989 09/01/2019 Rs.10000		Shortcoming communicated on 19-09-2019. No reply received yet. ➢ Pallets are imported from India, therefore, additional Fee is required for renewal of application. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Proof of availability of these medicines in reference regulatory authority.
1146.	053490	Cidpro 40mg Capsule Each capsule contains:- Omeprazole enteric coated pellets… 40mg	10/01/2009	Dy.No.989 09/01/2019 Rs.10000		
1147.	032068	Copamol Tablet Each tablet contains:- Paracetamol … 500mg Codeine Phosphate … 15mg	27/01/2004	Dy.No.989 09/01/2019 Rs.10000		
1148.	053491	Indpro 30 mg Capsule Each capsule contains:- Lansoprazole pallets… 30 mg. **Source of pallets:** M/s Pell Tech Health Care Private Limited, Plot No. 20-B, Tansa Farm Estate, Village Met-Gonsai, Bhiwani-Wada Road, Wada, Dist-Thane, Maharashtra-421312-India.	10-01-2009	Dy.No.989 09/01/2019 Rs.10000		
1149.	036588	Xed 500mg Injection Each 5ml contains:- Tranexamic Acid… 500mg	24/01/2004	Dy.No.989 09/01/2019 Rs.10000		
1150.	014855	Bromalex 3mg tablet Each tablet contains:- Bromazepam …. 3mg	24/2/1994	Dy.No.989 09/01/2019 Rs.10000		
1151.	04470-Ex	Bioran Neo Injection Each 3ml contains:- Diclofenac Sodium … 75mg	28/03/2014	Dy.No.989 09/01/2019 Rs.10000		
M/s. Ophth Pharma, Plot No. 241 Sector 24 Korangi Industrial Area Karachi.						
1152.	032399	Lincom Injection Each ml contains:- Lincomycin HCl. Eq. to Lincomycin base … 300mg	05/04/2004	Dy.No.1274 15/01/2019 Rs.10000		Shortcoming communicated on 19-09-2019. No reply received yet.
Shortcomings ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP.						

- Notarized copy of registration letter for confirmation of brand name and strength.
- An undertaking on stamp paper that the applied products has never been de-registered duly notarized.
- An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized.
- Detail of last manufactured batch.
- Proof of availability of product in reference regulatory authority.

M/s. Geofman Pharmaceutica, 20-23 Korangi Industrial Area Karachi.

1153.	04410	Betamethasone Tablet Each tablet contains:- Betamethasone … 0.5mg	1/15/1979	Dy.No.987 08/01/2019 Rs.10000		Shortcoming communicated on 19-09-2019. No reply received yet.

Shortcomings

- Please provide notarized copy of last submission of renewal application submitted after 2010 for availing opportunity under SRO 1005(i)/2017.
- Please provide Notarized copy of leter of approval of Tablet section (Steriod) for manufacturing of said product.
- Proof of availability of product in reference regulatory authority.

M/s. Olive Laboratories, Plot No.52-S-6 National Industrial Zone Rawat Rawalpindi.

1154.	079408	Nofaveer Tablet Each film coated Tablet contains:- Tenofovir Disrpoxil Fumarate … 300mg	1/16/2014	Dy.No.1773 15/01/2019 Rs.10000		Shortcomings communicated on 23-09-2019. Reply not received yet

Shortcomings

- Notarized copy of last submitted renewal application along with fee or renewal certificate.
- Notarized copy of valid Drug Manufacturing License.
- Notarized copy of last inspection report conducted by DRAP.
- Notarized copy of registration letter for confirmation of brand name and strength.
- An undertaking on stamp paper that the applied products has never been de-registered duly notarized.
- An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized.
- Detail of last manufactured batch.

M/s. Shrooq Pharmaceutical,21-Km Ferozepur Road, Lahore.

1155.	040298	Lortin D Tablet Each tablet contains:- Loratadine …. 10mg	6/13/2005	Dy.No.1851 15/01/2019 Rs.10000	13-6-2020	Firm has applied eighteen month before due date. Shortcomings communicated on 23-09-2019. Reply not received yet.

Shortcomings

- Notarized copy of last submitted renewal application along with fee or renewal certificate.
- Notarized copy of valid Drug Manufacturing License.
- Notarized copy of last inspection report conducted by DRAP.
- Notarized copy of registration letter for confirmation of brand name and strength.
- An undertaking on stamp paper that the applied products has never been de-registered duly notarized.
- An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized.
- Detail of last manufactured batch.

M/s. Sami Pharmaceutical (Pvt) Ltd,F-129 SITE Karachi.

1156.	022420	Sterile Distilled Water for Injection Each ampoule contains:-	16/03/1999	Dy.No.1407 11/01/2019 Rs.10000		Shortcoming was communicated on 23rd September, 2019. Reply yet not received

		Sterile distilled water for injection containing no antimicrobial agent or other added substance				➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized.
1157.	076308	Izato 500mg tablet Each film coated Tablet contains:- Nitazoxanide … 500mg	21/04/2014	Dy.No.1407 11/01/2019 Rs.10000		
1158.	076309	Izato 100mg/5ml Suspension Each 5ml of reconstituted suspension contains:- Nitazoxanide..100mg	21/04/2014	Dy.No.1407 11/01/2019 Rs.10000		
1159.	076310	Nixaf 200mg Tablet Each film coated Tablet contains:- Rifaximin … 200mg	21/04/2014	Dy.No.1407 11/01/2019 Rs.10000		
1160.	076311	Mevulak Sachet Each Sachet contains:- Mebeverin HCl.135mg Ispaghulla Husk..3.5g	21/04/2014	Dy.No.1407 11/01/2019 Rs.10000		
1161.	076306	Gpride-M SR 1/500mg Tablet Each bilayered tablet contains:- Glimepiride … 1mg Metformin Hcl (as sustained release) … 500mg	21/04/2014	Dy.No.1407 11/01/2019 Rs.10000		
1162.	076307	Gpride-M SR 2/500mg Tablet Each bilayered tablet contains:- Glimepiride … 2mg Metformin Hcl (as sustained release) … 500mg	21/04/2014	Dy.No.1407 11/01/2019 Rs.10000		
M/s. Flow Pharmaceutical (Pvt) Ltd, 17-Km Sheikhupura Road Lahore.						
1163.	022924	IAN Tablet Each tablet contains:- Clomiphene Citrate… 50mg	1/7/1999	Dy.No.794 07/01/2019 Rs.10000		Shortcoming was communicated on 24th September, 2019. Reply yet not received ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted
1164.	022925	Bacty Forte Tablet Each tablet contains:- Sulphamethoxazole … 800mg Trimethoprim..160mg	1/7/1999	Dy.No.793 07/01/2019 Rs.10000		
1165.	022922	Xany Dipersable Tablet Each tablet contains:- Diclofenac Sodium … 50mg	1/7/1999	Dy.No.792 07/01/2019 Rs.10000		
1166.	022450	Floret Tablet Each tablet contains:- Lortatidine … 10mg	1/7/1999	Dy.No.790 07/01/2019 Rs.10000		

1167.	022932	Oracap-T Tablet Each tablet contains:- Vitamin A… 5000IU Vitamin D … 500IU Vitamin B1… 10mg Vitamin B2… 10mg Vitamin B6… 4mg Vitamin B12… 5mcg Vitamin E … 50IU Vitamin C…. 300mg Calcium Pantothenate … 20mg Folic Acid … 1mg Biotin … 300mg Nicotinamide … 50mg Iron … 50mg Iodien … 100mcg	1/7/1999	Dy.No.791 07/01/2019 Rs.10000		by DRAP. ➢ Notarized copy of registration letter for confirmation of brand name and strength. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch.
1168.	022919	Opain Tablet Each tablet contains:- Diclofenac Sodium … 50mg	1/7/1999	Dy.No.798 07/01/2019 Rs.10000		
1169.	022452	OX-600 tablet Each tablet contains:- Oxaprozin … 600mg	1/7/1999	Dy.No.799 07/01/2019 Rs.10000		
1170.	022451	Bescard Tablet 5mg Each tablet contains:- Amlodipine (as besylate) … 5mg	1/7/1999	Dy.No.800 07/01/2019 Rs.10000		
1171.	022921	Ulcenor Tablet Each tablet contains:- Ranitidine (as HCl) … 150mg	1/7/1999	Dy.No.797 07/01/2019 Rs.10000		
1172.	022920	Troloc Capsule Each capsule contains:- Omeprazole … 20mg	1/7/1999	Dy.No.796 07/01/2019 Rs.10000		
1173.	022923	Gyny Viginal Tablet Each tablet contains:- Clotrimazole ..500mg	1/7/1999	Dy.No.795 07/01/2019 Rs.10000		
1174.	022453	Bescard tablet 10mg Each tablet contains:- Amlodipine (as besylate) … 10mg	1/7/1999	Dy.No.801 07/01/2019 Rs.10000		
Meditech Pharmaceuticals, 15-D, Industrial Estate, Jamrud Road, Peshawar.						
1175.	056803	Med Enema Each ml contains:- Dibasic Sodium Phosphate (Sodium Phosphate) … 6.00gm Mono Basic Sodium Phosphate (Sodium Biphosphate) …16.00gm	5/28/2009	Dy.No.4553 31/01/2019 Rs.10000		Shortcoming was communicated on 24th September, 2019. Reply yet not received ➢ Renewal application of Metzil Suspension is applied after due date as per letter No. F. No. 3-1/2018-RRR (M-277) dated 5th October, 2018 for
1176.	056804	Medicol Suspension Each 5ml contains:- Simethicone … 40mg	5/28/2009	Dy.No.4553 31/01/2019 Rs.10000		
1177.	060820	Medinase Drops	10/2/2009	Dy.No.4553		

		Each 5ml contains:- Sodium Chloride … 32.5mg (0.65%)		31/01/2019 Rs.10000		regularization of said product till 23-12-2018. Please deposit differential fee as per SRO 1005(I)/2017. ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized copy of registration letter for confirmation of brand name and strength. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last manufactured batch.
1178.	056123	Metzil Suspension Each 10ml contains:- Metronidazole Benzoate eq. to Metronidazole..200mg Diloxanide Furoate … 250mg	3/4/2009	Dy.No.4553 31/01/2019 Rs.10000		
1179.	033828	Gelcid Suspension Each 5ml cotains:- Aluminium Hydroxide Gel (Dried) … 215mg Simethicon… 25mg Magnesium Hydroxide … 80mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1180.	033829	Cotazole Suspension Each 5ml cotains:- Sulphamethoxazole … 200mg Trimethoprim… 40mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1181.	033830	Cotazole DS Suspensio Each 5ml cotains:- Sulphame thoxazole … 400mg Trimethoprim… 80mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1182.	033831	Hydil Syrup Each 5ml cotains:- Aminophyline.. 32mg Diphenhydramine … 8mg Ammonium Chloride … 30mg Menthol … 0.98mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1183.	033832	Hydil DM Syrup Each 5ml cotains:- Diphenhydramine HCl … 5mg Dextromethrphan … 6.25mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1184.	033833	Mefar Suspension Each 5ml cotains:- Mefenamic Acid…50mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1185.	033834	Mebz Suspension Each 5ml cotains:- Mebendazole..100mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1186.	033836	Histor Syrup Each 5ml cotains:- Lotratadine … 5mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1187.	033837	Zenest Syrup Each 5ml cotains:- Cetirizine Dihydrochloride..5mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		

1188.	033838	Domitech Suspension Each 5ml cotains:- Domperidone … 5mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1189.	033576	HB Malt Syrup Each 5ml cotains:- Iron (III) Hydroxide Polymatose Complex eq. to Elemental Iron … 50mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
1190.	033827	Fevernil Suspension Each capsule contains:- Paracetamol…120mg	9/6/2004	Dy.No.4553 31/01/2019 Rs.10000		
M/s. Polyfine Chem Pharma, 51 Industrial Estate Hayatabad, Peshawar.						
1191.	032077	Pantulcer Tablet Each tablet contains:- Pantoprazole Sodium Sesquihydrate..45.1mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		Shortcoming was communicated on 24th September, 2019. Reply yet not received. ➢ Notarized copy of last submitted renewal application along with fee or renewal certificate. ➢ Notarized copy of valid Drug Manufacturing License. ➢ Notarized copy of last inspection report conducted by DRAP. ➢ Notarized copy of registration letter for confirmation of brand name and strength. ➢ An undertaking on stamp paper that the applied products has never been de-registered duly notarized. ➢ An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. ➢ Detail of last
1192.	032078	Simtas 10mg Tablet Each tablet contains:- Simvastatin … 10mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		
1193.	032079	Simtas 20mg Tablet Each tablet contains:- Simvastatin … 20mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		
1194.	032081	Kaylan Capsules Each capsule contains:- Lansoprazole… 30mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		
1195.	032082	Tricosten 1 tablet Each tablet contains:- Clotrimazole...500mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		
1196.	032083	Tricosten 6 Tablet Each tablet contains:- Clotrimazole..100mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		
1197.	032084	Monocare Capsule Each capsule contains:- Fluconazole… 150mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		
1198.	032085	Polyxil Forte Suspension Each 5ml contains:- Amoxycillin Trihydrate eq. to Amoxycillin base … 250mg	1/30/2004	Dy.No.1971 16/01/2019 Rs.10000		
1199.	032086	Tonek Tablet 75mg Each capsule contains:- Diclofenac Potassium … 75mg	1/30/2004	Dy.No.1971 Dated.16/01/2019 Rs.10000		
1200.	032080	Polylact Syrup Each 5ml contains:- Lactulose … 3.35gm	2/23/2004	Dy.No.1971 Dated.16/01/2019 Rs.10000		

						manufactured batch.
M/s. Atco Laboratories, B-18 S.I.T.E Karachi.						
1201.	07124	Primox DS Suspension Each 5ml contains:- Trimethoprim...80mg Sulphamethoxazole … 400mg Sodium Citrate..100mg	2/23/1984	Dy.No.1973 16/01/2019 Rs.10000		Availability in reference regulatory authority.
M/s. Noa Hemis Pharmaceutical, Plot No. 154 Sector 23 Korangi Industrial Area Karachi.						
1202.	055560	Uflo Capsule Each capsule contains:- Tamsulosin HCl..0.4mg	30/03/2009	Dy.No.1113 09/01/2019 Rs.10000		Approval of source of pellets

Decision: Registration Board considered the case of above products and decision is given in the last column of above table.

Assistant Director (RRR-IV)

COMPLETE CASES

Locally Manufactured Registered Drugs (Human).

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Werrick Pharmaceuticals, 216-217,I-10/3, Industrial Area Islamabad						
1203.	54788	**Pasage Tablets 10mg** Each film coated tablet contains:- Rosuvastatin(as Calcium) …10mg	10/01/2009	Dy. No.257 02/01/2019 Rs.10000	09/01/2024	w.e.f. 10-01-2019 to 09-01-2024
1204.	54789	**Pasage Tablets 20mg** Each film coated tablet contains:- Rosuvastatin(as Calcium) …20mg	10/01/2009	Dy. No.257 02/01/2019 Rs.10000	09/01/2024	w.e.f. 10-01-2019 to 09-01-2024
1205.	54790	**Pasage Tablets 40mg** Each film coated tablet contains:- Rosuvastatin(as Calcium) …40mg	10/01/2009	Dy. No.257 02/01/2019 Rs.10000	09/01/2024	w.e.f. 10-01-2019 to 09-01-2024
1206.	77736	**Betanorm 2.5mg Tablets** Each tablet contains:- Nebivolol HCl eq to Nebivolol …2.5mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1207.	77737	**Betanorm 5mg Tablets** Each tablet contains:- Nebivolol HCl eq to Nebivolol …5mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1208.	77738	**Walsartan 40mg Tablets** Each film coated tablet contains:- Valsartan …40mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1209.	77739	**Walsartan 80mg Tablets** Each film coated tablet contains:- Valsartan …80mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1210.	77740	**Walsartan 160mg Tablets** Each film coated tablet contains:- Valsartan …160mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1211.	77741	**Walsartan 320mg Tablets** Each film coated tablet contains:- Valsartan …320mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024

1212.	77742	Newday-HCT Tablets 5/160/12.5mg Each film coated tablet contains:- Amlodipine Besylate eq to Amlodipine …5mg Valsartan …160mg Hydrochlorothiazide …12.5mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1213.	77743	Newday-HCT Tablets 10/160/12.5mg Each film coated tablet contains:- Amlodipine Besylate eq to Amlodipine …10mg Valsartan …160mg Hydrochlorothiazide …12.5mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1214.	77744	Newday-HCT Tablets 10/160/25mg Each film coated tablet contains:- Amlodipine Besylate eq to Amlodipine …10mg Valsartan …160mg Hydrochlorothiazide …25mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1215.	77745	Newday-HCT Tablets 10/320/25mg Each film coated tablet contains:- Amlodipine Besylate eq to Amlodipine …10mg Valsartan …320mg Hydrochlorothiazide …25mg	07/02/2014	Dy. No.257 02/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1216.	14875	Pulse Tablets 100mg Each tablet contains:- Atenolol …100mg	24/02/1994	Dy. No.257 02/01/2019 Rs.10000	23/02/2024	w.e.f. 24-02-2019 to 23-02-2024
1217.	14874	Pulse Tablets 50mg Each tablet contains:- Atenolol …50mg	24/02/1994	Dy. No.257 02/01/2019 Rs.10000	23/02/2024	w.e.f. 24-02-2019 to 23-02-2024
1218.	56104	Co-Eziday 100mg Tablets Each tablet contains:- Losartan Potassium …100mg Hydrochlorothiazide …25mg	25/02/2009	Dy. No.257 02/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24/02/2024
1219.	56103	Eziday Tablets 100mg Each tablet contains:- Losartan Potassium …100mg	25/02/2009	Dy. No.257 02/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24/02/2024
1220.	56100	Ezitab Tablets 40mg Each tablet contains:- Telmisartan …40mg	25/02/2009	Dy. No.257 02/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24/02/2024
1221.	56101	Ezitab Tablets 80mg Each tablet contains:- Telmisartan …80mg	25/02/2009	Dy. No.257 02/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24-02-2024
1222.	56105	Olanzia Tablets 7.5mg Each film-coated tablet contains:- Olanzapine … 7.5mg	25/02/2009	Dy. No.257 02/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24-02-2024
1223.	56102	Pasage Tablets 5mg Each film coated tablet contains:- Rosuvastatin(as Calcium) …5mg	25/02/2009	Dy. No.257 02/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24-02-2024
1224.	56349	Co-Pulse Tablets 50/12.5mg Each film-coated tablet contains:- Atenolol …50mg Chlorthalidone …12.5mg	25/03/2009	Dy. No.257 02/01/2019 Rs.10000	24/03/2024	w.e.f. 25-03-2019 to 24-03-2024
1225.	56346	Walsartan-H Tablets 160/25mg Each film-coated tablet contains:- Valsartan …160mg Hydrochlorothiazide …25mg	25/03/2009 Change of BN: 17/10/2017	Dy. No.257 02/01/2019 Rs.10000	24/03/2024	w.e.f. 25-03-2019 to 24-03-2024
1226.	56347	Walsartan-H Tablets 80/12.5mg Each film-coated tablet contains:- Valsartan …80mg	25/03/2009 Change of BN:	Dy. No.257 02/01/2019 Rs.10000	24/03/2024	w.e.f. 25-03-2019 to 24-03-2024

		Hydrochlorothiazide …12.5mg	17/10/2017			
1227.	56350	Momentium Plus Tablets 10/10mg Each film-coated tablet contains:- Atorvastatin(as calcium) …10mg Ezetimibe …10mg	25/03/2009	Dy. No.257 02/01/2019 Rs.10000	24/03/2024	w.e.f. 25-03-2019 to 24-03-2024
1228.	56345	Newday Tablets 10/160mg Each film-coated tablet contains:- Amlodipine(as Besylate) …10mg Valsartan …160mg	25/03/2009	Dy. No.257 02/01/2019 Rs.10000	24/03/2024	w.e.f. 25-03-2019 to 24-03-2024
1229.	56344	Newday Tablets 5/160mg Each film-coated tablet contains:- Amlodipine(as Basylate) …5mg Valsartan …160mg	25/03/2009	Dy. No.257 02/01/2019 Rs.10000	24/03/2024	w.e.f. 25-03-2019 to 24-03-2024
Shortcomings:						
M/s Dr. Raza Pharma, Plot # 44- C, Industrial Estate, Hayatabad, Peshawar.						
1230.	32096	Supreme 500mg Tablets Each film coated tablet contains:- Ciprofloxacin (as HCl) …500mg	09/02/2004	Dy. No.2225 dated 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
1231.	32097	Ezill 200mg Dry Suspension Each 5ml contains:- Azithromycin(as Dihydrate) …200mg	09/02/2004	Dy. No.2225 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
1232.	32098	Ezill 250mg Capsules Each Capsule contains:- Azithromycin(as Dihydrate) …250mg	09/02/2004	Dy. No.2225 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
1233.	32099	Nevotic 500mg Tablets Each tablet contains:- Naproxen (as sodium) …500mg	09/02/2004	Dy. No.2225 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
1234.	32100	Magifen 100mg Tablets Each film coated tablet contains:- Flurbiprofen …100mg	09/02/2004	Dy. No.2225 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
1235.	32101	Linatic 500mg Tablets Each film coated tablet contains:- Levofloxacin(as Hemihydrate) …500mg	09/02/2004	Dy. No.2225 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
1236.	32103	Cenex 10mg Tablets Each tablet contains:- Cetirizine (as 2HCL) …10mg	09/02/2004	Dy. No.2225 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
1237.	32105	Klary 250mg Tablets Each tablet contains:- Clarithromycin …250mg	09/02/2004	Dy. No.2225 17/01/2019 Rs.10000	08/02/2024	w.e.f. 09-02-2019 to 08-02-2024
Shortcomings:						
M/s. Tabros Pharma (Pvt) Ltd, Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area Karachi.						
1238.	00442 5-Ex	Paradrin Forte Tablet Each tablet contains:- Orphenadrine Citrate …50mg Paracetamol …650mg	11/03/2014	Dy. No.2206 17/01/2019 Rs.10000	10/03/2024	w.e.f. 11-03-2019 to 10-03-2024
1239.	55449	Co-Misomal DS Tablet Each tablet contains:- Artemether …40mg Lumefantrine …240mg	14/03/2009	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1240.	55450	Co-Misomal Dry Suspension Each 5ml contains:- Artemether …15mg Lumefantrine …90mg	14/03/2009	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1241.	55451	Cabedin Lotion Each gm contains:-	14/03/2009	Dy. No.2207 17/01/2019	13/03/2024	w.e.f. 14-03-2019 to

		Prednicarbate …0.25%w/w		Rs.10000		13-03-2024
1242.	55452	Scabrid Cream Each gm contains:- Permethrin …5%w/w	14/03/2009 Change if BN 05/11/2010	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1243.	55453	Scabrid Lotion Each ml contains:- Permethrin …5%w/w	14/03/2009 Change if BN 05/11/2010	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1244.	55454	Valsozol Cream Each gm contains:- Isoconazole Nitrate …10mg Diflucortolone Valerate …1mg	14/03/2009	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1245.	55455	**Treno Cream** Each gm contains:- Tretinoin …0.05%w/w	14/03/2009	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1246.	55457	**Beltapro Ointment** Each gm contains:- Clobetasol Propionate …0.05%w/w	14/03/2009	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1247.	55458	**Beltapro Cream** Each gm contains:- Clobetasol Propionate …0.05%w/w	14/03/2009	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1248.	55459	**Flytro Cream** Each gm Contains: Fluocinolone acetonide …0.1mg (0.01% w/w) Hydroquinone …40mg (4% w/w) Tretinoin …0.5mg (0.05% w/w)	14/03/2009	Dy. No.2207 17/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
Shortcomings:						
M/s. Xenon Pharmaceuticals (Pvt) Ltd, 9.5-Km Sheikhupura Road Lahore.						
1249.	32326	Panroz Tablets 40mg Each delayed release tablet contains: Pantoprazole (as sodium sesquihydrate) …40mg	10/03/2004	Dy. No.2214 17/01/2019 Rs.10000	09/03/2024	w.e.f. 10-03-2019 to 09-03-2024
1250.	32327	Candistat Oral Gel Each gm contains:- Miconazole Nitrate …20mg	10/03/2004	Dy. No.2209 17/01/2019 Rs.10000	09/03/2024	w.e.f. 10-03-2019 to 09-03-2024
1251.	32325	Halpol Liquid Each ml contains:- Haloperidol …2mg	10/03/2004	Dy. No.2210 17/01/2019 Rs.10000	09/03/2024	w.e.f. 10-03-2019 to 09-03-2024
1252.	32329	Hydrocortisone Cream Each gm contains:- Hydrocortisone …10mg	10/03/2004	Dy. No.2211 17/01/2019 Rs.10000	09/03/2024	w.e.f. 10-03-2019 to 09-03-2024
1253.	57500	Xegaba 100mg Capsule Each Capsule contains:- Gabapentin …100mg	19/05/2009	Dy. No.2219 17/01/2019 Rs.10000	18/05/2024	w.e.f. 19-05-2019 to 18-05-2024
1254.	57501	Xegaba 300mg Capsule Each Capsule contains:- Gabapentin …300mg	19/05/2009	Dy. No.2220 17/01/2019 Rs.10000	18/05/2024	w.e.f. 19-05-2019 to 18-05-2024
1255.	57502	Xegaba 400mg Capsule Each Capsule contains:- Gabapentin …400mg	19/05/2009	Dy. No.2221 17/01/2019 Rs.10000	18/05/2024	w.e.f. 19-05-2019 to 18-05-2024
Shortcomings:						
M/s. Maple Pharmaceutical, Plot No. 147 Sector 23 Korangi Industrial Area Karachi.						
1256.	76239	Doloraid Tablet Each bi layered tablet contains:- Paracetamol … 325mg Tramadol HCl … 37.5mg	03/02/2014	Dy. No.4323 30/01/2019 Rs.10000	02/02/2024	w.e.f. 03-02-2019 to 02-02-2024
Shortcomings:						

M/s. Munawar Pharma (Pvt) Ltd, 31-Km Multan Road Lahore.						
1257.	32059	Tranacid Capsule 250mg Each capsule contains:- Tranexamic Acid… 250mg	10/02/2004	Dy. No.4325 30/01/2019 Rs.10000	09/02/2024	w.e.f. 10-02-2019 to 09-02-2024
1258.	32060	Tranacid Injection 250mg Each 5ml ampoule contains:- Tranexamic Acid… 250mg	10/02/2004	Dy. No.4325 30/01/2019 Rs.10000	09/02/2024	w.e.f. 10-02-2019 to 09-02-2024
1259.	23040	Fosfomycin Dry Syrup 250mg Each 5ml contains:- Fosfomycin … 250mg	30/01/1999	Dy. No.4326 30/01/2019 Rs.10000	29/01/2024	w.e.f. 30-01-2019 to 29-01-2024
1260.	23041	Trisep Paediatric Suspension 80/400mg Each 5ml contains:- Trimethoprim … 80mg Sulphamethoxazole … 400mg	30/01/1999	Dy. No.4326 30/01/2019 Rs.10000	29/01/2024	w.e.f. 30-01-2019 to 29-01-2024
1261.	23042	Gastifam Tablet 20mg Each tablet contains:- Famotidine … 20mg	30/01/1999	Dy. No.4326 30/01/2019 Rs.10000	29/01/2024	w.e.f. 30-01-2019 to 29-01-2024
1262.	16580	Clocil Oral Supension 125mg Each 5ml contains:- Amoxycillin Trihydrate eq. to 125mg Amoxycillin Base	31/05/1995 Change of BN: 23/01/2004	Dy. No.2574 21/01/2019 Rs.10000	22/01/2024	w.e.f. 23-01-2019 to 22-01-2024
1263.	16581	Clocil Capsules 250mg Each Capsules contains:- Amoxycillin Trihydrate eq. to 250mg Amoxycillin Base	31/05/1995 Change of BN: 23/01/2004	Dy. No.2574 21/01/2019 Rs.10000	22/01/2024	w.e.f. 23-01-2019 to 22-01-2024
1264.	18130	Loxavid Tablet 200mg Each tablet contains:- Ofloxacin……200mg	24/09/1995 Change of BN: 31/01/2004	Dy. No.2574 21/01/2019 Rs.10000	30/01/2024	w.e.f. 31-01-2019 to 30-01-2024
1265.	18739	Clocil Capsules 500mg Each Capsules contains:- Amoxycillin Trihydrate eq. to 500mg Amoxycillin Base	11/03/1996 Change of BN: 23/01/2004	Dy. No.2574 21/01/2019 Rs.10000	22/01/2024	w.e.f. 23-01-2019 to 22-01-2024
1266.	32056	Munagestic Tabelt Each tablet contains:- Paracetamol … 450mg Orphenadrine Citrate … 35mg	24/01/2004	Dy. No.2575 21/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
1267.	32057	Oxytetracycline 250mg Capsules Each Capsules contains:- Oxytetracycline (as HCl)…. 250gm	24/01/2004	Dy. No.2575 21/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
1268.	32058	Cafitol Forte Suspension Each 5ml contains:- Cefixime as Trihydrate … 200mg	24/01/2004	Dy. No.2575 21/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
Shortcomings:						
M/s. Brookes Pharma (Pvt) Ltd, Plot No. 58-59 Sector No. 15 Korangi Industrial Area Karachi.						
1269.	32330	Dostin Suspension Each 100ml contains:- Erdosteine … 3.500gm	11/03/2004	Dy. No.4327 30/01/2019 Rs.10000	10/03/2024	w.e.f. 11-03-2019 to 10-03-2024
1270.	32332	Dostin Capsule 150mg Each capsule contains:- Erdosteine … 150mg	11/03/2004	Dy. No.4327 30/01/2019 Rs.10000	10/03/2024	w.e.f. 11-03-2019 to 10-03-2024
1271.	32333	Dostin Capsule 300mg Each capsule contains:- Erdosteine … 300mg	11/03/2004	Dy. No.4327 30/01/2019 Rs.10000	10/03/2024	w.e.f. 11-03-2019 to 10-03-2024
1272.	32334	Dostin Sachets 225mg Each Sachet contains:- Erdosteine … 225mg	11/03/2004	Dy. No.4327 30/01/2019 Rs.10000	10/03/2024	w.e.f. 11-03-2019 to 10-03-2024
Shortcomings:						

M/s. Stand Pharm Pakistan (Pvt) Ltd, 20 Km Ferozepur Road Lahore.						
1273.	29747	Coldrex-DM Syrup Each 5ml contains:- Pseudoephedrine HCl… 30mg Chlorpheniramine Maleate… 2mg Dextromethorphan HBr … 10mg	20/03/2003 Correction of formulation 16/02/2004	Dy. No.4312 30/01/2019 Rs.10000	15/02/2024	w.e.f. 16-02-2019 to 15-02-2024
Shortcomings:						
M/s. Adamjee Pharmaceutical, Plot No. 39 Sector 15 Korangi Industries Area Karachi.						
1274.	32216	Trovas 10mg Tablet Each tablet contains:- Atorvastatin (as calcium trihydrate)… 5mg	21/02/2004	Dy. No.1581 14/01/2019 Rs.10000	20/02/2024	w.e.f. 21-02-2019 to 20-02-2024
1275.	32217	Trovas 20mg Tablet Each tablet contains:- Atorvastatin (as calcium trihydrate)… 20mg	21/02/2004	Dy. No.1581 14/01/2019 Rs.10000	20/02/2024	w.e.f. 21-02-2019 to 20-02-2024
1276.	32218	Trovas 40mg Tablet Each tablet contains:- Atorvastatin (as calcium trihydrate)… 40mg	21/02/2004	Dy. No.1581 14/01/2019 Rs.10000	20/02/2024	w.e.f. 21-02-2019 to 20-02-2024
1277.	32219	Risp Oral Solution Each 5ml contains:- Resperidone … 5mg	21/02/2004	Dy. No.1581 14/01/2019 Rs.10000	20/02/2024	w.e.f. 21-02-2019 to 20-02-2024
1278.	15026	Dosik Liquid Each 5ml contains:- Haloperidol … 10mg	28/02/1994	Dy. No.1581 14/01/2019 Rs.10000	27/02/2024	w.e.f. 28-02-2019 to 27-02-2024
Shortcomings:						
M/s. Sante (Pvt) Ltd, A/97 S.I.T.E Super Highway Karachi.						
1279.	76183	**Zoproquine 500mg Tablet** Each film coated Tablet contains:- Ciprofloxacin HCl eq. to Ciprofloxacin … 500mg	29/01/2014	Dy. No.1571 Dated.14/01/ 2019 Rs.10000	28/01/2024	w.e.f. 29-01-2019 to 28-01-2024
Shortcomings:						
M/s. Weather Folds, Plot No. 69/2 Phase-II Industrial Estate Hattar.						
1280.	54920	Mypime 500mg Injection Each vial contains:- Cefepime (as HCl)… 500mg With L-arginine	28/01/2009	Dy. No.1584 14/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024
1281.	54921	Mypime 1gm Injection Each vial contains:- Cefepime (as HCl)… 1gm With L-arginine	28/01/2009	Dy. No.1584 14/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024
1282.	54922	Sokxil 125mg Dry Suspension Each 5ml contains:- Cefadroxil (as Monohydrate) … 125mg	28/01/2009	Dy. No.1584 14/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024
1283.	54923	Sokxil 250mg Dry Suspension Each 5ml contains:- Cefadroxil (as Monohydrate) … 250mg	28/01/2009	Dy. No.1584 14/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024
1284.	54924	Sokxil 250mg Capsule Each capsule contains:- Cefadroxil (as Monohydrate) … 250mg	28/01/2009	Dy. No.1584 14/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024
1285.	54925	Sokxil 500mg Capsule Each capsule contains:- Cefadroxil (as Monohydrate) … 500mg	28/01/2009	Dy. No.1584 14/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024

Shortcomings:						
M/s. Bio-Labs Research Lab, Plot No.145 Kahuta Triangle Industrial Estate Islamabad.						
1286.	54842	Bio-Sul Cream Each 100gm Contains:- Silver Sulphadiazine … 1%	24/01/2009	Dy. No.1582 14/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
1287.	54940	Bio Iron F Chewable Tablet Each tablet contains:- Iron III as Hydroxide Polymaltose … 100mg Folic Acid … 0.35mg	30/01/2009	Dy. No.1582 14/01/2019 Rs.10000	29/01/2024	w.e.f. 30-01-2019 to 29-01-2024
1288.	77755	Equasert 50mg Tablet Each film-coated tablet contains:- Sertraline (as HCl_ … 50mg	07/02/2014 Change in BN: 06/11/2017	Dy. No.1582 14/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
1289.	77756	Equasert 100mg Tablet Each film-coated tablet contains:- Sertraline (as HCl) … 100mg	07/02/2014 Change in BN: 06/11/2017	Dy. No.1582 14/01/2019 Rs.10000	06/02/2024	w.e.f. 07-02-2019 to 06-02-2024
Shortcomings:						
M/s. Paramount Pharmaceutical, 36 Industrial Triangle, Kahuta Road Islamabad.						
1290.	54846	Rapro Tablet 10mg Each enetric coated tablet contains:- Rabeprazole Sodium …. 10mg	24/01/2009	Dy. No.2573 21/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
1291.	54847	Rapro Tablet 20mg Each enetric coated tablet contains:- Rabeprazole Sodium …. 20mg	24/01/2009	Dy. No.2573 21/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
1292.	54848	Odequin 400mg Tablets Each tablet contains:- Moxifloxacin(as HCL)…..400mg	24/01/2009	Dy. No.2573 21/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
1293.	54849	Neo-Cetrin Tablet Each tablet contains:- Levocetirizine (as 2HCl) … 5mg	24/01/2009	Dy. No.2573 21/01/2019 Rs.10000	23/01/2024	w.e.f. 24-01-2019 to 23-01-2024
Shortcomings:						
M/s. News Pharma, Plot No. 42-Sundar Industrial Estate Raiwind Road Lahore						
1294.	77157	New-D Injection Each 1ml cotains:- Cholecalciferol (Vitamin D3)… 5mg	22/05/2014	Dy. No.2567 21/01/2019 Rs.10000	21/05/2024	w.e.f. 22-05-2019 to 21-05-2024
1295.	77156	New-Dine Injection Each 2ml cotains:- Ranitidine (as HCl)… 50mg	22/05/2014	Dy. No.2566 21/01/2019 Rs.10000	21/05/2024	Deferred for further deliberation for NDMA impurity
Shortcomings:						
M/s. Global Pharmaceuticals (Pvt) Ltd, Plot No 204-205 Kahuta Triangle Industrial Area Islamabad.						
1296.	56282	Besalic Ointment Besalic Ointment contains:- Betamethason Dipropionate..0.64% Salycylic Acid …. 3%	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1297.	56285	Co-Telmas Tablet 40mg Each tablet contains:- Telmisartan……..40mg Hydrochlorothiazide…..12.5mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1298.	56286	Co-Telmas Tablet 80mg Each tablet contains:- Telmisartan……..80mg Hydrochlorothiazide…..12.5mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024

1299.	56278	Esmazole Tablet 20mg Each tablet contains:- Esomeprazole MagnesiumTrihydate eq. to Esomeprazole … 20mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1300.	56279	Esmazole Tablet 40mg Each tablet contains:- Esomeprazole MagnesiumTrihydate eq. to Esomeprazole … 40mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1301.	56277	Falcitrin Injection Each ml contains:- Artemether……..80mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1302.	56283	Glocain Injection Each ml contains:- Bupivacaine HCL……7.5mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1303.	56289	Glomet Tablet 1mg Each tablet contains:- Glimipiride…..1mg Metformin HCL……..500mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1304.	56288	Glorin Tablet 150mg Each enteric coated tablet contains:- Aspirin……..150mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1305.	56287	Glorin Tablet 75mg Each enteric coated tablet contains:- Aspirin……..75mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
1306.	56281	Mirpin Tablet 30mg Each tablet contains:- Mirtazapine……30mg	20/03/2009	Dy. No.2576 21/01/2019 Rs.10000	19/03/2024	w.e.f. 20-03-2019 to 19-03-2024
Shortcomings:						
M/s. Highnoon Laboratries Ltd, 17.5 Km Multan Road Lahore.						
1307.	14900	Loprin 75mg Tablets Each enteric coated tablet contains:- Aspirin……75mg	27/02/1994	Dy. No.2572 21/01/2019 Rs.10000	26/02/2024	w.e.f. 27-02-2019 to 26-02-2024
1308.	32074	Pidogrel Tablets 75mg Each tablet contains:- Clopidogrel Bisulfate 97.87mg eq to Clopidogrel……75mg	28/02/2004	Dy. No.2572 21/01/2019 Rs.10000	27/02/2024	w.e.f. 28-02-2019 to 27-02-2024
1309.	77110	Irbest plus 150/12.5 tablet Each film coated tablet contains:- Irbesartan……150mg Hydrochlorothiazide……12.5mg	06/02/2014	Dy. No.2572 21/01/2019 Rs.10000	05/02/2024	w.e.f. 06-02-2019 to 05-02-2024
1310.	77111	Irbest plus 300/12.5 tablet Each film coated tablet contains:- Irbesartan……300mg Hydrochlorothiazide……12.5mg	06/02/2014	Dy. No.2572 21/01/2019 Rs.10000	05/02/2024	w.e.f. 06-02-2019 to 05-02-2024
Shortcomings:						
M/s. Genix Pharma (Pvt) Ltd, 44-45/B Korangi Creek Raod Karachi						
1311.	55527	Iril 10/10 Tablet Each tablet contains:- Ezetimibe … 10mg Simvastatin … 10mg	24/03/2009	Dy. No.2353 18/01/2019 Rs.10000	23/03/2024	w.e.f. 24-03-2019 to 23-03-2024
1312.	55528	Iril 10/20 Tablet Each tablet contains:- Ezetimibe … 10mg Simvastatin … 20mg	24/03/2009	Dy. No.2353 18/01/2019 Rs.10000	23/03/2024	w.e.f. 24-03-2019 to 23-03-2024
1313.	55529	Iril 10/40 Tablet Each tablet contains:- Ezetimibe … 10mg Simvastatin … 40mg	24/03/2009	Dy. No.2353 18/01/2019 Rs.10000	23/03/2024	w.e.f. 24-03-2019 to 23-03-2024

1314.	55530	Iril 10/80 Tablet Each tablet contains:- Ezetimibe … 10mg Simvastatin … 80mg	24/03/2009	Dy. No.2353 18/01/2019 Rs.10000	23/03/2024	w.e.f. 24-03-2019 to 23-03-2024
1315.	55589	Piobetic G 15/2 tablet Each tablet contains:- Pioglitazone (as Hcl) … 15mg Glimepiride …. 2mg	18/12/2008 Change of BN: 04/03/2009	Dy. No.2353 18/01/2019 Rs.10000	03/03/2024	w.e.f. 04-03-2019 to 03-03-2024
1316.	53390	Piobetic G 30/2 tablet Each tablet contains:- Pioglitazone (as Hcl) … 30mg Glimepiride …. 2mg	18/12/2008 Change of BN: 04/03/2009	Dy. No.2353 18/01/2019 Rs.10000	03/03/2024	w.e.f. 04-03-2019 to 03-03-2024
1317.	53391	Piobetic G 30/4 tablet Each tablet contains:- Pioglitazone (as Hcl) … 30mg Glimepiride …. 4mg	18/12/2008 Change of BN: 04/03/2009	Dy. No.2353 18/01/2019 Rs.10000	03/03/2024	w.e.f. 04-03-2019 to 03-03-2024
1318.	55679	Depsit 5mg Tablet Each film coated tablet contains:- Escitalopram (as Oxalate) … 5mg	03/04/2009	Dy. No.2353 18/01/2019 Rs.10000	02/04/2024	w.e.f. 03-04-2019 to 02-04-2024
1319.	55680	Depsit 20mg Tablet Each film coated tablet contains:- Escitalopram (as Oxalate) … 20mg	03/04/2009	Dy. No.2353 18/01/2019 Rs.10000	02/04/2024	w.e.f. 03-04-2019 to 02-04-2024
1320.	55675	Tics-G 25mg Tablet Each film coated tablet contains:- Topiramate … 25mg	03/04/2009	Dy. No.2353 18/01/2019 Rs.10000	02/04/2024	w.e.f. 03-04-2019 to 02-04-2024
1321.	55676	Tics-G 50mg Tablet Each film coated tablet contains:- Topiramate … 50mg	03/04/2009	Dy. No.2353 18/01/2019 Rs.10000	02/04/2024	w.e.f. 03-04-2019 to 02-04-2024
1322.	55677	Tics-G 100mg Tablet Each film coated tablet contains:- Topiramate … 100mg	03/04/2009	Dy. No.2353 18/01/2019 Rs.10000	02/04/2024	w.e.f. 03-04-2019 to 02-04-2024
1323.	55678	Tics-G 200mg Tablet Each film coated tablet contains:- Topiramate … 200mg	03/04/2009	Dy. No.2353 18/01/2019 Rs.10000	02/04/2024	w.e.f. 03-04-2019 to 02-04-2024
Shortcomings:						
M/s. English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Beg, Multan Road Lahore.						
1324.	36742	Gliclazide Tablet Each tablet contains:- Gliclazide … 80mg	31/01/2004	Dy. No.2347 18/01/2019 Rs.10000	30/01/2024	w.e.f. 31-01-2019 to 30-01-2024
1325.	77089	Zanzia 10mg Powder for Injection Each 2ml contains:- Olanzapine … 10mg	20/01/2014	Dy. No.2348 18/01/2019 Rs.10000	19/01/2024	w.e.f. 20-01-2019 to 19-01-2024
Shortcomings:						
M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-1/B, Block 22, Federal "B" Industrial Area, Karachi						
1326.	32545	Diltiazaf Tablet 30mg Each tablet contains:- Diltiazem HCl … 30mg	08/04/2004	Dy. No.2340 18/01/2019 Rs.10000	07/04/2024	w.e.f. 08-04-2019 to 07-04-2024
1327.	32546	Diltiazaf Tablet 60mg Each tablet contains:- Diltiazem HCl … 60mg	08/04/2004	Dy. No.2346 18/01/2019 Rs.10000	07/04/2024	w.e.f. 08-04-2019 to 07-04-2024
1328.	32547	Diltiazaf SR 90mg Tablet Each sustained release tablet contains:- Diltiazem HCl … 90mg	08/04/2004	Dy. No.2345 18/01/2019 Rs.10000	07/04/2024	w.e.f. 08-04-2019 to 07-04-2024
1329.	32548	Propofol 1% Injection Each 20ml ampoule contains:- Propofol … 200mg	08/04/2004	Dy. No.2344 18/01/2019 Rs.10000	07/04/2024	w.e.f. 08-04-2019 to 07-04-2024
Shortcomings:						

M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B Block 21, Federal B Industrial Area Karachi							
1330.	10119	Naptrol Tablet 500mg Each tablet contains:- Naproxen (as sodium) … 500mg		17/04/1989	Dy. No.2342 18/01/2019 Rs.10000		w.e.f. 17-04-2019 to 16-04-2024
Shortcomings:							
M/s. Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road Landhi Karachi.							
1331.	07160	Epival 250mg Tablet Each delayed release tablet contains:- Divalproex Sodium eq. to Valproic Acid … 250mg		25/02/1984	Dy. No.3691 28/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24-02-2024
1332.	07161	Epival 500mg Tablet Each delayed release tablet contains:- Divalproex Sodium eq. to Valproic Acid … 500mg		25/02/1984	Dy. No.3691 28/01/2019 Rs.10000	24/02/2024	w.e.f. 25-02-2019 to 24-02-2024
Shortcomings:							
M/s. Life Pharmaceutical Company, 24-III Industrial Estate Multan.							
1333.	00018 98-Ex	Nabusafe 500mg Tablet Each tablet contains:- Nabumetone…500mg		28/01/2014	Dy. No.597 04/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024
1334.	00018 99-Ex	Sitrap 100mg Tablet Each tablet contains:- Sitagliptin(as phosphate monohydrate…100mg		28/01/2014	Dy. No.596 04/01/2019 Rs.10000	27/01/2024	w.e.f. 28-01-2019 to 27-01-2024
Shortcomings:							
M/s. Davis Pharmaceutical Laboratories, Plot No. 121 Industrial Triangle Kahuta Road Islamabad.							
1335.	31916	Ciproday Tablets 250mg Each film coated tablet contains:- Ciprofloxacin HCL eq to Ciprofloxacin …250mg		24/11/2003 Change of BN: 08/01/2004	Dy. No.599 04/01/2019 Rs.10000	07/01/2024	w.e.f. 08-01-2019 to 07-01-2024
1336.	31917	Ciproday Tablets 500mg Each film coated tablet contains:- Ciprofloxacin HCL eq to Ciprofloxacin …500mg		24/11/2003 Change of BN: 08/01/2004	Dy. No.599 04/01/2019 Rs.10000	07/01/2024	w.e.f. 08-01-2019 to 07-01-2024
Shortcomings:							
M/s. Mcolson Research Laboratories (Pvt) Ltd, 26-Km Lahore Sharakpur Road District Sheikhupura.							
1337.	77086	M/s Vision Pharmaceuticals, Plot No.224, Street No.1, I-10/3, Islamabad.	Maylan 0.4mg Capsules Each Capsules contains:- Temsulosin Hydrochloride (Pellets) …0.4mg	07/01/2014	Dy. No.784 Dated.07/01/2019 Rs.10000	06/01/2024	w.e.f. 07-01-2019 to 06-01-2024
Shortcomings:							

Imported registered drugs (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Manufacturer as per registration letter	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision

Locally manufactured registered drugs (Veterinary)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Bio-Labs Research Lab, Plot No.145 Kahuta Triangle Industrial Estate Islamabad.						
1338.	21290	Bio-Enro 20% Liquid Each 100ml contains:- Enrofloxacin … 20gm	11/05/1998 Change of BN: 12/03/2009	Dy. No.1583 Dated.14/01/2019 Rs.10000	11/03/2024	w.e.f. 12-03-2019 to 11-03-2024
1339.	34566	Bio-Sulfadia Liquid Each liter contains:- Sulfadimethoxine … 50,000mg Diaveridine … 50,000mg Vit K3… 5000mg	13/12/2004 Change of BN: 14/03/2014	Dy. No.1583 Dated.14/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
1340.	34567	Fura-Bio Water Soluble Powder Each kg contains:- Furaltadone Tartrate … 200gm	13/12/2004 Change of BN: 14/03/2014	Dy. No.1583 Dated.14/01/2019 Rs.10000	13/03/2024	Deferred as product is under review
1341.	35042	Bio-Dek- C Water Soluble Powder Each kg contains:- Vitamin A … 100,000,000IU Vitamin D3, 30,000,000IU Vitamin E … 5000IU Vitamin K3… 3000mg Vitamin C… 30,000mg	13/12/2004 Change of BN: 14/03/2014	Dy. No.1583 Dated.14/01/2019 Rs.10000	13/03/2024	w.e.f. 14-03-2019 to 13-03-2024
Shortcomings:						
M/s. Martin Dow Ltd, Plot No. 37 Sector 19 Korangi Industrial Area Karachi.						
1342.	76437	Ribuvir Tablet 400mg Each film coated tablet contains:- Ribavirin …400mg	22/04/2014	Dy. No.1278 Dated.10/01/2019 Rs.10000	21/04/2024	w.e.f. 22-04-2019 to 21-04-2024
1343.	76438	Ribuvir Tablet 600mg Each film coated tablet contains:- Ribavirin …600mg	22/04/2014	Dy. No.1278 Dated.10/01/2019 Rs.10000	21/04/2024	w.e.f. 22-04-2019 to 21-04-2024
1344.	76439	Ribuvir Capsule 400mg Each Capsules contains:- Ribavirin …400mg	22/04/2014	Dy. No.1278 Dated.10/01/2019 Rs.10000	21/04/2024	w.e.f. 22-04-2019 to 21-04-2024
Shortcomings:						

Imported registered drugs (Veterinary)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

INCOMPLETE CASES

Locally manufactured registered drugs (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Werrick Pharmaceuticals, 216-217,I-10/3, Industrial Area Islamabad						
1345.	54914	Linderm Cream Each Tube contains:- Lindane(Gamma Benzene Hexachloride) …1%w/w	15/01/2009	Dy. No.257 dated 02/01/2019 Rs.10000		Deferred
1346.	23061	Caltab Tablets Each tablet contains:- Calcium Carbonate 1250mg (eq. to 500mg Elemental calcium)	30/01/1999	Dy. No.257 dated 02/01/2019 Rs.10000		Deferred
1347.	23060	Meprazol 40mg Capsules Each Capsule contains:- Omeprazole(Coated granules) eq to Omeprazole Activity …40mg	30/01/1999	Dy. No.257 dated 02/01/2019 Rs.10000		Deferred
1348.	56348	Co-Cardiovasc Tablets 5/12.5mg Each tablet contains:- Amlodipine(as Besylate) …5mg Hydrochlorothiazide …12.5mg	25/03/2009	Dy. No.257 dated 02/01/2019 Rs.10000		Deferred
Shortcomings: Evidence of approval of formulation in Reference Regulatory Authorities i.e. . Linderm Cream (Reg No. 54914), Caltab Tablets (Reg No. 23061) & Co-Cardiovasc Tablets 5/12.5mg (Reg No. 56348). Source of pellets for Meprazol 40mg Capsules (Reg. No. 23060) and differential fee in case of imported pellets.						
M/s Dr. Raza Pharma, Plot # 44- C, Industrial Estate, Hayatabad, Peshawar.						
1349.	32102	Dicfin 75mg Tablets Each tablet contains:- Diclofenac Potassium …75mg	09/02/2004	Dy. No.2225 dated 17/01/2019 Rs.10000	08/02/2024	Deferred
1350.	32104	Klary 125mg Dry Suspension Each 5ml contains:- Clarithromycin …125mg	09/02/2004	Dy. No.2225 dated 17/01/2019 Rs.10000	08/02/2024	Deferred
1351.	28914	Lapizole 20mg Capsules Each Capsules contains:- Omeprazole Pellets eq. to of Omeprazole ...20mg	8/22/2002 Change of BN 14/10/2002 Change of BN 05/11/2002 Change of BN **09/06/2009**	Dy. No.2223 dated 17/01/2019 Rs.10000	08/06/2024	Deferred
1352.	35289	CLA 1gm Tablets Each tablet contains:- Amoxicillin(as Trihydrate) …875mg Clavulanic Acid (as Potassium salt) …125mg	23/12/2004	Dy. No.2224 dated 17/01/2019 Rs.10000	22/12/2024	Deferred
1353.	35290	CLA 625mg Tablets Each tablet contains:- Amoxicillin(as Trihydrate) …500mg Clavulanic Acid (as Potassium salt) …125mg	23/12/2004	Dy. No.2224 dated 17/01/2019 Rs.10000	22/12/2024	Deferred

1354.	35497	**Mezonil Suspension** Each 5ml contains:- Mebendazole …100mg	24/12/2004	Dy. No.2224 dated 17/01/2019 Rs.10000	23/12/2024	Deferred
Shortcomings: Evidence of approval of formulation in Reference Regulatory Authorities i.e. . Dicfin 75mg Tablets (Reg No. 32102). Source of pellets for Klary 125mg Dry Suspension (Reg. No. 32104) and Lapizole 20mg Capsules (Reg No. 28914) and differential fee in case of imported pellets. Last renewal fee for CLA 1gm Tablets (Reg No. 35289), CLA 625mg Tablets (Reg No. 35290) & Mezonil Suspension (Reg No. 35497) was submitted after the due date, therefore, differential fee is required. An undertaking that the applied products has never been de-registered. **(on Stamp Papar)**. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. **(on Stamp Papar)**.						
M/s. Tabros Pharma (Pvt) Ltd, Plot No. L-20/B Karachi Industrial Area Sector-22 Federal B Area Karachi.						
1355.	55456	Zirith Cream Each gm contains:- Bufexamac …50mg Neomycin Sulphate …2500IU Nystatin …100000IU	14/03/2009	Dy. No.2207 dated 17/01/2019 Rs.10000	13/03/2024	Deferred
Shortcomings: Evidence of approval of formulation in Reference Regulatory Authorities.						
M/s. Tagma Pharma (Pvt) Ltd, 12.5 Km Lahore Raiwind Road Lahore.						
1356.	32036	Spactrum Tablets 100mg Each tablet contains:- Sparfloxacin …100mg	20/01/2004	Dy. No.2222 dated 17/01/2019 Rs.10000	19/01/2024	Deferred
1357.	32037	Spactrum Tablets 200mg Each tablet contains:- Sparfloxacin …200mg	20/01/2004	Dy. No.2222 17/01/2019 Rs.10000	19/01/2024	Deferred
1358.	22500	Trovit F Tablets Each tablet contains:- Ferrous Fumarate …250mg Thiamine Mononitrate …3.3mg Riboflavin …3.3mg Nicotinamide ..33.3mg Pyridoxine HCl …3.3mg Cyanocobalamine …50mcg Ascorbic Acid …100mg Folic Acid …1mg Manganese Chloride …0.2mg Copper Chloride …0.5mg	30/01/1999	Dy. No.2222 dated 17/01/2019 Rs.10000	29/01/2024	Deferred
Shortcomings: Evidence of approval of formulation in Reference Regulatory Authorities. Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.						
M/s. Xenon Pharmaceuticals (Pvt) Ltd, 9.5-Km Sheikhupura Road Lahore.						
1359.	24782	Xetac Tablets 150mg Each Film Coated tablet contains:- Ranitidine (as HCl) …150mg	12/06/1999	Dy. No.2208 17/01/2019 Rs.10000	11/06/2024	Deferred
1360.	24783	Respirate DM Syrup Each 5ml contains:- Phenylpropanolamine HCl ..12.5mg Dextromethophan HBr …10mg	12/06/1999	Dy. No.2215 17/01/2019 Rs.10000	11/06/2024	Deferred
1361.	24784	Respirate E Syrup Each 5ml contains:- Phenylpropanolamine HCl …12.5mg Guaifenesin …100mg	12/06/1999	Dy. No.2216 17/01/2019 Rs.10000	11/06/2024	Deferred
1362.	32328	Multifax Ointment Each gm contains:- Polymycin B Sulphate …10,000unit	10/03/2004	Dy. No.2212 17/01/2019 Rs.10000	09/03/2024	Deferred

		Zinc Bacitracin …500unit					
1363.	57498	M/s Cornileus Pharmaceuticals (Pvt) ltd, Plot No. 43H..NO 7-1-414/43, Santosh Mansion srinivas colony (EAST) S.R, Hyderabad-500038 Andhra Pradesh, India.	Somepra 20mg Capsule Each Capsule contains:- Esomeprazole magnesium trihydrate eq to Esomeprazole(P ellets) …20mg	19/05/2009	Dy. No.2217 dated 17/01/2019 Rs.10000	18/05/2024	Deferred
1364.	57499	M/s Cornileus Pharmaceuticals (Pvt) ltd, Plot No. 43H..NO 7-1-414/43, Santosh Mansion srinivas colony (EAST) S.R, Hyderabad-500038 Andhra Pradesh, India.	Somepra 40mg Capsule Each Capsule contains:- Esomeprazole magnesium trihydrate eq to Esomeprazole(P ellets) …40mg	19/05/2009	Dy. No.2218 dated 17/01/2019 Rs.10000	18/05/2024	Deferred
1365.	57511	M/s Ravoos Laboratories Ltd H. No 5-35/234/4 Plot No.6 Mythri Nagar, IDA Kukatpally Hyderabad-500072, India.	Omrazo 40mg Capsule Each Capsules contains:- Omeprazole (pellets) …40mg	30/05/2009	Dy. No.2213 dated 17/01/2019 Rs.10000	29/05/2024	Deferred
Shortcomings: Copy of evidence of Change of brand name for Xetac Tablets 150mg (Reg. No. 24782). Evidence of approval of formulation in Reference Regulatory Authorities i.e. . Respirate DM Syrup (Reg No. 24783), Respirate E Syrup (Reg No. 24784) & Multifax Ointment (Reg No. 32328). For imported pellets of Somepra 20mg Capsule (Reg No. 57498), Somepra 40mg Capsule (Reg No. 57499) & Omrazo 40mg Capsule (Reg No. 57511) differential fee is required for last as well as latest renewal for regularization.							
M/s.Polyfine Chem Pharma, 51 Industrial Estate Hayatabad Peshawar							
1366.	32426	Antinaus Injection Each 1ml ampoule contains:- Prochlorperazine Maleate … 12.50mg		07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1367.	32431	Polygenta 80mg Injection Each 2ml contains:- Gentamycin Sulphate eq. to Gentamycin …. 80mg		07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1368.	32433	Fendic S. Injection Each 1ml ampoule contains:- Diclofenac Sodium … 25mg		07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1369.	32434	Polytax Injection 250mg Each vial contains:- Cefotaxime Sodium eq. to Cefotaxime … 250mg		07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1370.	32435	Polytax Injection 500mg Each vial contains:- Cefotaxime Sodium eq. to Cefotaxime … 500mg		07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1371.	32436	Polytax Injection 1gm Each vial contains:- Cefotaxime Sodium eq. to Cefotaxime … 1gm		07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1372.	32437	Moklin Injection 250mg Each vial contains:-		07/04/2004	Dy. No.4328 dated	06/04/2024	Deferred

		Cefoperazone Sodium eq. to Cefoperazone … 250mg		30/01/2019 Rs.10000		
1373.	32438	Cefrozil Injection 500mg Each vial contains:- Cefoperazone Sodium eq. to Cefoperazone … 500mg	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1374.	32439	Cefrozil Injection 1gm Each vial contains:- Cefoperazone Sodium eq. to Cefoperazone … 1gm	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1375.	32443	Ceftrex Injection 250mg Each vial contains:- Ceftriaxone Sodium eq. to Cefriaxone … 250mg	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1376.	32444	Ceftrex Injection 500mg Each vial contains:- Ceftriaxone Sodium eq. to Cefriaxone … 500mg	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1377.	32445	Ceftrex Injection 1gm Each vial contains:- Ceftriaxone Sodium eq. to Cefriaxone … 1gm	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1378.	32447	Matric Injection Each 100ml contains:- Metronidazole … 500mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1379.	32448	Piroflam Injection Each 1ml ampoule contains:- Piroxicam … 20mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1380.	32449	Linco-Plus Injection Each 2ml contains:- Lincomycin (as Hcl)… 600mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1381.	32451	Silzolin Injection 500mg Each vial contains:- Cephazolin Sodium eq. to Cephazilon… 500mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1382.	32453	Water for Injection 5ml contains:- water for injection	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1383.	32454	Maxaclor Injection Each 2ml ampoule contains:- Metoclopramide Hcl… 10mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1384.	32456	Optibram Eye Drops contains:- Tobramycin …. 0.3%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1385.	32457	Cromosol Eye Drops 2% contains:- Sodium Cromoglyeate … 2%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1386.	32460	Polypred Eye Drops contains:- Prednisolone Acetate… 1%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1387.	32461	Naloroptic Eye Drops contains:- Naphazoline HCl… 0.025% Pheniramine Maleate …0.3%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1388.	32463	Polygenta Eye Drops contains:- Gentamycin (as Sulphate) … 0.3%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1389.	32464	Fendic-S Eye Drops contains:- Diclofenac Sodium … 0.1%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred

1390.	32465	Milosol Eye Drops contains:- Timolol (as maleate) … 0.5%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1391.	32430	Lexhal 500mg Injection Each vial contains:- Cephalexin Sodium eq. to Cephalexin … 500mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1392.	32432	Polygenta 40mg Injection Each 1ml contains:- Gentamycin Sulphate eq. to Gentamycin …. 40mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1393.	32440	Ceframed Injection 250mg Each vial contains:- Cephradine …250mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1394.	32441	Ceframed Injection 500mg Each vial contains:- Cephradine …500mg	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1395.	32442	Ceframed Injection 1gm Each vial contains:- Cephradine … 1gm	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1396.	32450	Kanan Injection 1gm Each ml contains:- Kanamycin Sulphate eq. to Kanamycin …1gm	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1397.	32455	Cromosol Eye Drops 4% contains:- Sodium Cromoglycate … 4%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1398.	32458	Polypred-S Eye Drops contains:- Prednisolone Acetate … 0.25% Sulphacetamide … 10%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1399.	32459	Polypred-C Eye Drops contains:- Prednisolone Acetate … 0.2% Sulphacetamide … 0.5%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1400.	32462	Sterifin Eye Drops contains:- Zinc Sulphate…. 0.25% Phenylephrine HCl … 0.12%	07/04/2004	Dy. No.4328 30/01/2019 Rs.10000	06/04/2024	Deferred
1401.	32427	Fazim Injection 250mg Each vial contains:- Ceftazidime Sodium eq. to Ceftazidime … 250mg	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1402.	32428	Fazim Injection 500mg Each vial contains:- Ceftazidime Sodium eq. to Ceftazidime … 500mg	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred
1403.	32429	Fazim Injection 1.0gm Each vial contains:- Ceftazidime Sodium eq. to Ceftazidime … 1gm	07/04/2004	Dy. No.4328 dated 30/01/2019 Rs.10000	06/04/2024	Deferred

Shortcomings:

Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO.

Evidence of approval of formulation for Lexhal 500mg Injection (Reg. No. 32430), Polygenta 40mg Injection (Reg. No. 32432), Ceframed Injection 250mg (Reg. No. 32440), Ceframed Injection 500mg (Reg. No. 32441), Ceframed Injection 1gm (Reg. No. 32442), Kanan Injection 1gm (Reg. No. 32450), Cromosol Eye Drops 4% (Reg. No. 32455), Polypred-S Eye Drops (Reg. No. 32458), Polypred-C Eye Drops (Reg. No. 32459) &Sterifin Eye Drops (Reg. No. 32462) in Reference Drug Agencies.

Evidence of approval of formulation for Fazim Injection 250mg (Reg. No. 32427), Fazim Injection 500mg (Reg. No. 32428), Fazim Injection 250mg (Reg. No. 32429) in Reference Drug Agencies as Ceftazidime Sodium eq. to Ceftazidime.

M/s. Maple Pharmaceutical, Plot No. 147 Sector 23 Korangi Industrial Area Karachi.							
1404.	86240	Mefsunate Tablet Each co-blister tablet, each contains:- Mefloquine HCl … 250mg 01 film coated tablet, each contains:- Artesunate … 100mg		03/02/2014	Dy. No.4323 dated 30/01/2019 Rs.10000	02/02/2024	Deferred
Shortcomings: Evidence of approval of formulation in Reference Drug Agencies.							
M/s. Amros Pharmaceutical, A-96 SITE Karachi.							
1405.	23033	Tobcin 20mg Injection Each 2ml contains:- Tobramycin Sulphate … 20mg		30/01/1999	Dy. No.4322 30/01/2019 Rs.10000	29/01/2024	Deferred
1406.	23034	Tobcin 80mg Injection Each 2ml contains:- Tobramycin Sulphate … 80mg		30/01/1999	Dy. No.4322 30/01/2019 Rs.10000	29/01/2024	Deferred
Shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Brief report of last batch manufactured. Notarized copy of Section approval letter issued by Licensing Division. An undertaking that the applied products has never been de-registered. (on Stamp Papar). An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).							
M/s. Trigon Pharmaceutical (Pvt) Ltd, 8- Km Thoker Raiwind Road Lahore.							
1407.	14328	Trisamin Injection Each 5ml contains:- Tranexamic Acid … 250mg		11/10/2009	Dy. No.2565 21/01/2019 Rs.10000		Deferred
Shortcomings: Copy of evidence of Change of brand name. Last renewal fee was submitted after the due date, therefore, differential fee is required.							
M/s. Global Pharmaceuticals (Pvt) Ltd, Plot No 204-205 Industrial Triangle, Kahuta Road, Islamabad.							
1408.	26986	Rama-D Capsule 50mg Each Capsules contains:- Tramadol HCl ….. 50mg		16/06/2001	Dy. No.2576 21/01/2019 Rs.10000		Deferred
1409.	26987	Rama-D Injection 100mg Each ml contains:- Tramadol HCl ….. 100mg		16/06/2001	Dy. No.2576 21/01/2019 Rs.10000		Deferred
Shortcomings: Copy of evidence of Change of brand name. Evidence of transfer of registration from 224, Street No.1, I-10/3, Industrial Area, Islamabad to Plot No 204-205 Industrial Triangle, Kahuta Road, Islamabad.							
M/s. English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Beg, Multan Road Lahore.							
1410.	77087	M/s Disto Pharmaceuticals (Pvt) lTd, Plot No. 22, Phase-I, IDA, Cherlapally, Hyderabad-500 051, A.P, India.	Urimax 0.4mg Capsules Each Capsules contains:- Tamsulosin HCl eq. to Tamsulosin …0.4mg	20/01/2014	Dy. No.2348 18/01/2019 Rs.10000	19/01/2024	Deferred
1411.	77088	Vit-K 1 Injection Each ml contains:- Phytomenadione (Vitamin K1) …. 2mg		20/01/2014 Change of BN: 15/02/2017	Dy. No.2348 18/01/2019 Rs.10000	19/01/2024	Deferred
Shortcomings: Differential fee is required as Urimax 0.4mg Capsules (Reg#77087) has imported pellets. Evidence of approval of formulation for Vit-K 1 Injection (Reg. No. 77088) in Reference Drug Agencies.							

M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd, A-46, S.I.T.E, North Karachi						
1412.	32543	Emkit DS Tablet Each tablet contains:- Levonorgestrel … 1.5mg	13/04/2004	Dy. No.2341 18/01/2019 Rs.10000	12/04/2024	Deferred
Shortcomings: Evidence for approval of Tablet (Hormone) section.						
M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B Block 21, Federal B Industrial Area Karachi						
1413.	23542	**Debridat Tablet 200mg** Each tablet contains:- Trimebutine Maleate … 200mg	24/04/1999	Dy. No.2343 18/01/2019 Rs.10000		Deferred
Shortcomings: Evidence of approval of formulation in Reference Drug Agencies.						
M/s. Sapient Pharma, 123-S Industrial Area Kot Lakhpat Lahore.						
1414.	06939	**Sevtol Lotion** Each 100ml contains:- Castor oil …6.3gm, Chloroxylenol …5gm Pot. Hydroxide … 1.36gm Spit.Methy …20ml	21/01/1984	Dy. No.2339 18/01/2019 Rs.10000		Deferred
Shortcomings: Evidence of approval of formulation in Reference Drug Agencies. Evidence of Transfer of registration of product from 123-S Industrial Area Kot Lakhpat Lahore to 157- Abdul Hameed Scheme, Samanabad, Lahore Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. An undertaking that the applied products has never been de-registered. **(on Stamp Papar)**. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. **(on Stamp Papar)**.						
M/s. Reckitt Benckiser Pakistan Limited, F-18 S.I.T.E Karachi.						
1415.	24262	**Disprin CnF Tablet** Each tablet contains:- Aspirin …. 300mg Paracetamol DC (Starch/pvp) …210mg eq. to Paracetamol … 200mg	20/06/2002 Change of BN: **23/01/2004**	Dy. No.2338 Dated.18/01/2019 Rs.10000	22/01/2024	Deferred
Shortcomings: Evidence of approval of formulation in Reference Drug Agencies.						
M/s. Obsons Pharmaceuticals, 209-S Industrial Estate Kot Lakhpat Lahore.						
1416.	54153	Levortizin Tablet 5mg Each tablet contains:- Levocetirizine Dihydrate … 5mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1417.	54154	Bonion Tablet 0.5mcg Each tablet contains:- Alfacalcidol … 0.5mcg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1418.	54155	Klario Tablet 500mg Each tablet contains:- Clarithromycin … 500mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1419.	54156	Klario Tablet 250mg Each tablet contains:- Clarithromycin … 250mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1420.	54157	Ob-Flox Tablet 500mg Each tablet contains:- Levofloxacin Hemihydrate eq. to Levofloxacin … 500mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1421.	54158	Cipcin Tablet 500mg Each tablet contains:- Ciprofloxacin HCl … 500mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1422.	54159	Obkast Tablet 5mg Each chewable tablet contains:- Montelukast Sodium eq. to Montelukast Base … 5mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred

1423.	54160	Vomson Tablet 10mg Each tablet contains:- Domperidone … 10mg		19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1424.	54161	Obkast Tablet 10mg Each tablet contains:- Montelukast Sodium eq. to Montelukast Base … 10mg		19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1425.	54448	Obfosfo Suspension Each 5ml contains:- Fosfomycin Calcium eq. to Fosfomycin …. 250mg		26/03/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1426.	54449	Klario 125mg Suspension Each 5ml contains:- Clarithromycin …. 125mg		26/03/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1427.	54165	M/s Smilax Labs, Ltd. Plot# 88-A, Flat# 401, Sarala Nivas, Street No.1, Sagar Society, Road # 2, Banjara Hills, Hyderabad, India.	Obpra Capsules 20mg Each Capsules contains:- Enteric coated pellets of Esomeprazole Magnesium trihydrate eq. to Esomeprazole … 20mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
1428.	54166	M/s Smilax Labs, Ltd. Plot# 88-A, Flat# 401, Sarala Nivas, Street No.1, Sagar Society, Road # 2, Banjara Hills, Hyderabad, India.	Obpra Capsules40mg Each Capsules contains:- Enteric coated pellets of Esomeprazole Magnesium trihydrate eq. to Esomeprazole … 40mg	19/02/2009	Dy. No.3855 28/01/2019 Rs.10000		Deferred
Shortcomings: For imported pellets of Obpra 20mg Capsule (Reg No. 54165) & Obpra40mg Capsule (Reg No. 54166) differential fee is required for last as well as latest renewal for regularization. Source of pellets for Klario 125mg Suspension (Reg. No. 54449) and differential fee in case of imported pellets. Evidence of approval of formulation in Reference Drug Agencies for Obfosfo Suspension (Reg#54448). Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Notarized copy of Section approval letter issued by Licensing Division. Notarized copy of Valid Drug Manufacturing License.							
M/s. Saturn Pharmaceutical (Pvt) Ltd, 23-Km Thokar Raiwind Road Lahore.							
1429.	71278	Satafenac Injection Each 3ml contains:- Diclofenac Sodium … 75mg		18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1430.	71279	Metroin Infusion IV Each 100ml contains:- Metronidazole … 500mg		18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1431.	71280	Levosat Infusion IV Each 100ml contains:- Levofloxacin (as hemihydrate) ..500mg		18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1432.	71281	Vortex Injection IV Each 5ml contains:- Iron Sucrose complex eq. to Elemental Iron … 100mg		18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1433.	71282	Domax Infusion IV Each 100ml contains:- Ciprofloxacin (as Lactate) … 200mg		18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred

1434.	71283	Water for Injection Each vial contains:- Water for injection … 5ml	18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1435.	71284	Satamin Injection Each ml contains:- Mecobalamin …. 500mcg	18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1436.	71285	Kanasat Injection IM Each 2ml contains:- Kanamycin …. 500mg	18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1437.	71286	Satacin Infusion IV Injection Each 100ml contains:- Ofloxacin … 200mg	18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred
1438.	71287	Ketalin Injection Each 10ml contains:- Ketamin … 500mg	18/08/2011	Dy. No.4555 31/01/2019 Rs.10000		Deferred

Shortcomings:
Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO.
Evidence of approval of formulation for Kanasat Injection IM (Reg. No. 71285) in Reference Drug Agencies.
Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.
Notarized copy of Valid Drug Manufacturing License.

M/s. Abbott Laboratories (Pakistan) Limited, Opposite Radio Pakistan Transmission Centre Hyderabad Road Landhi Karachi.

1439.	15104	Klaricid Granules Each 5ml contains:- Clarithromycin … 125mg	27/02/1994	Dy. No.3691 28/01/2019 Rs.10000		Deferred
1440.	07083	Somogel contains:- Lignocaine (Base) ... 0.6 w/w Cetylpyridinium Chloride … 0.02% w/w Menthol … 0.06w/w Eucalyptol …. 0.1%v/w Ethanol … 33%v/w	25/02/1984 Transfer of Reg: 19/07/2002 Transfer of mannufactring site: 22/01/2007	Dy. No.3691 28/01/2019 Rs.10000		Deferred

Shortcomings:
Source fixation letter of granules of Clarithromycin Suspension is required.
Evidence of approval of formulation for Somogel (Reg. No. 07083) in Reference Drug Agencies.

M/s. Lawari International Pharmaceutical, Gulkada Saidu Sharif Swat

1441.	54933	Cipwari 250mg Tablet Each tablet contains:- Ciprofloxacin HCl eq. to Ciprofloxacin … 250mg	29/01/2009	Dy. No.2352 18/01/2019 Rs.10000		Deferred
1442.	54934	Cipwari 500 mg tablet Each tablet contains:- Ciprofloxacin HCl eq. to Ciprofloxacin … 500mg	29/01/2009	Dy. No.2352 18/01/2019 Rs.10000		Deferred
1443.	54937	Livle 250mg Tablet Each tablet contains:- Levofloxacin Hemihydrate eq. to Levofloxacin … 250mg	29/01/2009	Dy. No.2352 18/01/2019 Rs.10000		Deferred
1444.	54938	Livle 500mg Tablet Each tablet contains:- Levofloxacin Hemihydrate eq. to Levofloxacin … 500mg	29/01/2009	Dy. No.2352 18/01/2019 Rs.10000		Deferred
1445.	54939	Piroxibet 20mg Tablet Each tablet contains:- Piroxicam as Beta Cyclodextrin … 20mg	29/01/2009	Dy. No.2352 18/01/2019 Rs.10000		Deferred
1446.	54935	M/s Murli Krishna Pharma (Pvt) Limited, Shop No. 08, Pearle Building Powai Vihar Complex Powai, India	Lesomep 40mg Capsules Each Capsules contains:- Esomeprazole	29/01/2009	Dy. No.2352 18/01/2019 Rs.10000	Deferred

			pellets eq. to Esomeprazole activity … 40mg				
1447.	54936	M/s Murli Krishna Pharma (Pvt) Limited, Shop No. 08, Pearle Building Powai Vihar Complex Powai, India	Omepak 20mg Capsules Each Capsules contains:- Omeprazole Pellets eq. to of Omeprazole Activity … 20mg	29/01/2009	Dy. No.2352 18/01/2019 Rs.10000		Deferred

Shortcomings:
For imported pellets of Lesomep 40mg Capsules (Reg No. 54935) Omepak 20mg Capsules (Reg No. 54936) differential fee is required for last as well as latest renewal for regularization.
Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.
Notarized copy of Section approval letter issued by Licensing Division.
Notarized copy of Valid Drug Manufacturing License.

M/s. Seatle (Pvt) Ltd, 45 KM Multan Road Lahore.

1448.	32494	Dowfen Gel 2.5%w/w Each gm contains:- Ketoprofen …25mg	10/04/2004 Change of BN: 03/02/2005 Transfer of Reg: 03/01/2014	Dy. No.785 07/01/2019 Rs.10000			Deferred

Shortcomings:
Renewal application has been received late but within 60 days. Therefore, prescribed late fee is required.
Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO.

M/s. Flow Pharmaceuticals (Pvt) Ltd, 17-km Sheikhupura Road, Lahore.

1449.	23044	Ficloran Injection Each 3ml ampoule contains:- Diclofenac Sodium…75mg	30/01/1999	Dy. No.804 07/01/2019 Rs.10000			Deferred
1450.	23098	Flozid Capsule Each Capsules contains:- Cefixime Trihydrate …400mg	30/01/1999 Change of BN: 06/03/2002	Dy. No.803 07/01/2019 Rs.10000			Deferred
1451.	23099	Flozid Suspension Each 5ml contains:- Cefixime Trihydrate…100mg	30/01/1999 Change of BN: 06/03/2002	Dy. No.802 07/01/2019 Rs.10000			Deferred

Shortcomings:
Evidence of change of brand name for Flozid Capsule (Reg#23098) &Flozid Suspension (Reg#23099) from 'Fixime Capsule & Fixime Suspension' to 'O-Fix Capsule & O-Fix Suspension' respectively.
Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.
Notarized copy of Valid Drug Manufacturing License.
Notarized copy of Section approval letter issued by Licensing Division.
An undertaking that the applied products has never been de-registered. (on Stamp Papar).
An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).

M/s. Venus Pharma, 23 Km Multan Road Lahore.

1452.	30758	Angilock Tablets Each tablet contains:- Losartan Potassium …50mg	28/01/2004	Dy. No.1333 11/01/2019 Rs.10000			Deferred

Shortcomings:
Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.
Notarized copy of Valid Drug Manufacturing License.
Notarized copy of Section approval letter issued by Licensing Division.
An undertaking that the applied products has never been de-registered. (on Stamp Papar).
An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy /

misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).
Brief report of last batch manufactured.
Complete description of tablet dosage form i.e. Film Coated or Plain etc.
Approval of technical staff issued by Licensing Division.
Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO.

M/s. Bayer Pakistan (Pvt) Ltd, Plot No. 108, Kot Lakhpat Industrial Estate, Lahore.

1453.	00697	Proviron Tablet Each tablet contains:- Mesterolone …25mg	Nil Transfer of reg to M/s Medipharm 12/01/1984	Dy. No.1257 Dated.10/01/ 2019 Rs.10000		Deferred
1454.	05829	Travogen Cream Each gm contains:- Isoconazole Nitrate …10gm	15/06/1982 Transfer to local mfg in name of M/s Medipharm 12/01/1984	Dy. No.1259 Dated.10/01/ 2019 Rs.10000		Deferred
1455.	04105	Nerisone Cream,Ointment & Fatty Ointment Each gm contains:- Diflucortolone Valerate …1mg	Nil Transfer of reg to M/s Medipharm 12/01/1984	Dy. No.1256 Dated.10/01/ 2019 Rs.10000		Deferred
1456.	05830	Travocort Cream Each gm contains:- Isoconazole Nitrate …1% Diflucortolone Valerate …0.1%	15/06/1982 Transfer to local mfg in name of M/s Medipharm 12/01/1984	Dy. No.1258 Dated.10/01/ 2019 Rs.10000		Deferred
1457.	04104	Nerisone C Cream Each gm contains:- Diflucortolone Valerate …1mg Chlorquinoldol …10mg	Nil Transfer of reg to M/s Medipharm 12/01/1984	Dy. No.1255 Dated.10/01/ 2019 Rs.10000		Deferred
1458.	0677	Primolut N Tablets Each tablet contains:- Norethisterone …5mg	Nil Transfer of reg to M/s Medipharm 12/01/1984	Dy. No.1260 Dated.10/01/ 2019 Rs.10000		Deferred

Shortcomings:
Notarized copy of Initial registration letter for Proviron Tablet (Reg#00697), Nerisone Cream,Ointment & Fatty Ointment (Reg# 04105), Nerisone C Cream (Reg# 04104) & Primolut N Tablets (Reg#00677)
Evidence of transfer of registrations from M/s Medipharm to new title i.e. M/s. Bayer Pakistan (Pvt) Ltd, C-21, S.I.T.E, Karachi .
Notarized copy of Valid Drug Manufacturing License of M/s. Bayer Pakistan (Pvt) Ltd, C-21, S.I.T.E, Karachi.
Notarized copy of Section approval letter issued by Licensing Division.
Evidence of approval of Tablet (Hormone) section by Licencing Board.
`Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.

M/s.Medicraft Pharmaceuticals (Pvt) Ltd, 126-B Industrial Estate Hayatabad, Peshawar.

1459.	51085	Sefitime 1gm Injection Each vial contains:- Cefoperazone(as Sodium)……500mg Sulbactum (as Sodium)…….500mg	21/08/2008 Change of BN: 03/12/2014	Dy. No.958 Dated.04/01/ 2019 Rs.10000		Deferred
1460.	56360	Sefitime 2gm Injection Each vial contains:- Cefoperazone(as Sodium)……1000mg Sulbactum (as Sodium)…….1000mg	26/03/2009 Change of BN: 03/12/2014	Dy. No.958 Dated.04/01/ 2019 Rs.10000		Deferred

Shortcomings:
Evidence of change of brand name from Bacticef to Cefopar for applied products.

M/s. Glitz Pharma, Plot No 265 Industrial Triangle Kahuta Road Islamadad.						
1461.	54725	Usid-B Cream 2%w/w Each gm contains:- Fusidic Acid …20mg	01/01/2009 Change of BN: 28/06/2011	Dy. No.145 01/01/2019 Rs.10000		Deferred
1462.	54926	G-Toco Tablet 100mg Each tablet contains:- Vitamin E Acetate…100mg	24/01/2009	Dy. No.1966 16/01/2019 Rs.10000		Deferred
Shortcomings: Renewal application for Usid-B Cream 2%w/w (Reg#54725) has been received late but within 60 days. Therefore, prescribed late fee is required. Evidence of approval of formulation G-Toco Tablet 100mg (Reg#54926) in Reference Drug Agencies. Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.						
M/s. Karachi Chemical Industries (Pvt) Ltd, F-25 Estate Avenue, SITE, Karachi.						
1463.	22959	Xylometazoline Nasal Spray contains:- Xylometazoline HCL …0.1%w/v	12/01/1999	Dy. No.425 03/01/2019 Rs.10000	11/01/2024	Deferred
1464.	22960	Iqanol Tablets 50mg Each tablet contains:- Atenolol …50mg	12/01/1999	Dy. No.424 03/01/2019 Rs.10000	11/01/2024	Deferred
1465.	22961	Iqanol Tablets 100mg Each tablet contains:- Atenolol …100mg	12/01/1999	Dy. No.423 03/01/2019 Rs.10000	11/01/2024	Deferred
1466.	22958	Clotrimazole Solution 1%w/v contains:- Clotrimazole …1%w/v	12/01/1999	Dy. No.422 03/01/2019 Rs.10000	11/01/2024	Deferred
Shortcomings: Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO. Notarized copy of Valid Drug Manufacturing License. Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Notarized copy of Section approval letter issued by Licensing Division. An undertaking that the applied products has never been de-registered. **(on Stamp Papar)**. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. **(on Stamp Papar)**.						

Imported registered drugs (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Manufacturer as per registration letter	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s.Novartis Pharma (Pakistan) Ltd, 15-West Wharf Dockyard Road Karachi.							
1467.	78120	Mfgd by: M/s Novartis pharma Stein AG, Schaffhausestrasse, 4332 Stein, Switzerland MA Holder: Novartis Europharm Ltd., Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom.	Jakavi 15mg Tablet Each tablet contains:- Ruxolitinib…15mg	20/03/2014	Dy. No.2831 dated 22/01/2019 Rs.20000		Deferred
1468.	078119	Mfgd by: M/s Novartis pharma Stein AG, Schaffhausestrasse, 4332 Stein, Switzerland MA Holder:	Jakavi 5mg Tablet Each tablet contains:- Ruxolitinib…5mg	3/20/2014	Dy. No.2830 Dated.22/01/2019 Rs.20000		Deferred

		Novartis Europharm Ltd., Wimblehurst Road, Horsham, West Sussex, RH12 5AB, United Kingdom.					
1469.	23119	M/s Novartis Farmaceutica S.A., Spain.	Exelon Capsules 1.5mg Each Capsules contains:- Carbamoylatine as hydrogen tartrate…..1.5mg	10/02/1999 Change of mfg site: 12/10/2002	Dy. No.2568 dated 22/01/2019 Rs.20000		Deferred
1470.	23120	M/s Novartis Farmaceutica S.A., Spain.	Exelon Capsules 3.0mg Each Capsules contains:- Carbamoylatine as hydrogen tartrate…..3mg	10/02/1999 Change of mfg site: 12/10/2002	Dy. No.2569 Dated.21/01/2019 Rs.20000		Deferred
Shortcomings: Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate							
M/s B.Braun Pakistan (Pvt) Ltd, Khayaban-e- Jami, Block No.9, The Forum, Suite 216, 75600, Clifton, Karachi							
1471.	33126	M/s B.Braun Melsungen AG, Carl- Braun-Strabe 1, 34212 Melsungen, Germany.	Propofol-Lipuro 1% Each ml contains:- Propofol … 10mg	03/12/2004	Dy. No.4318 Dated.30/01/2019 Rs.20000		Deferred
1472.	59042	M/s B.Braun Melsungen AG, Carl- Braun-Strabe 1, 34212 Melsungen, Germany.	Aminoplasmal B-Braun 10% E Solution for Infusion Each 1000ml contains:- Isoleucine …5gm Leucine …8.9gm Lysine HCl …8.56gm (eq. to Lysine 6.85gm) Methionine …4.4gm Phenylalanine …4.7gm Threonine …4.2gm Tryptophan …1.6gm Valine …6.2gm Arginine …11.5gm Histidine …3gm Alanine …10.5gm Glycine …12gm Aspartic Acid …5.6gm Glutamic Acid …7.2gm Proline …5.5gm Serine …2.3gm Tyrosine …0.4gm Sodium Acetate Trihydrate …2.858gm Sodium Hydroxide …0.36gm Potasium Acetate	02/09/2009	Dy. No.4316 Dated.30/01/2019 Rs.20000		Deferred

			…2.453gm Magnasium Chloride Hexahydrate …0.508gm Disodium Phophate dodecahydrate …3.581gm				
1473.	10222	M/s B.Braun Medical AG, Switzerland.	**Gelofusine** Each 100ml contains:- Modified Fluid Gelatin…….4.00gm Weight average molecular weight(Mw).30000 Number average molecular weight(Mw).23200 Sodium Chloride…..0.701gm Sodium Hydroxide..0.136gm Water for Injections to……..100ml Na……154 Cl……..120	Nil Transfer of Reg: 25/06/1996	Dy. No.4315 Dated.30/01/2019 Rs.20000		Deferred
1474.	23619	M/s B.Braun Melsungen AG, Carl- Braun-Strabe 1, 34212 Melsungen, Germany.	Etomidate-Lipuro Emulsion for Injection Each 10ml emulsion contains:- Etomidate…20mg	12/05/1999	Dy. No.4314 Dated.30/01/2019 Rs.20000		Deferred
1475.	11084	M/s B.Braun Melsungen AG, Carl- Braun-Strabe 1, 34212 Melsungen, Germany.	Lipofundin MCT/LCT 20% Each 1000ml contains:- Soybean Oil …100gm Medium Chain Triglycerides …100gm Glycerol …25gm Egg Yolk PhoPhelpids …12gm	Nil Transfer of Reg: 25/06/1996	Dy. No.4319 Dated.30/01/2019 Rs.20000		Deferred
1476.	59041	M/s B.Braun Melsungen AG, Carl- Braun-Strabe 1, 34212 Melsungen, Germany.	Aminoplasmal B-Braun 5% E Solution for Infusion Each 1000ml contains:- Isoleucine …2.5gm Leucine …4.45gm Lysine HCl …4.28gm (eq to lysine 3.43gm) Methionine …2.2gm Phenylalanine …2.35gm Threonine …2.1gm Tryptophan …0.8gm Valine …3.1gm Arginine …5.75gm	02/09/2009	Dy. No.4317 Dated.30/01/2019 Rs.20000		Deferred

			Histidine …1.5gm Alanine …5.25gm Glycine …6gm Aspartic Acid2.8gm Glutamic Acid3.6gm Proline …2.75gm Serine…1.15gm Tyrosine …0.40gm Sodium Acetate Trihydrate1.361gm Sodium Hydroxide …0.14gm Potasium Acetate …2.453gm Sodium Chloride …0.964gm Magnesium Chloride Hexahydrate …0.508gm Disodium Phophate dodecahydrate …3.581gm				
1477.	10053	M/s B.Braun Medical Industries SDN BHD, Bayan Lepas Free Industrial Zone, 11900 Bayan Lepas, Pulau Pinang, Malaysia.	Diazole Injection Each 100ml contains:- Meronidazole …500mg	Nil Transfer of Reg: 25/06/1996	Dy. No.4313 Dated.30/01/2019 Rs.20000		Deferred
Shortcomings: Differential fee is required for late submission of renewal application for latest and last renewal of Propofol-Lipuro 1% (Reg#33126). Notarized copy of initial registration letter of Diazole Injection (Reg#10053), Lipofundin MCT/LCT 20% (Reg#11084) & Gelofusine (Reg#10222). Evidence of change of manufacturing site from B.Braun Switzerland to B.Braun Malysia for Gelofusine (Reg#10222). Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate. Copy of **Valid** Drug Sale License.							
M/s Zam Zam Corporation, 205- 206, Beaumont Plaza 6-CL-10 Beaumont Road Karachi.							
1478.	15726	Mfgd by: M/s Leo Laboratories Ltd, 285 Cashel Road, Crumlin Dublin 12, D12 E923, Ireland MA Holder: M/s Leo Pharma A/S, Industriparken 55, DK-27500 Ballerup, Denmark.	Daivonex Ointment Each gm contains:- Calcipotrilol …50mcg	05/09/1994	Dy. No.260 02/01/2019 Rs.20000	04/09/2024	Deferred
1479.	31379	Mfgd by: M/s Leo Laboratories Ltd, 285 Cashel Road, Crumlin Dublin 12, D12 E923, Ireland MA Holder: M/s Leo Pharma A/S, Industriparken 55, DK-27500 Ballerup, Denmark.	Daivobet Ointment Each gm contains:- Calcipotrilol (as monohydrate) …50mcg Betamethasone (as dipropionate) …0.5mg	26/07/2004	Dy. No.259 02/01/2019 Rs.20000	25/07/2024	Deferred
Shortcomings: Copy of Valid Drug Sale License.							

Locally manufactured registered drugs (Veterinary)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Manhattan Pharma, 209/B, Sector-5 (Green Belt) Korangi Industrial Area Karachi.						
1480.	14574	Furazone-M Feed Supplement Powder Each 1000gm powder contains:- Furazolidone … 244gm	22/02/1994	Dy. No.4324 dated 30/01/2019 Rs.10000	21/02/2024	Deferred
1481.	14575	Terra-M 200 Feed Supplement Powder Each 1000gm powder contains:- Oxytetracycline HCl… 200gm	22/02/1994	Dy. No.4324 dated 30/01/2019 Rs.10000	21/02/2024	Deferred
Shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Brief report of last batch manufactured. Notarized copy of Section approval letter issued by Licensing Division. Notarized copy of Valid Drug Manufacturing License. Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO. An undertaking that the applied products has never been de-registered. (on Stamp Papar). An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).						
M/s. Amros Pharmaceutical, A-96 SITE Karachi. Veterinary local						
1482.	22711	Chlorophenaramine Maleate Injection Each ml contains:- Chlorpheniramine Maleate … 10mg	11/02/1999	Dy. No.4321 dated 30/01/2019 Rs.10000	10/02/2024	Deferred
Shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Brief report of last batch manufactured. Notarized copy of Section approval letter issued by Licensing Division. An undertaking that the applied products has never been de-registered. (on Stamp Papar). An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).						
M/s. Bio-Labs Research Lab, Plot No.145 Kahuta Triangle Industrial Estate Islamabad.						
1483.	14534	**Biolyte Water Soluble Powder** Each 1000mg contains:- Vit A … 11,500,000IU Vit D 1,800,000IU Vit E… 5,200IU Vit B2… 1200mg Cal. D. Pantothenate… 10,000mg, Folic Acid … 200mg, Biotine … 10mg, Sodium Chloride … 1600mg, Zinc Sulphate … 10,000.00mg, Magnanese Sulphate …10, 000mg, L-Lysine Hcl … 10,000mg DL-Methionine 10,000mg	22/04/1994	Dy. No.1583 Dated.14/01/2019 Rs.10000		Deferred
1484.	14536	Bio-HS Bacterin Injection Methionine … 60,000mg, Lysine … 100,000mg, Folic Acid … 550mg, Nicotinic Acid … 25000mg,	1994	Dy. No.1583 Dated.14/01/2019 Rs.10000		Deferred

		Cal. Pantothenate … 4,500mg, Arginine … 800mg, Tryptophan … 350mg Cysteine … 350mg, Manganese … 1,500mg, Iron Sulphate … 25,000mg				
Shortcomings: Clarification required regarding the address of firm as the address on Initial Registration Letter is different from Drug Manufacturing License. Clarification required regarding date of initial registration for Bio-HS Bacterin Injection (Reg No. 14536) as it is not mentioned on registration letter. Evidence for approval for injectable section (Veterinary).						
M/s. Noble Pharma, Plot No. B-1 Old Industrial Area Mirpur Azad Kashmir. Veterinary Local						
1485.	58728	Nobivet Oral Powder Each 100gm contains:- Spiramycin Adipate … 2.50gm Chlortetracycline Hydrochloride … 7.50gm	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1486.	58729	Nobi- Spectin Powder Each 150gm contains:- Lincomycin Hydrochloride ….33.3gm Spectinomycin Sulphate … 66.7gm	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1487.	58730	Nobinor Solution Each 1000ml Solution contains:- Norfloxacin …. 250gm	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1488.	58731	Nobitylox -60 Powder Each 100gm contains:- Tylosin Tartrate… 20gm Doxycycline Hydrochloride…. 40gm	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1489.	58732	Nobi-Enro 10% Oral Solution Each ml contains:- Enrofloxacin … 100mg	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1490.	58733	Nobioxy-200 Powder Each kg contains:- Oxytetracycline Base …. 222gm	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1491.	58734	Nobi-Esb3 Powder Each 100gm contains:- Sulphachlorpyridazine … 30%	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1492.	58735	Nobi-Cina TS Oral Solution Each ml contains:- Cenoxine … 75mg Sulphamethoxypridazine … 75mg Sulphamethazine … 50mg Trimethoprim … 25mg	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1493.	58736	Nobi-Trime Suspension Each 200ml contains:- Sulphadiazine … 80gm Trimethoprim …. 16gm Tylosin Tartate …. 2gm	23/07/2009	Dy. No.2351 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1494.	58737	Nobi-Dvd Oral Solution Each 100ml contains:- Sulphaquinoxaline … 2.56%w/v Diaveridine … 0.64%w/v	23/07/2009	Dy. No.2350 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1495.	58738	Colisel 200 Solution Each 1000ml contains:- Colistin Sulphate … 2,000,000,000IU	23/07/2009	Dy. No.2350 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred

1496.	58739	Freecox Oral Powder Each 500gm contains:- 2,4-diamino-5 Veratrylpyrimidine … 25gm Sulphabenzypyrazine … 100gm Vitamin A … 1.25MIU Menadione Sulphate Sodium (Vitamin K3) … 2.5gm	23/07/2009	Dy. No.2350 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1497.	58740	Nobi-Dine Oral Powder Each 100gm contains:- Sodium Sulphadiamidine … 80gm Diaveridine … 8gm	23/07/2009	Dy. No.2350 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1498.	58741	Coccizole Plus Oral Powder Each 1000gm contains:- Sulphaquinoxaline Sodium… 200gm Sulphadimidine Sodium.. 82.5gm Diaveridine …. 2.5MIU Vitamin A …5000mg Vitamin E … 5000mg	23/07/2009	Dy. No.2350 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1499.	58743	Nobiquin Oral Powder Each 100gm contains:- Trimethoprim ... 4.62gm Sulphaquinoxalline Sodium …15.02gm	23/07/2009	Dy. No.2350 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1500.	58744	Tigercin TD Powder Each 100gm contains:- Tylosin Tartrate … 10gm Doxycycline HCl … 20gm Colistine Sulphate … 3gm Bromhexine … 1gm	23/07/2009	Dy. No.2350 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1501.	58720	Nobicholivet Powder Each 100gm contains:- Colistine Sulphate …. 5,00,000,000IU	23/07/2009	Dy. No.2349 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1502.	58721	Nobicen Oral Liquid Each ml contains:- Tylosin Tartrate … 55mg Sulfadiazine … 175mg Trimethoprim … 35mg	23/07/2009	Dy. No.2349 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1503.	58722	Nobidar Oral Powder Each 100gm contains:- Amprollium Hydrochloride..30gm Sulphaquinoxaline Sodium..20gm Vitamin K3… 0.6gm	23/07/2009	Dy. No.2349 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1504.	58724	Nobillin-S Oral Solution Each ml contains:- Spiramycin Adipate … 12.5w/v Lincomycin Hydrochloride … 7.5w/v	23/07/2009	Dy. No.2349 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1505.	58725	Nobi PSBC Powder Each 1000gm contains:- Procain Penicillin ... 12gm Streptomycin Sulphate … 36gm Zinc Bacitracin … 52gm Colistin Sulphate … 60IU	23/07/2009	Dy. No.2349 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
1506.	58726	Nobineo Oral Powder Each 1000gm contains:- Neomycin Sulphate … 720gm	23/07/2009	Dy. No.2349 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred

1507.	58727	Nobicycline 50% Oral Powder Each kg contains:- Doxycycline Hyclate … 500gm	23/07/2009	Dy. No.2349 Dated.18/01/2019 Rs.10000	22/07/2024	Deferred
Shortcomings: Last renewal application of products was received late but within 60 days. Therefore, prescribed late fee is required. Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. An undertaking that the applied products have never been de-registered. **(on Stamp Papar)**. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. **(on Stamp Papar)**. Any post registration variation since grant of registration						
M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Plot No. A-127 SITE Super Highway Karachi. Veterinary Local						
1508.	52336	Colitylo Plus Injection Each 100ml contains:- Colistin sulphate …1250mg Tylosin tartarate …10mg Bromhexine HCl …100mg Dexamethasone …50mg	23/01/2009	Dy. No.2570 Dated.21/01/2019 Rs.10000		Deferred
Shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Notarized copy of Valid Drug Manufacturing License. Notarized copy of Section approval letter issued by Licensing Division.						

Imported registered drugs (Veterinary)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Manufacturer as per registration letter	Brand Name & Composition	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Pantex Pharmaceutica, 26-Abbott Road, Lahore.							
1509.	29650	M/s Pantex Holland B.V., Smaragdweg 15, 5527 LA Hapret, The Netherlands	**Tylin 20% Injection** Each ml contains:- Tylosin (as Tartrate) … 200mg	19/03/2003 Transfer of reg: **19/02/2009**	Dy. No.2562 Dated.21/01/2019 Rs.20000	18/02/2024	Deferred
1510.	26651	M/s Pantex Holland B.V., Smaragdweg 15, 5527 LA Hapret, The Netherlands	**Gentalin 10% Injection** Each ml contains:- Gentamycin (as Sulphate) …. 100mg	19/03/2003 Transfer of reg: **19/02/2009**	Dy. No.2563 Dated.21/01/2019 Rs.20000	18/02/2024	Deferred
1511.	22778	M/s Pantex Holland B.V., Smaragdweg 15, 5527 LA Hapret, The Netherlands	**Streptopen 25/20 Injection Suspension** Each ml contains:- Procaine Pencillin G… 200,000IU Dihydrostreptomycin Sulphate … 250mg	17/04/1999	Dy. No.2561 Dated.21/01/2019 Rs.20000		Deferred
Shortcomings: Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate.							
Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad.							
1512.	53953	M/s Laboratorio HOFARM S..A.C. (for Agrovert Market S.A.), Carretera Central Km 3.7, Santa Anita, Lima, Peru.	**Aminoplex Forte Injection Solution** Each 100ml contains:- Dextrose … 5.5gm Calcium Chloride … 15mg	12/02/2009	Dy. No.3830 Dated.22/01/2019 Rs.20000		Deferred

			Potassium Chloride …20mg Magnesium Sulphate … 20mg Sodium Acetate Trihydrate …250mg L-Histidine Hydrochloride … 34mg DL-Methionine … 34mg DL-Tryptophane …34mg L-Threonine …. 68mg L-Cysteine Hydrochloride …. 34mg DL-Isoleucine.... 68mg L-Arginine Hydrochloride ... 85mg DL-Phenylalanine ... 102mg				
1513.	53951	M/s Laboratorio HOFARM S..A.C. (for Agrovert Market S.A.), Carretera Central Km 3.7, Santa Anita, Lima, Peru.	Bovimec LA Injectable Solution Each 100ml contains:- Ivermectin …1gm	12/02/2009	Dy. No.1274 Dated.10/01/ 2019 Rs.20000		Deferred
1514.	52399	M/s Mavlab Pty Ltd., Australia.	Acemav Injection 10mg/ml Each ml contains:- Acepromazine…… ……10mg	04/02/2009	Dy. No.1266 Dated.10/01/ 2019 Rs.20000		Deferred
1515.	53955	M/s Laboratorio HOFARM S..A.C. (for Agrovert Market S.A.), Carretera Central Km 3.7, Santa Anita, Lima, Peru.	Cefa Milk Fort Intramammary Suspension Each 10ml contains:- Cephalexin Monohydrate eq to base …200mg Gentamycin Sulphate eq to base…100mg Dexamethasone 21 Phosphate.0.750mg Vitamin A…10000IU	12/02/2009	Dy. No.1265 Dated.10/01/ 2019 Rs.20000		Deferred
1516.	53952	M/s Laboratorio HOFARM S..A.C. (for Agrovert Market S.A.), Carretera Central Km 3.7, Santa Anita, Lima, Peru.	Hematofos B12 Injectable Solution Each 100ml contains:- Vitamin B12(cyanocobalamin e) …0.0011gm Tetrahydrate cobalt(ii) acetate…0.05gm	12/02/2009	Dy. No.1268 Dated.10/01/ 2019 Rs.20000		Deferred

			L-tryptophan …0.25gm Histidine…0.5gm Citric Acid…0.5gm DL Methionine …..1 gm Sodium Sulphate ….1 gm Ammoium Iron Citrate …2 gm Sodium Cacodylate…3gm Disodium Edetate…0.4gm Riboflavin 5 phosphate…0.2gm Nicotinamide…5gm Pyridoxine HCl … …1 gm Sodium Glycerophosphate …1gm				
1517.	52398	M/s Mavlab Pty Ltd., Australia.	Flumav Flunixin Injection Each ml contains:- Flunixin Meglumine 83mg eq to Flunixin …50mg	04/02/2009	Dy. No.1267 Dated.10/01/ 2019 Rs.20000		Deferred
1518.	53950	M/s Laboratorio HOFARM S..A.C. (for Agrovert Market S.A.), Carretera Central Km 3.7, Santa Anita, Lima, Peru.	Duramycin 300LA Injectable Solution Each 100ml contains:- Oxytetracycline Base …30gm	12/02/2009	Dy. No.1269 Dated.10/01/ 2019 Rs.20000		Deferred
1519.	53954	M/s Laboratorio HOFARM S..A.C. (for Agrovert Market S.A.), Carretera Central Km 3.7, Santa Anita, Lima, Peru.	Tri-ABZ Oral Suspension Each 100ml contains:- Triclabendazole …50gm Albendazole …37.5gm	12/02/2009	Dy. No.1271 Dated.10/01/ 2019 Rs.20000		Deferred
1520.	53948		Tylo-Combisone Injectable Solution Each 100ml contains:- Tylosin Tartrate Base …15gm Gentamycin Sulphate Base …6gm Dexamethasone 21 Phosphate …0.0265gm Chlorpheniramine Maleate …0.75gm	12/02/2009	Dy. No.1270 Dated.10/01/ 2019 Rs.20000		Deferred
Shortcomings: Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate.							

Locally Manufactured Registered Drugs (Human).

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. The Searle Company Limited., Plot# F-319, Sindh Industrial Trading Estate, Karachi.						
1521.	076023	**Tizax 2mg Tablet** Each tablet contains: Tizanidine …2mg	19/09/2013	Dy. No. 30953 dated 13/9/2018 10000/-	18/09/2023	w.e.f. 19-09-2018 to 18-09-2023
1522.	076022	**Tizax 4mg Tablet** Each tablet contains: Tizanidine …4mg	19/09/2013	Dy. No. 30953 dated 13/9/2018 10000/-	18/09/2023	w.e.f. 19-09-2018 to 18-09-2023
1523.	014479	**Maxaquin 400mg Tablet** Each Tablet Contains Lomefloxacin…400mg	21/10/1993	Dy. No. 30953 dated 13/9/2018 10000/-	20/10/2023	w.e.f. 21-10-2018 to 20-10-2023
Deferred for following: (M-290) Complete description of tablet dosage form i.e. Film Coated or Plain etc. Notarized copy of evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO for Maxaquin 400mg Tablet (Reg#014479). Evidence of transfer of registration of products to current address and name of firm.						
Evaluation by RRR: Now firm has submitted following: Complete description of tablet dosage form i.e. Film Coated or Plain etc. Notarized copy of evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO for Maxaquin 400mg Tablet (Reg#014479). Evidence of transfer of registration of products to current address and name of firm.						
M/s Geofman Pharmaceuticals, Plot No.20, Sector 23, Korangi Industrial Area, Karachi						
1524.	028633	**Septipan Capsule** Each Capsule Contains Cefixime…400mg	19/03/2003	Dy. NO. 31404 dated 18-09-2018 10,000/-		w.e.f. 19-03-2018 to 18-03-2023
Deferred for following: (M-290) Evidence of submission of fee for applied product. Applying late for renewal; therefore, differential fee is required.						
Evaluation by RRR: Evidence of submission of fee for applied product. Evidence of last renewal submitted within due date.						
M/s WnsFeild Pharmaceuticals, Plot#122, Block-A, Phase V, Indusrial Estate, Hattar						
1525.	77437	**Deslozam 5mg Tablet** Each dispersible tablet contains Desloratadine …5 mg	25/09/2013	31172 10,000 9/14/2018	24/09/2023	w.e.f. 25-09-2018 to 24-09-2023
1526.	77438	**Calciwns 1 mcg Injection** Each 1 ml ampoule contains: Calcitriol …1 mcg	25/09/2013	31172 10,000 9/14/2018	24/09/2023	w.e.f. 25-09-2018 to 24-09-2023
Deferred for following: (M-290) An undertaking that the applied products has never been de-registered. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws.						
Evaluation by RRR: Now firm has submitted following: An undertaking that the applied products has never been de-registered. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws.						

M/s. Focus &Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad						
1527.	77658	**Tenv 300mg Tablet** Each film coated tablet contains: Tenofovir Disoproxil Fumarate….300mg, (Eq to 245mg of Tenofovir disproxil)	05/11/2013	Dy.No.37129 dated 09.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05-11-2018 to 04-11-2023
Deferred for following: (M-291) Renewal fee was submitted after the due date, therefore, differential fee is required. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
Evaluation by RRR: Now firm has submitted following: Evidence of submission of late renewal fee.						
M/s Elko Organization (Pvt) Ltd, 27 & 28, Sector 12/B, North Karachi Industrial Area, Karachi						
1528.	9926	**Metron Infusion** Each 100ml contains:- Metronidazole …500mg	15/09/1988	9/11/2018 10,000 30543	14/09/2023	w.e.f. 15-09-2018 to 14-09-2023
1529.	21476	**Elkomin Injection** Each ml contains: Cyanocobalamin …250mcg	09/09/1998	9/11/2018 10,000 30543	08/09/2023	w.e.f. 09-09-2018 to 08-09-2023
1530.	21478	**Elkavil Injection** Each ml contains: Pheniramine maleate …25mg	09/09/1998	9/11/2018 10,000 30543	08/09/2023	w.e.f. 09-09-2018 to 08-09-2023
1531.	21479	**Elkogent Injection** Each ml contains: Gentamycin sulphate eq. to 200mg Gentamycin base	09/09/1998	9/11/2018 10,000 30543	08/09/2023	w.e.f. 09-09-2018 to 08-09-2023
1532.	21480	**Elkoneurin Injection** Each 3ml Contains: Thiamine HCl (B1) …100mg, Pyridoxine HCl (B6) …100mg, Cyanocobalamin (B12) …500mcg	09/09/1998	9/11/2018 10,000 30543	08/09/2023	w.e.f. 09-09-2018 to 08-09-2023
1533.	21481	**Elkocaine Injection** Injection Contains:- Lignocaine HCl …2%, Sodium Chloride ... 0.60%, Methyl Hydroxy Benzoate … 0.10%	09/09/1998	9/11/2018 10,000 30543	08/09/2023	w.e.f. 09-09-2018 to 08-09-2023
1534.	31475	**Leox D.S. Suspension**. Each 100 ml contains: Levamisole HCl …3gm. Oxyclozanide …6gm.	02/10/2003	9/11/2018 10,000 30543	01/10/2023	w.e.f. 02-10-2018 to 01-10-2023
1535.	31474	**Levanil D.S. Solution** Each 100 ml contains: Levamisol HCl … 3gm.	02/10/2003	9/11/2018 10,000 30543	01/10/2023	w.e.f. 02-10-2018 to 01-10-2023
Deferred for following: (M-290) Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO. An undertaking that the applied products has never been de-registered. **(on Stamp Papar)**. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. **(on Stamp Papar)**.						
Evaluation by RRR: Now firm has submitted following: Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO. An undertaking that the applied products has never been de-registered. **(on Stamp Papar)**. An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. **(on Stamp Papar)**.						

M/s. Hizat Pharmaceutical Industries (Pvt) Ltd, 170-Industrial Estate Jamrud Road, Peshawar						
1536.	031214	Pomex 100mg Suspension Each 5ml contains: Cefixime Trihydrate 111.90mg eq. to Cefixime …100mg	10/09/2003	Dy. No. 30116 7/9/2018 10,000	09/09/2023	w.e.f. 10-09-2018 to 09-09-2023
1537.	031213	Zoroxin Tablets Each tablet contains: Norfloxacin ……400mg	10/09/2003	Dy. No. 30115 7/9/2018 10,000	09/09/2023	w.e.f. 10-09-2018 to 09-09-2023
1538.	031215	Silkocin 250mg Tablets Each tablet contains: Clarithromycin ……250mg	18/09/2003	Dy. No. 30118 7/9/2018 10,000	17/09/2023	w.e.f. 18-09-2018 to 17-09-2023
1539.	031216	Silkocin 500mg Tablets Each tablet contains: Clarithromycin ……500mg	18/09/2003	Dy. No. 30119 7/9/2018 10,000	17/09/2023	w.e.f. 18-09-2018 to 17-09-2023
1540.	031217	Silkocin 125mg Suspension Each 5ml contains: Clarithromycin ……125mg	18/09/2003	Dy. No. 30117 7/9/2018 10,000	17/09/2023	w.e.f. 18-09-2018 to 17-09-2023
1541.	031218	Hizemox 250mg Dry Suspension Each 5ml contains: Amoxicillin Trihydrate 287mg eq to Amoxicillin ……..250mg	10/09/2003	Dy. No. 30120 7/9/2018 10,000	09/09/2023	w.e.f. 10-09-2018 to 09-09-2023
1542.	031219	Oflazat Tablets Each tablet contains: Ofloxacin ……200mg	10/09/2003	Dy. No. 30114 7/9/2018 10,000	09/09/2023	w.e.f. 10-09-2018 to 09-09-2023
1543.	031220	Ciprozat 250mg Tablets Each tablet contains: Ciprofloxacin HCl 277.52mg eq. to Ciprofloxacin….250mg	10/09/2003	Dy. No. 30122 7/9/2018 10,000	09/09/2023	w.e.f. 10-09-2018 to 09-09-2023
1544.	031221	Ciprozat 500mg Tablets Each tablet contains: Ciprofloxacin HCl 555mg eq. to Ciprofloxacin..500mg	10/09/2003	Dy. No. 30123 7/9/2018 10,000	09/09/2023	w.e.f. 10-09-2018 to 09-09-2023
1545.	031222	Hizexin Tablet Each tablet contains: Naproxen.....500mg	10/09/2003	Dy. No. 30121 7/9/2018 10,000	09/09/2023	w.e.f. 10-09-2018 to 09-09-2023

Deferred for following: (M-290)

Latest cGMP Inspection Report having conclusive recommendations regarding cGMP.
Notarized copy of Section approval letter issued by Licensing Division.
Notarized copy of Valid Drug Manufacturing License.
An undertaking that the applied products has never been de-registered. (on Stamp Papar).
An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).

Evaluation by RRR:

Now firm has submitted following:
Latest cGMP Inspection Report having conclusive recommendations regarding cGMP dated 26/12/2018
Notarized copy of Section approval letter issued by Licensing Division.
Notarized copy of Valid Drug Manufacturing License.
An undertaking that the applied products has never been de-registered. (on Stamp Papar).
An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).

M/s Bryon Pharmaceuticals Pvt Ltd. 48-Hayatabad Industrial Estate, Peshawar, K.P.K							
1546.	052562	Desolar Tablets. Each film Tablet contains;- Desloratadine…5mg.		24/09/2008	31077 10,000 14/9/2018	23/09/2023	w.e.f. 24-09-2018 to 23-09-2023
1547.	052563	Fluxaquin Tablets. Each Tablet contains:- Moxifloxacin as HCl…400mg.		24/09/2008	31077 10,000 14/9/2018	23/09/2023	w.e.f. 24-09-2018 to 23-09-2023
1548.	052566	Steady Tablets 4mg. Each Tablet contains:- Glimepiride…4mg.		24/09/2008	31077 10,000 14/9/2018	23/09/2023	w.e.f. 24-09-2018 to 23-09-2023
1549.	052567	Steady Tablets 3mg. Each Tablet contains:- Glimepiride…3mg.		24/09/2008	31077 10,000 14/9/2018	23/09/2023	w.e.f. 24-09-2018 to 23-09-2023
1550.	052568	Steady Tablets 2mg. Each Tablet contains:- Glimepiride…2mg.		24/09/2008	31077 10,000 14/9/2018	23/09/2023	w.e.f. 24-09-2018 to 23-09-2023
1551.	052569	Steady Tablets 1mg. Each Tablet contains:- Glimepiride…1mg.		24/09/2008	31077 10,000 14/9/2018	23/09/2023	w.e.f. 24-09-2018 to 23-09-2023
1552.	052661	Sopral Plus 10mg Tablets. Each tablet contains: Bisoprolol Fumarate..10mg Hydrochlorothiazide…6.25mg		16/10/2008	31077 10,000 14/9/2018	15/10/2023	w.e.f. 16-10-2018 to 15-10-2023
1553.	052662	Source of pellets: Vision pharmaceuticals, Plot # 224, Street#1, I-10/3, Industrial Area, Islamabad.	Esophag Capsules 20mg Each Capsule contains:- Esomeprazole as Magnesium Trihydate…20mg	16/10/2008 Change of pellets source: 15/10/2014	31077 10,000 14/9/2018	15/10/2023	w.e.f. 16-10-2018 to 15-10-2023
1554.	052663	Source of pellets: Vision pharmaceuticals, Plot # 224, Street#1, I-10/3, Industrial Area, Islamabad.	Esophag Capsules 40mg Each Capsule contains:- Esomeprazole as Magnesium Trihydrate…40mg.	16/10/2008 Change of pellets source: 15/10/2014	31077 10,000 14/9/2018	15/10/2023	w.e.f. 16-10-2018 to 15-10-2023
Deferred for following: (M-290) Source of pellets for Esophag Capsules 20mg (Reg. No. 52662) & Esophag Capsules 40mg (Reg. No. 52663) and differential fee in case of imported pellets. iAn undertaking that the applied products has never been de-registered. (on Stamp Papar). An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).							
Evaluation by RRR: Now firm has submitted following: Source of pellets for Esophag Capsules 20mg (Reg. No. 52662) & Esophag Capsules 40mg (Reg. No. 52663) and differential fee in case of imported pellets. An undertaking that the applied products has never been de-registered. (on Stamp Papar). An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).							
M/s Pakistan Pharmaceutical Products (Pvt) Ltd, D-122, S.I.T.E, Karachi							
1555.	03490	Combidine Syrup Each 5ml Contains Pholcodein…10mg Ephedrine HCl…5mg		13/03/1978 Change of B.N on 19/09/1978	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023

		Chlorpheniramine Maleate…4mg Sodium Citrate…150mg Sucrose…3.33gm Sodium Benzoate…10mg				
1556.	76043	Amoxynate Dry Suspension Each 5ml contains:- Amoxicillin as Trihydrate…125 mg Clavulanic Acid as Potassium …31.25 mg	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
1557.	76044	Amoxynate Dry Each 5ml contains:- Amoxicillin as Trihydrate…250 mg Clavulanic Acid as Potassium …62.5 mg	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
1558.	76045	Amoxynate 1gm Tablet Each tablet contains:- Amoxicillin as Trihydrate…875mg Clavulanic Acid as Potassium … 125 mg	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
1559.	76046	Arcofix Suspension DS200mg/5ml Each 5ml contains:- Cefixime…200mg	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
1560.	76047	Zentrix 250mg Capsule Each capsule contains:- Azithromycin…250mg	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
1561.	76048	Zentrix 500mg Capsule Each capsule contains:- Azithromycin…500mg	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
1562.	76049	Lumina 80mg/ml Injectio Each ampoule contains:- Artemether …80mg/ml	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
1563.	76050	Candinil 150mg Capsule Each capsule contains:- Fluconazole …150mg	19/09/2013	18/09/2018 11/9/2018 10,000	18/19/2023	w.e.f. 19-09-2018 to 18-09-2023
Deferred for following: (M-290) Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO.						
Evaluation by RRR: Now firm has submitted following: Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO.						
M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot #30, Phase I & II, Industrial Estate, Hattar						
1564.	25469	Kamcid Suspension Each 5ml contains:- Famotidine.....10mg	22/11/1999 Change of B.N on 16/09/2003	31076 10,000 14/9/2018	15/09/2023	w.e.f. 16-09-2018 to 15-09-2023
1565.	21702	Kanic Tablet 50mg Each Tablet Contains Diclofenac Potassium…50mg	20/05/1998 Change of B.N on 16/09/2003	31076 10,000 14/9/2018	15/09/2023	w.e.f. 16-09-2018 to 15-09-2023
1566.	21703	Myfer Tablet Contains Ferrous Fumarate…200mg Vitamin B1…25mg Vitamin B2…2.5mg Vitamin B6…25mg Vitamin B12…25mcg Nicotinamide…25mg	20/05/1998 Change of B.N on 16/09/2003	31076 10,000 14/9/2018	15/09/2023	w.e.f. 16-09-2018 to 15-09-2023

		Folic Acid…1mg Cal. Pantothenate…10mg				
1567.	21704	Myfer Syrup Each 5 ml Contains Ferrous Gluconate…130mg Vitamin B1…1.5mg Vitamin B2…1mg Vitamin B6…1.5mg Nicotinamide…15mg Cal. Pantothenate…1mg L-Lysine Mono HCl…50mg	20/05/1998 Change of B.N on 16/09/2003	31076 10,000 14/9/2018	15/09/2023	w.e.f. 16-09-2018 to 15-09-2023
Deferred for following: (M-290) Notarized copy of Initial Registration Letter.						
Evaluation by RRR: Now firm has submitted following: Notarized copy of Initial Registration Letter.						
M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad						
1568.	16831	Fadiphine Tablet 40mg Each tablet contains: Famotidine ...40mg	16/05/1997	Dy.No.36351 01.11.2018 Rs.10000/-	15/05/2022	w.e.f. 16-05-2017 to 15-05-2022
1569.	25195	Fericard 5mg Tablet Each tablet contains: Warfarin Sodium …5mg	12/10/1999 Change of BN: 30/01/2002	Dy.No.36351 01.11.2018 Rs.10000/-	11/10/2024	w.e.f. 12-10-2019 to 11-10-2024
1570.	52507	Clopirine Tablet Each tablet contains:- Clopidogrel ……. 75mg Aspirin …… 75mg	17/09/2008	Dy.No.36351 01.11.2018 Rs.10000/-	16/09/2023	w.e.f. 17-09-2018 to 16-09-2023
1571.	30533	Gloxil 250mg Injection Each vial contains:- Amocycillin (as sodium) …250mg	17/05/2003	Dy.No.36351 01.11.2018 Rs.10000/-	16/05/2023	w.e.f. 17-05-2018 to 16-05-2023
Deferred for following: (M-291) Last renewal for Fericard 5mg Tablet (Reg#25195), Fadiphine Tablet 40mg (Reg#16831) & Gloxil 250mg Injection (Reg#030533) was valid till 29/04/2013as per letter No.F.11-16/2007-RRR (Vol-I) issued on 02/11/2011, but the firm applied for renewal on 05/12/2013 with 20,000/- fee each. Last renewal of Clopirine Tablet (Reg#52507) was due on 16/09/2013 but the firm applied for renewal on 05/12/2013 with 20,000/- fee.						
Evaluation by RRR: Now firm has submitted following: Fee challan of Rs. 60,000 (Challan#1950016) Fee challan of Rs. 60,000 (Challan#1950017) Fee challan of Rs. 10,000 (Challan#1950018) Fee challan of Rs. 60,000 (Challan#1950020)						

Imported registered drugs (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Manufacturer as per registration letter	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Atco Laboratories (Pvt) Ltd,B-18 S.I.T.E Karachi.							
1572.	31333	M/s Feering Intrnational Center S.A., Chemin de la Vergognausaz 50 CH-1162 St. Prex, Switzerland	Pentasa 500mg prolonged release Tablet Each prolonged release tablet contains: Mesalazine …500mg	16/12/2003 Change of packaging site 07/08/2007Change of mfg site 13/08/2008 Change of mfg site 05/11/2014	Dy.No.38789 26/11/2018 Rs.20000		Deferred

Deferred for following: (M-291)
Notarized and valid copy of DSL.
Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate.

Evaluation by RRR:
Now firm has submitted following:
Firm has submitted commitment to submit valid DSL upon receiving and have submitted evidence of application for renewal of DSL.
Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate.

M/s Bayer Pakistan (Pvt) Limited, Bahria Complex II, 4th Floor, M.T. Khan Road, Karachi. (Import human)

1573.	52224	Manufactured by: M/s Bayer AG, Kaiser-Wilhelm – Allee, 51368, Leverkusen, Germany. Product License Holder: M/s Bayer AG, 51368, Leverkusen, Germany	Nexavar 200mg Tablets Each tablet contains: Sorafenib (as tosylate) …200mg.	25/09/2008 Change of name of parent company 09/08/2010 Change of mfg name: 06/03/2014 Change of mfg name: 16/07/2019	Dy. No. 32036 25/09/2018 20,000	24/9/2023	Deferred

Deferred for following: (M-291)
Firm has not submitted renewal for applied product since its registration. Furthermore, firm has stated that last renewal date for product was 09/08/2010 at the time of approval of company name change.
Notarized and valid copy of DSL.
Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate
Copy of attested invoices for respective applied products.
An undertaking that the applied product has never been de-registered. (on Stamp Papar).
An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).

Evaluation by RRR:
Now firm has submitted following:
Firm has stated that they have submitted original CoPP in Import section and have submitted copy of CoPP in RRR section.
Firm has applied for renewal in 25/09/2018 and initial Reg date is 25/09/2008. Last renewal was submitted on 24/06/2015 keeping in view the time of approval of company name change of 09/08/2010.
Copy of attested invoices for respective applied products.
An undertaking that the applied product has never been de-registered. (on Stamp Papar).
An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws. (on Stamp Papar).

Locally manufactured registered drugs (Veterinary)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Reg.	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Noa Hemis Pharmaceuticals, Plot no. 154, Sector 23, Korangi Industrial Area, Karachi						
1574.	013249	Dewomix Powder Each Kg Contains Phenothiazine 145gm, Piperazine Adipate 70gm, Dibutyltin Dilaurate 35gm	18/05/1992 Reg of vet drugs for local mfg and transfer from	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023

			M/s medicure 01/10/2003			
1575.	013250	Vitamax Super Water Soluble Powder Each Kg Contains vitamin A 15miu, vitamin D3 3miu, vitamin E 6,000iu, vitamin K3 4,000mg, vitamin B1 5,000mg, vitamin B2 6,000mg, vitamin B6 4,000mg, vitamin B12 9,000mcg, vitamin C 15gm, Nicotinic Acid 25gm, Calcium Pantothenate 10gm, Folic Acid 750mg	18/05/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1576.	013251	Cotrizin Water dispersible Powder Each 100gm Contains Trimethoprim 4gms Sulphadiazine 20gms	18/05/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1577.	013252	Clopidol-25 Powder Each Kg Contains: - Clopidol 250gm	18/05/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1578.	013668	Erysol FD Water dispersible Powder Each 10gm Contains Erythromycin Thiocynate (Eq. To 10.90gm Of Erthromycin) 12gm, Furaltadone Hcl 8gm	22/11/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	Deferred as formulation is under review
1579.	013669	Avamix Plus Powder Each 5kg Contains vitamin A 15miu, vitamin E 30,000iu, vitamin B1 3,000mg, Nicotinic Acid 60,000mg, Calcium Pantothenate 12,000mg, vitamin B12 40mg, Biotin 50mg, Di-Methionine 150,000mg, BHT 62,500mg, Zinc Sulphate 240,000mg, Copper Sulphate 30,000mg, vitamin D3 3miu, vitamin K3 3,000mg, vitamin B2 7,000mg, vitamin B6 4,000mg, Folic Acid 1,500mg, Choline Chloride 50% 800,000mg,	22/11/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023

		L-Lysine 75,000mg, Manganese Sulphate 258,000mg, Ferrous Sulphate 200,000mg, Potassium Iodide 2,000mg				
1580.	013670	Amproquin Powder Each Kg Contains: - Sulphaquinoxaline 9.0%, Amprolium Hcl 12.0%, vitamin A 5miu, vitamin K3 5gm	22/11/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1581.	013671	D.O.T Plus Powder Each Kg Contains: - Dinitolamide 25%, (3-5 Dinitro-O- Tolumide Ethopabate 1.6%	22/11/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1582.	013672	Coccidine Powder Each Kg Contains: - Robenidine 6.6% (66 Gm)	22/11/1992 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1583.	015433	Lychomin Powder Each Kg Contains: - Di-Methionine 40%, L-Lysine…30% Choline Chloride 50%...20%	08/06/1994 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1584.	015434	Tylosin - 10 Powder Each Kg Contains: - Tylosin 100gm	08/06/1994 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1585.	015435	Nefron Supplement Powder Each Kg Contains: - Furazolidone 240gms	08/06/1994 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	Deferred as formulation is under review
1586.	015436	Hymax Premix Powde Each 2.5kg Contains vitamin A 11miu, vitamin D3 2miu, vitamin E 6,000iu, vitamin K3 1,200mg, vitamin B1 1gm, vitamin B2 4gm, vitamin B6 1gm, vitamin B12 10,000mcg, Folic Acid 750mg, Calcium Pantothenate 6gm, Biotin 10mg,	08/06/1994 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023

		Nicotinic Acid 20gm, Lysine 30gm, Methionine 60gm, Choline Chloride 50% 200gm, Manganese 65gm, Iron 28gm, Zinc 42gm, Copper 2.5gm, Iodine 1gm, BHT 31.25gm				
1587.	015437	Amino Plus VM W/S Powder Each Kg Contains: - vitamin A 22miu, vitamin D3 3miu, vitamin E 8,000iu, vitamin K3 2gm, vitamin B1 2gm, vitamin B2 5gm, vitamin B6 2gm, vitamin B12 9,000mcg, vitamin C 20gm, Folic Acid 1gm, Calcium Pantothenate 10gm, Nicotinic Acid 25gm, Lysine 75gm, Methionine 75gm, Threonine 9.5gm, Tryptophan 2gm, Arginine 12gm, Histidine 4200mg, Isoleucine 8gm, Leucine 14gm, Phenylalmine 6gm, Valine 12gm	08/06/1994 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1588.	018850	Methesol Plus Powder Each Kg Contains: - Methenamine 950gm Thiamine Hcl (Vit B1) 3gm, Riboflavine (Vit B2) 4gm, D-Calcium Pantothenate 4gm, Pyridoxine Hcl (Vit B6) 3gm, Nicotinamide 3gm	07/04/1996 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1589.	019929	Adevit Plus Powder Each Kg Contains: - Vitamin -A10 Miu, Vitamin -D.3 Miu, Vitamin -E.5000 I.U. Vitamin-K3.3000mg, Vitamin-C.30,000mg	28/05/1997 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1590.	021424	Enrolone-20 Oral Solution Each 100 ml Contains: Enrofloxacin…20gm	04/09/1998 Reg of vet drugs for local mfg and transfer from M/s medicure	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023

			01/10/2003			
1591.	027443	Enrolone-10 Oral Solution Each 100 ml Contains: Enrofloxacin…10gm.	26/03/2002 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1592.	028507	Pro Sb Powder Each Kg Contains: - Procaine Penicillin B.P. 12.00gm. Streptomycin Sulphte 36.00gm. Zinc Bacitracin 52.00gm.(Antibacterial).	17/08/2002 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
1593.	028508	Pro Sb-Plus Powder Each Kg Contains: - Procaine Penicillin B.P. 12.00gm. Streptomycin Sulphte 36.00gm. Zinc Bacitracin 52.00gm. Colistin Sulphate 60 Miu.(Antibacterial).	17/08/2002 Reg of vet drugs for local mfg and transfer from M/s medicure 01/10/2003	Dy. No. 31498 dated 18-09-2018 10,000/-	30/09/2023	w.e.f. 01-10-2018 to 30-09-2023
Deferred for following: (M-290) Notarized copy of Initial registration letters of the mentioned products confirming the formulations.						
Evaluation by RRR: Now firm has submitted following: Notarized copy of Initial registration letters of the mentioned products confirming the formulations.						

Imported registered drugs (Veterinary)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Manufacturer as per registration letter	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. UM Enterprises, Plot#12, Sector No 5, Korangi Industrial Area, Karachi							
1594.	31513	M/s Shandong Qilu King-Phar Pharmaceutical Co. Ltd, No.21 Qinglong Road, Pingyin, Jinan, Shandong, China	Monensin 20% Powder Each Kg Contains Monensin…20%	07/10/2003	Dy. No. 29556 04/09/2018 20,000	06/10/2023	w.e.f. 07-10-2018 to 06-10-2023
1595.	21447	M/s Arab Veterinary Industrial Company (AVICO) Amman, Jordan	Try-Ban Powder for Injection Each Sachet Contains Quinapyramine Sulphate…1.5gm Quinapyramine Chloride…1.0gm	07/09/1998	Dy. No. 29557 04/09/2018 20,000	06/09/2023	w.e.f. 07-09-2018 to 06-09-2023
Deferred for following: (M-290) Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate							
Evaluation by RRR: Now firm has submitted free sale certificate and GMP certificate for Monensin 20% Powder (Reg#31513) & Try-Ban Powder for Injection (Reg#21447).							

MISCELLENEOUS CASE

a) Renewal application of M/s Marvi Pharmaceuticals Pvt Limited Karachi of Pain Gay Ointment (012777)

It is submitted that M/s. Marvi Pharmaceuticals had applied for renewal of registration of year 2015 for their following product vide SRO 1005(I)/2017 dated 05th October, 2017. Details of products are as under:

Sr. No.	Reg. No.	Brand Name & Composition	Date of registration as per Form-5B
1596.	012777	Pain Gay Ointment Each gm contains: Methyl Salicylate ……150mg Menthol……100mg	15-12-1992

The Firm was advised to submit the evidence of initial registration letter and post registration variation (if any) for further preceding the case. In the reply firm submitted only the evidence of renewal of year 2010, however the firm was again requested for submission of initial registration letter. The firm informed that they were granted the registration of Pain Gay Ointment containing Methyl Salicylate 150mg + Menthol 100mg, Registration No. 012777 vide approval letter No. F.3-6/91-Reg-II (M-94) dated 04th August, 1991.Since then they are marketing this product in whole country and export to other countries as well. Furthermore they have also taken Trade Mark Registration of their brand PainGay from the Trade Marks Registry, Government of Pakistan Karachi.

The firm further informed d that due to ill health followed by demise of one of their Director Mr. Nadir Fazwani, several documents were stolen or misplaced/lost which also include registration letters issued to them by Ministry of Health. Due to the reason they fail to apply renewal within due time.

Recently Drug Regulatory Authority of Pakistan's decision /policy vide SRO 1005(I)/2017 dated 5th October, 2017 regarding renewal of registration of products applied after stipulated time. Accordingly we have applied for renewal of Pain Gay Ointment (Reg.No. 012777) along with 3 time applicable fee i.e. Rs.30, 000/- .The firm also stated that that they had already applied for issuance of duplicate registration letter of subject product and applied in concerned section.

It is submitted that aforementioned product is included in the formulary and according to it Pain Gay Ointment was registered in the name of M/s. Marvi Pharmaceuticals Pvt Limited Karachi with the Registration No.012777 and formulation is mentioned as METHYL SALICYCILATE 15gm +MENTHOL 10gm.However initial registration date is not mentioned in the said formulary which is the date as provided by the firm in Form 5B with renewal application.

The above case was discussed in the 288th meeting of Registration Board wherein the board decided as under:

"Registration Board deferred the case for the submission of copy of FIR related to documents stolen/misplaced/lost for onward consideration of case"

The firm has submitted the copy of daily dairy record of concerned Police Station regarding the report of stolen/ misplaced/ lost registration letter. Case has been placed in 289th meeting of Registration for considering in the light of submitted documents and decision of the board is as under:

"Registration Board deferred the above case for opinion of Legal Affairs Division."

As per decision of Registration Board Case has referred to Legal Affair Division for its opinion and the reply is as under:

"The firm has submitted the copy of Police Report (Roznamcha) which is sufficient proof of misplacing the original documents required for renewal of its product. Therefore this Division is opined that the Registration Board may consider the request of the firm for renewal on the basis of these documents."

The case is deferred in 291st meeting for further delibration

Decision:- Regitration Board considered the case and decided to ask the firm to apply for issuance of duplicate registration letter for further grant of renewal.

b) M/s. Vision Pharmaceuticals, Islamabad

It is submitted that Registration Board in its 277th meeting considered the renewal applications of M/s Vision Pharmaceuticals, Islamabad of following product (s), and decided as under in light of SRO 1005(I)/2017 dated 05th October, 2017.

S. No.	Reg. No.	Product Name	Initial date of Registration	Decision in 277th meeting regarding regularization of renewal
1597.	037784	Cibrotam Injection 1gm Each 5ml contains:- Piracetam …1gm	22-03-2005	Regularized the renewal of 2010 till 2015 and grant the renewal from 22-3-2015 to 23-03-2020
1598.	038900	Acetofeb Extra Tablet Each tablet contains:- Paracetamol … 500mg Caffeine Anhydrous…65mg	30-06-2005	Regularized the renewal of 2010 till 2015 and grant the renewal from 30-06-2015 to 29-06-2020
1599.	041729	Adfin 400mg Tablet Each tablet contains:- Ibuprofen … 400mg	15-12-2005	Regularized the renewal of 2010 till 2015 and grant the renewal from 15-12-2015 to 14-12-2020
1600.	041736	Inflanil Tablet 250mg Each tablet contains:- Mefenamic Acid … 250mg	15-12-2005	-do-
1601.	037563	Protozid Tablet Each tablet contains:- Metronidazole … 250mg Di Iodohydroxyquinoline … 325mg	21-03-2005	Regularized the renewal of 2010 till 2015 and grant the renewal from 21-03-2015 to 20-03-2020
1602.	037572	Epilax 200mg Tablet Each tablet contains:- Carbamazepine … 200mg	21-03-2005	-do-
1603.	056309	Fevonor Suspension Each 5ml contains: - Paracetamol … 120mg	20-02-2009	Registration board acceded to request of the firm and decided to grant renewal from 20-02-2014 to 19-02-2019
1604.	056310	Fevonor Plus Suspension Each 5ml contains:- Paracetamol … 250mg	20-02-2009	-do-
1605.	050289	Coxyzin Syrup Each 5ml contains:- Cetirizine Dihydrochloride … 5mg	28-07-2008	Registration board acceded to request of the firm and decided to grant the renewal from 28-07-2013 to 27-07-2018
1606.	037573	Epilax Syrup Each 5ml contains:- Carbamazepine … 100mg	21-03-2005	-do-
1607.	037554	Mycomide 500mg Tablet Each tablet contains: - Pyrazinamide … 500mg	21-03-2005	-do-

The firm has granted the Drug Manufacturing License (DML no.000517) on 01-04-2014.Accordingly the product registered at their former manufacturing facility were transferred to the new site. The above mentioned products were not applied for the transfer of registration by the firm at that time presumably due to non submission of renewal application in2010 and 2015.Afeter notification of SRO 1005 the firm applied for regularization of renewal of aforementioned period which were approved by the Registration Board in its 277th meeting. Thereafter the concerned section take-up the matter in 278th meeting of Registration Board and decision is given as under:

a) Acceded to the request of firm for transfer of registration of products at S. No. 2, 3, 6, 11 form their previous site i.e. Plot No.224, Street No.1, I-10/3, Islamabad to new site i.e. Plot No.22-23, Industrial Triangle, Kahuta Road, Islamabad.

b) Deferred the request of firm for products at S. No. 1, 4, & 5 for evidence of Approval in reference regulatory authorities.
c) Deferred the request of the firm for products at S. No. 7-10 for evidence of Approval of section/manufacturing facility.

Now the firm is requesting for issuance of renewal letter, the previous history has been placed for the consideration of Registration Board please.

The case is deferred in 291st meeting for further delibration

Decision:- Registratio Board decided to communicate the status of their renewal application applied under SRO 1005(i)/2017 to concerned section for transfer of registration of their product to their new manufacturing site.

c) M/s. Ahad International Pharmaceuticals, Ltd., Dera Ismail Khan

The case was deferred in 278th Meeting for regularization of renewal of period 2017 – 2022 vide SRO-1005(I)/2017 for the rectification of shortcoming. Now the firm has rectified the shortcoming as mentioned below.

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Remarks (if any)
1608.	045824	Safemed Injection Each 100ml contains: Metronidazole….500mg Water for injection q.s to make 100ml	20-01-2007 Last renewal submitted 04-01-2012 (within time)	Fee as per S.R.O Required Initial Registration letter required DML Required. In this regard shortcoming letter has been communicated to the firm. Shortcoming has been rectified. Fee of Rs. 10,000/- has been paid on 04-12-2017, differential fee of Rs. 20,000/- paid on 27-07-2018

Decision:- Registratio Board acceded the request of the firm and regularize the renewal of the Firm under SRO 1005(i)/2017 from 20-01-2017 to 19-01-2022.

d) M/s. GlaxoSmithKline Pakistan Limited, Karachi deferred in 291st Meeting of Registration Board.

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration	Date of application (R&I) Fee submitted	Decision of RB in 288th meeting	Remarks	Decision
M/s. GlaxoSmithKline Pakistan Limited F-268, S.I.T.E. ,Karachi							
1609.	021770	Calpol Plus Tablet Each Tablet Contains: Paracetamol …500mg Caffeine…65mg	20-05-1998 30-08-2003	Dy. No. 25292 dated 20-7-2018 10000/-	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 06-05-2019 which has not yet been responded by the firm. a. Transfer of registration from D/43 Textile Avenue, S.I.T.E, Karachi to F-268, S.I.T.E., Karachi. Section approval letter issued by Licensing Division.	In response to letter firm stated they request the concerned section to issue the transfer letters in the name of manufacturing sites. Further firm did not provide the section approval letter issued by Licensing Division.	Deferred for clalrifcation from the firm for complete details regarding transfer of registration and sections since initial regsitation.

					Valid Drug Manufacturing License.		
1610.	012427	Calpol 6 Plus Suspension Each 5ml Contains: Paracetamol…250mg	14-03-1991	Dy. No. 25292 dated 20-07-2018 10000/-	-do-	-do-	-do-
1611.	000354	Calpol Suspension Each 5ml Contains: Paracetamol…120mg	17-04-1976	Dy. No. 25292 dated 20-07-2018 10000/-	-do-	-do-	-do-
1612.	001612	Calpol Tablet Each Tablet Contains: Paracetamol…500mg	15-08-1976	Dy. No. 25292 dated 20-07-2018 10000/-	-do-	-do-	-do-
1613.	000355	Cicatrin Powder Each gm Contains: Neomycin Sulphate…3300 Units Bacitracin Zinc…250 Units	17-04-1976	Dy. No. 25298 dated 20-07-2018 10000/-	-do-	-do-	-do-
1614.	000301	Cytacon Liquid Each 5ml Contains: Cyanocobalamin …25mcg	20-04-1976	Dy. No. 25298 dated 20-07-2018 10000/-	-do-	-do-	-do-
1615.	008382	Marzine Syrup Each 5ml Contains: Cyclizine HCl…12.5mg	18-06-1985	Dy. No. 25293 20-07-2018 10000/-	-do-	-do-	-do-
1616.	000179	Maxolon Syrup Each 5ml Contains: Metoclopramide HCl eq. to Anhydrous Sustance…5mg	16-04-1976	Dy. No. 25293 20-07-2018 10000/-	-do-	-do-	-do-
1617.	013321	Nemazole Suspension Each 5ml Contains: Mebendazole…100mg	25-05-1992	Dy. No. 25299 20-07-2018 10000/-	-do-	-do-	-do-
1618.	013320	Nemazole Tablet Each Tablet Contains: Mebendazole…100mg	25-05-1992	Dy. No. 25299 20-07-2018 10000/-	-do-	-do-	-do-

1619.	017306	Nemazole-500 Chewable Tablet Each Tablet Contains: Mebendazole…500mg	21-06-1995	Dy. No. 25299 dated 20-07-2018 10000/-	-do-	-do-	-do-
Reply of the firm: The firm has submitted the reply on 23-09-2019 wherein the relevant information regarding the transfer of registration and manufacturing facility for mentioned products is still insufficient. **Decision:- Registration Board deferred the application of the firm and advise to refer the case to concerned section for transfer of registration on manufacturing site address.**							
M/s. GlaxoSmithKline Pakistan Limited,35- Dockyard Road, West Wharf, Karachi							
1620.	003100	Dermovate Cream Contains: Clobetasol Propionate…0.05%w/w	10-12-1977	Dy. No. 25295 dated 20-07-2018 10000/-	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 06-05-2019 which has not yet been responded by the firm. Detail of shortcoming are as under: a) Information required regarding the pellets of FefolSpansule Capsule (Reg. No. 000401), Fesopen-Z Spansule Capsule (Reg. No. 000402) and Fefol Z Spansule Pellets (Reg. No. 020543). Either the pellets are imported or manufactured on the same facility. b) Change of brand name evidence required for the Fesopan-Z Spansule Capsule (Reg. No. 000402).	In their reply firm stated that the Spansule pellets are manufactured on the same facility. Further firm replied regarding the transfer from D/43 textile avenue to 35-Dockyard that they request the concerned section to issue the transfer letters in the name of manufacturing sites. Change of brand name evidence provided by the firm. Further firm did not provide the section approval letter issued by Licensing Division.	Deferred for clalrifcation from the firm for complete details regarding transfer of registration and sections since initial regsitation.

					c) Transfer of registration from D/43 Textile Avenue, S.I.T.E, Karachi to 35-Dockyard Road, West Wharf, Karachi. d) Section approval letter issued by Licensing Division. e) Valid Drug Manufacturing License.		
1621.	006230	Dermovate NN Ointment Contains: Clobetasol Propionate…0.05%w/w Neomycin Sulphate…0.5% w/w Nystatin…100,000 Units per gm	16-03-1982	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
1622.	003139	Dermovate Ointment Contains: Clobetasol Propionate…0.05 %w/w	10-12-1977	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
1623.	003100	Dermovate Cream Contains: Clobetasol Propionate…0.05 %w/w	10-12-1977	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
1624.	000401	FefolSpansule Capsule Each Spansule Capsule Contains: Exsiccated Ferrous Sulphate..150mg Folic Acid..0.5mg	24-03-1976	Dy. No. 25294 dated 20-07-2018 10000/-	-do-	-do-	-do-
1625.	000402	Feospen Z Spansule Capsule Each Capsule Contains: Exsiccated Ferrous Sulphate…150mg Zinc Sulphate Monohydrate…61.8mg	22-03-1976	Dy. No. 25294 dated 20-07-2018 10000/-	-do-	-do-	-do-
1626.	020543	Fefol Z Spansule Pellets	12-11-1997	Dy. No. 25294	-do-	-do-	-do-

		Each Capsule Contains: Dried Ferrous Sulphate…150mg Zinc Sulphate Monohydrate (eq. to 22.5mg Elemental Zinc)…61.8mg Folic Acid…0.5mg		dated 20-07-2018 10000/-			
1627.	089275	Maxolon Injection Each 2ml Contains: Metoclopramide …10mg	28-08-1977	Dy. No. 25293 dated 20-07-2018 10000/-	-do-	-do-	-do-
1628.	000357	Cortisporin Eye Ointment Each gm Contains: Polymyxin B Sulphate…5000 Units Bacitracin Zinc…400 Units Neomycin Sulphate…3400 Units Hydrocortisone… 10mg	17-04-1976	Dy. No. 25298 dated 20-07-2018 10000/-	-do-	-do-	-do-
1629.	000178	Maxolon Injection Each 2ml Contains: Metoclopramide …10mg	28-08-1977	Dy. No. 25293 dated 20-07-2018 10000/-	-do-	-do-	-do-
1630.	001608	Lanoxin Injection Each 2ml Ampoul Contains: Digoxin…0.5mg	15-08-1976	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
1631.	000365	Lidosporin Ear Drops Each ml Contains: Polymyxin B Sulphate…10,000 IU Lignocaine HCl…50mg Propylene Glycol…0.92ml	17-04-1976	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
1632.	000370	Otosporin Ear Drops Each ml Contains: Polymyxin B Sulphate…10,000	17-04-1976	Dy. No. 25291 dated 20-07-2018 10000/-	-do-	-do-	-do-

		IU Neomycin Sulphate…3,400 Units Hydrocortisone Acetate…10mg					
1633.	000060	Furacin Cream Contains: Nitrofurazone in Water-Soluble Base…0.2%w/w	22-03-1976	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
Reply of the firm: The firm has submitted the reply on 23-09-2019 wherein the relevant information regarding the transfer of registration and change of brand name is not provided. **Decision: Registration Board deferred the application of the firm and advise to refer the case to concerned section for transfer of registration on manufacturing site address.**							
M/s. GlaxoSmithKline Pakistan Limited, Plot 5, Sector 21, Korangi Industrial Area, Karachi							
1634.	003375	Ceporex Capsule 250mg Each Capsule Contains: Cephalexin Anhydrous (as Cephalexin)…250mg	04-01-1978	Dy. No. 25296 dated 20-07-2018 10000/-	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 06-05-2019 which has not yet been responded by the firm. Detail of shortcoming are as under: a) Section approval letter for Cephalosporin Injectable section issued by Licensing Division. b) Valid Drug Manufacturing License. c) Approval of products in reference regulatory agencies.	Firm replied regarding the transfer from D/43 textile avenue to Korangi Industrial Area, Karachi that they request the concerned section to issue the transfer letters in the name of manufacturing sites. Firm submitted the approval letter of Licensing division for confirmation of Cephalosporin Section.	Deferred for clalrifcation from the firm for complete details regarding transfer of registration and sections since initial regsitation.

1635.	005641	Ceporex Capsule 500mg Each Capsule Contains: Cephalexin Anhydrous (as Cephalexin)…500 mg	16-11-1980	Dy. No. 25296 dated 20-7-2018 10000/-	-do-	-do-	-do-
1636.	010806	CeporexPaediatric Drops Each 1.25ml Contains: Cephalexin…125 mg	24-03-1990	Dy. No. 25296 dated 20-07-2018 10000/-	-do-	-do-	-do-
1637.	003374	Ceporex Syrup 125mg/5ml Each 5ml Contains: Cephalexin Anhydrous (as Cephalexin)…125 mg	04-01-1978	Dy. No. 25296 dated 20-07-2018 10000/-	-do-	-do-	-do-
1638.	006408	Ceporex Syrup 250mg/5ml Each 5ml Contains: Cephalexin Anhydrous (as Cephalexin)…250 mg	07-08-1982	Dy. No. 25296 dated 20-07-2018 10000/-	-do-	-do-	-do-
Reply of the firm: The firm has not submitted any information regarding above mentioned clarifications. **Decision:- Registration Board deferred the application of the firm and advise to refer the case to concerned section for transfer of registration on manufacturing site address.**							
M/s. GlaxoSmithKline Pakistan Limited							
1639.	000068	Furadantin Tablet Each Tablet Contains: Nitrofurantoin… 100mg	22-03-1976	Dy. No. 25295 dated 20-07-2018 10000/-		Manufacturing did not confirm from documents submitted to the shortcoming letter.	Deferred for clalrifcation from the firm for complete details regarding transfer of registration and sections since initial regsitation.
Reply of the firm: The firm has not submitted any information regarding above mentioned clarifications. **Decision: - Registration Board deferred the application of the firm and advise to refer the case to concerned section for transfer of registration on manufacturing site address.**							

DELEGATION OF POWERS:

Registration Board after thorough delibration that in order to expedite the disposal of renewal cases decided to authorize Chairman Registration Board for grant of renewal of registration (locally Manufactured) which have been received within time as required under Rule 27 of Drug (LR&A) Rules 1976.

However the renewal cases which are received after expiry but within 60 days and renewal of imported finished registered products will be placed before Registration Board for its consideration.

Item No. III Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A	Imported Human Biologicals from Reference Countries	2
C	Imported Veterinary Biologicals from Reference Countries	2
D	Imported Veterinary Biologicals from Non Reference Countries	11
E	Miscellaneous/ Deferred cases	66
Additional Agenda		39
Total		120

Sr. No.	Assistant Director	Designated No.	No. of Cases
a.	Mr. Khurram Khalid	AD-I	30
b.	Mr. Saadat Ali Khan	AD-II	39
c.	Mr. M. Zubair Masood	AD-III	51

A: Imported Human Biologicals from Reference Countries.

1.	Name of Importer	M/s Sanofi-Aventis Pakistan Limited, Plot No. 23, Sector, 22, Korangi Industrial Area, Karachi.
	DSL details	No. 00849 dated 19-02-2019 valid till 25-12-2020
	Name of Manufacturer	M/s Sanofi Pasteur Limited, 1755 Steeles Avenue West Toronto, Ontario Canada, M2R 3T4
	Brand Name +Dosage Form + Strength	Adacel Vaccine Suspension
	Composition	Each dose contains: Filamentous Haemagglutinin……5mcg/0.5ml Pertussis Toxoid……....2.5mcg/0.5ml Pertactin…….3mcg/0.5ml Diphtheria Toxoid……..……2LF/0.5ml Tetanus Toxoid……..5LF/0.5ml Fimbriae Types 2 and 3 (FIM)…..5mcg/0.5ml
	Finished product specifications	In-House
	Pharmacological Group	Human Vaccine
	Shelf life	36 months (2^0C-8^0C)
	International availability	Adacel, USFDA
	Products already registered in Pakistan	New Entity
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5F (CTD) Dy. No. 6906 Dated: 22-05-2019 Rs. 100000/- Dated: 22-05-2019
	Demanded Price / Pack size	1's Vial & 5's Vials/ Not Provided.
	General documentation	• Legalized CoPP No. 69632 dated 20-06-2018 valid for one (01) year. • Legalized GMP certificate No. 71515 dated 07-02-2019 valid for one (01) year.
	Remarks of Evaluator	• The submitted CoPP was valid at the time of submission but is now expired as one month validity was remaining. • The firm mentioned the Ph. Eur Specifications at Specification point while for Pharmacopoeial reference the firm submitted the In-house and/or pharmacopoeia reference. • The above mentioned product is WHO Pre-qualified. The link for pre-qualification status is at https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=315 accessed on Pre-qualification status was accessed on 23-09-2019
Decision:	**Keeping in view the WHO Prequalification, valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product with Innovator specifications subject to compliance of current Import Policy for finished drugs.**	
2.	Name of Importer	M/s Punjab Medical Services Pharmacy, Sharf Manssion near ganga Ram Hospital, 16-Queens Road, Lahore.
	DSL details	No. 05-352-0063-01231P dated 09-08-2017 valid till 09-08-2019
	Name of Manufacturer	Product License Holder: M/s Aqvida, GmbH Kaiser-Wilhelm-Str. 89, 20355 Hamburg, Germany. Manufacturer: M/s Bag Health Care GmbH, Amtsgerichtstr. 1-5 35423 Lich, Germany
	Brand Name +Dosage Form + Strength	Leucita 300µg/1.2ml Solution for injection
	Composition	Each 1.2ml contains: Filgrastim……..30 MU(300µg)
	Finished product	Japanese Pharmacopoeia

	specifications	
	Pharmacological Group	Recombinant Human Granulocyte Colony Stimulating Factor
	Shelf life	24 months (2^0C -8^0C)
	International availability	Neupogen 30MU of M/s Amgen Ltd., UK
	Products already registered in Pakistan	Topneuter (Reg. No. 084991) of M/s Merixil Pharma, Islamabad.
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 9224, 42881, 44399, 2609, 6488, 4896 & 18541 Dated: 13-03-2018, 17-12-2018, 31-12-2018, 21-01-2019, 14-02-2019, 30-04-2019 & 24-09-2019 Rs. 100000/- Dated: 13-03-2018
	Demanded Price / Pack size	1's Vial/ As per SRO.
	General documentation	• Legalized CoPP No. AQV/190218/2 dated 12-07-2018 issued by Authority for Health and Consumer Protection of the Free and Hanseatic City of Hamburg, Germany. • Legalized copy of GMP certificate No. DE_HE_01_GMP_2017_1056 dated 17-11-2017.
	Remarks of Evaluator	• The firm Submitted the biosimilarity data (Quality, Non-clinical and Clinical) of Jilifen Injection of M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., China instead of their product. The firm submitted that the bulk is manufactured by M/s Hangzhou Jiuyuan Gene Engineering Co., Ltd., China, filled by M/s Bag Health Care GmbH, Amtsgerichtstr. 1-5 35423 Lich, Germany and released by M/s Aqvida, GmbH, Kaiser-Wilhelm-Str. 89, 20355 Hamburg, Germany. While, as per WHO guidelines: *"Non-clinical studies should be conducted with the final formulation of the SBP intended for clinical use, unless otherwise justified."* *AND* *"The main/pivotal clinical data should be generated using the product derived from the final manufacturing process and therefore reflecting the product for which marketing authorization is being sought."* The firm also submitted the Comparative Phase-I (Bioequivalence) and Non-comparative Phase-III studies indicating product as Jilifen/Leucita. • The firm submitted that their product is complying Japanese Pharmacopoeia while the finished product specifications provided by the firm are different from that of Japanese Pharmacopoeia. • In real time stability data, the protein content is out of limits of Japanese Pharmacopoeia for all the three batches at all time points. • In accelerated stability data, the protein content at all time points for all the three batches and biological activity at 3 and 6 months for one batch is out of limits of Japanese Pharmacopoeia. The firm has already been issued four deficiency letters and now the firm submitted the following: *"It is submitted our product is complying Japanese Pharmacopeia (JP) monograph which is attached for reference. The quality comparison with the innovator brand has already been submitted to you which shows that it is comparable with innovator product. Therefore, the comparative clinical studies were not carried out because product is compliant to JP specification. However, the clinical trial data has already been submitted.* *Keeping in view the approval status in Germany as per CoPP provided, quality comparison, clinical trial data and being Pharmacopoeial product, our case may kindly be included in the forthcoming meeting for grant of marketing authorization"*
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Complete biosimilarity data (Quality, Non-clinical & Clinical comparison with Innovator) of the finished product.** **b. Stability data as per finished product specification of Japanese Pharmacopoeia.**	

B: Imported Veterinary Biologicals From Reference Countries.

1.	Name of Importer	M/s Saadat International, 117-Habitat Appartments, Shadman-II, Jail Road, Lahore.
	DSL details	License No. 21-A/DGBT/11/2014 valid till 19-06-2018
	Name of Manufacturer	Product License Holder: M/s Merial, 29 Avenue Tony Garnier, 69007 Lyon, France. Manufacturer: M/s Merial, Rue De L'Aviation, 69800 St Priest, France.
	Brand Name +Dosage Form + Strength	Bioral H120 Neo Effervescent Tablet
	Composition	Each dose contains: Avian Infectious Bronchitis virus, H120 strain……..3.7-5.0$\log_{10}EID_{50}$(*) (*) EID_{50}: Egg Infectious dose 50%.
	Finished product specifications	Ph. Eur. Specifications.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (2^0C -8^0C)
	International availability	France
	Products already registered in Pakistan	Bioral H120 Neo 1x2000 doses (Reg. No. 083386)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 27158, 2822 & 10608 Dated 08-08-2018, 22-01-2019&03-07-2019 Rs. 100000/- Dated 16-07-2018
	Demanded Price / Pack size	10 x 1000 Doses/ De-controlled
	General documentation	• Legalized GMP Certificate No. 18/213927 dated 06-09-2018 issued by French Agency for Veterinary Medicinal Products. • Legalized FSC No. 18-221835 dated 06-12-2018 issued by French Agency for Veterinary Medicinal Products.
	Remarks of Evaluator	• The firm already has registration of above product in pack size of 1 x 2000doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin and approval of France (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
2.	Name of Importer	M/s Saadat International, 117-Habitat Appartments, Shadman-II, Jail Road, Lahore.
	DSL details	License No. 21-A/DGBT/11/2014 valid till 19-06-2018
	Name of Manufacturer	Product License Holder: M/s Merial, 29 Avenue Tony Garnier, 69007 Lyon, France. Manufacturer: M/s Merial, Rue De L'Aviation, 69800 St Priest, France.
	Brand Name +Dosage Form + Strength	Gallivac IB88 Neo Effervescent Tablet
	Composition	Each dose contains: Attenuated Infectious Bronchitis coronavirus, CR88121 strain…….≥4.0$\log_{10}EID_{50}$(*) (*) EID_{50}: Egg Infectious dose 50%.
	Finished product specifications	Ph. Eur. Specifications.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	15 months (2^0C -8^0C)
	International availability	France
	Products already registered in Pakistan	Gallivac IB88 Neo 10x1000 doses (Reg. No. 084634)

	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 26056, 3039& 10608 Dated:30-07-2018, 09-04-2019& 03-07-2019 Rs. 100000/- Dated 16-07-2018
	Demanded Price / Pack size	10 x 2000 Doses/ De-controlled
	General documentation	• Legalized GMP Certificate No. 18/213927 dated 06-09-2018 issued by French Agency for Veterinary Medicinal Products. • Legalized FSC No. 19-225100 dated 15-01-2019 issued by French Agency for Veterinary Medicinal Products.
	Remarks of Evaluator	• The firm already has registration of above product in pack size of 10 x 1000doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin and approval of France (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

C: Imported Veterinary Biologicals From Non Reference Countries.

1.	**Name of Importer**	**M/s UM Enterprises, Plot No. 12, Sector 15, Korangi Industrial Area, Karachi.**
	DSL details	DSL No. 2911 dated 11-07-2019 valid till 16-03-2021
	Name of Manufacturer	M/s Zoetis Industria De Produtos Veterinarios Ltda., Rua Luiz Fernando Rodriguez, 1701, Vila Boa Vista, Campinas, SP, Brazil
	Brand Name +Dosage Form + Strength	Poulvac Magniplex Live vaccine conjugated to antibodies against the Gumboro Disease
	Composition	Each dose of product contains: Suspension of the Gumboro V877 virus at minimum title on the release date…. $10^{2.0}DIE_{50}$ Suspension of the Gumboro V877 virus at minimum title on the expiration date…. $10^{1.3}DIE_{50}$ Antibody against the Gumboro Disease…….≥20U
	Finished product specifications	As per Innovator.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	International availability	Philippines.
	Products already registered in Pakistan	Cevac Transmune IBD Vaccine (Reg. No. 039910)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 40446 & 14206 Dated 05-12-2018 & 05-08-2019 Rs. 100000/- Dated 05-12-2018
	Demanded Price / Pack size	2000 Doses/ De-controlled
	General documentation	• Legalized GMP Certificate dated 31-08-2017 issued by Ministry of Agriculture, Livestock and Food Supply-MAPA, Brazil. • Legalized FSC No. 1285164 dated 29-06-2017 issued by Ministry of Agriculture, livestock and Food Supply, Brazil.
	Remarks of Evaluator	• The firm has not submitted the real time stability data of appropriate intervals. The firm submitted that the stability studies that are made to biological products are routine studies performed by team of Zoetis Campinas in accordance to internal procedures to attend the Brazilian requirements. Nowadays, the time points that need be tested in the follow up stability studies of Poulvac Magniplex in Brazil can be made every 6 months.
Decision: Registration Board deferred the case for submission of stability studies guidelines for veterinary vaccines of country of origin by the firm.		

2.	Name of Importer	M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	Product License Holder: M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. Contract Manufacturer: M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	Avi IB H120
	Composition	Each dose contains: Infectious Bronchitis Virus (IBV), Massachusetts (H120) strain……. min. $10^{3.3}$ EID_{50}
	Finished product specifications	Ph. Eur. Spec.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	International availability	Egypt, Indonesia, Moldova etc.
	Products already registered in Pakistan	Avi IB H120 (Reg. No. 062006)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8272 Dated 13-06-2019 Rs. 100000/- Dated 13-06-2019
	Demanded Price / Pack size	2500 Doses/ De-controlled
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-5/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	• The firm submitted the copy of letter of authorization. • The firm already has registration of above product in pack size of 20 x 1000 doses.

Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm will submit original letter of authorization before issuance of registration letter.

3.	Name of Importer	M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	Product License Holder: M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. Contract Manufacturer: M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	Avi IBD Plus
	Composition	Each dose contains: IBD virus Winterfield 2512, G-61 strain……. min. 2.0 log10EID_{50}

	Finished product specifications	Ph. Eur. Spec.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	International availability	Bangladesh, Guinea, Vietnam etc.
	Products already registered in Pakistan	Avi IBDPlus (Reg. No. 085012)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8271 Dated 13-06-2019 Rs. 100000/- Dated 13-06-2019
	Demanded Price / Pack size	2500 Doses/ De-controlled
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-3/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	• The firm submitted the copy of letter of authorization. • The firm already has registration of above product in pack size of 1000 doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm will submit original letter of authorization before issuance of registration letter.		
4.	Name of Importer	M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	Product License Holder: M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. Contract Manufacturer: M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	Avi ND HB1+IB
	Composition	Each dose contains: Newcastle disease virus (NDV), Hitchner B1 strain……. min. $10^{5.5}$ EID_{50} Infectious Bronchitis Virus (IBV), B-48 strain……. min. $10^{3.0}$ EID_{50}
	Finished product specifications	Ph. Eur. Spec.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (2^0C -8^0C)
	International availability	Bangladesh, Guinea, Vietnam etc.
	Products already registered in Pakistan	Avi ND HB1 IB (Reg. No. 062004)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8268 Dated 13-06-2019 Rs. 100000/- Dated 13-06-2019

	Demanded Price / Pack size	2500 Doses/ De-controlled
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/5565-2/2018 dated 12-11-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	• The firm submitted the copy of letter of authorization. • The firm already has registration of above product in pack size of 20 x 1000 doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm will submit original letter of authorization before issuance of registration letter.		
5.	**Name of Importer**	**M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.**
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	**Product License Holder:** M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. **Contract Manufacturer:** M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	Avi ND LaSota +IB
	Composition	Each dose contains: Newcastle disease virus (NDV), LaSota strain……. min. $10^{5.5}$ EID_{50} Infectious Bronchitis Virus (IBV), B-48 strain……. min. $10^{2.6}$ EID_{50}
	Finished product specifications	Ph. Eur. Spec.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (2^0C -8^0C)
	International availability	Bangladesh, Guinea, Vietnam etc.
	Products already registered in Pakistan	Avi ND LaSota-IB (Reg. No. 085011)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8274 Dated 13-06-2019 Rs. 100000/- Dated 13-06-2019
	Demanded Price / Pack size	2500 Doses/ De-controlled
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-8/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	• The firm submitted the copy of letter of authorization. • The firm already has registration of above product in pack size of 1000 doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of		

current Import Policy for finished drugs. The firm will submit original letter of authorization before issuance of registration letter.		
6.	Name of Importer	M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	Product License Holder: M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. Contract Manufacturer: M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	Avi ND HB1
	Composition	Each dose contains: Newcastle disease virus (NDV), Hitchner B1 strain……. min. $10^{5.5}$ EID_{50}
	Finished product specifications	Ph. Eur. Spec.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	International availability	Bangladesh, Guinea, Vietnam etc.
	Products already registered in Pakistan	Avi ND HB1 Vaccine (Reg. No. 062009)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8275 Dated 13-06-2019 Rs. 100000/- Dated 13-06-2019
	Demanded Price / Pack size	2500 Doses/ De-controlled
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-6/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	• The firm submitted the copy of letter of authorization. • The firm already has registration of above product in pack size of 20 x 1000 doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm will submit original letter of authorization before issuance of registration letter.		
7.	**Name of Importer**	**M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.**
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	**Product License Holder:** M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. **Contract Manufacturer:** M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	Avi ND LaSota

	Composition	Each dose contains: Newcastle disease virus (NDV), LaSota strain……. min. $10^{5.5}$ EID_{50}
	Finished product specifications	Ph. Eur. Spec.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	International availability	Bangladesh, Guinea, Vietnam etc.
	Products already registered in Pakistan	Avi ND LaSota Vaccine (Reg. No. 062008)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8273 Dated 13-06-2019 Rs. 100000/- Dated 13-06-2019
	Demanded Price / Pack size	2500 Doses/ De-controlled
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-7/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	• The firm submitted the copy of letter of authorization. • The firm already has registration of above product in pack size of 20 x 1000 doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm will submit original letter of authorization before issuance of registration letter.		
8.	**Name of Importer**	**M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.**
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	**Product License Holder:** M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. **Contract Manufacturer:** M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	AviIBD Inter
	Composition	Each dose contains: Infectious Bursal disease virus (IBDV), LIBDV strain……. min. $10^{3.0}$$TCID_{50}$
	Finished product specifications	Ph. Eur. Spec.
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	International availability	Bangladesh, Guinea, Vietnam etc.
	Products already registered in Pakistan	AviIBD Inter Vaccine (Reg. No. 062007)
	Type of Form Dy. No & Date of	Form-5A Dy. No. 8270

	application, Fee submitted	Dated 13-06-2019 Rs. 100000/- Dated 13-06-2019
	Demanded Price / Pack size	2500 Doses/ De-controlled
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-2/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	• The firm submitted the copy of letter of authorization. • The firm already has registration of above product in pack size of 20 x 1000 doses.
Decision: Keeping in view valid legalized GMP & Free Sale Certificate indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm will submit original letter of authorization before issuance of registration letter.		
9.	**Name of Importer**	**M/s Mustafa Brothers P-186-D, People Colony No. 1, Faisalabad**
	DSL details	CDSL No: 06-331-0168-031770D Expiry Date: 21-06-2020 Place: Faisalabad
	Name of Manufacturer	M/s Federal Governmental Budgetary Institution "Federal Centre for Animal Health" (FGBI"ARRIAH") 600901, Russia, Vladimir region, Vladimir, microrayonYur' evets
	Brand Name +Dosage Form + Strength	**Arriah ND** Vaccine Against Newcastle disease Inactivated emulsified.
	Composition	Inactivated virus of Newcastle disease (La-Sota strain) in the quantity quaranteeing in 28 days after the vaccination the antibody titer in the hemagglutination-inhibition reaction not lower than 5 log2 (One immunization dose contains: Newcastle disease virus (La-Sota strain) inactivated with dimer amino ethyl ethyleneimine adding the oil adjuvant Montanide ISA 70 VG at ratio of 30/70
	Finished product specifications	Eur. Ph. Specification
	Pharmacological Group	Poultry Vaccine
	Shelf life	12 months (2^0C -8^0C)
	Products already registered in Pakistan	Medivac ND Emulsion by Hilton Provac AIK by Huzaifa International
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 7602 (R&I) Dated 29-05-2019 Rs. 100,000/- 27-05-2019
	Demanded Price / Pack size	Decontrolled/ 5,000 Doses (500mL Vial)
	General documentation	Legalized Certificate of Free Sale of the Veterinary Preparation dated 26-02-2019 issued by Veterinary Department, Administration of the Vladimir Region **Russian Federation.** Certificate of Conformity which confirm the compliance of GMP dated 17-09-2018 issued by Rosstandart-Certification Body of Management Systems Moscow(Voluntary Certification System)

<table>
<tr><td></td><td>Remarks of Evaluator</td><td colspan="2">i. Stability study data & Protocol is not provided instead some laboratory level studies for five batch are provided
<table>
<tr><th>Batch Size</th><th>Storage period (Study duration)</th><th>Test perform</th></tr>
<tr><td>12</td><td>7 months</td><td>Antibody titres</td></tr>
<tr><td>15</td><td>6 months</td><td>-do-</td></tr>
<tr><td>16</td><td>5 months</td><td>-do-</td></tr>
<tr><td>18</td><td>4 months</td><td>-do-</td></tr>
<tr><td>19</td><td>3 months</td><td>-do-</td></tr>
</table>
ii. GMP certificate provided by the firm has been issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System). The regulatory status is not clear.</td></tr>
<tr><td></td><td colspan="3">Decision: Registration Board deferred the case for submission of following by the firm:
a. Complete stability study data.
b. Evidence of authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by Federal Service for Veterinary and Phytosanitary Surveillance, Russia.</td></tr>
<tr><td>10.</td><td>Name of Importer</td><td colspan="2">M/s Mustafa Brothers P-186-D, People Colony No. 1, Faisalabad</td></tr>
<tr><td></td><td>DSL details</td><td colspan="2">CDSL No: 06-331-0168-031770D
Expiry Date: 21-06-2020
Place: Faisalabad</td></tr>
<tr><td></td><td>Name of Manufacturer</td><td colspan="2">M/s Federal Governmental Budgetary Institution “Federal Centre for Animal Health” (FGBI”ARRIAH”)
600901, Russia, Vladimir region, Vladimir, microrayonYur’ evets</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td colspan="2">ArriahH9N2 + ND
Vaccine associated against avian influenza (H9N2) and Newcastle disease Inactivated emulsified.</td></tr>
<tr><td></td><td>Composition</td><td colspan="2">One immunization dose contains:
avian influenza (H9N2) and Newcastle disease inactivated with dimer amino ethyl ethyleneimine adding the oil adjuvant Montanide ISA 70 VG at ratio of 30/70
(Vaccine associated against avian influenza (H9N2) and Newcastledisease inactivatedemulsified is produced from the extraembryonic liquid of chicken embryos infected with thevirus of low pathogenic avian influenza (strain H9N2) and Newcastle disease virus (“La-Sotastrain), inactivated with amino ethyl ethyleneimine adding the oil adjuvantMontanide ISA 70 VG at the ratio of 30÷70)</td></tr>
<tr><td></td><td>Finished product specifications</td><td colspan="2"></td></tr>
<tr><td></td><td>Pharmacological Group</td><td colspan="2">Poultry Vaccine</td></tr>
<tr><td></td><td>Shelf life</td><td colspan="2">12 months (2^0C -8^0C)</td></tr>
<tr><td></td><td>Products already registered in Pakistan</td><td colspan="2">Newcastle Disease & Avian Influenza disease Vaccine by Vetline International</td></tr>
<tr><td></td><td>Type of Form
Dy No & Date of application,
Fee submitted</td><td colspan="2">Form-5A
Dy. No. 7601 (R&I) Dated 29-05-2019
Rs. 100,000/-
27-05-2019</td></tr>
<tr><td></td><td>Demanded Price / Pack size</td><td colspan="2">Decontrolled/ 1000 Doses</td></tr>
<tr><td></td><td>General documentation</td><td colspan="2">Legalized Certificate of Free Sale of the Veterinary Preparation dated 26-02-2019 issued by Veterinary Department, Administration of the Vladimir Region Russian Federation.</td></tr>
</table>

		Certificate of Conformity which confirm the compliance of GMP dated 17-09-2018 issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System)
	Remarks of Evaluator	i. Field trial data (Clinical trial data) is not provided instead the published reports/Research paper of the antigen virus (for other brands) is provided. ii. In Stability study data Batch size is not mentioned. iii. GMP certificate provided by the firm has been issued by Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System). The regulatory status is not clear. iv. The firm mentioned EU. Ph. Specification for the product but the product is not included in the said Pharmacopoeia.
Decision: Registration Board deferred the case for submission of following by the firm: **a. Clinical Trial data** **b. Stability study protocol.** **c. Evidence of authorization of Rosstandart-Certification Body of Management Systems Moscow (Voluntary Certification System) for issuance of GMP certificate by Federal Service for Veterinary and Phytosanitary Surveillance, Russia.** **d. Pharmacopoeial reference of finished product specifications.**		
11.	Name of Importer	M/s Hilton Pharma (Pvt) Ltd,Plot No.13 & 14, Sec 15, Korangi Industrial Area, Karachi
	DSL details	CDSL No: 0751Expiry Date: 19-06-2020 Place: Karachi
	Name of Manufacturer	PT. MedionFarma Jaya Address Office: JI. BabarkanCiparay No.282, Bandung 40223, Indonesia Address Plant: JI. Raya Batujajar No.29, Bandung, Indonesia
	Brand Name +Dosage Form + Strength	Medivac AE Pox Freeze dried live vaccine for poultry
	Composition	Composition as per CoPP: Each dose contains:- Avian encephalomyelitis (AE) virus Calnek 1143 strain and fowl pox virus of M-92 strain Composition as per Form 5-A: Each dose of vaccine contains: Live attenuated Avian encephalomyelitis (AE) virus Calnek 1143strain……. ……..at least $10^{2.5}$ EID_{50} Live attenuated fowl pox virus of M-92 strain….at least $10^{3.0}EID_{50}$
	Finished product specifications	Ph. Eur. Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C -8^0C)
	Products already registered in Pakistan	Gallivac AE+FP (Reg. No. 084603)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 8355 (R&I) Dated 13-06-2019 Rs. 50,000/- Dated 24-05-2019
	Demanded Price / Pack size	Decontrolled/ 5,00 Doses& 1000 doses with diluent

	General documentation	CoPP No.04135/PI.500/F/06/2018 dated 04-06-2018 issued by Ministry of Agriculture Directorate General of Livestock And Animal Health Services Indonesia
	Remarks of Evaluator	i. Stability Study is not provided ii. Diluent is not mentioned on CoPP iii. The firm has submitted 50,000/- Fee.
Decision: Registration Board deferred the case for submission of stability study data by the firm.		

D: Miscellaneous/ Deferred Cases

1. Minutes of 7th meeting of committee on availability of life saving drugs held on 12-06-2019.

Following minutes of 7th meeting of committee on availability of life saving drugs related to Division of Biological were received:

Sr. No.	Name of Product	Name of Manufacturer	Status	Decision of Committee
1.	Humatrope 5 mg Injection	M/s Eli Lilly Pvt Ltd., Karachi	Firm has applied for the cancellation of registration.	PE&R Division is requested not to de-register the product and the firm may be directed to ensure complete availability in public interest.
2.	MMR & Varicella Vaccine	M/s Sanofi Aventis Pakistan Limited, Karachi	The firm has informed that the principle manufacturer has discontinued the production of drug.	Matter is referred to the Biological Drugs Division for resolution of issue as it is unavailable since the creation of this committee and no effort has been made by any of the firm to make the product available.
3.	Anti-Rabies Vaccine	M/s Hakimsons Impex (Pvt.) Ltd., Karachi	Firm has applied for product registration since March 2016 which is still pending.	It is recommended that the product is direly needed in the market. The registration process may be prioritized to ensure the availability of life saving drug in the market.
4.	Clexane	M/s Sanofi Aventis Pakistan Limited, karachi	Firm has informed that due to high global demand, they are facing disruption in supply over past several months.	Show cause notice to be issued to the firm to maintain sufficient stocks to avoid shortage of drug in the market.

The minutes further states that shortage alert were issued to following firms but till date no any reply has been received for following products:

Sr. No.	Name of Product	Name of Manufacturer
1.	MMR & Varicella Vaccine	M/s GSK, Karachi – 35 Dockyard Road, West Wharf, Karachi M/s Amson Vaccine & Pharma, 154, Industrial Triangle, Kahuta Road, Islamabad. M/s Hi-Warble Pharmaceuticals, 44-B, Phase 1, Johar Town, Lahore.

The committee recommends PE&R Division for appropriate legal action under the law to ensure availability of drug because they fail to submit their reply.

Moreover, in its 07th meeting, Committee on availability of life saving drugs identified major reasons as under:

i. Product manufacturing/ import is not feasible as its production/ import cost is more than its MRP awarded by DRAP.

ii. Firm has applied for revision of MRP under the hardship category that is under-process.
iii. Firm has informed that quota of controlled drugs was awarded by DRAP is not sufficient to fulfill market needs or the allocated quota for the year has been consumed.
iv. Firm has informed that the quota for controlled drugs has been allocated but the raw material is under process of import.
v. Firm has informed that raw material is not available in the local market hence it is being imported from abroad. Some firms have also informed that they are searching for raw material suppliers abroad and hence their product is short in market.
vi. Firm has applied for the deregistration of the drug due to various reasons.
vii. Firm is facing disruption in supply over past several months and is continually improving the supply chain.
viii. Firm has informed that production area is under planned renovation.

Decision of the committee is as under:

"It was decided that despite of shortage alerts issued, the manufacturers are not seriously taking the matter of shortage of life saving drugs and most of the firms even did not replied to the shortage alerts issued by the committee. Furthermore, issues related to pricing of drugs and quota allocation of controlled drugs etc also require policy decisions by the competent forums to resolve the issues on permanent basis. So, the cases of shortage of life saving drugs linked with the price issue will be referred to the Division of Costing & Pricing and linked with quota issue will be referred to the Division of Controlled Drugs.

02. Since the committee is not empowered to take any coercive action under the law against the manufacturers/ importers found violating the Rule 30(4)(5)(6)(7) of the Drugs (Licensing, Registration and Advertising) Rules, 1976 and conditions of the Registration by not fulfilling the market demand of their registered drug resulting in shortage of life saving drugs, the cases will be referred to the division of PE&R for necessary legal action."

Decision: Registration Board advised to refer case to DRAP's Authority for its consideration.

2. Exemption of Urdu text, registration number & MRP on Thyrogen 0.9mg/mL Injection (Thyrotropin Alfa) (Reg. No. 095288) and Import of product in standard export packs applied by M/s Sanofi Aventis Pakistan Limited, Karachi.

M/s Sanofi Aventis Pakistan Limited has requested for the exemption of Urdu Text, Registration Number & MRP on packs of below mentioned human biological:

Reg. No.	Name of Product	Pack Size
095288	Thyrogen 0.9mg/mL, Injection Powder for solution (Thyrotropin Alfa)	Box of 2 Vials

The firm has submitted the following documents:

1. Application with fee challan of Rs. 5000/-
2. Copy of Initial registration letter.
3. SOPs for control of repacking operations.
4. An undertaking that we will print the Registration Number and Maximum Retail Price (MRP) on each pack of Thyrogen 0.9mg/mL, Injection(Reg. No. 095288) at our Karachi site bearing DML No. 000007, before releasing the goods into the market.

The firm further informed that Thyrogen is indicated for use with serum thyroglobulin (Tg) testing with or without radioiodine imaging for the detection of thyroid remnants and well-differentiated thyroid cancer in post throidectomy patients maintained on hormone suppression therapy (THST).

Low risk patients with well-differentiated thyroid carcinoma who have undetectable serum Tg levels on THST and no rh (recombinant human) TSH-stimulated increase of Tg levels may be followed-up by assaying rhTSH-stimulated Tg levels.

Thyrogen is indicated for pre-therapeutic stimulation in combination with a range of 30 mCi (1.1 GBq) to 100 mCi (3.7 GBq) radioiodine for ablation of thyroid tissue remnants in patients who have undergone a near-total or total thyroidectomy for well-differentiated thyroid cancer and who do not have evidence of distant metastatic thyroid cancer.

Since this is a rare disease medicine, it has limited number of patients worldwide. Therefore, it is not possible for manufacturer to follow the packaging and labeling rules of every country at the time of export plus production, packaging, quality controls of these sterile and temperature sensitive products require specialized methods and techniques of handling under highly controlled environment.

Repacking or overprinting is generally avoided so as not to compromise on the cold chain process. However, in order to be compliant to the Pakistan Drugs Labeling and Packaging rules once the product is released by customs and come in to their warehouse, they have given the undertacking that they will print registration number and MRP on each pack under cold chain process before releasing the goods into the market.

In this context, it is submitted that the firm has not informed whether Urdu text will be printed locally or not.

Decision: Registration Board deferred the case for clarification about status of request at time of submission and grant of registration application.

3. Registration of human biologicals from M/s Seignior Pharma, Karachi to M/s The Searle Company Limited, Karachi applied by M/s The Searle Company Limited, Karachi deferred in 287th meeting of Registration Board.

M/s The Searle Company Limited, Karachi applied for the registration of following human biologicals in their name from M/s Seignior Pharma, Karachi. The detail of the product is as follows:

Reg. No.	Name of Manufacturer	Brand Name & Composition	Document Details/ Pack Size	Dy. No. Date of Application Fee Status
031321	M/s Bio Sidus S.A., Av de los Quilmes 137, Bernal Qeste, Quilmes, Province of Buenos Aires, Argentina	Neutromax 300ug Injection Each vial contains: Figrastim……300ug Shelf Life: 24 months (2^0C-8^0C)	Valid legalized CoPP No. 20132020000142-18 dated 05-03-2018/ 1's Vial	Dy. No. 83(R&I) 24-04-2017 Rs. 100000/- 24-04-2017
031322		Neutromax480ug Injection Each vial contains: Figrastim……480ug Shelf Life: 24 months (2^0C-8^0C)	Valid legalized CoPP No. 20132020000145-18 dated 05-03-2018/ 1's Vial	Dy. No. 81(R&I) 24-04-2017 Rs. 100000/- 24-04-2017

The firm has submitted the following documents:

a. Application on Form-5A
b. Fee Challan of Rs. 100000/-
c. Copy of Initial Registration letter dated 11-11-2003.
d. Last renewal submissions dated 24-10-2013
e. Termination letter (original) from manufacturer for previous importer

f. Authority letter/sole agent letter (original) from manufacturer
g. NOC from M/s Seignior Pharma, Karachi dated 18-09-2018
h. Biosimilarity data submitted by the firm is detailed below:

Bio-similarity studies of the finished product of same source (bulk concentrate or ready to fill) manufactured from country of origin.	
WHO Bio-similarity guidelines	**Data submitted by the firm**
Quality Comparison Physicochemical characterization	Primary Structure: a. Determination of Primary Structure (Full Amino Acid and Disulfide Bond Sequencing) b. Determination of the number of free sulfhydryl groups c. Verification of the correct formation of disulfide bonds d. N and C Terminal Sequence Analysis e. Peptide Mapping by RP-HPLC Secondary and Tertiary Structure: a. Circular Dichorism b. Fluorescence Molecular Mass and Quaternary Structure a. Molecular mass determination by LC ESI-TOF-MS b. SDS-PAGE Electrophoretic Profiles a. Characterization by Isoelectric Focusing b. SDS-PAGE c. Western Blot HPLC a. RP-HPLC b. SEC-HPLC
Biological Activity	Stimulating effect on the specific proliferation of a line cell derived frommyeloid leukemia.
Immunochemical properties	To evaluate the immunogenicity of filgrastim in rats that received differentpreparations of recombinant human filgrastim
Impurities	Product Related Impurities 1. Forced Degradation a. Impurities with molecular masses that differ from that of Filgrastim b. Dimer and related substances with higher molecular mass c. Impurities with charges that differ from that of Filgrastim d. Related proteins: Oxidized and deamidated species 2. Natural degradation a. Impurities with molecular masses that differ from that of Filgrastim b. Dimer and related substances with higher molecular mass c. Impurities with charges that differ from that of Filgrastim d. Related proteins: Oxidized and deamidated species Process derived impurities a. Absence of Host Cell DNA b. Absence of Host Cell Protein
Non-clinical Studies	a. To evaluate the biological activity by means of an in vivo technique in Balb C mice. b. To observe the response at different doses, in pre-treated mice with cyclophosphamide c. Acute Toxicity studies in mice. d. Chronic toxicity studies in mice. e. To evaluate the toxicity of Neutromax and Neupogen in rats, by the administration of high doses (the dose equivalent to the maximum used in humans to a dose 10-fold the highest dose) for 28 days by subcutaneous route.
Clinical Studies	a. Bioequivalence study of generic Filgrastim Injection to an Innovator Neupogen in Healthy Thai Volunteers. b. Use of Filgrastim (Neutromax) in patients with leukemia during

	inductionand consolidation treartment. c. Utilization study of Neutromax during autologushaematopoietic precursortransplantation for myeloma and lymphoma patients. d. Assessment of two Neutromax formulations containing Mannitol orSorbitol in the hematologic recovery and Survival outcomes in theAutologus Bone Marrow Transplantation.
Decision of RB in 287th meeting	*Registration Board deferred the case for submission of following by the firm:* *a. List of countries where the above products are imported along with regulatory requirements of respective countries.* b. *Regulatory requirements for registration of Filgrastim containing products in country of origin.*

The firm now submitted that the said product is registered in following countries:

Argentina	Bolivia	Brazil
Chile	Colombia	Dominican Republic
Ecuador	El Salvador	Georgia
Guatemala	Honduras	Ivory Coast
Lebanon	Mexico	Nicaragua
Pakistan	Paraguay	Peru
Republic of Congo	Sri Lanka	Thailand
Tunisia	Ukraine	Uruguay
Vietnam		

The firm has submitted the regulatory guidelines of above countries out of which guidelines of only following countries were in English while the rest were in their own language:
Brazil Georgia Lebanon Mexico Vietnam
All the above guidelines indicate that the therapeutic equivalence is part of comparability exercise.
The firm has now submitted the following studies:

a. Use of filgrastim (Neutromax) in Non-Hodgkin lymphoma treated with R-CHOP scheme (Phase-IV)
b. Low dose Filgrastim enhances neutrophil recovery and decrease incidence of febrile neutropenia following CHOP regimen in Non Hodgkin lymphoma patient.
c. Periodic Benefit-Risk Evaluation Report from January, 2014-December, 2017.

Decision: Registration Board deferred the case for submission, of safety and efficacy studies of the product in comparison with Innovator.

4. Imported Human Biologicals applied by M/s SMS Corporation, Karachi deferred in 285th meeting of Registration Board.

Following products of M/s SMS Corporation, Karachi were deferred in 285th meeting of Registration Board as per following details:

1	**Name of Importer**	**M/s SMS Corporation,13-B/1,Block6,P.E.C.H.S.,Shahrah-e-Faisal,Karachi-75400,Pakistan**
	DSL Details	No. 00831 dated 08-01-2019 valid till 20-06-2020.
	Name of Manufacturer	M/s Chengdu Rongsheng Pharmaceuticals Co., Ltd.7 Keyuan South Road, Hi-tech Zone, Chengdu, Sichuan, P.R. China.
	Brand Name +Dosage Form + Strength	Hepron (Human Hepatitis B Immunoglobulin, Solution for Intramuscular Injection) ,2ml - 200 IU/vial
	Composition	Active ingredient (s) and amount (s) per unit dose: Protein content ≤ 180 mg/ml, IgG monomer + dimmer content ≥ 90%. Anti-HBs potency ≥ 100IU/ml
	Finished product specifications	Chinese Pharmacopoeia's Specs
	Approval status in reference countries	Hepatitis B Immunoglobulin 100IU/ml-2ml vial (EMC)
	International Availability	India
	Products already registered in Pakistan	Hepatect 200IU/ml byNabiqasim Industries (Pvt) Ltd
	Anatomical therapeutic chemical (ATC) code	B05AA01
	Shelf life	36 months
	Type of Form Dy No & Date of application Fee submitted	Form 5-A, Dy. No. 1247(R&I) Date: 03-05-2017 Rs. 100,000/- Date: 24-04-2017
	Demanded Price/ Pack size	Rs. 14843.00/2 ml vial (Box)
	General documentation	Legalized CoPP issued on 28-06-2016, Legalized GMP No.SC20160026 issued on 29-08-2016, Legalized Market Authorization Letter valid up to 31/12/2017
	Decision of RB in 285th meeting	*Registration Board decided to defer the application and advised the firm to submit any legalized document from regulatory body of country of origin indicating that clinical trial data regarding Immunoprophylaxis with human hepatitis B immunoglobulin (HBIG) is not required for Hepatitis B Immunoglobulin.*
2	**Name of Importer**	**M/s SMS Corporation,13-B/1, Block 6, P.E.C.H.S., Shahrah-e-Faisal,Karachi-75400,Pakistan.**
	DSL Details	No. 00831 dated 08-01-2019 valid till 20-06-2020.
	Name of Manufacturer	M/s Chengdu Rongsheng Pharmaceuticals Co., Ltd.7 Keyuan South Road, Hi-tech Zone, Chengdu, Sichuan, P.R. China.
	Brand Name +Dosage Form + Strength	Hepron (Human Hepatitis B Immunoglobulin, Solution for Intramuscular Injection) ,1ml - 100 IU/vial
	Composition	Active ingredient (s) and amount (s) per unit dose: Protein content ≤ 180 mg/ml, IgG monomer + dimmer content ≥ 90%. Anti-HBs potency ≥ 100IU/ml
	Finished product specifications	Chinese Pharmacopoeia's Specs
	Approval status in reference countries	Hepatect CP 100IU/2ml vial (EMC)
	International Availability	India
	Products already registered in Pakistan	No formulation Registered in 100IU/ml

	Anatomical therapeutic chemical (ATC) code	B05AA01
	Shelf life	36 months
	Type of Form Dy No & Date of application Fee submitted	Form 5-A, Dy. No. 1246(R&I) Date: 03-05-2017 Rs. 100,000/- Date: 24-04-2017
	Demanded price/ Pack size	Rs. 10602/ 1 ml vial (Box)
	General documentation	Legalized CoPP issued on 28-06-2016, Legalized GMP No.SC20160026 issued on 29-08-2016, Legalized Market Authorization Letter valid up to 31/12/2017
	Decision of RB in 285th meeting	*Registration Board decided to defer the application and advised the firm to submit any legalized document from regulatory body of country of origin indicating that clinical trial data regarding Immunoprophylaxis with human hepatitis B immunoglobulin (HBIG) is not required for Hepatitis B Immunoglobulin.*

The firm now submitted a legalized document of China Food and Drug Administration with the title "**Notice of the General Administration of Food and Drug Administration on Further Regulating the Acceptance of Drug Registration Food and Drug Administration Chemicals (2015) No. 122"** released on 30th July, 2015 which states as follows:

1. Application for registration of new drugs
   (1) Domestic and Imported drugs applied in accordance with the new drug procedures and new drugs should be submitted to the clinical trial application first, after the clinical trial application was approved, the application for production/import registration can be submitted.
   (2) Normal or specific human immunoglobulin for Intramuscular injection, human albumin, compound electrolyte injection, blood volume expander can be directly submitted to the application for production / import registration.

The above document was accessed on 23-09-2019 at
http://samr.cfda.gov.cn/WS01/CL0844/126000.html

Decision: Registration Board deferred the case and advised DBER to check the requirements of European Medicine Agency (EMA) and other Reference Regulatory Authorities.

5. Change in address of importer applied by M/s Vet Line International, Lahore.

M/s Vet Line International, Lahore applied for the change in address of importer for their following veterinary vaccines as per following details:

Sr. No.	Reg. No. & Date of Reg.	Name of Product	Previous address	Newly Applied Address
1.	062004 07-01-2010	Avi ND HBI+IB Vaccine	55/S, 1st Main Floor, Main Shadman Market, Lahore.	Plot No. 939-A, Block-J, Phase-I, LDA Avenue, Lahore
2.	062006 07-01-2010	Avi IB H120 Vaccine.		
3.	062007 07-01-2010	Avi IBD Inter Vaccine		
4.	062008 07-01-2010	Avi ND Lasota Vaccine		
5.	062009 07-01-2010	Avi ND HB1 Vaccine		
6.	085009 01-11-2017	ITA New (ND).		
7.	085010 01-11-2017	Avipox.		
8.	085011 01-11-2017	Avi ND Lasota-IB.		
9.	085012 01-11-2017	Avi IBD Plus.		
10.	085013 01-11-2017	Avi ND+IB.		
11.	085014 19-02-2018	ITA ND+IBD.		

12.	091919 31-08-2018	Avian Influenza Vaccine Inactivated.		
13.	091920 31-08-2018	New Castle Disease and Avian Influenza (H9N2 Subtype) Vaccine, Inactivated.		
14.	085015 28-03-2018	ITA Coryza ABC Gel.		
15.	Under Process. Deferred in 285th meeting	ITA New Flu H9.		
16.	Under Process. Deferred in 291st meeting	Avi IB Var.		
17.	Under Process. Approved in 291st meeting	Sterile Diluent for Avipox.		
18.	Under Process for Panel Inspection. Approved in 286th meeting.	Foot and Mouth disease Trivalent Inactivated Vaccine		

The firm has submitted the follwong documents;

a. Fee Challan of Rs.5,000/- for each product.
b. Copy of initial registration letter and last renewal submission.
c. Copy of previsous DSL.
d. Copy of new DSL indicating proprietor is same.

The original renewal applications for the products at Sr.No.1–5 are available in this Division.

Decision: **Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s Vet Line International, 55/S, 1st Main Floor, Main Shadman Market, Lahore to M/s Vet Line International, Plot No. 939-A, Block-J, Phase-I, LDA Avenue, Lahore for above products subject to storage facility verification report of new address**

6. **Registration of Dengue Vaccine applied by M/s Sanofi Aventis Pakistan Limited, Karachi.**

Following vaccines of M/s Sanofi Aventis Pakistan Limited, Karachi were approved by the Registration Board in its 260th meeting held on 28th-29th June, 2016 on recommendations of WHO Strategic Advisory Group of experts (SAGE) dated 12th-14th April, 2016, expert from PMRC and representative of WHO in Pakistan:

Sr.No.	Brand Name	Composition
1.	DENGVAXIA, powder and solvent for suspension for Injection Single dose.	One dose (0.5 ml) contains: CYD dengue virus serotype1,2,3,4…….each 4.5-6.0 log10 CCID50/dose
2.	DENGVAXIAMD, powder and solvent for suspension for Injection Multi dose.	One dose (0.5 ml) contains: CYD dengue virus serotype1,2,3,4…….each 4.5-6.0 log10 CCID50/dose

Registration letters of above products were issued to M/s Sanofi Aventis Pakistan Limited, Karachi in the light of decision of Registration Board in its 273rd meeting held on 28th-29th August, 2017 wherein it was decided to issue letters for govt. supplies only.

Meanwhile, it was noticed that Registration of Dengvaxia vaccine and Dengue Immunizationprogramme was suspended by Philippines due to the new findings by M/s Sanofi Pasteur, France that severe cases of dengue can occure in the longer term among those vaccinated without prior infection. Accordingly, WHO on 22ndDecember, 2017 published its interim position regarding the use of Dengvaxia vaccine which is reproduced as under:

"WHO acknowledges that in high seroprevalence settings, the vaccine can have significant population-level benefits. However, until a full review has been conducted, WHO recommends vaccination only in individuals with a documented past dengue infection, either by a diagnostic test or by a documented medical history of past dengue illness.
Any further guidance, including a review by SAGE and update of the WHO position paper on Dengvaxia®, will likely be available no earlier than April 2018 after a rigorous review of the new data and additional activities, such as population based modeling, are undertaken."

Keeping in view WHO interim position, Registration Board in its 277th meeting held on 27th-29th December, 2017 decided that the vaccine is not indicated for a mass vaccination program as Dengvaxiavaccineis indicated only in individuals with a documented past dengue infection (seropositive persons), confirmed either by a diagnostic test or by a documented medical history of past dengue illness. Moreover, in case of not using the vaccine, possibility of mortality can be high as observed in previous years. It was further decided that Registration Board will review case further as soon as the decision of WHO Strategic Advisory Group of Experts (SAGE) on immunization becomes available in April 2018.

On 19th April, 2018, WHO published "Revised SAGE recommendation on use of Dengue vaccine" which is at **Annex-I**. Keeping in view revised SAGE recommendations, Registration Board in its 283rd meeting held on 27th-29th June, 2018 decided to deliberate the said matter in next Registration Board meeting withconcerned departments.

Discussion in 286th meeting:

Dr. Asaaf Deputy Director, Federal EPI and Mr. Massab Umair Sr. Scientific Officer, NIH attended the meeting and submitted the following:

Dr. Asaaf Deputy Director, Federal EPI:

Exact disease burden of Dengue fever is yet unknown. In the absence of disease burden data the age bracketing is not possible which is essential for primary health care vaccines. Screening of seropositivity is very difficult as no assay will be 100% specific.Moreover, once vaccinated the efficacy of vaccine for 2-3 years is established. What will happen after that period is yet unknown. Further, dengue surveillance centers and proper storage facilities for dengue vaccines should be established first. Therefore, until the exact disease burden, seropositivity identification and safety data, the vaccine should not be registered.

Mr. Massab Umair, Sr. Scientific Officer, NIH:

Sensitivity and specificity of dengue diagnostic test is a major hurdle.Therefore, sampling time and type of diagnostic test should be assessed properly.Highly sensitive and specific dengue diagnostic kits are available in NIH. NIH can provide technical support regarding the development of diagnostic test facilities.

Registration Board after discussion decided as follows:

"Registration Board considered the matter in light of comments by EPI and NIHon disease burden data, cost and effectiveness of available Dengue Diagnostic tests. Registration Board deferred the case for further deliberation and advised DBER to come up with the current status of Dengvaxia vaccine in neighboring and tropical countries in next registration Board meeting."

In this context, it is submitted that in Philippines Dengue Immunization Programme is still suspended while in India and Sri Lanka, Dengvaxia is not yet

registered. However, European Medicine Agency has granted the approval to Dengvaxia vaccine with following conditions:

*"**Conditions or restrictions regarding supply and use**:*

Medicinal product subject to medical prescription.

***Official batch release**:*

In accordance with Article 114 Directive 2001/83/EC, the official batch release will be undertaken by a state laboratory or a laboratory designated for that purpose.

***Other conditions and requirements of the marketing authorization**:*

Periodic Safety Update Reports

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal. The marketing authorisation holder shall submit the first periodic safety update report for this product within 6 months following authorisation.

***Conditions or restrictions with regard to the safe and effective use of the medicinal product**:*

Risk Management Plan (RMP)

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the marketing authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- *At the request of the European Medicines Agency*
- *Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.*

***Additional risk minimisation measures**:*

Prior to launch of Dengvaxia in each Member State the Marketing Authorisation Holder (MAH) must agree the content and format of the educational programme, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority.

The MAH shall ensure that in each Member State where Dengvaxia is marketed, all healthcare professionals who are expected to use Dengvaxia have access to/are provided with the following educational package:

- *Physician educational material*

The physician educational material should contain:

- *The Summary of Product Characteristics*
- *Guide for healthcare professionals*

The Guide for healthcare professionals shall contain the following key elements:

- *That there is an increased risk of severe and/or hospitalized dengue following vaccination in individuals not previously infected by dengue virus*
- *That healthcare professionals have to document before vaccination the previous dengue infection, which has to be assessed by laboratory confirmed history of dengue or through serotesting*
- *The healthcare professionals should be aware that the test they use should have adequate performance in terms of specificity and cross-reactivity based on the local disease epidemiology.*

- *That healthcare professionals should be aware of dengue early warning signs."*

Moreover, FDA has also granted the approval to Dengvaxia vaccine but with following limitations and warnings:

*"**Limitations of use:***

- *DENGVAXIA is not approved for use in individuals not previously infected by any dengue virus serotype or for whom this information is unknown. Those not previously infected are at increased risk for severe dengue disease when vaccinated and subsequently infected with dengue virus. Previous dengue infection can be assessed through a medical record of a previous laboratory-confirmed dengue infection or through serological testing prior to vaccination.*
- *The safety and effectiveness of DENGVAXIA have not been established in individuals living in dengue non-endemic areas who travel to dengue endemic areas.*

WARNINGS AND PRECAUTIONS:

- *Increased Risk of Severe Dengue Disease Following DENGVAXIA in Persons not Previously Infected with Dengue Virus in unvaccinated individuals, first dengue infections rarely cause severe dengue, while second dengue infections with a different serotype are associated with an increased risk of severe dengue. DENGVAXIA administration to individuals not previously infected by dengue virus is associated with an increased risk of severe dengue disease when the vaccinated individual is subsequently infected with any dengue virus serotype. Therefore, healthcare professionals must evaluate individuals for prior dengue infection to avoid vaccinating individuals who have not been previously infected by dengue virus.*
- *Previous infection by dengue virus can be evaluated through a medical record of previous laboratory-confirmed dengue infection or through serotesting prior to vaccination.*

There is no FDA cleared test available to determine a previous dengue infection. Available non-FDA cleared tests may yield false positive results (e.g., due to cross-reactivity with other flaviviruses)."

Decision: Registration Board deferred the case for submission of all the documents as advised by EMA and USFDA by the firm and advised DBER to process the case before finalization of the minutes.

7. Information regarding change of city name applied by M/s GETZ Pharma, Karachi.

M/s GETZ Pharma, Karachi has intimated for change in city name for registered product with explanation as under;

"This is to bring to your kind attention that manufacturer of Trastuget 150mg &Trastuget 440mg, M/s Biocon Limited, India has informed us that as per local state government notification, **the spelling of city name "Bangalore" has been changed to "Bengaluru".** Kindly note that because of the change in city name, complete address of M/s Biocon Limited will be written as under:

M/s Biocon Limited

Special Economic Zone, Plot No.2,3,4&5, Phase-IV, Bommasandra-jigani Link Road, Bommasandra Post, Bengaluru-560 099, India

Furthermore, kindly note that there is no change in the location of manufacturing facility of M/s Biocon Limited, India. We are enclosing the copy of notification issued by Karnataka State Government notifying that city name has been changed from "Bangalore" to "Bengaluru" along with its translation and copy of Drug manufacturing License of M/s Biocon Limited – India with revised city name."

Decision: Registration Board acknowledged the above information.

8. Request for leaflet update for Cyramza applied by M/s Eli Lilly Pakistan (Private) Limited Karachi.

M/s Eli Lilly Pakistan (Private) Limited Karachi submitted documents regarding leaflet update for products detailed as under;

Sr. No	Reg. No	Brand Name	Pack Size	Requested Change/ updated indication
1.	089814	Cyramza (Concentrate for solution for infusion)	10mL vial	1. Cyramza, as a single agent, is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have an alpha fetoprotein (AFP) of ≥400 ng/mL and have been treated with sorafenib.
2.	091269	Cyramza (Concentrate for solution for infusion)	50mL vial	

The firm has submitted following documents;

i. Fee of Rs. 5030/- for each product.
ii. Copy of Registration letters
iii. Copy of supplement approval from Department of Health and Human Service
iv. Existing leaflet
v. New leaflet
vi. Undertaking that proposed label complies all provisions of Drugs (Labelling & Packing) Rules, 1986.

It is submitted that to verify the indication, leaflet was checked on FDA website and the said change was found included. https://www.accessdata.fda.gov/scripts/cder/daf/

Moreover, in this context, for such changes, rule position of LRA Rules, 1976, Rule 30(10)(b) states following;

"if a clinical information for a drug is approved by the Drug Regulatory Authority in any of the said countries, the same clinical information shall be considered as approve for drug registration in Pakistan unless modified by Registration Board on the basis of scientific data available to it, and such clinical information may include indications, contra-indications, side effect precautions, dosage., etc.

Moreover, one of the conditions of registration letter is as under;

"Any change in the formulation or the manufacturing process or the quality control testing procedures or any change in the posology, safety profile, prescribing information, clinical indications or any new condition imposed by the regulatory authorities of the country of origin, shall be communicated to DBER and shall require fresh approval."

In the above context a generalized decision is required for all such cases where the applicant applies for minor changes which have already been approved by NRA of the country of origin.

Registration Board discussed that in case of change/ addition of an indication, the firm will submit the application and the application will be placed before the Registration Board for decision.

Decision: Keeping in view the approval of USFDA; Registration Board approved the new indication for Cyramza 10ml (Reg. No. 089814) and Cyramza 50ml (Reg. No. 091269).

9. Case for information of Change of authority name from Anhui FDA to Anhui Medical products Administration applied by M/s Foray Pharmaceuticals, Rawalpindi:

M/s Foray Pharmaceuticals, Rawalpindi has been granted with change of manufacturer/ company name dated 19th September 2019. It is to inform the board that the said Post Registration Approval was approved by Chairman Registration who is authorized by the Registration Board for approval of such cases. The said case was approved on the basis of documents as per SOPs mentioned for such change in 283rd meeting of Registration Board. CoPP is also one of the required documents.

It is submitted that legalized CoPPsubmitted by the firm has been issued by Anhui Medical products Administration instead of China/ Anhui FDA. Regarding this difference in signing authority of CoPP, the manufacturer has claimed change of authority name from Anhui FDA to Anhui Medical products Administration.

To verify the same SFDA website was visited on below mentioned link;

http://www.sfdachina.com/

The website mentions a following note;

> Since 1-Sep, 2018, CFDA (China Food and Drug Administration) has changed its name to NMPA (National Medical Product Administration). So, all CFDA and SFDA on this website default mean NMPA.

It is submitted that many departments are mentioned on the website and are detailed as under;

NMPA(National Medical Product Administration)

MOA

CNCA (Certification and Accreditation Administration of China)

CIQ (China Entry-Exit Inspection and Quarantine Bureaus), directly governed by the General Administration of Quality Supervision, Inspection and Quarantine(**AQSIQ**).

One of the responsibilities of **CIQ** is "responsible for the entry-exit inspection and quarantine, appraisal, **certification**, supervision and law enforcement within area under its jurisdiction"

To assess whether the change applies to provinces or not,the same site addresses that;

> *"There are 35 CIQ offices in China's 31 provinces, near 300 branches and more than 200 local offices across the country."*

Registration board is informed for instant case & for consideration of similar cases in future please.

Decision: Registration Board acknowledged the above information.

10. Cancellation of registration of Intraglobin® F Injection (Reg No. 006759), applied by M/s The Eastern Trade & Distribution, Karachi.

M/s The Eastern Trade & Distribution, Co (Private) Limited Karachi applied for the cancellation of registration of following human biologicals:

Sr. No.	Reg. No.	Name of Manufacturer	Brand Name & Composition	Packing
1.	006759	M/s Biotest Pharma, Germany	Intraglobin® F Injeciton Each 100ml contains: Human Immunoglobulin 5g	250mg vial 500mg vial 2.5gm vial

The firm has submitted the following documents:

a. Copy of Registration letter dated 14-5-1983.
b. Copy of last renewal application submission dated 17-7-2017.
c. An undertaking that no case is pending at any forum/ court of law regarding above products.

Justification for cancellation:

"Our Principal M/s. Biotest Pharma Germany has discontinued the manufacturing of "Intraglobin® F Injection" (Human Immunoglobulin 5g/100ml). However, we have the registration of similar therapeutic drug Intratect 5% Solution for Infusion (Registration No.081614). Therefore, we request you to kindly cancel the registration of "Intraglobin® F Injection."

List of alternative brands provided by the firm:

Sr. No.	Reg. No.	Name of Product
1.	081614	Intratect 5% Solution for Infusion
2.	077515	Gamunex-C 10%

Decision: Registration Board deferred the case for submission of following by the firm:

a. Reason for cancellation of registration.
b. Confirmation of availability of alternates.

11. Cancellation of registration of Intraglobin CPSolution (Human Plasma Protein 50mg/ml) (Registration No.028408), applied by M/s The Eastern Trade & Distribution, Karachi.

M/s The Eastern Trade & Distribution, Co (Private) Limited Karachiapplied for the cancellation of registration of following human biologicals:

Sr. No.	Reg. No.	Name of Manufacturer	Brand Name & Composition	Packing
1.	028408	M/s Biotest Pharma, Germany	Intraglobin CP Solution for Infusion Each ml contains: Human plasma protein…….50mg	10ml 20ml 50ml 100ml 200ml

The firm has submitted the following documents:

a. Photocopy of Registration letter dated 14-5-1983.
b. Photocopy of last renewal application submission dated 17-7-2017.
c. An undertaking that no case is pending at any forum/ court of law regarding above products.

Justification for cancellation:

"Our Principal M/s. Biotest Pharma Germany has discontinued the manufacturing of "Intraglobin CP Solution for Injection" (Human plasma protein 50mg/ml). However, we will continue to market similar therapeutic drug Biseko Injection (Registration No.006760)."

List of alternative brands provided by the firm:

Sr. No.	Reg. No.	Name of Product
1.	006760	Biseko Injection Human Plasma Protein 50mg/ml

Decision: Registration Board deferred the case for submission of following by the firm:

a. **Reason for cancellation of registration.**
b. **Confirmation of availability of alternates.**

12. Inclusion of source name applied by M/s Amson Vaccines and Pharma (Pvt.) Ltd., Islamabad

M/s Amson Vaccines and Pharma (Pvt.) Ltd., Islamabad submitted requested to notify the source for the product detailed as under;

Reg. No.	Brand name & composition	Pack size as per initial registration letter	Desired source for inclusion
017373	**Imatet Injection** Tetanus Toxoid Vaccine Each 0.5mL dose contains Purified tetanus toxoid not less than 40I.U	10x0.5mL 10x 5mL 10x10mL	BIOLOGICAL E. LIMITED

The firm has informed that while getting clearance from DRAP (QA&LT/ I&E) Department to import bulk material, query was raised regarding source of *Imatet* which is not mentioned in initial registration letter, although they have been importing the bulk from M/s Biological E. Ltd India for all these years.

It is submitted thatin the initial registration letter name of bulk manufacturer is missing. Moreover, letter for correction in formulation do not mentions name "Imatet" but "Tetanus Toxoid Vaccine" however, registration number is same.

The firm has submitted following documents;

i. Initial registration letter in the name of M/s AmsonFarmacoBiologico dated 27-06-1995
ii. Transfer of registration from M/s AmsonFarmacoBiologico to M/s Amson Vaccines and Pharma (Pvt.) Ltd., Islamabad dated 22-10-2003.
iii. Correction in formulation dated 03-02-2010
iv. Last renewal dated 18-10-2018 (with in due date)

In the above context the firm was asked to provide the records of invoices. The invoices were provided by the firm, latest of which is of 19th January 2019. Invoices mention the following address of manufacturer and exporter;

"BIOLOGICAL E. LIMITED 18/1 AND 3, AZAMABAD, HYDERABAD500 020 INDIA.
WORKS:
BIOLOGICAL E. LIMITED, PLOT NO. 1, SP BIOTECH PARK, PHASE II, KOLTHUR VILLAGE, SHAMEERPER MANDAL, RANGA REDDY DISTRICT 500 078 TELANGANA INDIA.

Decision: Registration Board deferred the case for documents confirming source of bulk and confirmation of WHO PQ status of the product (if any) manufactured from the same bulk.

13. Change of address for importer on registration letter of Tetanus Vaccine (Reg. No. 074632):

M/s Amson Vaccine & Pharma has applied for change of address on registration letter of Tetanus Vaccine (Reg. No. 074632). The detail is as under;

Reg No	Brand Name of Product	Manufacturer	Address of importer on Reg. Letter	Applied / desired address of importer
074632	Absorbed Tetanus Vaccine BP	Biological E. Limited 7-4-114, Gaganpahad, Ragendra Nagar (M), Ranga Reddy (Dist), Andhra Pradesh, India.	**M/s. Amson Vaccines & Pharma (Pvt.) Ltd** 154, Industrial Triangle, Kahuta Road, Islamabad	**M/s. Amson Vaccines & Pharma (Pvt.) Ltd** 115, Industrial Triangle, Kahuta Road, Islamabad

The firm has submitted;

i. Fee Rs. 5030/-
ii. Copy of registration letter.

It is pertinent to mention that in DSL, mentioned address is "*115, Industrial Triangle, Kahuta Road, Islamabad"* and cold storage facility report is also available for the same address.

Decision: Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s Amson Vaccines & Pharma (Pvt.) Ltd., 154, Industrial Triangle, Kahuta Road, Islamabad to M/s Amson Vaccines & Pharma (Pvt.) Ltd., 115, Industrial Triangle, Kahuta Road, Islamabad for above product.

14. Change of address of importer for products under registration / approved Biological drugs of M/s CCL Pharmaceuticals Pvt. Limited, Lahore.

Following products of M/s CCL Pharmaceuticals Pvt. Limited, Lahore have been approved in 288th meeting of Registration Board held on 14th -15th February 2019. The details are as under;

Sr. No	Name of Manufacturer	Brand Name & Composition	Shelf life/ Pack size	Document Details	Decision of RB in 88th meeting
1.	M/s AryoGen Pharmed., address No: 140, corner of Tajbakhsh street, 24th Km Tehran- Karaj Makhsous road, Alborz, Iran	AryoTrust(Trastuzumab) 150mg White to pale yellow powder for concentrate for solution for IV infusion. Each vial contains: Trastuzumab…150mg	2 years at 2-8^{0}C 1's vial	CoPP, Certificate No. 665/37430 Dated 21/07/2018	Keeping in view the biosimilarity data and valid legalized CoPPs provided by the firm indicating the products are available in country of origin; Registration Board approved the products subject to compliance of current Import policy for finished drugs.
2.		AryoTrust(Trastuzumab) 440mg White to pale yellow powder and solvent for concentrate for solution for IV infusion. Each vial contains: Trastuzumab.…440mg + Bacteriostatic water for injection….20ml	2 years at 2-8^{0}C (1'sPowder vial + 1's 20ml BWFI vial) Combo pack	CoPP, Certificate No. 665/37442 Dated 21/07/2018	

The firm has been granted inspection exemption by the competent authority.

It is submitted that the firm has submitted two (2) DSLs which are in their name i.e.

DSL for which the product was registered	DSL for which cold storage facility has been verified
65-Industrial Estate, Kot Lakhpat, District Lahore	5-km, Sheikhupura Road, Tehsil Muridke

It is submitted that somewhat similar case for another firm i.e. M/s Martin Dow Marker Specialities (Pvt.) Ltd was taken in 291st meeting of RB wherein the board decided as under (as per draft minutes available);

a. Reason for changing the storage facility from Karachi to Lahore.
b. Legal provision as per Drug Act, 1976 and rules framed there under covering instant request of the firm.

Decision: Registration Board refer the case to Legal Division of DRAP for confirming the legal provision as per Drug Act, 1976 and rules framed there under covering instant request of the firm.

15. Change in manufacturing site of already registered human biological product RhoGam Ultra Filtered UF Plus (Reg. No.005571) applied by M/s Majeed Sons, Rawalpindi.

M/s Majeed Sons, Rawalpindi applied for the change of filling and release site of registered human biologicals as per following details:

Reg. No. & Date of Reg.	Brand Name & Composition	Already Approved Manufacturing Site	Newly Applied Manufacturing Site
005571 23-08-1995	RhoGAM® Ultra-Filtered Injection	M/s Ortho Clinical Diagnostics (OCD), USA	M/s Kedrion Biopharma USA 155, Duryea Road, Melville N.Y 11747, USA

The firm has submitted the following documents which are evaluated as per SOP approved in 283rd meeting Registration Board for change of manufacturing site.

Required Documents As per SOP	Documents submitted by the firm
a) Application on Form 5A/Form-5F with required fee as per relevant SRO.	• Covering letter company letter head, • Fee Challan of Rs.100,000/ • Application on CTD format are submitted
b) Copy of registration letter and last renewal status.	• Photocopy of initial registration letter dated 23-8-1995 • Photocopy of Change of Brand Name letter dated 23-8-1999. • Application for last renewal of Registration are submitted to Biological Division dated 15-08-2018.
c) Original and legalized Certificate of Pharmaceutical Product as per WHO format for new manufacturer's name OR Original and legalized GMP certificate of new manufacturing site with free sale certificate from regulatory body of country of origin.	Original Legalized CoPP No.9G3F-4W5K-WHO dated 23-05-2019 issued by USFDA is provided which indicate two sites. **Product License Holder** (Which is marked as (a) Manufacturer: M/s Kedrion Biopharma USA 155, Duryea Road, Melville N.Y 11747, USA **Contract Manufacturing Facility:** M/s Ortho Clinical Diagnostics (OCD),Inc.1 001 US Hwy 202, Raritan NJ, USA
d) Site master file of new manufacturing site in case of change of manufacturing site/ source.	Site master file is provided
e) Revised Sole Agency Agreement when	Original Legalized Power of Attorney in the Name of

there is change in MAH.	Majeed Sons Islamabad by M/s Kedrion Biopharma, USA.
f) Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.	Copy of No Objection Letter issued by M/s Ortho Clinical Diagnostics (OCD), USA.
g) Undertaking that the provided information/ documents are true/ correct.	Undertaking is provided on the company letter head.

Decision: **Keeping in view the valid legalized CoPP and approval of USFDA (Reference Regulatory Authority); Registration Board approved the change in manufacturing site for RhoGAM® Ultra-Filtered Injection (Reg. No. 005571) from M/s Ortho Clinical Diagnostics (OCD), USA to M/s Kedrion Biopharma USA 155, Duryea Road, Melville N.Y 11747, USA as per current Import Policy for finished drugs.**

16. Application of Renewal of Registration for below mentioned veterinary vaccines applied By M/s Marush Pvt Ltd., Lahore.

M/s Marush Pvt Ltd Lahore has applied for the renewal of the following Veterinary. As per available record the product against above registration number are transferred from the previous importer M/s Electro Vet Pharma, Islamabad to M/s Marush (Private) Limited, Lahore on dated **25th August 2011** accordingly the renewal submitted by M/s Marush (Private) Limited, Lahore dated **24th March 2016**.

Sr. No.	Reg. No.	Brand Name	Date of Initial Registration	Date of Transfer	Date of Application (R&I)Fee Submitted
1	022790	Cevac FP L Vaccine	17-04-1999	25-08-2011	Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-
2	022791	Cevac LT L Vaccine	17-04-1999	-do-	-do-
3	022793	Cevac EDS K Vaccine	17-04-1999	-do-	-do-
4	022794	Cevac New K Vaccine	17-04-1999	-do-	-do-
5	022797	Cevac ND EDS K Vaccine	19-04-1999	-do-	-do-
6	022798	Cevac ND IB IBD K Vaccine	19-04-1999	-do-	-do-
7	022800	Cevac NEW L Vaccine	19-04-1999	-do-	-do-
8	023401	Cevac BI L Vaccine	19-04-1999	-do-	-do-
9	023402	Cevac ND IB IBD EDS K Vaccine	19-04-1999	-do-	-do-
10	026449	Cevac IBD L Vaccine	06-02-2001	-do-	-do-
11	027469	Cevac BRON 120L Vaccine	25-04-2002	-do-	-do-
12	039913	Cevac Gumbo L Vaccine	03-09-2005	-do-	-do-

The renewal applications are evaluated as per SOPs approved in 276th meeting of registration Board and evaluation for each product is as follows:

1) Cevac FP L Vaccine

Sr. No.	Documents required to be submitted as per SOP and Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed	Covering letter on the M/s Marush's letter head for renewal of registered drug along with Form 5-B and 20,000 fee for each product	

	fee (endorsed by DRAP‟s Budget & Accounts Division). This will be submitted in DRAP‟s R&I Division.	(endorsed by DRAP‟s Budget & Accounts Division) submitted in DRAP's R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of Drug Sale License.	

i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

2) Cevac LT L Vaccine

Sr. No.	Documents required to be submitted as per SOP and Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP‟s Budget & Accounts Division). This will be submitted in DRAP‟s R&I Division.	Covering letter on the M/s Marush 's letter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP‟s Budget & Accounts Division) submitted in DRAP‟s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
C	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy /	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any	Undertaking is given on the letter head of the firm.

	misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by BiomuneCompany a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of Drug Sale License.	
i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided

*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550

3) Cevac EDS K Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP"s Budget & Accounts Division). This will be submitted in DRAP"s R&I Division.	Covering letter on the M/s Marush'sletter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP"s Budget & Accounts Division) submitted in DRAP"s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
C	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by BiomuneCompany a subsidiary of	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA),

		CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of Drug Sale License is provided	
i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

4) Cevac EDS K Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP‟s Budget & Accounts	Covering letter on the M/s Marush‘sletter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP‟s Budget & Accounts	

	Division). This will be submitted in DRAP"s R&I Division.	Division) submitted in DRAP"s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of Drug Sale License	

i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

5) Cevac ND EDS K Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP‟s Budget & Accounts Division). This will be submitted in DRAP‟s R&I Division.	Covering letter on the M/s Marush 's letter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP‟s Budget & Accounts Division) submitted in DRAP‟s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy /	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any	Undertaking is given on the letter head of the firm.

	misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary**while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License	
i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided

*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550

6) Cevac ND IB IBD K Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP"s Budget & Accounts Division). This will be submitted in DRAP"s R&I Division.	Covering letter on the M/s Marush'sletter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP"s Budget & Accounts Division) submitted in DRAP"s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA),

		Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License (for imported drugs)	
i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

7) Cevac NEW L Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP‟s Budget & Accounts Division). This will be submitted in DRAP‟s R&I Division.	Covering letter on the M/s Marush 's letter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP‟s Budget & Accounts Division) submitted in DRAP‟s R&I Division.	

b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License (for imported drugs)	

i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

8) Cevac BI L Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP‟s Budget & Accounts Division). This will be submitted in DRAP‟s R&I Division.	Covering letter on the M/s Marush'sletter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP‟s Budget & Accounts Division) submitted in DRAP‟s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the	Undertaking is given on the letter head of the firm.

	discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License (for imported drugs)	
i.	Legalized CoPP as per WHO"s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP"s attested import invoice (for imported products)		Not Provided

*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550

9) Cevac ND IB IBD EDS K

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP"s Budget & Accounts Division). This will be submitted in DRAP"s R&I Division.	Covering letter on the M/s Marush 's letter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP"s Budget & Accounts Division) submitted in DRAP"s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm

		Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License (for imported drugs)	
i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

10) Cevac IBD L Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP‟s Budget & Accounts Division). This will be submitted in DRAP‟s R&I Division.	Covering letter on the M/s Marush 's letter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP‟s Budget & Accounts Division) submitted in DRAP‟s R&I Division.	

b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License (for imported drugs)	

i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

11) Cevac BRON 120L Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP‟s Budget & Accounts Division). This will be submitted in DRAP‟s R&I Division.	Covering letter on the M/s Marush'sletter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP‟s Budget & Accounts Division) submitted in DRAP‟s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
C	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy /	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any	Undertaking is given on the letter head of the firm.

	misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License (for imported drugs)	
i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided

*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550

12) Cevac BRON 120L Vaccine

Sr. No.	Documents required to be submitted as per SOP Form 5B	Documents submitted by the firm	Remarks
a.	Covering letter on applicant's letter head for renewal of registered drug along with Form 5-B and prescribed fee (endorsed by DRAP"s Budget & Accounts Division). This will be submitted in DRAP"s R&I Division.	Covering letter on the M/s Marush 's letter headfor renewal of registered drug along withForm 5-B and 20,000 fee for each product (endorsed by DRAP"s Budget & Accounts Division) submitted in DRAP"s R&I Division.	
b.	Signature on the covering letter and undertaking on Form 5-B should be from Chief Executive Officer/ Managing Director / Director / Authorized Officer not below the manager level.	Covering letter and undertaking on Form-5B signed by Dr. Muzammil Hussain Shah Chief Executive Officer of M/s Marush Pvt. Ltd., Lahore. (As per submitted Form-5 B)	
c	An undertaking that the applied product has never been de-registered.		
d.	An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws.	The CEO of the firm has submitted an undertaking that "submitted documents are true copy of the originals and that, if at any stage any discrepancy/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws."	Undertaking is given on the letter head of the firm.
e.	Authority letter shall be submitted along with application.	Notarized Copy of Letter of Appointment as Sole importer and Distributor in Pakistan for the products of CevaSanteAnimale and its worldwide subsidiaries issued by CevaBiomune Company Lenexa USA dated Notarized Copy of Power of Attorney in the name of M/s Marush Pvt Ltd	The Product is manufactured and imported from **Ceva-Phylaxia Hungary** while the Authorization letter/Power of Attorney has been given by **Biomune Company USA a subsidiary of CevaSanteAnimale.** The firm has submitted a notarized copy of document with the name of Credentials of Manufacturer Abroad where it has been mentioned that the share company directly belongs to the French Firm

		Pakistan by Biomune Company a subsidiary of CevaSanteAnimale USA. Copy of Authorization letter from Ceva Animal Health Asia Pacific region.	CevaCevaSanteAnimale (CSA), the company headquarter is located inLibourne.
f.	Also attach attested copy of registration letter for confirmation of brand name.	Attested copy of approval letter of transfer of registration in name of M/s Marush Pvt. Ltd., Lahore & copy of initial registration letter for confirmation of brand name.	
g.	Furnish information of approved strength as per valid registration letter.	Provided in Form 5 B.	
h.	Attested copy of valid Drug Sale License (for imported drugs)	Attested copy of valid Drug Sale License (for imported drugs)	
i.	Legalized CoPP as per WHO‟s format or legalized free sale certificate and GMP certificate (for imported products).	Legalized free sale certificate and Copy of GMP are submitted	The facility has Eudra GMP certificate which has been confirmed online from below mentioned links
j.	Inspection report by regulatory authority of country of manufacture.	Inspection report by regulatory authority of country of manufacture.	Copy of Last inspection report submitted by the firm indicates some deficiencies pointed out by the Inspection team. But Copy of GMP certificates issued on the basis of the same inspection (dated 09-01-2019) submitted with inspection report has been verified from Eudra GMP website vide link given below *
k.	DRAP‟s attested import invoice (for imported products)		Not Provided
*http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53512 *http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=53550			

Decision: **Registration Board granted the renewal of above products as per following details subject to submit an undertaking on notarized stamp paper that the valid authorization of below mentioned products in their name is true & correct, nothing has been concealed and that if at any stage any discrepancy / misinformation is detected / observed the firm/ company will be held responsible as per relevant laws:**

Sr. No.	Reg. No.	Name of Product	Date of Initial Registration	Date of Transfer	Date of Application (R&I) Fee Submitted	Registration Validity
1.	**022790**	**Cevac FP L Vaccine**	**17-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**

2.	**022791**	**Cevac LT L Vaccine**	**17-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
3.	**022793**	**Cevac EDS K Vaccine**	**17-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
4.	**022794**	**Cevac New K Vaccine**	**17-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
5.	**022797**	**Cevac ND EDS K Vaccine**	**19-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
6.	**022798**	**Cevac ND IB IBD K Vaccine**	**19-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
7.	**022800**	**Cevac NEW L Vaccine**	**19-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
8.	**023401**	**Cevac BI L Vaccine**	**19-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
9.	**023402**	**Cevac ND IB IBD EDS K Vaccine**	**19-04-1999**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
10.	**026449**	**Cevac IBD L Vaccine**	**06-02-2001**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
11.	**027469**	**Cevac BRON 120L Vaccine**	**25-04-2002**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**
12.	**039913**	**Cevac Gumbo L Vaccine**	**03-09-2005**	**25-08-2011**	**Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-**	**w.e.f. 25-08-2016 to 24-08-2021.**

17. Change in address of importer of already registered veterinary vaccines applied by M/s Marush Pvt. Ltd. Lahore deferred in 291st meeting of Registration Board.

M/s Marush Pvt. Ltd. Lahore has applied for change of address for company head office for below mentioned products as per following details:

Previous Address	New Address
Khoti No.123-K First Floor, Model Town Lahore	117-A, Ahmad Block, New Garden Town Lahore.

The case was taken up in 291st meeting of Registration Board and the Board deferred the case for the following documents;

Decision of Registration Board in 291st meeting :

Registration Board deferred the case for submission of following by the firm:

a. Copy of previous Drug Sale License

b. Copy of new Drug Sale License

*c. Copies of registration letters and last renewal submissions of all the products***.**

All the above documents are submitted by the firm. The firm has further submitted that the their cold room facility is located at the same address and the Address of cold storage facility:

"Plot No.3, Old Bone Factory, near Ittefaq Foundary, opposite Kot Lakhpat Railway station, District Lahore"

For this purpose the firm has submitted copy of previous DSL issued on 21-02-2009 in which **change of Godown is written** and same address is mentioned as narrated by the firm in his request .While in the New DSL submitted by the firm , the address of the Godown is the same. The Cold storage verification report is not submitted by the firm so the address of the Cold Storage facility is not confirmed.

The details of the products are as under:

Sr. No.	Reg. No.	Brand Name	Date of Initial Registration	Date of Transfer	Date of Application (R&I) Fee Submitted
1	022790	Cevac FP L Vaccine	17-04-1999	25-08-2011	Dy. No. 1360 Dated 24-03-2016 Rs. 20000/-
2	022791	Cevac LT L Vaccine	17-04-1999	-do-	-do-
3	022793	Cevac EDS K Vaccine	17-04-1999	-do-	-do-
4	022794	Cevac New K Vaccine	17-04-1999	-do-	-do-
5	022797	Cevac ND EDS K Vaccine	19-04-1999	-do-	-do-
6	022798	Cevac ND IB IBD K Vaccine	19-04-1999	-do-	-do-
7	022800	Cevac NEW L Vaccine	19-04-1999	-do-	-do-
8	023401	Cevac BI L Vaccine	19-04-1999	-do-	-do-
9	023402	Cevac ND IB IBD EDS K Vaccine	19-04-1999	-do-	-do-
10	026449	Cevac IBD L Vaccine	06-02-2001	-do-	-do-
11	027469	Cevac BRON 120L Vaccine	25-04-2002	-do-	-do-
12	039913	Cevac Gumbo L Vaccine	03-09-2005	-do-	-do-
13	*039911*	*Cevac Broiler ND K Vaccine*	Renewed up to 24-08-2021.		
14	*039910*	*CevacTransmune IBD Vaccine*			
15	*022799*	*Cevac ND IB EDS K Vaccine*			
16	*022796*	*Cevac ND IBD K Vaccine*			
17	*022792*	*Cevac ND IB K Vaccine*			

Decision: **Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s Marush Pvt. Ltd., Khoti No. 123-K First Floor, Model Town Lahore to M/s Marush Pvt. Ltd., 117-A, Ahmad Block, New Garden Town Lahore for above products subject to cold storage facility verification of their godown.**

Item No. IV Division of Quality Assurance & Laboratory Testing

S No.	Subject	Remarks
	A– NEW/ONGOING CASES	
01.	MANUFACTURE & SALE OF SUB-STANDARD COLISTIN S WATER SOLUBLE POWDER (FOR VETERINARY USE ONLY), BATCH NO. U08J17 BY M/S ALINA COMBINE PHARMACEUTICALS (PVT.) LTD., KARACHI.	Personal hearing
02.	MEETING OF COMMITTEE ON AVAILABILITY OF LIFE SAVING DRUGS.	
03.	MANUFACTURE AND SALE OF SPURIOUS DRUG (QUINOZEF 250MG TABLETS, BATCH NO. AP0014) – M/S AMBRO PHARMA (PVT.) LTD., ISLAMABAD.	
04.	MANUFACTURING AND SALE OF COUNTERFEIT PRODUCT T DROP D BY M/S. TRIGON PHARMACEUTICALS, LAHORE – IMITATION OF INDROP D BY M/S. NEUTRO PHARMA, LAHORE.	
05.	MANUFACTURE & SALE OF SUB-STANDARD RAYLOX (LEVOFLOXACIN 250MG) TABLETS BATCH NO. A002 BY M/S RAY PHARMA (PVT) LTD. KARACHI	

S No.	Subject	Status
	B – OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONOURABLE DRUG COURT QUETTA.	
01.	MANUFACTURING AND SALE OF SUBSTANDARD DRUG PARACETAMOL TABLET B.NO.10 – M/S AHSON DRUGS COMPANY, TANDO ADAM.	Personal hearing
02.	MANUFACTURING AND SALE OF ADULTERATED DRUG 0.5% METRIDA INFUSION B.NO.21086	Personal hearing
03.	SALE OF SUBSTANDARD DRUGS WITHOUT HAVING DRUG SALE LICENSE - INJ FARMOX LA BATCH NO.: NO.VV019	Personal hearing
04.	MANUFACTURE AND SALE OF MISBRANDED AND SUBSTANDARD DRUG BICOLAX TABLET B.NO.4E009	Personal hearing
05.	MANUFACTURE AND SALE OF MISBRANDED AND SUBSTANDARD ZOLERIC 20MG CAPSULES B.NO.18 MFG BY M/S GENIX PHARMA PVT LTD KARACHI	Personal hearing
06.	MANUFACTURE AND SALE OF MISBRAND AND SUBSTANDARD NAMELY FREESIA TABLETS B.NO.F03R2	Personal hearing
07.	MANUFACTURING AND SALE OF MISBRANDED ZOLTAR 40MG INJECTION B.NO.0908041 M/S SHANGHI NO.1 BIOCHEMCIAL AND PHARMCEUTICAL CO LTD CHINA	Personal hearing
08.	MANUFACTURING AND SALE OF MISBRANDED AND SUBSTANDARD THYORIN TABLET B.NO.TY-05 MFG BY M/S PHARMEDIC LABORATORIES PVT LTD LAHORE.	Personal hearing
09.	CASES DECIDED BY BOARD FOR WHICH IMPLEMENTATION PART IS NOT TRACEABLE/PENDING.	

A– NEW/ONGOING CASES

Case No. 01: **Manufacture & Sale of Sub-Standard Colistin S Water Soluble Powder (For Veterinary Use Only), Batch No. U08J17 by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi.**

The FID-VI, DRAP Karachi visited the premises of M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachion 27-08-2018 to check the GMP compliance level of the firm and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3. Details are as under:

Name:	Colistin S water Soluble powder
Composition:	Each gram contain colistin Sulphate 4800000 I.U
Registration No:	058872
Batch No:	U08J17
Manufacturing Date:	10-17
Expiry Date:	09-20
Manufactured By:	M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi

The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-123-125/2018-FID-VI (K) dated 03-09-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

The sealed portion of samples were also sent to Chairman, Registration Board, DRAP, Islamabad vide letter No.ARS-123-125/2018-FID-VI (K) dated 03-09-2018 as required under the provision of clause (b) (3) Schedule V (Procedure for Inspector) of DRAP Act, 2012.

The Government Analyst, CDL, Karachi declared the sample as of **Sub-standard** quality **on the basis of assay content** vide test/analysis report **No.KQ.627/2018** dated 01st November, 2018 which is violation of Section 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under. Results of the test are reproduced as under;

Description: *White powder in plastic container.*
Identification: *Colistin and Sulphate identified.*
Assay for Colistin Sulphate:
Determined amount/gm: *6913183.38 I.U*
Stated amount/gm: *4800000 I.U*
Percentage: *144%*
Limits: *90.0% to 110.0%* ***Does not comply.***
Remarks:- *The sample is of* ***" substandard"*** *quality under the Drugs Act. 1976.*

The area FID-VI, Karachi vide letter No.ARS-123-125/2018-FID-VI (K) dated 12th November & 12th December, 2018 has asked the firm M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi to explain their position in the matter of manufacturing and selling of substandard drug with direction to recall the above said batch from the market.

In response, M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi submitted their reply vide letters dated 07-12-18 & 21-12-18 wherein they have informed that total quantity of the batch manufactured was 50kg which is lying in their warehouse however they didn't accept the test report based on their finding and commercial viability.

That the firm did not request to retest the sample from Appellate laboratory, NIH, Islamabad rather they requested FID to kindly withdraw the show cause notice.

That the firm in another letter dated 07-01-2019 requested to send the sample to NIH, for retesting of the sample but their request was not acceded as the request was not made within stipulated time of 30 days under the Drugs Act, 1976.

Name of the technical persons provided by the FID are as under:

- Imran Rehman Memon, Director (CNIC No. 42201-2142624-1)
- Muhammad Abdul Aziz Moosa, Production Manager (CNIC No.42101-9964252-1)
- Mrs. Rizwan Nighat, QC Manager (CINC No. 42201-0657326-6)

The Drugs Licensing Division was requested to verify the names provided by the FID-VI, DRAP, Karachi for further processing of the case and they provided the following names being responsible persons;

M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi.	Imran Rehman Memon **(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi
Abdul Rehman Memon **(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi	Farida Rehman Memon **(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi
Ali Rehman Memon **(Director)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi	Rizwana Nighat **(Q.C Incharge)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi
Ajmal Ali Huda **(Production Incharge)** M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi	

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-87/2018-(QC) dated 28-08-2019.

M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi submitted their reply to show cause notice vide letter No. nil dated 06-09-19 which is reproduced as under:

This is in reference to your letter No.F.03-87/2018-QC dated 28th August, 2019 concerning our veterinary product Colistin S water soluble powder (B# V08K17) which was drawn from our premises by the respected Area FID during routine GMP inspection of our plant and was sent to CDL for test/analysis. The Government Analyst of the CDL, Karachi declared our sample substandard on the basis of an assay percentage of 144%. The same was informed to us by the area FID.

We are enclosing herewith a copy of the area FID's letter No. ARS-123-125/2018-FID-VI (K) dated 12-12-2018 which was received by us on 21-12-18. Vide this letter the area FID in point No. 7 inquired from us if we would like to challenge the CDL test report. To its reply, through our letter dated 07-01-2019 we categorically stated that we are challenging the CDL test report. A copy of our reply dated 07-01-2019 is enclosed which also shows the receiving signature of the area FID's office. Hence we did not contravene any provisions of the Drugs Act, 1976 as we replied to the area FID within the stipulated time period of 30 days of receipt of this letter dated 12-12-18 requesting him to send our sample to NIH for retesting.

Unfortunately, despite our request our sample has not been sent to NIH for retesting which is in contravention of our rights under the Drugs Act, 1976. Hence we are again requesting you to please heed to our request to send our product for retesting in NIH before the product is expired. We further reiterate that the entire stock manufactured of the subject batch is still lying in our warehouse and has not been sold in the local o export market.

Proceeding of the 292ndMeeting of Registration Board.

Mr. Rehmat Ullah Baig, Regulatory Representative (42201-0462916-1) appeared on behalf of M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., A-127, SITE Super Highway, Karachi to plead instant case of manufacture & Sale of Sub-standard Colistin S Water Soluble Powder (For Veterinary Use Only), Batch No. U08J17, manufactured by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi.

Representatives of the firm re-iterated points already mentioned in their letter as recorded herein above and requested to retest their product from Appellate laboratory, NIH, Islamabad as they have applied for retesting within one month of the letter of FID wherein they were asked for retesting.

Decision: The Board after hearing the representative of the firm deliberated the matter in depth in the light of available record/ investigation report of FID and letters issued by the FID to the manufacturer decided as under:

i. **That the Board's portion of the sample (Colistin S Water Soluble Powder (For Veterinary Use Only), Batch No. U08J17, manufactured by M/s Alina Combine Pharmaceuticals (Pvt.) Ltd., Karachi) shall be sent for testing by Appellate Laboratory, NIH, Islamabad.**

ii. **QA&LT Division shall prepare an SOP for processing of cases pertaining to test / analysis of samples and their further processing by Federal Inspector of Drugs.**

Case No. 02: Meeting of Committee on Availability of Life saving drugs.

A committee was constituted to address the issues of availability of Life saving drug on 06th Feb 2018 vide office order No. F.9-1/2018-CEO (DRAP). In its first meeting held on 09th Feb 2018 the committee deliberated the terms of reference in the light of said office order. Initially, a list of 46 critically needed drugs (generic names) was forwarded by CDC Punjab and a list of 32 drugs (brand name) was forwarded by Drug Inspector Islamabad.Similar reports were obtained from Chief of Pharmacy, M/s Shifa International Hospital Islamabad. The committee requested the list of manufactures/importers of these drugs may be obtained from PE&R Division and will be shared with the field offices of DRAP and Provincial Government for verification regarding availability. It was also decided that quarterly production reports will be obtain from product registration holder in the light of Rule 30(4)(5)(6)(7) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. A large number of letters were issued to the manufacturers and importers repeatedly. 7 meetings of the committee on availability of life saving drugs were convened since the creation of this committee. Every effort has been put on to ensure the availability of life saving drugs. As this committee lacks the power of coercive action against the defaulters, availability of life saving drugs could not be ensured across the board. However, the situation has improved to certain extent.

Following reports of shortage were evaluated by the committee regarding the shortage of life saving drugs which are given as under:

S. No.	Name of Product	Name of Manufacturer	Reply of firm
01.	Acetazolamide	M/s Bio Mark-Pharmaceuticals Lahore	Firm informed that raw material "Acetazolamide" is not present in the local market and they are searching for it in the international market
02.	Phenobarbitone	M/s Atco Laboratories	Firm has informed that due to unavailability of quality material of API, they are unable to manufacture this product
		M/s Treat Pharmaceutical	Raw material is in process of import

		Industry Pvt Ltd	
		M/s Shaheen Pharmaceuticals Pvt Ltd Swat	Raw material is in process of import
		M/s. Tagma Pharma (Pvt) Ltd., 12.5 km Lahore Raiwind Road, Lahore	The raw material is in process of import
03.	Hydroxyurea	M/s GSK Pvt Ltd Karachi	Firm has applied for de-registration of product due to low market demand and availability of advanced and better alternatives
		M/s Phamedic Pvt Ltd Lahore	Firm has informed that their Oncology section is shut down due to planned annual maintenance
04.	Soranib Tablet (Sorafenib)	M/s A.J Mirza Pharma Pvt Ltd Karachi	Product specifications awarded by DRAP are "As per Innovator's Specification" whereas the specification applied were "Manufacturer's specifications"
05.	Verapamil tablet	M/s Geofman Pharmaceuticals	Firm has informed that they did not applied for the renewal of the product hence the product is now de-registered
		M/s Getz Karachi	The product has been de-registered
06.	Humatrope 5 mg Injection	M/s Eli Lilly Pvt Ltd Karachi	Firm has applied for the deregistration of the drug
07.	Lopresor Injection 5 mg	M/s Novartis Pharmaceutical Karachi	Firm has informed that the product is de-registered in the country of origin
08.	Glyceryl Trinitrate Patches 5mg Injection & Injection Isoket 0.5mg/ml	M/s Atco Laboratories Pvt Ltd Karachi	Firm has informed that their contract with the principle manufacturer expired in 2016 and also the principle manufacturer served a notice of discontinuation of product supply and non-renewal of distribution agreement
09.	MMR & Varicella Vaccine	M/s Sanofi Aventis Pvt Ltd Karachi	Firm has informed that the principle manufacturer has discontinued the production of drug
10.	Atropine Injection	M/s Bajwa Pharmaceuticals Pvt Ltd Lahore	Firm is waiting for panel to conduct inspection of stability study data of the product since 28-02-2019
11.	Utrogestan Capsule (Progesterone)	M/s Galaxy Pharma Pvt Ltd Karachi	Firm has informed that they do not possess sufficient stock to fulfill market needs and has requested to highlight the area where shortage is reported
12.	Envepe Tablet (oxylamine Succinate:10mg, Pyridoxine:10mg)	M/s RG Pharmaceutical Pvt Ltd Karachi	Firm has informed that shortage occurs due to limited inventory maintained by the pharmacies
13.	Anti-Rabies Vaccine (ARV)	M/s Hakimsons Impex Pvt Ltd Karachi	Firm has applied for product registration since March 2016 which is still pending
14.	Clexane (Enoxparin)	M/s Sanofi Aventis Pvt Ltd Karachi	Firm has informed that due to high global demand, they are facing disruption in supply over past several months
15.	Lohexol Injection	M/s Graton Pharma Lahore	Firm has applied for registration of product and has requested to grant registration at the earliest to avoid shortage
16.	Dacarbazine	M/s Pharmedic Laboratories, Lahore	The firm has informed that production area is under renovation which is near to completion
		M/s Medinet	The firm informed that dur to Pak Rupee

		Pharmaceuticals, Karachi	devaluation import of medicines is getting difficult day by day. However, the firm has initiated the process of local manufacturing from a good cGMP compliant local manufacturer.
17.	Thyroxine	M/s Platinum Pharmaceuticals Karachi	Firm has requested for deregistration of product
18.	Chlorpheniramine Maleate tablet	M/s Kohs Pharmaceuticals (Pvt) Ltd P/8, S.I.T.E, Hyderabad Pakistan	Firm has informed that they import raw material from India and due to current situation they are not able to import raw material.
19.	Hepatitis A Vaccine	M/s GSK Karachi	The firm submitted that they are facing supply constraints of vaccines from Global manufacturing site i.e. GSK Biological Belgium
20.	Priorix – MMR Vaccine	M/s GSK Karachi	The firm submitted that they are facing supply constraints of vaccines from Global manufacturing site i.e. GSK Biological Belgium
21.	Zeldox Capsules 40mg and 60mg	M/s Pfizer Pakistan Ltd Karachi	The firm stated that since the supply is maintained from packaging side i.e. R-pharm Germany GmbH for multiple countries of the world, therefore the site is facing capacity constraints leading to temporary supply shortage due to excessive increase in demand of said product
22.	Isoket injection	M/s. Atco Karachi imported from M/s. Schwartz Pharma Germany	The said product of Schwartz Pharma has been purchased by M/s. GSK globally. M/s. Atco has submitted that they are neither giving us the said product nor themselves marketing it. While GSK has submitted that our site is under maintenance.

Shortage alert were issued to following firms but till date no any reply has been received:

S. No.	Name of Product	Name of Manufacturer
01.	Acetazolamide	M/s Don Valley Pharmaceuticals, Lahore.
02.	Atropine Injection	M/s Aulton Pharmaceuticals, Plot 84/1, Block A, Phase 5, Industrial Estate, Hattar M/s Uni-Tech Pharmaceuticals (Pvt.) Ltd., Plot No.4/116, Sector 21, Korangi Industrial Area, Karachi. M/s Swiss Pharmaceutical (Pvt) Ltd., A-159 SITE, North Karachi Scheme No.33, Karachi. M/s. Siza International (Pvt.) Ltd., 65/2, Syed Maratib Ali Road, F.C.C. Gulberg lV, Lahore M/s. Surge Laboratories (Pvt.) Ltd, 10 Km Faisalabad road, Bikhi District, Sheikhupura. M/s Lawrence Pharma (Pvt) Ltd, 10.5 KM Sheikhupura Road, Lahore M/s. Venus Pharma, 23 K.M Multan Road, Lahore. M/s. Shaheen Agency KatchiGali no 1, Marriot Road, Karachi
03.	Digoxin	M/s Platinum Pharmaceuticals (Pvt.) Ltd., A-20 North Western Industrial ZoneBin Qasim, Karachi M/s. Evron Lahore,64-T, Gulberg II, Lahore
04.	Ergotamine Combination tablet	M/s. Farooq Corporation, MR 1/108,Kutchi Gali #2 Off Marriot Road, Karachi.
05.	Hydrochlorthiazide tablet	M/s Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Korangi Highway, Korangi, Karachi.

06.	Methyl Ergotamine	M/s Indus Pharma, Plot No.65, Sector 27, Korangi Industrial Area, Karachi M/s. Novartis Pharma (Pakistan) Ltd, 15 West Wharf Road Karachi M/s. Sandoz Pharma, 5 W Wharf Rd, West Wharf Karachi
07.	Nifedipine tablet	M/s. Bayer Pakistan (Pvt.)Ltd., B-28, K.D.A Scheme No.1, Shahrah-e-Faisal, Karachi. M/s. Mass Pharma (Pvt) Ltd. 17-Km, Ferozepur Road, Lahore
08.	Phenobarbitone	M/s MBL Pharma, B-77-A Lasbella Industrial Estate, Baluchistan M/s Uni-Tech Pharmaceuticals (Pvt.) Ltd., Plot No.4/116, Sector 21, Korangi Industrial Area, Karachi. M/s Safe Pharmaceuticals (Pvt.) Limited; Plot # C-I-20, Sector 6-B, North Karachi Industrial Area,Karachi. M/s Pliva Pakistan Ltd., P. No. B-77 Hub Industrial Estate, Lasbela, Balochistan M/s. Regent Laboratories, Plot No. C-20 S.I.T.E, Super Highway Industrial Area, Karachi. M/s Fozan Pharmaceuticals (Pvt.) Ltd. 36A- Industrial Estate, Hayatabad, Peshawar M/s Aries Pharmaceuticals (Pvt) Ltd. 1-W, Industrial Estate, Hayatabad, Peshawar. M/s Lowitt Pharmaceuticals, 24-Hayatabad Industrial Estate, Peshawar M/s Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Industrial Estate, Jamrud Road, Peshawar M/s Navegal Laboratories, 41/1-A-2, Phase-1, Industrial Estate, Hattar M/s Saydon Pharmaceuticals Industries Ltd., 77/A, Hayatabad, Industrial Estate, Peshawar. M/s Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Industrial Estate, Jamrud Road, Peshawar M/s. Synchro Pharma, 77 Industrial Estate KotLakhpat, Lahore M/s Ameer Pharma (Pvt) Ltd, 23-KM, Sheikhupura Road, Lahore M/s Fynk Pharmaceuticals, 19 K.M. G.T. Road, Kala Shah Kaku, Lahore M/s Venus Pharma, 23 K.M, Multan Road, Lahore M/s Neutro Pharma (Pvt) Ltd., 9.5-KM, Sheikhupura Road, Lahore. M/s Friends Pharma (Pvt.) Ltd, 31 KM Ferozepur Road, Lahore M/s Arreta Pharmaceuticals (Pvt) Ltd., Plot No. 13, Street No. N-5, RCCI, Industrial Estate Rawalpindi M/s. Tayyab Laboratories (Pvt) Ltd. Plot # 13-A, Street #N-5, RCCI Rawat, Islamabad M/s. Sulson Pharma, 17-Old F.C.0 Ferozepur Road, Lahore M/s. Regent Laboratories, Plot No. C-20 S.I.T.E, Super Highway Industrial Area, Karachi
09.	Thyroxine tablets	M/s Nabi Qasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Korangi Highway, Korangi, Karachi M/s. Healers Laboratories, 96-102C S.I.E, Kohat Road, Peshawar M/s. Danas Pharmaceutical (Pvt) Ltd, 312-Industrial Triangle Kahuta Road, Islamabad M/s Glitz Pharma 265, Industrial Estrate, Kahuta Triangle Islamabad M/s Glitz Pharma 265, Industrial Estrate, Kahuta Triangle Islamabad M/s Pharmedic Lab., 5-16 Km. Multan Road, Lahore M/s Libra (Pvt) Ltd. 77 Industrial Estate Jamrud Road, Peshawar
10.	Verapamil tablets	M/s Knoll Pharmaceutical Ltd., Plot 13, Sector 20, Korangi Industrial Area, Karachi M/s. Getz Pharma Pakistan (Pvt.) Ltd, 30-31/27, Korangi Industrial Area, Karachi
11.	Chlorpheniramine Maleate tablet	M/s Ahson Drug Company T/1, S.I.T.E, Tando Adam M/s Standard Drug Company, E/6, S.I.T.E, Hyderabad M/s Uni-Tech Pharmaceuticals (Pvt.) Ltd., Plot No.4/116, Sector 21, Korangi Industrial Area, Karachi. M/s Krka Pak Pharmaceuticals, & Chemical Works, Wahab Arcade M.A. Jinnah Road, Karachi on contract manufacturing from M/s. Elko

		Organization, Karachi M/s. Welmed Pharmaceutical Industries (Pvt) Ltd., 108 R-2 Industrial Estate Gadoon, Swabi M/s. PharmEvo (Pvt) Ltd., 402, Business Avenue Block-6 PECHS, Shahrah-e- Faisal, Karachi M/s Swat Pharmaceuticals, Saidu Sharif Road Amankot, Swat M/s Alson Pharmaceuticals, 169-Hayatabad Industrial Estate, Peshawar M/s Medicraft Pharmaceuticals (Pvt) Ltd., 126-B, Industrial Estate, Jamrud Road, Peshawar M/s. WellbornePharmachem and Biologicals, Plot#51/1 Phase I&II Industrial Estate, Hattar M/s. Healers Laboratories, 96-102C S.I.E, Kohat Road, Peshawar M/s. Soma Laboratories, 692-N, Samanabad, Lahore M/s. Ideal Pharmaceuticals Industries, 18-Km, Ferozepur Road, P.O Unico Lahore M/s Friends Pharma (Pvt.) Ltd, 31 KM Ferozepur Road, Lahore M/s. Basel Pharmaceuticals, 227-Phase II, Multan Industrial Estate, Multan. M/s. BJ Pharmaceuticals, 19Km Sheikhupura Road Lahore M/s. Empire Pharmaceuticals (Pvt) Ltd., 35 K.M Lahore Raiwind Road, Lahore. M/s. IPP 34, Industrial Triangle Kahuta Road, Islamabad M/s. Festel Laboratories, Jinnah Industries Link Kattarband, Thokar Niaz baig Multan Road, Lahore M/s Rasco Pharma, 5.5 KM Raiwind Road Ali Raza Abad, Lahore M/s Lawrence Pharma (Pvt) Ltd, 10.5 KM Sheikhupura Road, Lahore M/s Prime Labs (Pvt) Ltd, 9.5 Km Sheikhupura Road, Lahore M/s Fynk Pharmaceuticals, 19 K.M. G.T. Road, Kala Shah Kaku, Lahore
12.	Tranxene (Clorazepate)	M/s The Searle Company Limited – F-319, S.I.T.E. Karachi
13.	Hydroxyurea	Al-Habib Pharmaceuticals, Plot # 143, Block-A,، Sindhi Muslim Cooperative Housing Society (SMCHS), Karachi Z-Jans Pharmaceutical (Pvt) Ltd., 148-A Industrial Estate, Peshawar, Khyber Pakhtunkhwa
14.	Adalat Retard tablet (Nifedipine)	Bayer Pakistan (Private) Limited, Bahria Complex II, 4th. Floor, M.T. Khan Road, Karachi
15.	Vinblastin	M/s ATCO Laboratory, Manghopir Rd, B-18 Sindh Industrial Trading Estate, Karachi. M/s Shaheen Agency, GK 3/13, Adamjee Dawood Road, Karachi. M/s Mehran International, 2nd Flr., Zainab Manzil, Kutchi Gali # 2, Karachi. M/s Al Habib Pharmaceuticals, Karachi - Plot # 143, Block-A Sindhi Muslim Cooperative Housing Society (SMCHS), Karachi. M/s Pharmedic Laboratories, Lahore - 16km. Multan Road, Lahore -53800 - Lahore. M/s PAK China International, 233 Sunny Plaza, HasratMohani Road, Karachi M/s AJM Pharma, 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi. M/s Ali Gohar & Company, Karachi – State Life Building 1-B, I.I. Chundrigar Road, Karachi
16.	Dacarbazine	M/s Al Habib Pharmaceuticals, Karachi - Plot # 143, Block-A Sindhi Muslim Cooperative Housing Society (SMCHS), Karachi, Karachi City, Sindh
17.	MMR & Varicella vaccine	Amson Vaccine & Pharma, 154, Industrial Triangle, Kahuta Road, Islamabad, Pakistan M/s Hi-Warble Pharmaceuticals, 44-B II, Phase 1, Johar Town, Lahore

Decision of the committee:

The Committee in its 07th meeting decided that despite of shortage alerts issued, the manufacturers are not taking the matter of shortage of life saving drugs seriously and most of the firms did not even replied to the shortage alerts issued by the committee. Since the committee is not empowered to take any coercive action under the law against the manufacturers/importers found violating the Rule 30(4)(5)(6)(7) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 and conditions of the Registration by not fulfilling the market demand of their registered drugs resulting in shortage of life saving drugs, the cases will be referred to the division of PE&R for necessary legal action. Therefore the cases are being submitted for the consideration of Board for appropriate action under the law in the best public interest.

Decision of 291st meeting of Registration Board.

The Registration Board decided to defer the case till next meeting of the registration board.

Decision of 292nd meeting of Registration Board.

The Board decided to refer the case to Authority for seeking guidance in the matter. The Board further advised to apprise the Authority about reasons of shortages of drugs as identified by the Committee on Availability of drugs.

Case No. 03:- Manufacture And Sale Of Spurious Drug (Quinozef 250mg Tablets, Batch No. AP0014) – M/S Ambro Pharma (Pvt.) Ltd., Islamabad.

That the FID-I,DRAP, Islamabad stated that he has been notified as a Federal Inspectors of Drugs for area jurisdiction of Industrial Triangle Kahuta Road Islamabad since 31st May, 2018 vide S.R.O. 686 (I)/2018.

That the Federal Government Analyst, Central Drugs Laboratory(CDL) Karachi declared the following sample as **"Spurious"** vide test analysis report No.NAS.111/2018 dated 14.11.2018. The sample was sent by Drug Inspector, Gilgit Baltistan (GB) vide memorandum No.103/DI-GLT/97/298 dated 23.10.2018 to CDL.

Name of Drug	Reg. No.	Batch No.	Date/Mfg	Date/Exp	Claimed to be Mfd By
Quinozef 250mg Tablets	046368	AP0014	08-17	08-20	M/s Ambro Pharma Pvt Ltd., Islamabad

That Assistant Director (Quality Control) vide letter No.04-74/2018-QC dated 26th November, 2018 conveyed the undersigned about the above said report with the request to look into the matter and submit complete investigation. Undersigned along with FID-IV visited the firm on 26th November, 2018 on the direction of Additional Director, QA&LT. The panel noticed number of serious GMP violations during the inspection. The report was submitted to the Additional (Director), QA&LT vide letter No.F.3-7/2003-FID–I (ISD) dated 28th November, 2019 with the recommendation to carry out a thorough investigation for manufacturing of spurious drugs and inspection of firm by a larger panel (in order to cover all facets/aspects mentioned in the report) and to probe the matter more carefully.

That in response to the above, AD (QC) vide letter No.04-74/2018-QC dated 30th November, 2018 conveyed the approval of following panel to conduct thorough inspection of firm by the competent authority to probe the manufacturing of Spurious product Quinozef (Ciprofloxacin) 250mg Tablets Reg. No. 046368 Batch No.AP0014 and to see overall GMP compliance (Annex - E):

a) Mr. Nadeem Iqbal, Expert member
b) Mr. Abdul Sattar Sohrani, Additional Director, QA&LT

c) Mahvash Ansari, FID-IV/DD (QC), QA&LT, DRAP.
d) Area Federal Inspector of Drugs, DRAP, Islamabad.

That the inspection was conducted by the above panel on 03rd December, 2018 and again a number of violations were noticed and conveyed to Secretary, Central Licensing Board and Secretary, Registration Board via the inspection report vide letter No. F.3-7/2003-FID-I dated 24th December, 2018 (Annex - F). It is pertinent to mention here that DML of the firm was cancelled by Central Licensing Board on the basis of gross violations as reported above.

That during the inspection, undersigned took following samples on form-3 (Annex - G) for test/analysis and sent to Federal Government Analyst, CDL, Karachi vide memorandum No.F.3-7/2003-FID-I dated 07th December, 2018 (Annex - H).

Name of Drug	Reg. No.	Batch No.	Date/Mfg.	Date/Exp.	Claimed to be Mfg. by
Quinozef (Ciprofloxacin) 250mg Tablets	046368	AP0014	08/2017	08/2020	M/s Ambro Pharma Pvt. Ltd., Islamabad
Polymal-F Tablet (Iron III hydroxide polymatose complex 100 mg + Folic acid 350 mcg)	045897	AP0028	04/2018	04/2020	-do-

That Federal Government Analyst (FGA), Central Drug Laboratory, Karachi vide test reports No.R.IP.309/2018 dated 11th January, 2019 (Annex - I) declared the drug mentioned at S.No.1 in above table, as **Spurious** with the remarks that the sample is under section 3 (z-b) (i) of the Drugs Act, 1976. While the drug mentioned at S.No.2 in above table, declared as "Standard" by the FGA vide test reports No.R.IP.310/2018 dated 09th January, 2019 with the remarks that "the sample is of standard quality with regard to the tests performed". Results of the test report are reproduced as under:

Description: *Yellow colored oval shaped film coated with line of bisection on one side.*
Identification: *Ciprofloxacin Hydrochloride NOT Identified.*
Remarks: *The sample is under section 3 (z-b) (i) of the Drugs Act, 1976.*
Note:
1) *The HPLC and FTIR studies show that the sample contains Levofloxacin (237.3120 mg/tablet) instead of ciprofloxacin HCl as stated on the label.*
2) *Section 3 (Definition): In this act unless there is anything repugnant in the subject or context 3 (z): "Specification" when applied to a drug:*
3 (z-b): Spurious drug means a drug:
i. *Which purports to be a drug but does not contain the active ingredient of that drug*

The Assistant Director (Quality Control) again requested the undersigned to look into the matter and submit a complete case for further consideration by the concerned Board vide letter No.04-74/2018-QC dated 18th January, 2019. The said reports (certificate of test or analysis) were forwarded/delivered to the firm as required under section 22(3)(a) of Drugs Act, 1976 vide letter No.F.3-7/2003-FID–I (ISD) dated 12th February, 2019. The firm was asked for explaining its position in this regard.

M/s Ambro Pharmaceuticals, Islamabad through its owner Mr. Abdul Majeed Chaudhary replied vide letter No.APL/FID-003/2018-19 dated 19th February, 2019 stated that:

"…..they are not satisfied above Analytical Report of our product as declared "Spurious". Now, we have challenged in the Appellate Laboratory i.e. National

Institute of Health, Islamabad, because we tested our product in Quality Control Laboratory, as per our Q.C. Lab. report the sample is declared up to standard as a Ciprofloxacin. You are requested to kindly send samples of our product to National Institute of Health for further testing please".

In the light of the firm's above request, the Board portion was sent for appellate testing under section 22(5) of Drugs Act, 1976 to Appellate Board. The Appellate Laboratory, NIH, Islamabad also declared the said sample as **"Spurious"** vide test report No.016-M/2019 dated 19th July, 2019. Results are reproduced as under:

Description: *Yellow colored oblong shaped, biconvex, film coated tablets having bisectional line on one side whereas plain from the other side packed in blister packing further contained in an outer carton along with leaflet.*

Identification: *Ciprofloxacin not identified.*
Levofloxacin identified.

Dissolution test: *Determined:*
Ciprofloxacin not identified.
Levofloxacin identified.
Does not comply with manufacturer specifications.

Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Ciprofloxacin as Hydrochloride	*250mg/tab*	*Nil*	*90-110%*	*Nil*

Does not comply with manufacturer specifications and official pharmacopoeia.

In the opinion of the undersigned the sample is of spurious as defined in the Drugs Act, 1976 for the reasons given below:

Dissolution test: *Determined:*
Ciprofloxacin not identified.
Levofloxacin identified.
Does not comply with manufacturer specifications.

Assay:	***Stated:***	***Found:***	***Limit:***	***Percentage:***
Ciprofloxacin as Hydrochloride	*250mg/tab*	*Nil*	*90-110%*	*Nil*

During investigation, original warranty and bill invoices confirming the sale/trading of drug under question to Gilgit Baltistan from stock register were traced. It has now proved that product under question was manufactured by M/s Ambro Pharmaceuticals, Islamabad and following persons are responsible for the offence:

a) M/s Ambro pharmaceuticals, Islamabad through owner Ch. Abdul Majeed.
b) Ch. Abdul Majeed, (claimed) Owner of firm.
c) Mr. Muhammad Asif Awan, Production Manager.
d) Ms. Rohi Asif, Quality Control Manager.

That in the light of substantial evidence, it is therefore, requested to grant permission for registration of FIR or direct prosecution in the competent Drug Court against the above mentioned persons responsible for violation of Schedule-II (1) (a) (i) r/w Section 23(1)(a)(i) punishable under Schedule-III(1)(a) read with Section 27(1)(a) which is cognizable offence under Schedule-IV of DRAP Act, 2012 read with Section 30 of the Drugs Act, 1976.

Proceeding and Decision of 292nd meeting of Registration Board.

The case was presented before the Registration Board in its 292nd meeting held on 01st – 02nd October, 2019 and the Board considered and evaluated the following record:

- Test report No.NAS.111/2018 dated 14th November, 2018 by CDL, Karachi.

- Inspection report vide No.F.3-7/2003-FID-I dated 28th November, 2018 by FID-I, DRAP, Islamabad.
- Test report No.R.IP.309/2018 dated 11th January, 2019 by CDL, Karachi.
- Inspection report vide No.F.3-7/2003-FID-I dated 24th December, 2018 by FID-I, DRAP, Islamabad.
- Test report No.016-M/2019 dated 19th July, 2019 by the Appellate laboratory, NIH, Islamabad.
- Complete case forwarded by FID-I, DRAP, Islamabad vide No.F.3-7/2003-FID-I dated 23rd September, 2019.

The Board after detailed discussion and deliberation decided as under:

- **To serve show cause notice and personal hearing to the firm and responsible persons for manufacturing and sale of Spurious Drug Quinozef 250mg Tablets, Registration number 046368, Batch No. AP0014, manufactured by M/s Ambro pharmaceuticals, Islamabad in violation to Schedule-II (1) (a)(i) r/w Section 23(1)(a)(i) punishable under Schedule-III(1)(a) read with Section 27(1)(a) which is cognizable offence under Schedule-IV of DRAP Act, 2012 read with Section 30 of the Drugs Act, 1976.**

Case No. 04:- Manufacturing and sale of counterfeit product T Drop D manufactured by M/s. TrigonPharmaceuticals, Lahore – imitation of Indrop D manufactured by M/s. Neutro Pharma, Lahore.

01. Brief facts of the case are as under;

02. A complaint was received from Deputy Director, QC, DRAP to then Assistant Director QC-V regarding the manufacturing and sale of counterfeit product T Drop-D manufactured by M/s. Trigon Pharmaceuticals, Lahore that is imitation of Indrop D manufactured by M/s. Neutro Pharma, Lahore.

03. A letter vide F. No. 13-58/2018-QC dated 30-10-2018 was sent to Additional Director Lahore, Islamabad, Peshawar, Karachi and Quetta with request to initiate legal action as per rules.

04. Federal Inspector of Drugs, Lahore vide letter No. 14131/2018-DRAP(L-IV) dated 2nd November, 2018 informed about the inspection of the premises and the details are reproduces as under;

"Reference to DRAP Islamabad letter No.F.13-85/2018-QC dated 30.10.2018, undersigned along with Mr. Shoaib Ahmed, FID inspected M/s Trigon Pharmaceuticals on 31.10.2018.

2. At the time of inspection, CEO of the firm Mr. Muhammad Safdar along with other technical staff was present. The team discussed the matter of manufacturing of counterfeit drug product with the CEO of the firm. He informed that this drug is a registered product and provided the registration letter. Team noted that this drug is a registered product and provided the registration letter. Team noted that the firm has got the registration of the product with the name and style of "T Drop-D Injection" bearing registration No. 077194 with a packing size of 5's x 1ml vide DRAP letter F. No. 15-2/2014-Reg-V (M-242) dated 27.05.2014. Team checked the product with the packing and size of 5's and found it to be different in respect to design and colour scheme of label and outer packing of complainant's product "Indrop D", though the name was quiet resembling.

3. The firm latter on, got approval for additional pack of 1's x 1ml vide DRAP letter No.F.9-24/2017-DD(P)(Vol-I) dated 03.0902018. The firm produced first batch of this product in September 2018 which was released by QC on 11.10.2018 and dispatched to distribution. At the time of inspection there was no stock of this product in the FG store, management of firm told that the whole batch has been dispatched to distributors. Only 10

packs were kept as retaining samples. These samples were compared with the complainant's product i.e. "indrop D" and found to be very closely in resemblance with respect to name, design and colour scheme of label and outer packing. Therefore the product is considered to be counterfeit/imitation product under section 3(f) of the Drugs Act, 1976.

4. During inspection, the team also found some quantity of packing material (outer packing/unit carton) of drug under consideration. It was also noted that printed price on label of the drug was higher than the price fixed by federal government as per DRAP letter No. F. 9-24/2017-DD (P) (Vol-I) dated 03.09.2018. Since, manufacturing and sale of counterfeit drugs and manufacturing and sale of drugs at a price over and above the maximum retail price fixed by Federal Government is prohibited under Schedule II (A)(1) of the DRAP Act, 2012 read with section 23 (1) of the Drugs Act, 29176 and Schedule II (A)(3) of the DRAP Act, 2012 vide SRO No. 913(I)/2017 dated 06.09.2017, respectively, thus these drugs were seized on form No. 2 (Copy attached) as case property (evidence of commission of offence) under Section 18(a)(f) of the Drugs Act, 1976 and Schedule V of the DRAP Act, 2013 as per following detail:

Sr#	***Name of drug/Material***	***Batch No.***	***Manufacturer***	***QTY***	***Price on pack (Rs)***	***Approved MRP (Rs)***
1.	*T Drop-D 1ml ampoule*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*10 Packs*	*110/1ml Ampoule*	*93/1ml x1's*
2.	*Outer pack/unit carton (printed packing material of T Drop-D)*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*2800 Nos*	*110/1ml Ampoule*	*93/1ml x1's*

5. All the above mentioned drugs were recovered and seized on From 2 in the presence of Mr. Muhammad Safdar, CEO of the firm and other witnesses as per Form 2. The competent authority (in both the counterfeit and higher price case) is requested to grant permission for safe custody of seized drugs as mentioned above till the decision of the case.

6. The firm was directed to stop manufacturing of above mentioned counterfeit drug and to recall all of the distributed stock immediately. The firm was also directed to explain their position that why were they manufacturing and selling these drugs in violation of provisions of the DRAP Act, 2012 and rules framed there under. Complete case will be submitted after further investigation. Submitted for information and necessary action and directions, please."

05. Federal Inspector of Drugs, Lahore in continuation of the mentioned letter sent another letter vide No. 14245/2018-DRAP(L-IV) dated 6th November, 2018 wherein he informed about the re-inspection of the M/s. Trigon Pharmaceuticals, Lahore on 05.11.2018 to check the status of recall of the T Drop-D. The details of letter are reproduced as under;

"In continuation to this office letter No.14130/2018-DRAP (L-IV) dated 02.11.2018, undersigned along with Mr. Abdul Rashid Sheikh, FID inspected M/s Trigon Pharmaceuticals on 05.11.2018 to check the recall of T Drop-D.

2. At the time of inspection CEO of the firm, Mr. Muhammad Safdar along with other technical staff was present. The firm informed that they have received 37979 packs of T Drop-D from their distributor. Another quantity of 2600 ampoule of said drug without blistering were also available in the firm (which was told to be in-process ampoules quarantined for blistering). All of this quantity was placed in the recalled area of FG store of the firm. Undersigned ordered not to dispose of all this quantity under Section 18(1) of the Drugs Act, 1976 on Form 1 as per following detail:

Sr #	***Name of drug/Material***	***Batch No.***	***Manufacturer***	***QTY***	***Price on pack (Rs)***	***Approved MRP (Rs)***
1.	*T Drop-D 1ml*	*TP-*	*M/s Trigon*	*37979*	*110/1ml*	*93/1ml x1's*

	ampoule	*001*	*Pharmaceuticals (Pvt) Ltd., Lahore*	*Packs*	*Ampoule*	
2.	*Naked ampoules of T Drop-D*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*2600 Nos*		

5. All the above-mentioned drugs were ordered not to dispose of on From 1 in the presence of Mr. Muhamamd Safdar, CEO of firm and other witnesses as per Form 1The competent authority (in both the counterfeit and over-pricing case) is requested to grant extension in not to dispose of period, under clause (i) of Section 1 of Schedule V of the DRAP Act, 2012, for three (3) months or till the decision of the case."

06. FID-IV, Lahore vide letter F. No. 3-1/2018-FID-V/1380 dated 24.01.2019 in response to letter vide F. No. 13-58/2018-QC dated 30-10-2018 submitted as under;

"Reference to this office earlier letters No. 14131/2018-DRAP (L-IV) dated 02.11.2018 and No. 14245/2018-DRAP (L-IV) dated 06.11.2018. To remind the case; with reference to DRAP Islamabad letter F.No.13-85/2018-QC dated 30.10.2018, undersigned along with Mr. Shoaib Ahmed, FID inspected M/s Trigon Pharmaceuticals on 31.10.2018.

2. At the time of inspection, CEO of the firm, Mr. Muhammad Safdar along with other technical staff was present. The team discussed the matter of manufacturing of counterfeit drug product with the CEO of the firm. He informed that this drug is a registered product and provided the registration letter. Team noted that the firm has got the registration of the product with the name and style of "T Drop-D Injection" bearing registration No. 077194 with a packing size of 5's x 1ml vide DRAP letter No. F.15-2/2014-Reg-V (M-242) dated 27.05.2014. Team checked the product with the packing size of 5's and found it to be different in respect to design and colour scheme of label and outer packing of complainant's product "Indrop D" though the name was quite resembling.

3. The firm later on, got approval for additional pack of 1'2 x 1ml vide DRAP letter No. F.9-24/2017-DD (P)(Vol-I) dated 03.09.2018. The firm produced first batch of this product in September 2018 which was released by QC on 11.10.2018 and dispatched to distribution. At the time of inspection there was no stock of this product in FG store, management of firm told that the whole batch has been dispatched to distributors. Only 10 packs were kept as retaining samples. These samples were compared with the complainant's product i.e. "indrop D" and found to be very closely in resemblance with respect to name, design and colour scheme of label and outer packing. Therefore, the product was considered to be counterfeit/imitation product under section 3(f) of the Drugs Act, 1976.

4. During inspection, the team also found some quantity of packing material (outer packing/unit carton) of drug under consideration. It was also noted that printed price on label of the drug was higher than the price fixed by Federal Government as per DRAP Letter No. F. 9-24/2017-DD (P) (Vol-I) dated 03.09.2018. Since, manufacturing and sale of counterfeit drugs and manufacturing and sale of drugs at a price over and above the maximum retail price fixed by Federal Government is prohibited under Schedule II (A)(1) of the DRAP Act, 2012 read with Section 23 (1) of the Drugs Act, 1976 and Schedule II (A)(3) of the DRAP Act, 2012 vide SRO No. 913(I)/2017 dated 06.09.2017, respectively, thus these drugs were seized on form No. 2 (copy attached) as case property (evidence of commission of offence) under Section 18(l)(f) of the Drugs Act, 1976 and Schedule V of the DRAP Act, 2012 as per following detail:

Sr. #	***Name of drug/Material***	***Batch No.***	***Manufacturer***	***QTY***	***Price on pack (Rs)***	***Approved MRP (Rs)***
1.	*T Drop-D 1 ml ampoule*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*10 Packs*	*110/1ml Ampoule*	*93/1ml x 1's*

2.	*Outer pack/unit carton (printed packing material of T Drop-D)*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*2800 Nos*	*110/1ml Ampoule*	*93/1ml x 1's*

5. The competent authority (in both the counterfeit and higher price case) was requested to grant permission for safe custody of seized drugs as mentioned above till the decision of the case. It is pertinent to mention here that undersigned received the permission to keep the safe custody of seized goods from the Chairman Drug Pricing Committee with reference to over pricing case, however, no permission is granted from Chairman Registration Board with reference to counterfeit case.

6. The firm was directed to stop manufacturing of above-mentioned drug and to recall all of the distributed stock immediately. The firm was also directed to explain their position that why were they manufacturing and selling these drugs in violation of provisions of the DRAP Act, 2012 and rules framed thereunder.

7. Reference to above para, undersigned along with Mr. Abdul Rashid Sheikh, FID inspected M/s Trigon Pharmaceuticals on 05.11.2018 to check the status of recall of T Drop-D. The firm informed that they have received 37979 packs of T Drop-D form their distributor. Another quantity of 2600 ampoules of said drug without blistering were also available in the firm (which was told to be in-process ampoules quarantined for blistering). All of this quantity was placed in the recalled area of FG store of firm. Undersigned ordered not to dispose of all this quantity under Section 18 (1) of the Drugs Act, 1976 on Form 1 as per following detail:

Sr. #	***Name of drug/Material***	***Batch No.***	***Manufacturer***	***QTY***	***Price on pack (Rs)***	***Approved MRP (Rs)***
1.	*T Drop-D 1 ml ampoule*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*37979 Packs*	*110/1ml Ampoule*	*93 / 1ml x 1's*
2.	*Naked ampoules of T Drop-D*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*2600 Nos*		

8. The competent authority (in both the counterfeit and over-pricing case) was requested to grant extension in not to dispose of period, under clause (i) of Section 1 of Schedule V of the DRAP Act, 2012, for three (3) months or till the decision of the case. However, it is pertinent to mention here that undersigned has not received any extension in this regard yet.

9. The firm in response issued a letter to its distributor on 31.10.2018 for recall of product under investigation (Copy enclosed). The firm also submitted a written reply (Copy enclosed) wherein, the firm claimed certain differences in the label and packing of both the drugs and said that they did not have any intention of resemblance with anyone. The firm further submitted that it was their first batch of the product and they will change the packing of their product in future batch. With reference to over-pricing of the product the firm submitted that they have already submitted a price increase request to concerned section of DRAP Islamabad on 23rd July 2018 and in this regard referred the SRO No. 41 (I)/2018.

10. The firm has now submitted the details of further recalled quantity of the product, according to which, 61647 units have been recalled from the market out of 91850 sent to distributor, 2600 unblistered ampoules were placed in the firm and thus a total quantity of 64247 ampoules is now present in the firm.

11. Names of the management and qualified persons of the firm are as below:

i. *Mr. Muhammad Safdar, CEO, CNIC # 36501-3646813-9*
ii. *Ms. Sumera Hafeez, Production Manager, CNIC # 31202-9368224-4*
iii. *Mr. Muhammad Umar, Quality Control Incharge,CNIC#35202-*

13. Since, the firm is found involved in manufacturing and sale of counterfeit drug which is prohibited under Schedule II (A)(1) of the DRAP Act, 2012 read with Section 23 (1) of the Drugs Act, 1976 and manufacturing and sale of drugs at a price over and above the maximum retail price fixed by Federal Government which is prohibited under Schedule II (A)(3) of the DRAP Act, 2012 vide SRO No. 913(I)/2017 dated 06.09.2017. Hence the case is submitted for consideration of concerned boards."

07. In response to the mentioned letter, a letter vide F. No. 13-85/2018-QC dated 22-07-2019 was sent to FID IV Lahore requesting to thoroughly investigate the matter and after completing all the formalities, submit a comprehensive report including all the requisite documents to this office, highlighting the nature of violation, fixing of responsibility (Names, Designations, complete addresses and copies of CNIC of the accused persons) and comments /views of the response of accused, if any for the consideration of the Board.

08. Furthermore, FID IV vide letter No. 2922/2019-DRAP (L-IV) dated 28-02-2019 informed as under;

"I am directed to refer to your letter No. Nil dated 12-01-2019 on the subject cited above.

2. You are hereby allowed to resume manufacturing of T Drop Injection (Registration No. 077194) with packing/labeling in accordance with registration conditions.

3. However, the counterfeit/seized batch of drug shall not be disposed of till the decision of concerned Board."

09. In response to the letter F. No. 13-85/2018-QC dated 22-07-2019, FID IV vide letter No. F. 3-1/2018-FID (IV)/10809 dated 08-08-2019 provided a comprehensive report on the matter as under;

"2. At the time of inspection, CEO of the firm, Mr. Muhammad Safdar along with other technical staff was present. The team discussed the matter of manufacturing of counterfeit drug product with the CEO of the firm. He informed that this drug is a registered product and provided the registration letter. Team noted that the firm has got the registration of the product with the name and style of "T Drop-D Injection" bearing registration No. 077194 with a packing size of 5's x 1ml vide DRAP letter No. F.15-2/2014-Reg-V (M-242) dated 27.05.2014. Team checked the product with the packing size of 5's and found it to be different in respect to design and colour scheme of label and outer packing of complainant's product "Indrop D" though the name was quite resembling.

3. The firm later on, got approval for additional pack of 1'2 x 1ml vide DRAP letter No. F.9-24/2017-DD(P)(Vol-I) dated 03.09.2018. The firm produced first batch of this product in September 2018 which was released by QC on 11.10.2018 and dispatched to distribution. At the time of inspection there was no stock of this product in FG store, management of firm told that the whole batch has been dispatched to distributors. Only 10 packs were kept as retaining samples. These samples were compared with the complainant's product i.e. "indrop D" and found to be very closely in resemblance with respect to name, design and colour scheme of label and outer packing. Therefore, the product was considered to be counterfeit/imitation product under section 3(f) of the Drugs Act, 1976.

4. During inspection, the team also found some quantity of packing material (outer packing/unit carton) of drug under consideration. It was also noted that printed price on label of the drug was higher than the price fixed by Federal Government as per DRAP Letter No. F. 9-24/2017-DD (P) (Vol-I) dated 03.09.2018.Since, manufacturing and sale of counterfeit drugs and manufacturing and sale of drugs at a price over and above the maximum retail price fixed

by Federal Government is prohibited under Schedule II (A)(1) of the DRAP Act, 2012 read with Section 23 (1) of the Drugs Act, 1976 and Schedule II (A)(3) of the DRAP Act, 2012 vide SRO No. 913(I)/2017 dated 06.09.2017, respectively, thus these drugs were seized on form No. 2 (copy attached) as case property (evidence of commission of offence) under Section 18(l)(f) of the Drugs Act, 1976 and Schedule V of the DRAP Act, 2012 as per following detail:

Sr. #	Name of drug/Material	Batch No.	Manufacturer	QTY	Price on pack (Rs)	Approved MRP (Rs)
1.	T Drop-D 1 ml ampoule	TP-001	M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore	10 Packs	110/1ml Ampoule	93/1ml x 1's
2.	Outer pack/unit carton (printed packing material of T Drop-D)	TP-001	M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore	2800 Nos	110/1ml Ampoule	93/1ml x 1's

5. The competent authority (in both the counterfeit and higher price case) was requested to grant permission for safe custody of seized drugs as mentioned above till the decision of the case. It is pertinent to mention here that undersigned received the permission to keep the safe custody of seized goods from the Chairman Drug Pricing Committee with reference to over pricing case, however, no permission is granted from Chairman Registration Board with reference to counterfeit case.

6. The firm was directed to stop manufacturing of above-mentioned drug and to recall all of the distributed stock immediately. The firm was also directed to explain their position that why were they manufacturing and selling these drugs in violation of provisions of the DRAP Act, 2012 and rules framed there under.

7. Reference to above para, undersigned along with Mr. Abdul Rashid Sheikh, FID inspected M/s Trigon Pharmaceuticals on 05.11.2018 to check the status of recall of T Drop- D. The firm informed that they have received 37979 packs of T Drop-D form their distributor. Another quantity of 2600 ampoules of said drug without blistering were also available in the firm (which was told to be in-process ampoules quarantined for blistering). All of this quantity was placed in the recalled area of FG store of firm. Undersigned ordered not to dispose of all this quantity under Section 18 (1) of the Drugs Act, 1976 on Form 1 as per following detail:

Sr. #	*Name of drug/Material*	*Batch No.*	*Manufacturer*	*QTY*	*Price on pack (Rs)*	*Approved MRP (Rs)*
1.	*T Drop-D 1 ml ampoule*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*37979 Packs*	*110/1ml Ampoule*	*93 / 1ml x 1's*
2.	*Naked ampoules of T Drop-D*	*TP-001*	*M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore*	*2600 Nos*		

8. The competent authority (in both the counterfeit and over-pricing case) was requested to grant extension in not to dispose of period, under clause (i) of Section 1 of Schedule V of the DRAP Act, 2012, for three (3) months or till the decision of the case. However, it is pertinent to mention here that undersigned has not received any extension in this regard yet.

9. The firm in response issued a letter to its distributor on 31.10.2018 for recall of product under investigation (Copy enclosed). The firm also submitted a written reply (Copy enclosed) wherein, the firm claimed certain differences in the label and packing of both the drugs and said that they did not have any intention of resemblance with anyone. The firm further submitted that it was their first batch of the product and they will change the packing of their product in future batch. With reference to over-pricing of the product the firm submitted that they have already submitted a price increase request to concerned section of DRAP Islamabad on 23rd July 2018 and in this regard referred the SRO No. 41 (I)/2018.

10. The firm has now submitted the details of further recalled quantity of the product, according to which, 61647 units have been recalled from the market out of 91850 sent to distributor, 2600 unblistered ampoules were placed in the firm and thus a total quantity of 64247 ampoules is now present in the firm."

10. FID-IV vide letter No. F. 3-1/2018-FID (IV)/10809 dated 08-08-2019 provided nature of violation as under;

"4. During inspection, the team also found some quantity of packing material (outer packing/unit carton) of drug under consideration. It was also noted that printed price on label of the drug was higher than the price fixed by Federal Government as per DRAP Letter No. F. 9-24/2017-DD (P) (Vol-I) dated 03.09.2018. Since, manufacturing and sale of counterfeit drugs and manufacturing and sale of drugs at a price over and above the maximum retail price fixed by Federal Government is prohibited under Schedule II (A)(1) of the DRAP Act, 2012 read with Section 23 (1) of the Drugs Act, 1976 and Schedule II (A)(3) of the DRAP Act, 2012 vide SRO No. 913(I)/2017 dated 06.09.2017, respectively, thus these drugs were seized on form No. 2 (copy attached) as case property (evidence of commission of offence) under Section 18(l)(f) of the Drugs Act, 1976 and Schedule V of the DRAP Act, 2012 as per following detail:

Sr.#	Name of drug/Material	Batch No.	Manufacturer	QTY	Price on pack (Rs)	Approved MRP (Rs)
1.	T Drop-D 1 ml ampoule	TP-001	M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore	10 Packs	110/1ml Ampoule	93/1ml x 1's
2.	Outer pack/unit carton (printed packing material of T Drop-D)	TP-001	M/s Trigon Pharmaceuticals (Pvt) Ltd., Lahore	2800 Nos	110/1ml Ampoule	93/1ml x 1's

12. Since, the firm is found involved in manufacturing and sale of counterfeit drug which is prohibited under Schedule II (A) (1) of the DRAP Act, 2012 read with Section 23 (1) of the Drugs Act, 1976 and manufacturing and sale of drugs at a price over and above the maximum retail price fixed by Federal Government which is prohibited under Schedule II (A)(3) of the DRAP Act, 2012 vide SRO No. 913(I)/2017 dated 06.09.2017. Hence the case is submitted for consideration of concerned boards."

11. FID-IV Lahore has further submitted that the mentioned offence is non-cognizable and does not warrant for any further investigation. Furthermore, FID-IV Lahore has requested that the case may please be referred to the concerned boards i.e. DRB for the case of counterfeit drug and DPC for the case of over-pricing. Hence the case is being referred to the Board for the case of counterfeit drug.

Proceeding and Decision of 292nd meeting of Registration Board.

The case was presented before the Registration Board in its 292nd meeting held on 01st – 02nd October, 2019 and the Board after detailed discussion decided as under:

- **To serve the show cause notice and personal hearing to the firm and responsible persons for manufacturing and sale of counterfeit drug(T Drop-D Injection, Registration No. 077194) which is prohibited under Schedule II (A) (1) of the DRAP Act, 2012 read with Section 23 (1) of the Drugs Act, 1976.**
- **Referred the case to Costing & Pricing Division for manufacturing and sale of drugs at a price over and above the maximum retail price fixed by Federal Government which is prohibited under Schedule II (A)(3) of the DRAP Act, 2012 vide SRO No. 913(I)/2017 dated 06.09.2017.**

Case No. 5 Manufacture & Sale of Sub-Standard Raylox (levofloxacin 250mg) Tablets Batch No. A002 By M/S Ray Pharma (Pvt) Ltd. Karachi

The sample of Raylox Tablet Batch No.A002, Reg. No.053306, manufactured by M/S Ray Pharma (Pvt) Ltd Karachi, has been declared as Sub-standard. The sample of sub-standard drug was taken by FID Karachi-II, on 13-05-2016 from manufacturer's premises for test/analysis. The sample was declared substandard by Federal Government Analyst vide his test report No.KQ.168/2016, dated 14th July 2016. On explanation letter issued by the FID, M/S Ray Pharma (Pvt) Ltd Karachi has submitted a reply vide its letter No. Nil, dated Nil, which is self explanatory & has not challenged the test/analysis report of CDL Karachi. The firm submitted that CDL analyst tested their product keeping the parameter of RPM of paddle at 50 whereas USP recommends that product should be tested at 75RPM. The wrong parameter of RPM might lead to poor disintegration of tablet and ultimately the poor solubility and relevant release rate of drug. However they further mentioned that they have taken measures very seriously and assured that there will be no such issue in future and have requested that their product can be sampled at any time.

The results of test/analysis of CDL, Karachi are as under:

Sr. No.	Tests Performed	Results of Test/Analysis
1.	Dissolution test	**Determined:**AllTwelve (12) tablets are below 65% and seven (07) tablets are below 55%. **Limits:** Average of 12 units is equal to or greater than Q (80%) and no unit is less than Q-15% (80-15=65%). **Does not comply with manufacturer's specifications.**

The FID Karachi-II furnished the names of the responsible persons of the firm as under;

M/s Ray Pharma (Pvt) Ltd. Karachi.

i. Mr. Nadeem Ahmed, Director Marketing
ii. Mr. Ekram Uddin, Production Manager
iii. Mrs. Rizwana Waseem Quality Control Manager

As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board.

In response to show cause notice to the firm dated 04th November 2016 the firm vide its reply dated 11th November 2016 stated that they want to avail the opportunity of the personal hearing before the Registration Board.

The accused persons of the firm have also been called for personal hearing.

263rd meeting of Registration Board held on 29-30th November 2016

Proceeding:

The representative of the firm appeared before the board and argued that CDL analyst tested the dissolution of their product at 50rpm whereas according to specifications, the product should be tested at 75rpm.

Decision:

The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to get the product tested from Appellate Laboratory NIH Islamabad as per specifications."

Current Status of the case:

As per decision of 263rd meeting of Registration Board the sample was sent to the Appellate Lab NIH Islamabad for retesting the sample. The Appellate Lab NIH has declared the samples as of substandard quality vide test report No. 01-M/2017 dated 15th March 2017. The result on the basis of which the sample has been declared substandard is as under:-

Dissolution Test:

Determined Amount: 57.56%

Limit: Not less than 80% after 30 minutes

(Does not comply with manufacturers specifications)

Tablet No.	Absorbance of sample	% contents by Formula
1.	0.592	47.44%
2.	0.791	63.38%
3.	0.709	56.81%
4.	0.651	52.16%
5.	0.857	68.66%
6.	0.604	48.39%
Average%= 57.56%		

The firm was issued the show cause notice on 21st April 2017, the firm replied the show cause notice on 28th April 2017 wherein the firm requested to give chance to be heard personally before reaching to any decision, so that they could explain their position in detail. The accused persons have been called for personal hearing.

Proceedings & Decision of 270th Meeting:

Mr. Raees on behalf of Quality Control Manager appeared before the Board and pleaded their case. He explained that they have a compression and hardness issue before but now they have improved their in process checking facility. The area FID has now picked the samples of different batches of the same product and sent to CDL Karachi for testing and they have passed all the quality control tests.

Decision:

"The Board after detailed discussion, deliberation, considering the facts and legal provision decided to suspend the Registration of Raylox (levofloxacin 250mg) Tablets Batch No. A002 By M/S Ray Pharma (Pvt) Ltd. Karachi for six months and to conduct the PSI by following panel:-

a. Additional Director QA&LT, DRAP, Islamabad.
b. Director DTL, Karachi
c. Area FID Karachi.

Proceeding of the 286th Meeting.

FID-V, Karachi forwarded the said PSI report of M/s Pharma (Pvt.) Ltd. Karachi in reference to letter No.F.03-29/2016-QC dated 03rd August, 2018 and the conclusion of the report is reproduced as under:-

> *"In the light of the meeting with staff, documents review including manufacturing, testing and ware house record and finding of the inspection, the firm is found non complying in manufacturing of the said product. However the firm has purchased new dissolution apparatus and replaced the older one. Based on the facts, it is recommended that the suspension time for production of tablets Raylox 250mg may please be extended and the manufacturing in tablet manufacturing section may be suspended till the up gradation and re-inspection by the panel. "*

Evaluation remarks by the Deputy Director QC-II.

> *"As per inspection report by the panel for PSI, record showed that product was tested as per specifications approved by registration Board, however the*

document record/ log sheet and record of relevant raw calculations was found to be unsatisfactory and non traceable. Panel concluded that the firm is not complying in manufacture of said product. So, suspension may be extended till remodeling of section."

Proceeding and Decision of the 286th Meeting of Registration Board.

The case was presented before the Registration Board in its 286th meeting on 16th November, 2018 and the Board after perusing the record/ document of the instant case deliberated the matter in depth and decided as under:

"The registration Board acceded the recommendation of the panel constituted by the Board who conducted the product specific inspection and extended the suspension period till the submission of product development data and re-inspection by the panel."

The above said decision was communicated to M/s Ray Pharma (Pvt.) Ltd., Karachi vide letter No.F.03-86/2018-QC (286-RB) dated 16-01-2019.

In response to the above said letter (No.F.03-86/2018-QC (286-RB) dated 16-01-2019) M/s Ray Pharma (Pvt.) ltd., Karachi vide reference No. nil dated 23-04-2019 provided product development data of Raylox (Levofloxacin 250mg).

The Director QA&LT has constituted the following panel for verification of product development data, re-inspection of the firm and submission of clear and candid report for consideration of the Registration Board.

i. Prof. Ghulam Sarwar.
ii. Area Federal inspector of Drugs, DRAP, Karachi.
iii. Area Assistant Director, I&E, DRAP, Karachi.

The panel was requested vide letter No.F.03-29/2016-QC dated 12-07-2019 to verify the product development data, re-inspect the firm and submit the clear and candid report for consideration of the Registration Board.

The panel inspected the premises on 12-09-2019 and conclusion of the report is reproduced as under:

1) *On the basis of stated facts, people met, the documentation system, the production floor and quality control laboratory, the product development data submitted by the firm is verifiable and authentic.*
2) *The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Raylox 250mg tablets.*

Recommendations:

The panel recommends the restoration of production of Raylox 250mg tablets.

Proceeding and Decision of 292nd meeting of Registration Board.

The case was presented before the Registration Board in its 292nd meeting held on 01st – 02nd October, 2019. The Board considered the panel inspection report and evaluated the development data including stability studies for three months.

Decision of 292nd meeting of Registration Board.

After threadbare discussion Board decided as follows;

- **to resume the production of the product (Raylox 250mg Tablets, Registration No.053306 which was under suspension since the decision of Registration Board in its 286th meeting held on 14 – 16th November, 2018).**
- **The firm shall submit complete 6 months accelerated and real time data of the product.**
- **The firm shall inform respective FID for taking sample from 1st commercial batch.**

B – OLD CASES RELATED TO DRAP OFFICE, QUETTA REFERRED BY HONOURABLE DRUG COURT QUETTA.

It is submitted that the FID,Q@K vide letter vide letter 3-1/2009-FID(Q)K dated 28.01.2019 stated that the Honorable Drug Court, Quetta has passed the orders during proceedings on 3rd December, 2018 in the case titled "Surat Khan Medical Store and others" to provide the list of pending cases of DRAP, Quetta. Moreover, the FID Quetta requested vide letter No.3-1/2019-FID(Q) K dated 05th August 2019 "the old pending cases may kindly be discussed in the Boards concerned on priority basis and necessary decisions may kindly be passed in order to submit the status/copies of decisions in the Honorable Drug Court, Quetta".

As per information provided regarding the cases referred by the Honorable Drug Courts, Quetta and FID, Quetta @ Karachi, as per records shared by DRAP Office Quetta, following are the details of cases. The FID Quetta claimed that the cases were submitted to the Chairman CLB&RB, Government of Pakistan, de-funct Ministry of Health, Islamabad in the said years. As per available record of the section it seems that the referred cases by the FID Quetta were not processed and found pending to date due to reasons not revealed yet.

In light of request of FID Quetta, the agenda of said pending cases have been prepared according to records available in the section and the records shared by DRAP Office Quetta,for the consideration of Board please. The details of the cases are as under:-

Case No.1:- MANUFACTURING AND SALE OF SUBSTANDARD DRUG PARACETAMOL TABLET B.NO.10 – M/S AHSON DRUGS COMPANY, TANDO ADAM.

That Mr. Adnan Faisal Saim, FID Quetta forward the case vide letter No.F.12-32/DCA-QTA/Paracetamol-5096 dated 23rd January 2006. The FID Quetta visited M/s Islama Agencies Yet Road Quetta on 17th August 2005 from where a sample of drug namely Paracetamol Tablet B.No. 10 labeled to be manufactured by M/s Ahson Drug Company; Tando Adam (along with other samples of drugs) was taken from the purpose of test/analysis under section 19(2) of Drug Act 1976

02. The then FID Quetta stated that the sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide office memorandumNo.F.5/DCA-QTA/sample-3394 dated 20th August 2005on Form-4 under section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB and RB Islamabad vide office letter No.F.5/DCA-QTA/Sample-3393 dated 20th August, 2005. A portion as manufacture portion of said drug was also send to M/s Ahson Drug Company Tando Adam vide office letter No.F.5/DCA-QTA/Sample-3398 dated 20th August 2005.

03. As stated by the then FID Quetta that M/s Islamia Agencies yet Road Quetta was asked to provide invoice with warrantee in respect of drug in question vide office letter No.F.5/DCA-QTA/Sample-3443 dated 25th August 2005. M/s Islamia Agencies Yet Road Quetta submitted invoice with warrantee bearing No.564 dated 01.08.2005 of M/s A.S Traders Karachi on in respect of drug in question.M/s A.S Traders Karachi was asked vide office letter No.F.5/DCA-QTA/Sample-3720 dated 22.10.2005 to verify the said invoice with warrantee and provide the further warrantee from they had purchased the referred to drug.

04. As stated and informed by the then FID that the Director CDL Karachi vide his test report no.1953/2005 dated 28th October 2005 declared the sample of Paracetamol Tablet

B.No.10 as substandard copy of test analysis certificate is enclosed as required under section 22(3)(b) of Drug Act 1976.

05. Furthermore, the then FID Quetta informed that a show cause notice was issued to M/s Ahson Drug Company Tando Adam for manufacturing a substandard drug issuing false warranty stocking for sale and selling substandard drug namely paracetamol Tablet B.No.10 and also asked for provision of following documents vide office letter No.F.12-32/DCA-QTA/paracetamol-3849 dated 30.11.2005.

a). Production/analysis and sale record with copies of invoice of paracetamol tablet B.No.10.
b). Copy of Registration certificate of paracetamol Tablets.
c). Recall all the stocks of paracetamol tablet B.No.10 from the market under intimation to this office.
d). Name addresses and attested copies of CNIC of the following personal of the firm
    i. Management Director/Chief Executive/owner/partner
    ii. Director/Directors.
    iii. Plant Manager
    iv. Approved productionIncharge.
    v. Approved QC Incharge
    vi. Warehouse Incharge.

06. That on no response from the firm a reminder vide office letter No.F.12-32/DCA-QTA/Paracetamol-4053 dated 26.12.2005 was also issued but no any response/reply of firm is received as yet

07. That M/s Islamia Agencies Quetta was also asked for provision of stock position of referred to batch of Paracetamol Tablet and ordered not to dispose the stock if any until further orders vide office letter No.12-32/DCA-QTA/Paracetamol-3838 dated 29-11-2005

08. The then FID, Quetta stated that M/s A.S Traders Karachi was informed that the drug in question in declared as substandard and also for provision of invoice with warrantee of whom from they had purchased the drug in question vide office letter No.F.12-32/DCA-QTA/Paracetamol-3873 dated 05.12.2005 as advised previously M/s A.S Traders Karachi verified their invoice with warrantee bearing No.564 dated 01.08.2005 issued to M/s islamia Agencies Quetta for drug in question vide their letter No. Nil dated Nil received in the office on 14.01.2006 M/s A.S Traders Karachi was again directed to provide the further invoice with warrantee in respect of drug in question vide this office letter No.12-32/DCA-QTA/paracetamol-5011 dated 14.01.2006 but no reply is received as yet

09. That keeping in view the details investigation it is proposed by the then FID, Quetta that a panel (in which the FID Quetta also nominated as member) may kindly be constituted for detail inspection for checking the production test/analysis and sale record of firm it is not responded despite of several reminders of this office.

10. That keeping in view the above the then FID, Quetta stated that it seems that the firm M/s Ahson Drug Company Tando Adam has violated the sections 23(1)(a)(v), 23(1)(x),23(2)(b), 23(2)(c),27(2)(b), 27(3) and 27(4) of the Drugs Act 1976 and M/s A.S Traders Karachi violated the section 23(1)(a)(v), 23(1)(a)(x), 23(2)(c), 23(1)(f), 23(1)(i), 27(2)(b),27(3) & 27(4) of Drug Act 1976.

11. The then FID Quetta submitted the case for placement before CLB & RB for its consideration and permission of prosecution against the firm M/s Ahson Drugs Company Tando Adam & M/s A.S Traders Karachi for above mentioned violations of the Drug Act 1976.

12. As per information obtained from the company file available in Division of Drugs Licensing following are the responsible persons for manufacturing of Paracetamol Tablet B.NO.10, Manufacturing date 02/05:

i. Production Incharge –Tanveer Ahmed
ii. Quality Control Manager – Anwar Ali Bukhari
iii. Partners:
   a) Abdul Razzaq
   b) Abdul Hameed
   c) Abdul Wahab
   d) Abdul Saleem

13. Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board.The Board after detailed deliberation decided**to issue the show cause noticefor violating the sections 23(1)(a)(v), 23(1)(x),23(2)(b), 23(2)(c),27(2)(b), 27(3) and 27(4) of the Drugs Act 1976, against the following responsible person(s) of firm (M/s Ahson Drugs Company Tando Adam):**

1. M/s Ahson Drugs Company Tando Adam through its CEO/MD
2. Partners/Directors of M/s Ahson Drugs Company Tando Adam:
   a) Abdul Razzaq
   b) Abdul Hameed
   c) Abdul Wahab
   d) Abdul Saleem
3. Tanveer Ahmed – Production Incharge – M/s Ahson Drugs Company Tando Adam
4. Anwar Ali Bukhari –Quality Control Manager –M/s Ahson Drugs Company Tando Adam

"AND"

5. M. Anwar S/o Muhammad Akbar – Warrantor & Proprietor – M/s A.S. Traders Whole Sale Chemists & Order Suppliers, Shop # 9, Ground Floor, Commerce Centre, Hasrat Mohani Road, Karachi for violating the section 23(1)(a)(v), 23(1)(a)(x), 23(2)(c), 23(1)(f), 23(1)(i), 27(2)(b),27(3) & 27(4) of Drug Act 1976.

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:
   i. Prosecution in the Court of competent jurisdiction.
   ii. Cancellation/suspension of registration.
   iii. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

14. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

> *"That Federal Inspector of Drugs, Quetta during inspection of Islamia Agencies, Yet Road, Quetta on dated 20.08.2005 took the samples of the Drug detailed below under Section 18 of the Drug Act, 1976:-*
>
> ***Name of Product:*** *Paracetamol Tablet 500MG*
> ***Batch No.*** *10*
> ***Manufacturing Date:*** *02-2005*
> ***Expiry Date:*** *02-2008*

Manufacturer: *M/s Ahson Drug Company, Tando Adam.*

2. The Federal Government Analyst, vide test/analysis report No.1953/2005 dated 28th October, 2005 had declared the sample as of "Sub-standard" quality.

3. Whereas the-then FID, stated that the firm ***M/s Ahson Drug Company, Tando Adam has violated the sections 23(1)(a)(v), 23(1)(x), 23(2)(b), 23(2)(c), 27(2)(b), 27(3) and 27(4) of the Drugs Act 1976 and M/s A.S Traders Karachi violated the section 23(1)(a)(v), 23(1)(a)(x), 23(2)(c), 23(1)(f), 23(1)(i), 27(2)(b),27(3) & 27(4) of Drug Act 1976.***

4. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided to issue the show cause notice for violations of the Drugs Act 1976 as referred in para 03 above.

5. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. Prosecution in the Court of competent jurisdiction.
ii. Cancellation/suspension of registration.
iii. Any other action the Board may deem fit under the law.

6. The Registration Board further directed you to appear in person before the Board in its 292nd Meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record."

Proceeding and Decision of 292nd meeting of Registration Board.

15. That M/s Ahson Drug Company submitted their reply to the above said show cause notice vide reference No. ADC-H-79/19 dated 26-09-19 wherein they have stated that show cause/personal hearing notice has been served upon them on 23-09-2019 and aforementioned case is fixed for 01-10-2019 before Registration Board in Islamabad at 2:00PM.They further added that the counsel of the petitioner namely Rana Maqsood Afzal Khan Advocate Supreme Court of Pakistan have to appear before supreme court of Pakistan at Lahore Registry on 01-10-19 and would be unable to appear in the said case before the Honorable Board. They further prayed that the said case may kindly be adjourned to any other convenient date.

Decision of 292nd meeting of Registration Board.

The Board after considering the request of accused (M/s Ahson Drug Company, Tando Adam), decided to grant last opportunity of personal hearing to the accused persons on their request before the Registration Board in its upcoming meeting with direction that no further adjournments will be granted.

Case No. 2: MANUFACTURING AND SALE OF ADULTERATED DRUG 0.5% METRIDA INFUSION B.NO.21086

That the then FID, Quetta forwarded the case vide letter No.12-44/DCA-QTA/Metrida-5224 dated 07th February 2006. The FID Quetta visited the premises of M/s Zafa Pharmaceuticals Laboratories Pvt Ltd Hub on 06th September 2005 from where a sample of drug namely 0.5% metrida Infusion b.No.21086 labeled to be manufactured by M/s Zafa Pharmaceutical Lab Pvt Ltd Hub (along with other sample of drugs) was taken from the purpose of test/analysis under section 19(2) of Drugs Act 1976 on Form-3

02. That the then FID Quetta informed that the sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide office letter No.F/5/DCA-QTA sample-3485 dated 09.09.2005 on form-4 under section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB & RB Islamabad vide letter No.F.5/DCA-QTA/Sample-3486 dated 09.09.2005

03. That the then FID Quetta also informed the Director CDL Karachi vide his test report No.2062/2005 dated 21.12.2005 declared the sample of 0.5% Metrida infusion b.No.21086 as Adulterated.

04. That the then FID Quetta stated that a show cause notice was issued to M/s Zafa Pharmaceutical Lab Pvt Ltd HUB for manufacturing issuing false warranty stocking for sale and selling Adulterated drug namely 0.5% Metrida Infusion B.No.21086 and also asked for provision of following documents vide office letter No.F.12-44/DCA-QTA/Metrida-5017 dated 14.01.2006

a. Production/analysis and sale record with copies of invoices of 0.5% metrida infusion B.No.21086.
b. Copy of Registration certificate of 0.5% Metrida Infusion.
c. Recall all the stocks of 0.5% Metrida Infusion B.No.21086 from the market under intimation to this office.
d. Names address and attested copies of CNIC of the following personnel of the firm
    i. Managing Director/Chief Executive/Owner Partner
    ii. Director/Directors.
    iii. Plant Manager.
    iv. Approved Production Incharge.
    v. Approved QC Incharge
    vi. Warehouse Incharge.

05. That the then FID Quetta informed that M/s Rehman Corporation Quetta M/s Bilal traders yet Road Quetta and M/s New Mehran Agencies Quetta were asked to provide the stock position along with purchase and sale record of 0.5% Metrida infusion B.No.21086 and stop further sale of referred to batch of 0.5% Metrida Infusion vide office letter No.F.12-44/DCA-QTA/trida-393 dated 14.01.2006 but no response from all of above as received as yet.

06. That the then FID Quetta reported that M/s Zafa Pharmaceutical Laboratories Pvt Ltd HUB submitted their reply without documents/information asked for vide letter No. Nil dated 01.02.2006and challenged the test report and requested for hearing in Board. The firm quoted the European Pharmacopoeia wrongly because the firm wanted to apply appendix XIII A which is for sub visible particle and not for visible particle. The firm has quoted in their reply for the application of an independent analyst for example a hospital quality control pharmacist as a mean parental preparation.

07. That the then FID Quetta reported that according to the interpretation of the FID the application of the above said independent analyst be appointed in house laboratory of the firm before releasing the batch the opinion of the FID is strengthened from book quoted by the firm itself **N. particulate contamination** under point–o it is emphasized that these criteria are not intended for use by a manufacturer would obtain assurance of the quality of his product with respect to visible particulate matter by 100% inspection or by other appropriate means in accordance with good pharmaceutical manufacturing practice GMP furthermore one of the reason of particles in parental is non GMP compliance of the firm which was observed and reported vide office letter No.F-14-7/DCA-QTA/Zafa-2995 dated 07.0.2005. In that letter doubt of reused bottles was indicated this may be one of the reasons of adulterated infusion.

08. That the then FID Quetta reported that keeping in view the above stated facts the firm **M/s Zafa Pharmaceutical Lab Pvt Ltd HUB has violated the sections 23(1)(a)|(v), 23(1)(a)(x), 23(1)(b), 23(1)(c) 23(1)(i), 27(2)(b), 27(3) and 27(4) of Drugs Act 1976.**

09. That the then FID, Quetta keeping in view the large number of misbranded/substandard/adulterated samples of drugs and as proposed previously, that on declaration of samples of drugs of any firm as Misbranded/adulterated or substandard a plenty may kindly be imposed in addition to other legal actions against the that firm as firms are not ready to recalling the batch from the market and earn money from that misbranded/substandard drug.If the firm recalls that drugs, a minor quantity of said batch recovered.By imposing plenty a huge amount will deposit in the government accounts which can be used for some other purposes i.e. research improvement in laboratories etc The amount of plenty can be determined by

"Total packs of batch produced X retail price of pack of drug X4 or 5"

10. That the then FID Quetta submitted the case for placement before CLB &RB for its consideration and **permission for prosecution against M/s Zafa Pharmaceutical Laboratories Pvt Ltd HUB for above mentioned violations of Drug Act 1976.**

11. As per information obtained from the company file available in Division of Drugs Licensing following are the responsible persons for manufacturing of 5% Metrida Infusion Batch No. 21086, Manufacturing date Aug 05:

i. Production Incharge –Jawaid Akhtar (as on DML 2005 to 2010)
ii. Quality Control Manager – Muhammad Ashfaq(as on DML 2005 to 2010)
iii. Directors(as on DML renewal application for year 2010):
   a) Mohammad Amin Khan
   b) Jawad Amin Khan
   c) Zafar Khan
   d) Saba Ahmed

12. Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05thAugust 2019, the case was placed before the Registration Board.The Board after detailed deliberation decided to issue the show cause notice for violating the sections 23(1)(a)(v), 23(1)(x), 23(2)(b), 23(2)(c), 27(2)(b), 27(3) and 27(4) of the Drugs Act 1976 against following responsible person(s) of the firm (M/s Zafa Pharmaceutical Lab Pvt Ltd HUB):
   1. **M/s Zafa Pharmaceutical Lab Pvt Ltd HUB through its CEO/MD**
   2. Directors (as on DML renewal application for year 2010):
      a) Mohammad Amin Khan
      b) Jawad Amin Khan
      c) Zafar Khan
      d) Saba Ahmed
   3. Jawaid Akhtar – Production Incharge (as on DML 2005 to 2010)
   4. Muhammad Ashfaq – Quality Control Manager (as on DML 2005 to 2010)

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:
   i. Prosecution in the Court of competent jurisdiction.
   ii. Cancellation/suspension of registration.
   iii. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

13. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

"That Federal Inspector of Drugs, Quetta during inspection of M/s Zafa Pharmaceuticals Laboratories Pvt Ltd Hub on dated 06.09.2005 took the samples of the Drug detailed below alongwith other samples under Section 18 of the Drug Act, 1976:-

Name of Product:	*0.5% Metrida Infusion*
Batch No.	*21086*
Manufacturing Date:	*Aug-2005*
Expiry Date:	*Aug-2008*
Manufacturer:	*M/s Zafa Pharmaceuticals Laboratories Pvt Ltd Hub.*

2. The Federal Government Analyst, vide test/analysis report No.2062/2005 dated 21st December, 2005 had declared the sample as of "Adulterated" quality.

3. Whereas the-then FID, stated that the firm M/s Zafa Pharmaceuticals Laboratories Pvt Ltd Hub has violated the sections 23(1)(a)(iv), 23(1)(a)(x), 23(1)(b), 23(1)(c), 23(1)(f), 27(2)(b), 27(3) and 27(4) of the Drugs Act 1976.

4. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided to issue the show cause notice for violations of the Drugs Act 1976 as referred in para 03 above.

5. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. Prosecution in the Court of competent jurisdiction.
ii. Cancellation/suspension of registration.
iii. Any other action the Board may deem fit under the law.

6. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record."

Proceeding and Decision of 292nd meeting of Registration Board.

14. Mr. Aquil Ahmad, QA Manager (42101-1826955-3) of M/s Zafa Pharmaceuticals Laboratories Pvt Ltd Hub appeared before the Registration Board to plead the instant case before theRegistration Board in its 292nd meeting held on 01st – 02nd October, 2019.

15. The representative of firm submitted that they have already submitted their reply vide letter No. nil dated 01-02-2006 to the-then FID, Quetta. In the light of that reply he pleaded the case. Copies of aforesaid replies were submitted before the Board. The reply is reproduced as under:

"Reference to our letter No.F.12-44/DCA-QTA/Metrida 5017 dated 14th January, 2006, which was received by us on 30.01.2006 on above subject. We would like to state as under:

- ***Samples was picked from our premises on 6th September, 2005, which was received at Central Drugs Laboratory on 09.09.2005 vide your memorandum 5/DCA-QTA/Sample-3485 dated 09.09.2005. Report is dated 21st December, 2005 i.e. after103 days of the receipt of sample collected. According to the Drugs Act, 1976 section 22(2) the report must be***

forwarded within 60 days unless further extension was sought, which was not taken in this case as we were not informed in this respect.

Hence this report has no legal value as such.

We controvert the test report on. 2065/2005 dated 21st December, 2005 issued by Director / Government Analyst, Central Drugs Laboratories Karachi under Sec. 22(4) of the Drugs Act, 1976 and would like to be heard by QC Board Ministry of Health, Islamabad.

Further to the above, we would like to sate the guarantor's sample which was received at out end is still intact, sealed by you does not show any such thing which is mentioned in the report/ letter and each every bottle was examined before release. Please also refer BP 2005 (Copy enclosed) which is states that "3. The test for visible particles included as is method test of the European Pharmacopoeia. This text describes standardized viewing conditions but sets not criteria of acceptance. Contamination by visible particles is governed instead by the requirement of the Ph Eur general monograph for Parenteral Preparations that injections and intravenous infusions that are solutions are required to be clear and practically free from particles. It is recognized that this latter requirement can give rise to problems of interpretation. These problems could, perhaps, be overcome by providing simple criteria for the test for visible particles suitable for application as a pharmacopoeial check-test, that is, for application"

16. The firm admitted before the Board that as per Pharmacopoeia, the solution of product in question shall be clear without having any visible particle.

17. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

A. Suspension of the registration of 0.5% Metrida I.V. Infusion (Reg. No. 026232) for a period of Six (06) months or till the verification of root cause analysis with CAPA, product development data and satisfactory report by the panel whichever is later.

B. Product Specific Inspection including verification of product development data and confirmation of CAPA by the following panel:

- **i. Dr. Rafiq Alam, Member Registration Board**
- **ii. Area Federal Inspector of Drugs**
- **iii. Assistant Director (I&E), Quetta**

D. In the light of panel inspection report, Registration Board will decide the fate of the product.

E. Fresh Sampling from the premises of firm and one sample each from the market in area jurisdiction of five (05) regional offices of DRAP.

Case No. 3: SALE OF SUBSTANDARD DRUGS WITHOUT HAVING DRUG SALE LICENSE - INJ FARMOX LA BATCH NO.: NO.VV019

That Mr. Syed Abdul Saleem, the then FID Quetta forwarded the case to the Chairman, Central Registration Board, Government of Pakistan, Ministry of Health, Islamabad vide letter No.SAS-94-102/2009-FID (Q)/177 dated 16th February 2010. The FID Quetta stated that during visit the M/s Al-Rehman Veterinary Quarry Road Quetta on 06.10.2009 and sample of drug namely inj. Farmox LA B.No. V019 claimed to be manufactured by M/s Farvet Laboratories Netherlands distributed by M/s Prix Pharmaceutical Lahore was taken along with other samples of drugs for the purpose of test/analysis some other unregistered drug and labels of drugs were also recovered and seized on Form-2.The case regarding said seizure was reported to the office of Chairman CLB Ministry of Health Islamabad vide letter No.F12-1/DCA-QTA/M survey dated 09.10.2009 for further instructions and permission of

safe custody of said seized drugs and subsequent request vide No. 12-1/DCA-QTA/M Survey dated 12.12.2009.

02. The then FID Quetta submitted that the sealed sample of Farmox LA B.No. V019 along with other samples of drugs was sent to the Government Analyst, Central Drug Laboratory, Karachi for the purpose of test analysis vide his office memorandum No. SAS-94-102/2009-FID (Q)-3024 dated 07-10-2009 a portion of the said drugs also sent to the Chairman Central Licensing Board and Registration Board Islamabad vide his office letter No. SAS-94-102/2009-FID(Q)/3025 dated 07-10-2009 and portion of the said drug also sent to said importer vide office letter No. SAS-94-102/2009-FID(Q)-3033 dated 07.10.2009 with advise to provide the copy of registration of Inj Farmox LA but not response is received as yet.

03. The then FID Quetta further informed that the Government Analyst, CDL, Karachi vide his test report bearing No.744/2009 dated 12-12-2009 **declared the sample of injection Batch No.VV019 as Sub-standard.**

04. The FID Quetta submitted that in the light of above test report of Government Analyst CDL Karachi M/s Prix Pharmaceutical Lahore violated the section 23(1)(a)(v), 23(1)(a)(x),23(1)(c) and 27(3) of the Drugs Act 1976. M/s Prix Pharmaceutical Lahore was served with a show cause notice vide letter No.SAS-94-102/2009-FID(Q)/102 dated 23.12.2009 to show the cause and explain its position for importing, stocking for sale and selling Substandard drug namely inj. Farmox LA B.No.V019 and stop further sale of said drug.

05. The then FID, Quetta reported that the firm M/s Prix Pharmaceutica Lahore submitted its reply vide letter No. 1043 dated 23.12.2009 disowning the said sample of drug and stated that said drug was not supplied to M/s Al-Rehman Veterinary Quetta nor said whole seller appointed as its distributor.

06. It is also to mention that M/s Al-Rehman Veterinary Quetta as asked to provide invoice with warrantee vide office letter No.12-1/DCA-QT/M. Survey dated 10.10.2009 and subsequent reminders vide No.F.12/DCA-QTA/M Survey dated 19.11.2009 and 18.12.2009 but no response is received as yet.

07. That the then FID, Quetta also informed that on receipt of letter of M/s Prix Pharmaceutical Lahore dated 23.12.2009 M/s Al-Rehman Veterinary Quetta was served with a show cause notice vide No.SAS-94-102/2009-FID(Q)/149 and submitted to residential addresses of Mr. Muhammad Ejaz Proprietor and Mr. Tahir Ahmed of M/s Al Rehman Veterinary Quetta (as said whole seller windup its business and escaped their selves and at present there is other business is carried out at same premises by other persons)

08. That the then FID, Quetta stated that M/s Prix Pharmaceutical Lahore was again directed to provide required information/documents as asked vide letter dated 23.12.2009 along with import and sale record of said substandard drug vide letter No. SAS-94-102/2009-FID(Q)/164 dated 03.02.2010 for investigation M/s Prix Pharmaceutical Lahore submitted its reply vide letter No. PM1123 dated 10.02.2010 without any information/documents and did not cooperate in investigation of said matter.

09. That the then FID Quetta forwarded the case for placement before the central Registration board for its consideration and permission of prosecution against the following persons for importing/selling substandard drugs in addition to the following offences

i. without Drug Sale License
ii. without invoice warranty

Responsible persons are:

a) Muhammad Ejaz of M/s Al-Rehman Veterinary Quetta

b) Tahir Ahmed of M/s Al-Rehman Veterinary Quetta

iii. Syed Hassan Mehdi, General Manager/Proprietor and Qualified Person of M/s Prix Pharmaceutical Lahore for disobeying the lawful authority of any Inspector under section 27(3) of the Drug Act, 1976 which is punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both.

10. Proceedings and Decision of 291st Meeting of Registration Board:

I. On the request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board.The Board after detailed deliberation decided to issue the show cause notice for importing/selling substandard drugs without Drug Sale License & without invoice warranty against following accused persons:

1. M/s Al-Rehman Veterinary, Quetta through its owner/proprietor

2. Muhammad Ejaz of M/s Al-RehmanVeterinary, Quetta

3. Tahir Ahmed of M/s Al-Rehman Veterinary, Quetta

AND

4. Syed Hassan Mehdi, General Manager/Proprietor and Qualified Person of M/s Prix Pharmaceutical Lahore for disobeying the lawful authority of any Inspector under section 27(3) of the Drug Act, 1976 which is punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both.

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:

a. Prosecution in the Court of competent jurisdiction.
b. Cancellation/suspension of registration.
c. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

11. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

*"That Federal Inspector of Drugs, Quetta during inspection of M/s Al-Rehman Veterinary, Quarry Road Opp. Fiasal Tailor, Quetta on dated 06.10.2009 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976**:-***

Name of Product:	*Farmox LA Injection (For Vet. Use Only)*
Reg. No.:	*018837*
Batch No.	*V019*
Manufacturing Date:	*04-2008*
Expiry Date:	*04-2011*
Manufacturer:	*M/s Farvet Laboratories Netherlands*
Imported By:	*M/s Prix Pharmaceutical, Lahore [26 Abbott Road, Lahore]*

*2. The Federal Government Analyst, vide test/analysis report No.744/2009 dated 12th December, 2009 had declared the sample as of "**Sub-Standard**" quality.*

3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:

> *[…] to issue the show cause notice for importing/selling substandard drugs without Drug Sale License & without invoice warranty against following accused persons:*
>
> 1. *M/s Al-Rehman Veterinary, Quetta through its owner/proprietor*
> 2. *Muhammad Ejaz of M/s Al-Rehman Veterinary, Quetta*
> 3. *Tahir Ahmed of M/s Al-Rehman Veterinary, Quetta*
>
> ***AND***
>
> 4. *Syed Hassan Mehdi, General Manager/Proprietor and Qualified Person of M/s Prix Pharmaceutical Lahore for disobeying the lawful authority of any Inspector under section 27(3) of the Drug Act, 1976 which is punishable with imprisonment for a term which may extend to one year, or with fine which may extend to ten thousand rupees, or with both. […]*

4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

- ***i. Prosecution in the Court of competent jurisdiction.***
- ***ii. Cancellation/suspension of registration.***
- ***iii. Any other action the Board may deem fit under the law.***

5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record."

12. The firm M/s Prix Pharmaceutica, 26-Abbot Road, Lahore-54000 vide letter no. Nil dated 25.09.2019 submitted their reply to Show Cause Notice issued by DRAP vide letter No. F. 03-41/2019-QC(291-DRB) dated 19.09.2019. The contents of reply is reproduced as under:

"*Respected Sir,*

Reference DRAP's show cause notice No.F. 03-41/2019-QC(291-DRB) dated 19.09.2019 on the subject cited above.

Insha Allah, we will appear before the Board to clarify our position our position regarding the show cause notice.

We ensure you that Prix Pharmaceutica is a law abiding firm The management favors abiding by the law (our record with DRAP lawful authority will substantiate that claim). The general manager/qualified person or any other member of the company can not even think of disobeying the lawful authority of the DRAP official.

You are requested to give your kind consideration for the withdrawal of show cause notice issued to our firm i.e. M/s Prix Pharmaceutica and Ex General Manager Mr. Hassan Mehdi.

Favorable action will be highly appreciated.

Thanking you in anticipation

Yours truly

For Prix Pharmaceutica

-sd-
S.Baqar Abbas
Managing Partner"

13. The same reply vide letter No. Nil dated 25.09.2019 was also submitted by the accused Syed Hassan Mehdi as Ex General Manager of M/s Prix Pharmaceutica, Lahore.

Proceedings and Decision of 292nd Meeting of Registration Board held on 01st-02nd October, 2019

14. That Advocate M. Zohaib Shahid Lodhi alongwith Mr. Syed Baqar Abbad Naqvi (CNIC NO. 35201-1556328-7) appeared before the Boardon behalf of accused *Syed Hassan Mehdi, General Manager/Proprietor and Qualified Person of M/s Prix Pharmaceutical Lahore* to plead the instant case.

The pleaders informed the worthy Board that accused *Syed Hassan Mehdi, General Manager/Proprietor and Qualified Person of M/s Prix Pharmaceutical Lahore* (Age 77 years) is Ex-Managing Director of M/s Prix Pharmaceutica and currently hospitalized in CCU of Shalimar Hospital, Lahore, therefore unable to attend the personal hearing. They also submitted a Medical Admission Certificate to the Board issued by Shalimar Hospital, Lahore in favor of Syed Hassan Mehdi.

The Attorney for the accused (*Syed Hassan Mehdi, General Manager/Proprietor and Qualified Person of M/s Prix Pharmaceutical Lahore*) submitted a written statement before the Registration Board.

Decision of 292nd meeting of Registration Board.

15. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

- **A. Cancel the registration of Farmox LA Injectionable Suspension 100ml (For Vet.) (Reg. No. 18837).**
- **B. To serve show cause notice and personal hearing to M/s Al-Rehman Veterinary, Quetta and responsible persons for selling substandard drugs without Drug Sale License & without invoice warranty**

CASE NO. 4:- MANUFACTURE AND SALE OF MISBRANDED AND SUBSTANDARD DRUG BICOLAX TABLET B.NO.4E009

That the then FID Quetta Mr. Syed Abdul Saleem vide letter no.F.12-26/DCA-QTA/1708 dated 08th September, 2008informed that the instant case was sent by the then FID Mr. Adnan Faisal Saim vide his letter No.12-26/DCA-QTA/Bicolax-3752 dated 28thOctober 2005.

02. As per case forwarded by the then FID Quetta Mr. Adnan Faisal Saim that he visited the premises of T.K Traders Dr. Bano Road Quetta on 21st May 2005 from where a sample of drug namely BicolaxB.No.4E009 labeled to be manufactured by M/s Epoch Pharmaceuticals Pvt Ltd Karachi (along with other samples of drugs) was taken from the purpose of test/analysis under section 19(2) of Drugs Act 1976 on Form-3.

03. That the then FID Quetta informed that the sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide his office letter No.F.5/DCA-QTA/Sample-3020 dated 25th May 2005 on form-4 under section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB & RB Islamabad vide his letter No.F.5/DCA-QTA/Sample-3028 dated 25th May,2005. A portion as manufacturer portion of said drug was also send to M/s Epoch Pharmaceutical Pvt Ltd Karachi vide his office letter No.F.5/DCA-QTA/Sample-3022 dated 25th May,2005.

04. That the then FID Quetta informed that M/s T.K traders Quetta was asked to provide invoice with warrantee in respect of drug in question vide office letter No.F.5/DCA-QTA/Sample-3047 dated 28thMay 2005 and on non-responding reminders vide letter No.F.5/DCA-QTA/Sample-3143, 3179, 3297 dated 21.06.2005, 11.07.2005 and 29.07.2005 respectively & show cause notice vide letter No.F.5/DCA-QTA/Sample-3390 & 3427 dated 20.08.2005 & 24.08.2005 respectively.M/s T.K Traders Quetta submitted vide letter No. TK/16-8/05 dated 23.08.2005, copy of theirletter addressed to M/s Epoch Pharmaceutical Pvt Ltd Karachi for provision of invoice for said drug.Thereafter a letter vide No.F.5/DCA-QTA/Sample-3426 dated 24th August 2005 was dispatched to M/s Epoch Pharmaceutical Pvt Ltd Karachi for explanation but firm submitted copy of their invoice with warrantee bearing No.1091 dated 28.03.2005 for said drug vide letter No. Nil dated 30.08.2005. M/s T.K Traders Quetta has also submitted invoice with warrantee bearing No.1091 dated 28.03.2005 of M/s Epoch Pharmaceuticals Pvt Ltd Karachi vide their letter No. T.K/17-08/2005dated 05.08.2005 received on 05th September 2005.So the warrantor portion of said sample of drug was sent to M/s Epoch Pharmaceuticals Pvt Ltd Karachi vide his office letter No.F.5/DCA-QTA/Samples-3518 dated 13th September 2005.

05. That the then FID Quetta also informed that the Director, CDL, Karachi vide his test report no.R.1286/2005 dated 26thAugust 2005 dated 26th August 2005 declared the sample of **Bicolax Tablet Tablet B.No.4E009** as **Misbranded & Substandard.**

06. That the then FID Quetta also reported that a show cause notice was issued to M/s Epoch Pharmaceuticals Pvt Ltd Karachi for manufacturing a substandard drug, issuing false warranty, stocking for sale and selling substandard drug namely Bicolax Tablet B.4E009 and also asked for provision of following documents vide office letter No.F.12-26/DCA-QTA/Bicolax-3530 dated 21st September 2005.

a). Production/analysis and sale record with copies of invoice of paracetamol tablet b.no.10.
b). Copy of Registration certificate of Bicolax Tablets.
c). Recall all the stocks of Bicolax Tablet B.No.4E009 from the market under intimation to this office.
d). Name addresses and attested copies of CNIC of the following personal of the firm
    i. Management Director/Chief Executive/owner/partner
    ii. Director/Directors.
    iii. Plant Manager
    iv. Approved production Incharge.
    v. Approved QC Incharge.
    vi. Warehouse Incharge.

07. That the then FID Quetta also informed that M/s Epoch Pharmaceuticals Pvt Ltd instead of submitting their reply along with information asked for,challenge the test report and requested for test/analysis of said product from NIH Islamabad vide letter No.Nil dated 11th October 2005.

08. That the then FID Quetta also stated that M/s T.K Traders Quetta was asked for provision of stock position of referred batch of Bicolax Tablet and that stop further sale vide office letter No. F.12-26/DCA-QTA/Bicolax-3532 dated 21st September 2005. M.K Traders Quetta submitted Nil report vide letter No. T.K 18-10/05 dated 26.10.2005

09. That keeping in view the detail investigation the then FID Quetta proposed that a panel (in which the FID Quetta also nominated as member) may kindly be constituted for details inspection for checking the production test/analysis and sale record of firm

10. That keeping in view the above stated facts the then FID Quetta also stated that it seems that the firm M/s Epoch Pharmaceuticals has violated the sections 23(1)(a)(iii), 23(1)(v),23(1)(x), 23(2)(b), 23(2)(f) and 27(4) of the Drugs Act 1976 and M/s T.K Traders Quetta violated the section 23(1)(a)(x), 23(1)(i).

11. As per information obtained from the company file available in Division of Drugs Licensing following are the responsible persons for manufacturing of BICOLAX TABLET B.NO.4E009 withmanufacturing date 12/04:

i. Production Incharge – Qamar ul Huda
ii. Quality Control Manager – Mrs Seema Ashaqeen
iii. Managing Director – Salim Ismail Patel

12. Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board. The Board after detailed deliberation decided to issue the show cause notice for violating the sections 23(1)(a)(iii), 23(1)(v), 23(1)(x), 23(2)(b), 23(2)(f) and 27(4) of the Drugs Act 1976 and M/s T.K Traders Quetta violated the section 23(1)(a)(x), 23(1)(i) against following responsible person(s) of the firm i.e. M/s Epoch Pharmaceuticals:
   i. M/s Epoch Pharmaceuticals through it CEO/MD
   ii. Managing Director – Salim Ismail Patel
   iii. Production Incharge – Qamar ul Huda
   iv. Quality Control Manager – Mrs Seema Ashaqeen

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:
   a. Prosecution in the Court of competent jurisdiction.
   b. Cancellation/suspension of registration.
   c. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

13. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

That Federal Inspector of Drugs, Quetta during inspection of M/s T.K Traders, Asad Building, Dr. Bano Raod, Quetta on dated 21.05.2005 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976:-

Name of Product:	*Bicolax Tablet*
Batch No.	*4E009*
Manufacturing Date:	*12-04*
Expiry Date:	*12-07*
Manufacturer:	*M/s Epoch Pharmaceutical, Karachi*

2. The Federal Government Analyst, vide test/analysis report No.1286/2005 dated 26th August, 2005 had declared the sample as of "Misbranded &Sub-Standard" quality (Copy Annexed).

3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:

[…] to issue the show cause notice for violating the sections 23(1)(a)(iii), 23(1)(v), 23(1)(x), 23(2)(b), 23(2)(f) and 27(4) of the Drugs Act 1976 and M/s T.K Traders Quetta violated the section 23(1)(a)(x), 23(1)(i) against following responsible person(s) of the firm i.e. M/s Epoch Pharmaceuticals:

1. *M/s Epoch Pharmaceuticals through it CEO/MD*
2. *Managing Director – Salim Ismail Patel*
3. *Production Incharge – Qamar ul Huda*
4. *Quality Control Manager – Mrs Seema Ashaqeen**. […]***

4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. Prosecution in the Court of competent jurisdiction.
ii. Cancellation/suspension of registration.
iii. Any other action the Board may deem fit under the law.

5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record.

Proceedings and Decision of 292nd Meeting of Registration Board held on 01st-02nd October, 2019.

14. That None appeared on behalf of the accused before the Board (neither in person nor by any attorney/pleader) nor submitted any written reply to the show cause notice till 01st October, 2019.

Decision of 292nd meeting of Registartion Board.

15. The Board decided to grant last opportunity of personal hearing to the accused persons before the Registration Board in its upcoming meeting with direction that no further adjournments will be granted.

CASE NO. 5:- MANUFACTURE AND SALE OF MISBRANDED AND SUBSTANDARD ZOLERIC 20MG CAPSULES B.NO.18 MFG BY M/S GENIX PHARMA PVT LTD KARACHI

That Mr. Usman Hameed the then FID Quetta, forwarded the case vide letter No.12-15/06-DCA-Q(MB&Substandard)-1166 dated 06th April 2007. It was informed by Mr. Usman Hameed, that the then FID Mr. Muhammad Adnan Faisal Saim visited the premises of M/s Muhammadi Traders Natha Singh Street, Quetta on 23-11-2005 and took the sample Zoleric Capsules B.No.18 claimed to be manufactured by M/s Genix Pharma Pvt Ltd Karachi along with other samples of the purpose of test/analysis on prescribed Form-3.

02. That the then FID Quetta informed that sealed sample of above said drug along with other samples of drug was sent to the Government Analyst/Director CDL Karachi vide office memorandum No.F.5/DCA-QTA/Sample-3810 dated 24-11-2005 on form-4 under section 19(3)(i) of Drug Act 1976 and a portion of the said drugs also sent to the Chairman CLB & RB Islamabad vide letter No.F.5/DCA-QTA/Sample-3811 dated 24-11-2005under section 19(3)(ii) of Drug Act 1976.

03. The FID Quetta submitted that the sealed sample as purported to be manufactured M/s Genix Pharma Pvt Ltd Karachi of said drug was also sent vide office letter No. F.5/DCA-QTA/Sample-3696 dated 25-11-2005 under section 19(3)(iv) and warrantor portion of said drug was sent to M/s Genix Pharma Pvt Ltd Karachi vide letter No.F.5/DCA-QTA/Sample-5057 dated 19-01-2006.

04. The Government Analyst CDL, Karachi declared the sample Zoleric Capsules B.No.18 Manufactured by M/s Genix Pharma Pvt Ltd Karachi is Substandard and Misbranded drug vide test report No.R.2649/2005 dated 17-04-2006.

05. The FID Quetta submitted that in the light of above Government Analyst, CDL, Karachi a show cause notice letter No.F.12-150/06-DCA(MB&Substandard)-820 dated 09-09-2006 was accordingly issued to M.s Genix Pharma Pvt Ltd Karachi for explaining the position in the matter of manufacturing and selling of above mentioned Misbranded and substandard drug. The FID Quetta further informed that the response of the above letter was not received in the office So the firm was issued a reminder vide letter No. No.F.12-150/DCA-QTAMB& S.S-1119 dated 09-03-2007. In response of the above letter of the office of FID Quetta reference No.GPPL-QC/024/07 dated 03-04-2007 according to which the firm intends to get the sample retested from Appellate Lab at their own cost. The firm has violated section 23(1)(a)(iii), 23(1)(a)(v), of Drug Act 1976 as per above referred test of Government Analyst CDL Karachi.

11. The firm replied vide their reference letter no. GPPL-QC/025/07 dated 03-04-2007 wherein they submitted the names of owner and technical staff of the firm as follows formanufacturing of Capsule Zoleric 20mg Batch No. 18 mfg date – 12/04:

i. Managing Director – Chaudhary Muhammad Israr Sharif
ii. Manager Quality Control –Zafar Ullah Baig
iii. Manger Production – Munsif Ali Qureshi

12. Proceedings and Decision of 291st Meeting of Registration Board:

On the request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case presented before the Registration Board in its 291st Meeting on 4th September, 2019 and the Board after detailed deliberation decided to issue the show cause notice to the firm (M/s Genix Pharma Pvt. Ltd., Karachi) for violating section 23(1)(a)(iii), 23(1)(a)(v), of Drug Act 1976 and its following responsible persons:

i. Managing Director – Chaudhary Muhammad Israr Sharif
ii. Manager Quality Control – Zafar Ullah Baig

iii. Manger Production – Munsif Ali Qureshi

13. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. 3-41/2019-QC (291-DRB) dated 19.09.2019. The contents of the letter are reproduced as under:

> ***"****That Federal Inspector of Drugs, Quetta during inspection of M/s Muhammadi Traders Natha Singh Street, Quetta on 23-11-2005 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976****:-***
>
> | | |
> |---|---|
> | ***Name of Product:*** | *Zoleric 20mg Capsules* |
> | ***Batch No.*** | *18* |
> | ***Manufacturing Date:*** | *07-05* |
> | ***Expiry Date:*** | *08-07* |
> | ***Manufacturer:*** | *M/s Genix Pharma Pvt Ltd Karachi* |
>
> *2. The Federal Government Analyst, vide test/analysis report No.2649/2005 dated 17th April, 2006 had declared the sample as of "Misbranded &Sub-Standard" quality.*
>
> *3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:*
>
> *[…]* ***to issue the show cause notice to the firm (M/s Genix Pharma Pvt. Ltd., Karachi) for violating section 23(1)(a)(iii), 23(1)(a)(v), of Drug Act 1976 and its following responsible persons****:*
>
> *i. Managing Director –Chaudhary Muhammad Israr Sharif*
> *ii. Manager Quality Control – Zafar Ullah Baig*
> *iii. Manger Production – Munsif Ali Qureshi.* ***[…]***
>
> *4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.*
>
> *i. Prosecution in the Court of competent jurisdiction.*
> *ii. Cancellation/suspension of registration.*
> *iii. Any other action the Board may deem fit under the law.*
>
> *5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record.****"***

Proceeding and Decision of 292nd meeting of Registration Boardheld on 01st –02nd October, 2019.

14. Mr. Maqsood-ur-Rehman, AGM Quality Assurance, Genix Pharma Pvt. Ltd. 44, 45-B, Korangi Creek Road, Karachi appeared before the Registration Board to plead the instant case before the Registration Board. The representative of firm submitted a written reply before the Board. The reply is reproduced as under:

> *"With reference to your letter No.F. 03-41/2019-QC(291-DRB) dated 19.09.2019, received in Genix Pharma on 26.09.2019, wherein, the product Zoleric 20mg Capsule (Esomeprazole), batch No. 018 mfg. date 07-2005 was declared as*

misbranded and substandard vide test analysis report 2649/2005 dated 17.04.2006.

Genix Pharma (Private) Limited was founded with the vision to help and provide top quality and affordable medicine for all those in need. Since inception, Genix has grown from being a relatively humble contender to being one of the fastest growing companies in the Pakistani Pharmaceutical Arena, the company's aim to become the benchmark in the pharmaceutical industry.

Genix Pharma is making an ever increasing contribution to the export of Pakistan by exporting medicines to more than 20 countries including, South Asian, North American, African and Russian Countries. Genix is strongly committed to its responsibility towards community and patients. Genix's products bring a promise of QUALITY, and ensure smooth and flawless operations at its facility with local manufacturing in compliance with global quality standards which are strictly maintained and followed meticulously at every level in the process of manufacturing.

Genix Pharma believes on continual improvement and for that we enhance our cGMP according to National and International Guidelines, our sterile area is developed with high class imported prefabricated sheets, we have developed dedicated and well equipped Quality Control laboratory and Currently (August & September- 2019) our QMS have certified as cGMP compliant by the Ministry of Health Uzbekistan and Azerbaijan and also many more countries.

We would like to inform that FID Quetta send letter for the case mentioned above on 09.09.2006, which was unfortunately not received at Genix Pharma Pvt Ltd., for that FID sent us reminder letter on 09.03.2007, upon receiving that letter Genix Pharma sent reply letter number GPPL/QC/024/07 & GPPL/QC/025/07 dated 03-04-2007 in response of reminder letter. After that we did not receive any letter in the matter subjected above and it seems that our position is clear and case has been closed. Now after 12 years we receive this show cause notice and personal hearing letter.

We request you to kindly consider the above reference. We look forward to the pleasure of hearing from you favorably.

Decision of 292nd meeting of Registration Board.

17. The Board deliberated the matter in depth, considered the facts of the case and perused the available record and decided as under:

- **A. Suspension of the registration of Zoleric Capsules 20mg (Reg. No. 039087) for a period of Six (06) months or till the verification of root cause analysis, CAPA, product development data and satisfactory report by the panel whichever is later.**
- **B. Product Specific Inspection including verification of product development data and confirmation of CAPA by the following panel:**
  - **i. Dr. Rafiq Alam Khan, Member Registration Board**
  - **ii. Area Federal Inspector of Drugs**
  - **iii. Assistant Director (I&E)**
- **C. In the light of panel inspection report, Registration Board will decide the fate of the product.**
- **D. Fresh Sampling from the premises of firm and one sample each from the market in area jurisdiction of five (05) regional offices of DRAP.**

CASE NO. 6:- MANUFACTURE AND SALE OF MISBRAND AND SUBSTANDARD NAMELY FREESIA TABLETS B.NO.F03R2

That Mr. Syed Abdul Saleem the then FID Quetta, forwarded the case vide letter No.5-75/2006.DCA(Q)U-R-1788 dated 15th November, 2008. The then FID informed that he visited the premises of M/s Shan Enterprises Quetta on 21-09-2005 and took samples of drug namely Freesia Tablet B.No.F03R2 labeled to be manufactured by M/s Karachi Chemical Industries, Karachi along with other samples of drug for the purpose of test analysis under the Drug Act 1976.

02. That the then FID Quetta informed that the sealed sample of said drug along with other samples of drugs was sent to the Government Analyst/Director CDL Karachi vide office memorandum No.F/5/DCA-QTA/Sample-3548 dated 23-09-2005 on form-4 and a portion of the said drugs also sent to the Chairman CLB Islamabad vide letter No.F.5/DCA-QTA/Sample-3547 dated 23-09-2005.

03. That the then FID Quetta informed that the Director, CDL, Karachi vide his test report No.2279/05 dated 27-03-2006the sample of Freesia Tablet B.NO.F03R2 labeled to be manufactured by M/s Karachi Chemical Industries Karachi as Misbranded/Substandard.

04. The then FID, Quetta informed that in the light of Government Analyst, CDL, Karachi a show cause notice vide letter No.12-118/2006 DCA (Q)-MB.S.S-177 was accordingly issued to M/s Karachi Chemical Industries Karachi explaining the position in the matter of manufacturing and selling of the above mentioned Misbranded and substandard Drug. In response of the above letter No.F.12-118/2006 DCA Q (MB.SS-177 dated 22-4-2006 the firm submitted reply.

05. The firm have violated section 23(1)(a)(iii)(v) and 34 of the Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi. The then FID, Quetta solicited the approval for prosecution in the Drug Court.

06. As per information obtained from the company file available in Division of Drugs Licensing following are the responsible persons for manufacturing of Freesia Tablet Batch No. F03R2 withmanufacturing date 07/05:

i. Production Incharge – Zafar Khursheed
ii. Quality Control Manager – Muhammad Irshad
iii. Managing Director – Saboor Ahmed

07. Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board.The Board after detailed deliberation decided to issue the show cause notice for violating section 23(1)(a)(iii)(v) and 34 of the Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi against following responsible person(s) of firm (M/s Karachi Chemical Industries Karachi):

i. M/s Karachi Chemical Industries Karachi through its MD
ii. Production Incharge – Zafar Khursheed
iii. Quality Control Manager – Muhammad Irshad
iv. Managing Director – Saboor Ahmed

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:

a. Prosecution in the Court of competent jurisdiction.
b. Cancellation/suspension of registration.
c. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

08. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

That Federal Inspector of Drugs, Quetta during inspection of M/s Shan Enterprises Quetta on 21-09-2005 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976:-

Name of Product:	*Freesia Tablet*
Batch No.	*F03R2*
Manufacturing Date:	*07-05*
Expiry Date:	*01-08*
Manufacturer:	*M/s Karachi Chemical Industries Pvt Ltd., Karachi*

*2. The Federal Government Analyst, vide test/analysis report No.2279/2005 dated 27th March, 2006 had declared the sample as of "**Misbranded &Sub-Standard**" quality **(Copy Annexed)**.*

3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:

> *[…]* ***to issue the show cause notice for violating section 23(1)(a)(iii)(v) and 34 of the Drug Act 1976 as per above referred test report of Government Analyst CDL Karachi against following responsible person(s) of firm (M/s Karachi Chemical Industries Karachi):***

i. M/s Karachi Chemical Industries Karachi through its MD
ii. Production Incharge – Zafar Khursheed
iii. Quality Control Manager – Muhammad Irshad
iv. Managing Director – Saboor Ahmed. ***[…]***

4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. Prosecution in the Court of competent jurisdiction.
ii. Cancellation/suspension of registration.
iii. Any other action the Board may deem fit under the law.

5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record.

Proceedings and Decision of 292nd Meeting of Registration Board held on 01st-02nd October, 2019

09. That None appeared on behalf of the accused before the Board (neither in person nor by any attorney/pleader) nor submitted any written reply to the show cause notice till 01st October, 2019.

10. The Board decided to granted last opportunity of personal hearing to the accused persons before the Registration Board in its upcoming meeting with direction that no further adjournments will be granted.

CASE NO.7. MANUFACTURING AND SALE OF MISBRANDED ZOLTAR 40MG INJECTION B.NO.0908041 M/S SHANGHI NO.1 BIOCHEMCIAL AND PHARMCEUTICAL CO LTD CHINA

That Mr. Sajjad Ahmed Abbasi FID Quetta @ Karachi vide letter No.03-01/2019-FID(Q)K dated 11th June 2019 enclosed copy of case file of Zoltar 40mg Injection for consideration of the Board Concerned.

That the-then FID Quetta Syed Abdul Saleem visited the premises of M/s premier agencies Abdullah Pal Street near shahnawaz autos Jinnah Road Quetta dated 21-07-2010 and taken sample of Zoltar 40mg Injection B.No.0908041 Mfd by M/S Shanghi No.1 Biochemcial and Pharmaceutical Co Ltd China marketed by M/s PharmEvo Pvt Ltd Karachi on prescribed on Form-3 for the purpose of test analysis

That the-then FID Quetta forwarded the sample to the CDL Karachi for test/analysis vide letter No.SAS-80-90/2010-FID (Q)-413 dated 23rd July 2010

That the-then FID Quetta forwarded a Boards portion of sample to the Chairman CL&RB vide letter No.SAS-80-90/2010-FID (Q)-418 dated 26th July 2010

That Premier Agencies Quetta provided Invoice No.5875 dated 17-06-2010 claimed to be issued by Nadeem Rehmat for M/s PharmEvo Pvt Ltd Karachi.

That the-then FID Quetta forwarded a manufacturer/warrantor's portion of sample to vide letter No.SAS-80-90/2010-FID(Q)-423 dated 29th July 2010.

That the CDL Karachi vide test report No.756/2010 dated 30th August 2010 declared Zoltar 40mg Injection B.No.0908041 as **Misbranded** with remarks reproduce as under:-

> "A label of transparent sticker pasted on glass vial is easily removable and do not resist the possibility of tempering. Hence sample is declared Misbranded under the Drugs labeling and packaging rules 1986 of the Drugs Act 1976, unless otherwise justified and authorized."

That the-then FID Quetta vide letter No.SAS-80-90/2010-FID(Q)-451 dated 9th September, 2010 to submit their reply alongwith documentary evidence and explain their position for import, stocking and sale and selling of **Misbranded** drug namely Injection Zoltar 40mg Batch no. 098041.

That the-then FID Quetta forwarded a copy of test report to M/s PharmEvo Pvt Ltd Karachi vide letter No.SAS-80-90/2010-FID(Q)-460 dated 20th September, 2010 in reference to their letter No. QAD 07/16092010 dated 16th September 2010.

That M/s PharmEvo Pvt Ltd Karachi vide letter No. QAD 010/05102010 dated 5th October 2010 submitted their reply wherein they contested the stance taken by CDL, Karachi in declaring the product as "**MISBRANDED**" and requested to withdraw the notice under reply submitted.

As per record shared by Mr. Sajjad Ahmed Abbasi FID Quetta @ Karachi following person is the warrantor of the product "Zoltar 40mg Injection B.No.0908041" as per available invoice No. 5875 dated 17-06-2010 issued to Premier Agencies Quetta by M/s PharmEvo Pvt Ltd Karachi:

i. Nadeem Rehmat for M/s PharmEvo Pvt Ltd Karachi.
ii. M/s Pharmevo, Pvt Ltd Karachi thorugh its owner/proprietor.

That as per record shared, the-then FID, Quetta gave no recommendations regarding said violations. The case is being submitted for consideration of the Board as per available status of the case.

Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board. The Board after detailed deliberation decided **to issue the show cause notice for import, stocking and sale and selling of Misbranded drug namely Injection Zoltar 40mg Batch no. 098041 against following responsible person(s) of the firm (M/s Pharmevo, Pvt. Ltd. Karachi):**

i. M/s Pharmevo, Pvt Ltd Karachi through its owner/proprietor
ii. Nadeem Rehmat for M/s PharmEvo Pvt Ltd Karachi

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:
    a. Prosecution in the Court of competent jurisdiction.
    b. Cancellation/suspension of registration.
    c. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

*That Federal Inspector of Drugs, Quetta during inspection of M/s premier agencies Abdullah Pal Street near shahnawaz autos Jinnah Road Quetta dated 21-07-2010 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976**:-***

Name of Product:	*Zoltar 40mg Injection*
Reg. No.:	*077654*
Batch No.	*0908041*
Manufacturing Date:	*08-2009*
Expiry Date:	*07-2011*
Manufacturer:	*M/s Shanghai No.1 Biochemical and pharmaceutical Co. Ltd. China*
Imported By:	*M/s Pharmevo, Karachi*

*2. The Federal Government Analyst, vide test/analysis report No.756/2010 dated 30th August, 2010 had declared the sample as of "**Misbranded**" quality **(Copy Annexed)**.*

3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:

> *[…]* ***to issue the show cause notice for import, stocking and sale and selling of Misbranded drug namely Injection Zoltar 40mg Batch no. 098041 against following responsible person(s) of the firm (M/s Pharmevo, Pvt. Ltd. Karachi):***
>
> *i. M/s Pharmevo, Pvt Ltd Karachi through its owner/proprietor*
>
> *ii. Nadeem Rehmat for M/s PharmEvo Pvt Ltd Karachi.* ***[…]***

4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. Prosecution in the Court of competent jurisdiction.
ii. Cancellation/suspension of registration.
iii. Any other action the Board may deem fit under the law.

5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record.

14. Mr. Muhammad Imran Panawala, (Director Strategy & planning) & Tahir Aleem, (General Manager Regulatory Affairs) of M/s Pharm Evo (Private) Limited, Karachi appeared before the Registration Board to plead the instant case. The pleader provided copies of replies to the Board which they have already submitted to the-then area FID, Quetta in 2010, wherein they contended the declaration of sample of Zoltar 40mg Injection, Batch No. 0908041 as misbranded by CDL, Karachi on sole ground i.e. the transparent label pasted on glass ampoule is easily removable and do not resist the possibility of tempering. Furthermore, the Board was apprised by pleader that M/s Pharm Evo Karachi has stopped import from China and started manufacturing this product locally in Pakistan and also made improvements in the labeling of product in question. During meeting the pleader presented a sample of Zoltar 40mg Injection having improvements in its labeling before the Board.

Decision of 292nd Meeting of Registration Board.

"That the Board is satisfied with compliance of Drugs (Labelling & Packing) Rules, 1986 done by M/s Pharm Evo Karachi for Zoltar 40mg Injection, but to ascertain the quality aspect of Zoltar 40mg Injection decided to draw samples from the premises of firm and one sample each from the market in area jurisdiction of five (05) regional offices of DRAP".

CASE NO. 8:- **MANUFACTURING AND SALE OF MISBRANDED AND SUBSTANDARD THYORIN TABLET B.NO.TY-05 MFG BY M/S PHARMEDIC LABORATORIES PVT LTD LAHORE.**

That Mr. Usman Hameed, Assistant Drug Controller/FID Quetta forwarded the case vide letter No. 12-240/06-DCA-Q(MB & Substandard)-1142 dated 29th March 2007. The FID Quetta informed that then FID Mr. Muhammad Adnan Faisal Saim visited the premises of M/s Nazir &Sons Dr. Bano Road Quetta on 23-11-2005 and took the sample of Thyorin Tablet B.No.TY-05 claimed to be manufactured by M/s pharmadic Labs Pvt Ltd Lahore along with the other samples for the purpose of test/analysis on prescribed Form-3.

02. The FID Quetta informed that the sealed sample of above drug along with other samples of drug was sent to the Government Analyst/Director, CDL Karachi vide his office memorandum No. F.5/DCA-QTA/sample-3553 dated 24th September 2005 on Form-4 under section 19(3)(i) of Drugs Act 1976 and a portion of the said drugs also sent to the Chairman Central Licensing and Registration board Islamabad vide his letter No.F.5/DCA-QTA/Sample-3552 dated 24-05-2005 under section 19(3)(ii) of Drugs Act 1976. A sealed portion as purported to manufactured M/s Pharmedic Laboratories Pvt Ltd Lahore of said drug w3as also sent vide this office letter No.F.5/DCA-QTA/sample-3596 dated 07-10-2005 under section 19(3)(iv) and warrantor portion of said drug was sent to M/s Pharmedic Laboratories Pvt Ltd Lahore vide letter No.F.5/DCA-QTA/sample-3680 dated 20-10-2005

03. As per information of FID Quetta the Government Analyst Central Drug Laboratory Karachi an show cause letter No.12-240/06-DCA (MB & Substandard)-1088 dated 09-03-2007 was accordingly issued to M/s Pharmedic Laboratories Lahore for explaining the position in the matter of manufacturing and selling of above mentioned Misbranded and substandard drug in response of the above letter of office reference No-PH/LHR/9424 dated 26-03-2007 according to which the firm intends to get the sample retested from Appellate Laboratory at their own cost**.** The copy of reply as received is enclosed herewith for your kind perusal. The firm has violated section 23(1)(a)(iii) & Section 23(1)(a)(v) & Section

23(b) of Drug Act 1976 as per above referred test of Government Analyst Central Drug Laboratory Karachi

04. That as per available file record it was highlighted by the then ADC(QC) That it was observed CDL report was issued in the same month the sample was expiring i.e. 11-2006 moreover the report was issued after more than a year of receipt of the sample by the Laboratory. Apparently the firm has not noticed the above fact while making the request for Appellate Testing. Under the above situation the-then ADC(QC) submitted according to situation that the Appellate Testing cannot be done we may therefore we may call the clarification from CDL for delayed reporting and case be placed in the next meeting of Quality Assurance of Drug for further instruction.

05. Proceedings and Decision of 291st Meeting of Registration Board:

I. The request of FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board.The Board after detailed deliberation decided to issue the show cause notice for violating section 23(1)(a)(iii) & Section 23(1)(a)(v) & Section 23(b) of Drug Act 1976 as per above referred test of Government Analyst Central Drug Laboratory Karachi against following responsible person(s) of the firm i.e. M/s Pharmedic Laboratories Pvt Ltd Lahore

   i. M/s Pharmedic Laboratories Pvt Ltd Lahore through its Chief Executive
   ii. Chief Executive - Iftikhar A. Shaikh

II. That why not the following actions shall be taken against the above mentioned accused persons for the said violations:

   a. Prosecution in the Court of competent jurisdiction.
   b. Cancellation/suspension of registration.
   c. Any other action the Board may deem fit under the law.

III. That all the accused persons may also be given final opportunity of personal hearing either in person or through authorized legal counsel in the forthcoming meeting of Registration Board.

06. In the light of minutes of the meeting Show Cause & Personal Hearing Notice has been issued to the accused persons vide letter no. **03-41/2019-QC (291-DRB)** dated 19.09.2019. The contents of the letter are reproduced as under:

*"That Federal Inspector of Drugs, Quetta during inspection of M/s Nazir &Sons Dr. Bano Road Quetta dated 23-11-2005 and took samples of the Drug detailed below under Section 18 of the Drug Act, 1976**:-***

Name of Product:	*Thyorin Tablets*
Reg. No.:	*025601*
Batch No.	*TY-05*
Manufacturing Date:	*11-2003*
Expiry Date:	*11-2006*
Manufacturer:	*M/s Pharmedic Laboratories Pvt Ltd. Lahore*

*2. The Federal Government Analyst, vide test/analysis report No.756/2010 dated 30th August, 2010 had declared the sample as of "**Sub-Standard & Misbranded**" quality **(Copy Annexed)**.*

3. That in the light of request of the FID, Quetta @ Karachi vide letter No.3-1/2019-FID(Q) K dated 05th August 2019, the case was placed before the Registration Board in its 291st Meeting held on 02-04th September, 2019. Furthermore, the matter

was also referred by the Honorable Drug Court, Quetta. The Board after detailed deliberation decided as under:

> *[…]* ***to issue the show cause notice for violating section 23(1)(a)(iii) & Section 23(1)(a)(v) & Section 23(b) of Drug Act 1976 as per above referred test of Government Analyst Central Drug Laboratory Karachi against following responsible person(s) of the firm i.e. M/s Pharmedic Laboratories Pvt Ltd Lahore***
>
> ***i. M/s Pharmedic Laboratories Pvt Ltd Lahore through its Chief Executive***
>
> ***ii. Chief Executive - Iftikhar A. Shaikh […]***

4. It is therefore you are hereby show caused in writing as to why the following action(s) should not be initiated against you. Your reply should reach within (07) days of receipt of this letter.

i. Prosecution in the Court of competent jurisdiction.
ii. Cancellation/suspension of registration.
iii. Any other action the Board may deem fit under the law.

5. The Registration Board further directed you to appear in person before the Board in its 292nd meeting on 01st October, 2019 at 2:00PM. It is the final opportunity of personal hearing. In case of failure to reply and/or attend personal hearing an ex-parte decision will be taken on the merits of the case as per available record."

Proceeding and Decision of 292nd meeting of Registration Boardheld on 01st – 02nd October, 2019.

07. That Mr. Noman Ahmed, Manager Quality Control, Syed Anees Ur Rehman Kirmani, Manger Regulatory and Shahid Ashfaq Sulehri, Manager Legal, M/s Pharmedic Laboratories, (Pvt.) Ltd 16Km Multan Road, Lahore appeared before the Registration Board to plead the instant case. Pleaders submitted a written statement before the Board, which is reproduced as under:

"The said case was initiated in 2005, and, after DTL report, no correspondence was done with the company as indicated in out letter PH LHR 8423 dated 24.03.2007. In response of the above mentioned letter we received fax copy of FID letter No. F12.240.06.DCA(MB & Sub Standard) dated 09.03.2007. we submit and state as under:

- *That, no distribution rules were followed (manufacturer portion of sample along with letter, not received), which is also indicated in our lter No. PH LHR 9424 dated 26.03.2007.*
- *The sample was picked in 2005 while the FID letter to company was issued in 2007. Which is, time barred and against the prescribed provisions of the law.*
- *After letter of 2007, no further correspondence was made with the company regarding this case and in 2019, this case was reinitiated, which is also time barred and against the drug law.*
- *During this period, management of the company has been changed and new the management has no clue regarding this case.*
- *That after careful study of the show cause notice we come to the following conclusions*
    1. *That our drug has expiry date of 11.2006.*
    2. *That the samples were picked on 23.11.2005, as stated by the FID, Quetta, but the memorandum of sample sent to DTL Karachi bearing date 24.09.2005, while sample receiving date is 10.10.2005. As per report attached with show cause notice. Which is not possible.*

3. *DTL report No.R2320/2005 indicates that the test has been carried out on 30.11.2006, which is again time barred as sample received in October, 2005 and test was conducted on November, 2006.*
4. *That keeping in mind our product expiry date that was 11.2006, so expired medicine had been tested, for which company cannot be made responsible.*

- *The show cause notice also indicates a test analysis report no. 756/2010 of Federal Government Analyst dated 30.08.2010, in which he declared the product misbranded and substandard. Copy annexed, but this copy is not attached with the show and also this rest report have no legal bindings as this report was generated in 2010, after 4 years of the expiry of the medicine, for which company cannot be made responsible.*
- *That the case is of mala file intention as per common understanding because the dates mention in the whole case do not any linkage and compatibility with each other.*
- *No distribution rules were followed in this case as per Drug Act, 1976.*
- *No time limitations for sampling, sample retention, testing and report generation, have been followed as per law.*

In view of above discussion, it is submitted that the authority has not followed any rules and provisions of the law, all the case bears irregularities and irrelevancies. The manufacturer cannot be held for the penalties as mentioned in show cause notice. The general principle of fair and due process was not followed. The product Tablet Thyorin 50mcg was already expired when tested and it had already been deregistered. So, it is humbly requested that the case under discussion should be discarded."

08. The Board deliberated the matter in depth, considered the facts of the case, perused the available record and observed that admittedly the firm has discontinued the production of their registered product since 2005 which is violation of condition of registration.

Decision of 292nd meeting of Registration Board.

Keeping in view the test report, record of the case and violation of condition for registration, the Registration Board decided to cancel the registration of Thyorin Tablets (Reg. No. 025601).

Case No. 09: CASES DECIDED BY BOARD FOR WHICH IMPLEMENTATION PART IS NOT TRACEABLE/PENDING.

Name of drug	Manufact-ured by	Declared by CDL as	Current Status of case	Decision of 291st Meeting of RB held on 02-04th September, 2019	Communication of Decision of 291st RB	Proceeding & Decision of 292nd meeting of RB held on 01-02 Oct, 2019
1. Tabs. Paracetamol **Batch No.** 1595	M/s Pakistan Pharmaceutical and chemical Hyderabad	Substand-ard	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of registration of Paracetamol 500mg Tablet (Reg. No. 004251) for 2 months, • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board. • Sampling of drug after resumption of production. The decision of the Board was communicated vide letter no. 03-33/2009-DDC(QC-I) dated 10th August, 2012 and 29th August, 2012 to the quarter concerned for its implementation.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.
2. AB-Clor **Batch No.** D-173	M/s Alience Pharmaceuticals Peshawar	Sub-Standard and Adulterated	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC	The Board was apprised that the reply from the Federal Inspector of

			registration of AB-Clor 250mg/5ml Suspension till the submission of stability data by the firm, • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman, Registration Board. • Sampling of drug after resumption of production. The decision was communicated vide no.F.3-28/2009-QC-I dated 10th August, 2012 and 29th August, 2012 to the quarter concerned for its implementation.	directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/ enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law	(291-DRB) dated 19-09-2019 for compliance of the decision of Board.	Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.
3. Iso top 20 mg Capsule **Batch No.** 003	M/s Panacea Pharmaceuticals, Islamabad	Substandard	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of registration of Isotop 20mg Capsule (Reg. No. 0054948) for 2 months, • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of chairman,	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP

			Registration Board. • Sampling of drug after resumption of production. The decision was communicated vide **No. F. 3-46/2010-DDC (QC-I)** dated 10th August, 2012 and 29th August, 2012 to the quarter concerned for its implementation**.** That the area FID-II, Islamabad vide letter No. 3-12/2004-FID-I(ISD) dated 29th January, 2013 informed panel inspection has been conducted on 23.01.2013 and forwarded the copy of panel inspection report. The conclusion is as under: "the panel recommended that the firm may be allowed manufacturing of a trial batch with approved source of M/s Taizhou Tlanrui Pharmaceutical, China for conducting the stability studies and submission of the results to the registration Section. Later on the sample could be taken for the testing of the product from the Central Drug Laboratory Karachi. the Resumption of production of ISOPTOP Capsule (Isotretinoin) shall be granted after satisfactory report from the CDL Karachi**"** That the-then ADC(QC) vide letter No. F. 3-	members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		office and place the case in forthcoming meeting of Registration Board.

			46/2010-DDC (QC-I)dated 14th February, 2013 conveyed the approval granted by Chairman, Registration Board for manufacturing of trial batch of ISOTOP Capsule by utilizing approved source of M/s Taizhou Tlanrui Pharmaceutical, China for conducting stability studies and proceeding further as per recommendations of the panel. That FID-II, Islamabad vide letter no. 3-12/2004-FID-I (ISD) dated 12th November, 2013 forwarded report test/analysis report of CDL Karachi wherein the CDL, Karachi declared the trial batch sample taken by FID from firms' premises as **MISBRANDED** for not mentioning the retail price on outer carton as required under law. That the FID-II, Islamabad pertinently mentioned that the tiral batch sent for the purpose of analysis on the direction of Registration Board the firm was not allowed to sell the batch in market.			
4. Narobe Infusion **Batch No.** 104092	M/s. Razee Therapeutis (pvt) Ltd	Substandard	Case decided by Drug Registration Board in its 234th Meeting held on 23.07.2012 and decided as under: • Suspension of registration of	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated	The Board was apprised that the reply from the Federal Inspector of Drugs are

			Narobe Infusion (Metronidazole) (R.No. 046772) for 2 months, • Re-sampling from manufacturer's premises and from market. • Panel inspection of the firm for qualitative investigation of case. • Resumption of production will be after satisfactory inspection report of panel and approval of Chairman, Registration Board. • Sampling of drug after resumption of production. The decision was communicated vide No. F. 3-50/2010-DDC (QC-I) dated 10th August 2012. That the-then DDC(QC) mentioned that the firm forwarded order on order of Islamabad High Court dated 07-08-2012 and 10-08-2012 received on 17-08-2012 wherein the Honorable Court has restrained the respondents from suspending registration of the petitioner i.e. Razee Therapeutics Lahore the copy of the write petition was not 2587/2012 is being obtained from the Court, which will be processed accordingly. That the parawise comments in afore said writ petition was submitted on	communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.	19-09-2019 for compliance of the decision of Board.	still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

			26.09.2012 in the Honorable Islamabad High Court. That in response to U.O. Note No. F.3-50/2012-DDC/QC-I (Pt) dated 06.09.2012 the Law & Justice Division vide No. F.2 (1424)/2012-Sol-III dated 20.09.2012 nominated the DAG in the case.			
5. Nutrival Powder **Batch No.** 05855	M/s Sogeval Labs; France	Misbranded & Spurious	As per available record of 219th Meeting of RB held on 20th August, 2009 wherein the case was presented before the Board and the Board after scrutiny of the record has decided to • Conduct CGMP inspection • Investigate the matter through a panel • To draw the fresh samples. Furthermore, according the available record with Section the CDL test report of the said sample is time barred and received after 392 days.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status along with supporting documents/evidences/ annexures/ inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.
6. Susp. Amocilline DS	M/s CCL Pharmaceutical	Substandard	The case was presented in 214th DRB held on	The Registration Board considered the facts/available record	The decision has been communicated to	The Board was apprised

Batch No. K229	(Pvt) Ltd; Lahore.		29.10.2008 After detailed scrutiny the Board decided to drop the case with directions to the firm to rectify the problem. The same was communicated vide letter No. 03-326/07-QC dated 20.11.2008	of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.	quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.
7. Inj. Tripentazine **Batch no:** JFI-34003	M/s Jfrin Pharmaceuticals Labs, Hub	Substandard & Misbranded	The case was presented in 222nd meeting of Registration Board (RB) and Board decided as under: Suspension of registration for a period of three months and also to take fresh samples from the premises of the firm. The decision was communicated vide letter No. 3-11/2009-DDC (QC-I) dated 20-10-10 to the	The Registration Board considered the facts/ available record of the case and after thorough deliberation decided as under: That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further

			quarter concerned for its implementation.	of following panel members and submit report: The area Additional Director, field office DRAP The area FID The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports within 15 days positively. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law		directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.
8. Caps. Epoclox 500mg **Batch no:** 5A001	M/s Epoch Pharmaceuticals, Karachi	Substandard & Misbranded	As per available record of 219th Meeting of RB held on 20th August, 2009 wherein the case was presented before the Board and the Board after scrutiny of the record has decided to • Conduct CGMP inspection • Investigate the matter through a panel • To draw the fresh samples. The decision vide letter No. F. 03-59/2006-QC dated 30-09-2009 communicated to the-then Deputy Director (QA) for its implementation.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports within 15 days positively. Non-	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

				compliance to the aforesaid directions will lead to disciplinary proceedings as per law.		
9. Inj. Neutim 250mg **Batch No.** 0265P061	M/s Neutro Pharma (Pvt) Ltd; Lahore.	Substandard	As per available record the case was presented in 228th Meeting of RB held on 12 & 13th October, 2010 wherein the Board decided as under: • strict warning to the firm. • Panel GMP inspection • Sampling of the raw material.	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: That area FID be directed to communicate the implementation of aforesaid Board's decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of Board.	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.
10. Polybion Z Capsule **Batch No:** 461	M/s Merck (Pvt) Ltd, Quetta	Substandard	The case was presented in 244th meeting of RB and Board decided as under: i. To suspend the Registration of Polybion Z Capsules (R.No. 039495) of the firm for a period	The Registration Board considered the facts/available record of the case and after thorough deliberation decided as under: • That area FID be directed to communicate the implementation of aforesaid Board's	The decision has been communicated to quarter concerned vide letter 03-41/2019-QC (291-DRB) dated 19-09-2019 for compliance of the decision of	The Board was apprised that the reply from the Federal Inspector of Drugs are still awaited because 15 days period

			of 03 months. ii. The Board constituted a panel comprising of Director QA/LT, Area FID and Director DTL Karachi to inspect the premises for product specific inspection. The decision was communicated to Merck Quetta which is manufacturing the said product in Karachi vide letter 3-26/2012-DDC (QC) dated 22-09-2014 The said PSI was conducted on 22-12-14 by Mrs. Muneeza Khan, Area FID M/s Merck Pvt Ltd., Karachi and recommend to grant resumption of production.	decision of the case. • The Board further directed area FID to comply with/enforce the Board's decision in its letter & spirit and where required conduct the panel inspection comprising of following panel members and submit report: 1. The area Additional Director, field office DRAP 2. The area FID 3. The area Assistant Director (I&E) That the area FID shall submit a complete report including implantation status alongwith supporting documents/evidences/ annexures/inspection reports **within 15 days positively**. Non-compliance to the aforesaid directions will lead to disciplinary proceedings as per law.	Board.	was given to them for the said purpose which has yet not expired. The Board further directed to update Drug Court as per report of respective DRAP office and place the case in forthcoming meeting of Registration Board.

Item No. V Additional Agenda.

A. Biological Division

Online Applications Received through IRIMS.

A: Imported Human Biologicals from Reference Countries

Discussion:

Director Biological Drug Division briefed the Registration Board regarding the first time submission of biological drugs applications by the firms through IRIMS System (Integrated Regulatory Information Management System). In this regard, Biological Drug Division with MIS division initiated the first step towards digitalization with a hope that this system will progress towards robust evaluation and swift disposal of applications.

The Board admired, appreciated and acknowledged the working of MIS & Biological Drug Division. However, the board deliberated that format of application should display concomitance to the format already under practice.

Moreover, the board advised DBE&R to change the format of instant applications as per previous practice.

1.	Name of Importer	M/s OBS Pakistan (Pvt.) Ltd., Plot No. C-14, Manghopir Road, Site Area, Karachi.
	DSL details	License No. 0950 dated 19-04-2019 valid till 26-03-2021
	Name of Manufacturer	Product License Holder & Manufacturer: M/s Merck Sharp & Dohme Corp., 770 Sumneytown Pike, West Point, PA 19486, US. Primary Packaging Site: M/s Merck Sharp & Dohme Corp., 5325 Old Oxford Road, Durham, NC 27712, USA. Secondary Packaging & Batch Release Site: M/s Merck Sharp & Dohme BV, Waarderweg 39, P.O. 581 2031 BN, 2003 PC Haarlem, Netherlands.
	Brand Name +Dosage Form + Strength	Varivax Vaccine
	Composition	After reconstitution, one dose (0.5ml) contains: Varicella virus** Oka/Merck strain (live, attenuated)……..…≥1350PFU*** **Produced in human diploid cells (MRC-5) ***PFU=Plaque-forming units
	Finished product specifications	Ph. Eur. Specifications.
	Pharmacological Group	Human Vaccine
	Shelf life	02 years (2^0C -8^0C)
	International availability	Varivax Vaccine of M/s Merck Sharp & Dohme, Uk
	Products already registered in Pakistan	Varilrix (Reg. No. 028421)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 734 & 5995 Dated 07-01-2019 & 11-02-2019 Rs. 100000/- Dated 07-01-2019
	Demanded Price / Pack size	I's Vial (0.5ml)/ As per SRO.
	General documentation	• Legalized CoPP No. 6Y9D-TU2T WHO dated 07-06-2018 valid till 06-06-2020.

	Remarks of Evaluator	• The firm has provided accelerated stability data of 14 days instead of 06 months. The firm submitted that Merck has carried out accelerated stability studies for Varivax Refrigerated that are useful in supporting the allowed time out of the labeled refrigerated conditions for manufacturing operations to temperature greater than 8'0C. The expiry dating and allowable time out of refrigeration are supported by real time/ real temperature data as well as a loss model calculation which accounts for the accumulated potency over the shelf life of the vaccine. Based upon the stability profile for Varivax Refrigerated, the accelerated 25'0C stability study period of 14 days is considered appropriate and sufficient to support expiry analysis and the time out of refrigeration allowance period. In addition, the duration time of the stability study at the 25'0C storage condition is well beyond the controlled time out of refrigeration at this temperature. Additionally, the WHO guidelines for stability evaluation of vaccines describes that testing at accelerated conditions should be performed to support short time temperature excursions outside of the labeled storage conditions. Therefore, the accelerated stability data submitted in the original marketing application are appropriate to support Varivax drug product manufacturing. Data of a 6 month accelerated stability study is not required. • The aforementioned vaccine is WHO Prequalified: https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0 &ID=313 accessed on 23-09-2019
Decision: Keeping in view the WHO Prequalification, valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
2.	Name of Importer	M/s OBS Pakistan (Pvt.) Ltd., Plot No. C-14, Manghopir Road, Site Area, Karachi.
	DSL details	License No. 0950 dated 19-04-2019 valid till 26-03-2021
	Name of Manufacturer	Product License Holder: M/s Merck Sharp & Dohme Corp., 770 Sumneytown Pike, West Point, PA 19486, US. Manufacturer: M/s Jubilant HollisterStier LLC., 3525 North Regal Street, Spokane, WA 99207, USA Packaging Site: M/s Merck Sharp & Dohme BV, Waarderweg 39, P.O. 581 2031 BN, 2003 PC Haarlem, Netherlands.
	Brand Name +Dosage Form + Strength	Sterile Diluent for Varivax Vaccine
	Composition	Each vial contains: Water for Injection…….approx. 0.875ml.
	Finished product specifications	Ph. Eur. Specifications.
	Pharmacological Group	Solvent
	Shelf life	02 years
	International availability	Sterile diluents for Varivax Vaccine of M/s Merck Sharp & Dohme, Uk
	Products already registered in Pakistan	Sterile Water for injection (Reg. No. 077529)
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 735 Dated 07-01-2019 Rs. 100000/- Dated 07-01-2019
	Demanded Price / Pack size	1's Vial/ As per SRO.

	General documentation	• Legalized CoPP No. 6Y9D-TU2T WHO 07-06-2018 valid till 6-6-2020.
	Remarks of Evaluator	• The firm has not provided the accelerated stability data of the diluent. The firm submitted that Sterile diluent for Live Virus Vaccines does not contain any active ingredients or preservatives. Hence, there are no quantitative attributes to monitor on stability. Therefore, accelerated stability would not produce any product degradation. • The diluent will be used for WHO Prequalified Varivax vaccine.
Decision: Keeping in view the WHO Prequalification, valid legalized CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
3.	Name of Importer	Novo Nordisk Pharma (Private) Limited., 113 Shahra-e-Iran, Clifton, Karachi , Karachi
	DSL details	License No. 0950 dated 19-04-2019 valid till 10-04-2021
	Name of Manufacturer	Product License Holder: M/s Novo Nordisk Pharma AG Thurgauerstrasse 36/38 8050 Zürich, Switzerland. Manufacturer: M/s Novo Nordisk A/S, Novo Alle, 2880 Bagsvaerd, Denmark.
	Brand Name +Dosage Form + Strength	Ozempic® Dual Dose
	Composition	Each ml contains: Semaglutide…….1.34mg
	Finished product specifications	Innovator Specs.
	Pharmacological Group	Glucagon Like Peptide-1 (GLP-1)
	Shelf life	03 years (2^0C -8^0C)
	International availability	*Product is NDA submission. No Me-too product is available in Domestic Market.*
	Products already registered in Pakistan	*Product is itself NDA Submission and as per submitted CoPP product is available in SRA Country i.e Switzerland.*
	Type of Form Dy. No & Date of application, Fee submitted	Form-5A Dy. No. 9881 Dated: 27-06-2019 Rs. 50000/- Dated 18-06-2019
	Demanded Price / Pack size	1 Dual Dose Pen plus 06 NovoFine disposable needles/ As per SRO.
	General documentation	• Legalized CoPP No. 19003864 dated 27-06-2019 issued by Swiss medic.
	Remarks of Evaluator	• The firm has provided Real time stability data of 36 months on 3 pilot scale batches and of 36 months on 3 production scale batches.
Decision: Registration Board deferred the case for submission of clarification by the firm regarding non-availability of product in European Medicine Agency (EMA).		
4.	Name of Importer	Novo Nordisk Pharma (Private) Limited., 113 Shahra-e-Iran, Clifton, Karachi , Karachi
	DSL details	License No. 0950 dated 19-04-2019 valid till 10-04-2021
	Name of Manufacturer	Product License Holder & Manufacturer: M/s Novo Nordisk A/S, Novo Alle, 2880 Bagsvaerd, Denmark.
	Brand Name +Dosage Form + Strength	Ozempic 1mg
	Composition	Each ml contains: Semaglutide…….1.34mg
	Finished product specifications	Innovator Specs.
	Pharmacological Group	Glucagon Like Peptide-1 (GLP-1)

	Shelf life	03 years (2^0C -8^0C)
	International availability	*Product is NDA submission. No Me-too product is available in Domestic Market.*
	Products already registered in Pakistan	*Product is itself NDA Submission and as per submitted CoPP product is available in SRA Country i.e. Denmark.*
	Type of Form Dy. No & Date of application, Fee submitted	Form-5A Dy. No. 9880 Dated: 27-06-2019 Rs. 50000/- Dated 18-06-2019
	Demanded Price / Pack size	1 Prefilled Pen & 4 disposable needles/ As per SRO.
	General documentation	• Legalized CoPP No. 2019061906 dated 17-06-2019 valid till 17-06-2021 issued by Danish Medicines Agency.
	Remarks of Evaluator	• The firm has provided Real time stability data of 30 months on 3 pilot scale batches and of 12 months on 3 production scale batches.
Decision: Keeping in view the valid legalized CoPP indicating product availability in country of origin and approval of Denmark (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		
5.	Name of Importer	M/s Eli Lilly Pakistan (Private) Limited 5-A, 5th Office Floor, Al-Tijarah Centre, 32-1-A,Block 6, PECHS, Main Shahrah-e- Faisal Karachi
	DSL details	License No. 00501valid till 02-01-2020
	Name of Manufacturer	Product License Holder & Manufacturer: M/s Eli Lilly and company, Lilly Corporate Center, Indianapolis, IN 46285, USA
	Brand Name +Dosage Form + Strength	**Emgality™** 120mg/mL solution
	Composition	Each pre-filled pen contains: galcanezumab……120mg/mL
	Finished product specifications	innovator specifications
	Pharmacological Group	Antimigraine
	Shelf life	24 months when stored at 2-8ºC
	International availability	FDA.EMA
	Products already registered in Pakistan	New molecule
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5F Dy. No 1581 Dated 25-03-2019 Rs. 100,000/- Dated 25-02-2019
	Demanded Price / Pack size	As per SRO /1's pre-filled pen
	General documentation	Legalized **CoPP No. 3PS3-5CTA** valid till 8th November 2020 issued by USFDA.
	Remarks of Evaluator	i. The product is innovator and registered in FDA and EMA. ii. Indicated for preventive treatment of migraine in adults.
Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin and approval of FDA (Reference Regulatory Authority); Registration Board approved the product subject to compliance of current Import Policy for finished drugs.		

B. Imported Human Biologicals from Non-Reference countries.

1.	Name of Applicant	M/s Sindh Medical Store, Sector 13B/B-10, Block-6, PECHS, Karachi
	DSL details	DSL No. 00873 dated 07-02-2019 valid till 01-07-2020
	Name of Manufacturer	M/s Yuxi Walvax Biotechnology Co., Ltd., No. 83, South Dongfeng Road, High & New Technology Industries Development Zone, Yuxi City, Yunnan Prov., P.R. China.
	Brand Name +Dosage Form + Strength	23-valent Pneumococcal Polysaccharide Vaccine, Pre-filled syringe
	Composition	Each human dose (0.5ml) contains: Pneumococcal polysaccharide 1…….25µg Pneumococcal polysaccharide 2…….25µg Pneumococcal polysaccharide 3…….25µg Pneumococcal polysaccharide 4…….25µg Pneumococcal polysaccharide 5…….25µg Pneumococcal polysaccharide 6B……..……25µg Pneumococcal polysaccharide 7F……..……25µg Pneumococcal polysaccharide 8…….25µg Pneumococcal polysaccharide 9N……25µg Pneumococcal polysaccharide 9V……..25µg Pneumococcal polysaccharide 10A……25µg Pneumococcal polysaccharide 11A……25µg Pneumococcal polysaccharide 12F……25µg Pneumococcal polysaccharide 14…..……25µg Pneumococcal polysaccharide 15B……25µg Pneumococcal polysaccharide 17F……25µg Pneumococcal polysaccharide 18C……25µg Pneumococcal polysaccharide 19A……25µg Pneumococcal polysaccharide 19F…..……25µg Pneumococcal polysaccharide 20……25µg Pneumococcal polysaccharide 22F……25µg Pneumococcal polysaccharide 23F……25µg Pneumococcal polysaccharide 33F……25µg
	Finished product specifications	In-house Specifications
	Pharmacological Group	Human Pneumococcal Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Pneumococcal Polysaccharide vaccine of M/s Merck Sharp & Dohme, UK
	Alternate Products already registered in Pakistan	Not Available
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No. 8968, 8964 & 17531 Dated: 27-02-2019, 19-06-2019 & 16-09-2019
	Demanded Price / Pack size	1's PFS/ Rs. 2382/-
	General documentation	Valid legalized CoPP No. 2018-039 dated 06-08-2018 valid for 24 months.
	Remarks of Evaluator	The firm submitted that their product has In-house specifications which are stricter than Eur. Pharmacopoeia specifications.
Decision: Registration Board deferred the case for submission of tabulated comparison of In-house and European Pharmacopoeia specifications for the product.		

2.	Name and address of Importer	M/s Hakimsons (Impex) (Private) Ltd., Hakimsons Building, 19 West Wharf Road, Karachi
	Detail of DSL	Copy of DSL No. 0481 valid till 15-09-2019
	Name and address of Manufacturer	Bharat Serums and Vaccines Limited Plot No. K-27, Jambivili Village ,Anand Nagar, Additional Midc, Ambernath (East), Thane Maharashtra State, India
	Brand Name +Dosage Form + Strength	U-Tryp-100.000 I.U Ulinastatin for injection 100,000 I.U (Lyophilized)
	Diary No. Date of R& I & fee	Dy. No. 4137(R&I) Date: 02-02-2018 Dy. No. 28155(R&I) Date: 17-08-2018 Dy. No. 31561(R&I) Date: 19-09-2018 Dy. No. 4137(R&I) Date: 28-02-2019 Dy. No. 9877(R&I) Date: 27-06-2019. Rs. 50,000/- dated 17-10-2018
	Composition	Each vial contains: Ulinastatin JP…….100000IU
	Pharmacological Group	Enzyme Inhibitors
	Type of Form	Form-5A
	Finished Product Specification	Japanese Pharmacopoeia
	Shelf Life	24 Months at 2-8^{0}C
	Document Details	Legalized CoPP No. COPP/CERT/KD/81354/2019/11/26789/138600 valid up to 15-06-2022
	Pack size & Demanded Price	5ml vial/as per SRO
	International Availability	Marclid by PMDA, Japan
	Products already registered in Pakistan	Roan of M/s Allmed approved in 262nd meeting.
	Remarks of the evaluator	The firm has demanded Japanese Pharmacopoeia specifications but in pharmacopoeia monograph of finished product is not available.

Decision: Registration Board deferred the case for submission of Japanese Pharmacopoeia monograph of Ulinastatin Injection and confirmation for importability as per IPO.

3.	Name of Applicant	M/s. AGP Limited B-23-C, S.I.T.E., Karachi
	DSL details	Copy of DSL No. 0427 valid till 21-09-2019
	Name of Manufacturer	Manufacturer & Product License Holder M/s Biocon Limited, Special Economic Zone,Plot No.2, 3, 4 & 5 Phase IV, Bommasandra – Jigani Link Road,Bommasandra Post, Bengaluru – 560 099, India. Applicant for Certificate M/s. Mylan Pharmaceuticals Pvt Ltd., Plot No.1-A/2, MIDC Industrial Estate, Taloja, Panvel, Dist-Raigad, Maharashtra – 410208.
	Brand Name Dosage Form Strength	FULPHILA PFS 6mg/0.6mL
	Composition	Each prefilled syringe contains: Pegfilgrastim……6mg/0.6ml
	Finished product specifications	As per Innovator
	Pharmacological Group	Immunostimulants
	Shelf life	36 Months (2^{o}C to 8^{o}C)
	International availability	Neulasta
	Alternate Products	Peg- Filgen PFS by M/s BF Biosciences

	already registered in Pakistan	
	Type of Form Dy. No.&Date Fee submitted	Form 5-F. Dy.No.35617/(R&I)DRAP dated 26thOct, 2018. 100,000/-
	Demanded Price / Pack size	Rs. 59,668.47/ I's PFS
	General documentation	Legalized CoPP No. DCD/CR- 215/Spl.Cell – 1/2018-19 valid up to 10-01-2020

Biosimilarity data provided by the Firm is with NEULASTA

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison 1. Physicochemical Characterization	**IDENTITY (PEG-GCSF)** Intact Mass Analysis (Determination of Protein Molecular Mass) - MALDI-TOF-MS Reduced SDS-PAGE analysis **PRIMARY STRUCTURAL CHARACTERISTICS (PEG-GCSF)** i. Non-reduced Peptide Mapping - Endoproteinase Glu-C - primary structure identification (amino acid sequence identification) and Disulphide linkage identification - RP-HPLC with UV(@215 nm)-ESI-MS and MSMS detection ii. Non-reduced Peptide Mapping - Trypsin (2nd protease) - primary structure identification - RP-HPLC with UV(@215 nm)-ESI-MS detection iii. N-terminal PEGylation (PEG + Fragment 1) Mass analysis – MALDI-TOF-MS analysis of PEG + Fragment 1 derived after Glu-C and Trypsin digest. iv. Average Molecular Mass and Polydispersity of the PEG moiety **HIGHER ORDER STRUCTURAL CHARACTERISTICS - SECONDARY AND TERTIARY (PEG-GCSF)** a. Secondary structural analysis - Far UV - CD Spectroscopy b. Secondary structural analysis – FT-IR Spectroscopy c. Tertiary folding structural analysis - Intrinsic Fluorescence Assay d. Tertiary folding structural analysis – Extrinsic Fluorescence Assay e. Free cysteine analysis by UV spectroscopy **PRIMARYANDHIGHERORDERSTRUCTURALCHARACTERISTICS – IDENTIFICATION (Intermediate GCSFstage)** a. Intact Mass Analysis (Protein Molecular Mass) – RP-HPLC-ESI-MSdetection b. Non-Reduced Glu-C Peptide Mapping - RP-HPLC-ESI-MS/MSMSdetection - Primary structural (amino acid sequence) identification and **SIZE VARIANTS** a. SE-HPLC – identity, purity and Size variants analysis b. Non-reduced CE-SDS analysis c. SE-HPLC coupled with Static Light Scattering (SLS); SE-HPLCcoupled with Dynamic Light Scattering (DLS) **CHARGE VARIANTS** a. CIEX-HPLC – identity, purity and Charge/PEGylation variants analysis b. Determination of pI by Capillary Iso-Electric Focusing analysis **HYDROPHOBIC VARIANTS**

	a. RP-HPLC – identity, purity and Hydrophobic variants analysis.
2. Biological Activity	Biological activity using M-NFS-60 proliferation assay
3. Immunochemical properties	GCSF-R Binding kinetic assay
Impurities	i. HMWP (PEG-GCSF): aggregates, Dimers of PEG-GCSF, Di-PEG-GCSF ii. LMWP (PEG-GCSF): Des PEG (GCSF), N-terminal truncation (LMWP-1, LMWP-2, LMWP-3) iii. Post translational modification (PEG-GCSF): Methionine oxidationM122, M127, and M138, Q108 deamidation iv. Post translational modification (GCSF): Methionine oxidation, Misfolded or partially reduced GCSF species, Acetylated form,Cysteinylated v. Co-translational modification (GCSF): Formyl-Met-GCSF variant, Norleucine substitution at methionine residue, Sequence variants, MGO adduct, Gluconoylated GCSF
Stability Studies	The firm has submitted the stability study
Non-clinical Comparison i. In-vitro Studies ii. In-vivo Studies a. Biological/ Pharmacodynamic activity b. Non- clinical toxicity as determined in one repeat dose toxicity study	• Comparative 28-day subcutaneous repeat-dose toxicity study in Sprague Dawley rats of MYL-1401H and EU- NEULASTA followed by a 2-week treatment-free recovery period. • Pharmacology Studies a. In vitro GCSF-R binding assay b. In vitro bioactivity assay c. In vivo pharmacodynamic study • Toxicology Studies a. 28 days repeat-dose toxicity study in Rats/Hsd:Sprague Dawley
Clinical Comparison	Phase-I single center, randomized, double-blind, 3-period, 3-treatments, 3-way crossover trial toevaluate the PK, PD, safety and tolerability ofpegfilgrastim from a test product (MYL-1401H) compared toreference products EU- and US-Neulasta®. In 216 individuals. Phase single center, randomized, open-label, parallel trial to compareimmunogenicity, safety, and tolerability of myl-1401h and us-licensedpegfilgrastim (neulasta®) after two subcutaneous (sc) injections at onedose level (6 mg) in healthy subjects. 50 Subjects. Phase III, Multicenter, Double-Blind, Randomized, Comparative Efficacy andSafety Study of MYL-1401Hand European Sourced Neulasta® in Stage II/III Breast Cancer Patients Receiving Neoadjuvant or AdjuvantChemotherapy. 194 patients were randomized and received study treatment; 127 (MYL-1401H) and 67 (EU-Neulasta) **(Above mentioned studies are sponsored by: Mylan GmbH Thurgauerstrasse 408050 Zurich, Switzerland**

Remarks of Evaluator	1. All clinical data and some non-clinical data provided in biosimilarity reveals that it is sponsored by Mylan GmbH Thurgauerstrasse 40 8050 Zurich, Switzerland. The product with a brand name Fulphila is also approved in FDA. However, the product label shows following; **Manufactured by: Mylan GmbH, Turmstrasse 24, 6312 Steinhausen, Switzerland U.S. License No. 2062 Product of India. Code No.: KR/DRUGS/KTK/28D/7/2006 Distributed by: Mylan Institutional LLC, Rockford, IL 61103 U.S.A.** The firm claims that the product registered in FDA is manufactured by Biocon India and there is collaboration between Mylan GmbH & Biocon. 2. The firm has also submitted a copy of CoPP from USFDA which is not legalized and notarized and mentions following; Manufacturer name and address Biocon Limited PlotNo.2-5 Phase IV, Bommasandra – Jigani Link Road, Bengalore, Karnataka – 560099, India. Applicant for Certificate Mylan GmbH, Thurgauerstrasse 40, Zurich, Zurich CH-8050 Switzerland U.S. License No. 2062 3. The manufacturing address Special Economic Zone, Plot No.2, 3, 4 & 5 Phase IV, Bommasandra – Jigani Link Road, Bommasandra Post, Bengaluru –560 099, India, has been exempted for ABEVMY in 290th meeting of Registration Board.
Decision: Registration Board deferred the case for submission of clarification regarding the provision of clinical and non-clinical trials of product manufactured by Mylan GmbH, Turmstrasse 24, 6312 Steinhausen, Switzerland instead of the applied product manufactured by M/s Biocon Limited, India.	

4.	Name of Importer	Genome Pharma House No. 166-A, Seet no. 09, Chalala Scheme III, District Rawalpindi
	DSL details	License No.01-374-0170-035873D valid upto 28thAugust,2020.
	Name of Manufacturer	M Product License Holder: M/s BlauFarmacêutica S.ARodovia.Raposo Tavares, nº2833, km 30,5, Barro Branco – Cotia SP – Brasil Manufacturer: M/s BlauFarmacêutica S.ARodovia.Raposo Tavares, nº2833, km 30,5, Prediêo 200 Barro Branco – Cotia SP – Brasil.
	Brand Name Dosage Form Strength	Eritromax® Lyophilized Powder for Injection 2000 IU
	Composition	Details mentioned by Manufacturer: Each vial contains: Epoetin alfa……2,000IU/mL.
	Finished product specifications	BP
	Pharmacological Group	Antianemic preparation
	Shelf life	24 months (below30ºC)
	International availability	Eprex
	Products already registered in Pakistan	ROPO by M/s Sami Pharmaceutical, Karachi
	Type of Form Dy. No.&Date Fee submitted	Form 5-A dated NIL. Dy.No.43840(R&I) dated 26thDec, 2018 Rs.100,000/- dated26thDec, 2018
	Demanded Price/Pack size	As per SRO/ 12's Vial + 12's Ampoule(water for Injection; 1mL each
	General documentation	Legalized CoPP issued by ANVISA (National Agency of Sanitary Surveillance of Brazil) valid till 10/2029.
	Remarks of Evaluator	1. Under biosimilarity, comparative clinical data with EPREX is not provide.

		2. Clarification is required regarding validity of CoPP as the dry seal of the ANVISA is not present on it.
5.	Name of Importer	Genome Pharma House No. 166-A, Seet no. 09, Chaklala Scheme III, District Rawalpindi
	DSL details	License No.01-374-0170-035873D valid upto 28thAugust,2020.
	Name of Manufacturer	M Product License Holder: M/s BlauFarmacêutica S.ARodovia.Raposo Tavares, nº2833, km 30,5, Barro Branco – Cotia SP – Brasil Manufacturer:M/s BlauFarmacêutica S.ARodovia .Raposo Tavares, nº2833, km 30,5, Prediêo 200 Barro Branco – Cotia SP – Brasil.
	Brand Name Dosage Form Strength	Eritromax® Lyophilized Powder for Injection 4000 IU
	Composition	Details mentioned by Manufacturer: Each vial contains: Epoetin alfa……4,000IU/mL.
	Finished product specifications	BP
	Pharmacological Group	Antianemic preparation
	Shelf life	24 months (below30ºC)
	International availability	Eprex
	Products already registered in Pakistan	ROPO by M/s Sami Pharmaceutical, Karachi
	Type of Form Dy. No.&Date Fee submitted	Form 5-A dated NIL. Dy.No.43840(R&I) dated 26thDec, 2018 Rs.100,000/- dated26thDec, 2018
	Demanded Price / Pack size	As per SRO/ 12's Vial + 12's Ampoule(water for Injection; 1mL each
	General documentation	• Legalized CoPP issued by ANVISA (National Agency of Sanitary Surveillance of Brazil) valid till 10/2029.
	Remarks of Evaluator	Details of biosimilarity is mentioned below

Biosimilarity data provided by the Firm is with EPREX

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison 1. Physicochemical Characterization	**Primary Structure** i. Complete Sequence Verification by LC-ESI-MS and MS/MS ii. N-Terminal Sequence Analysis by LC-ESI-MS and MS/MS iii. C-Terminal Sequence Analysis by LC-ESI-MS and MS/MS iv. Peptide Mapping by LC-ESI-MS and MS/MS **High Order Structure** Secondary Structure by Circular Dichroism (CD) in the Far Ultraviolet (UV) Region i. Tertiary Structure ii. Fluorescence Spectroscopy iii. Differential Scanning Calorimetry (DSC) for Protein Stability due to Correct Folding. iv. Disulfide Linking Analysis by MALDI- and LC-ESI-MS and MS/MS **Molecular Weight and Protein Size** Molecular Mass (Weight) by Mass Spectrometry i. MALDI-MS of Intact Protein ii. SEC-MALLS iii. Analytical Ultracentrifugation (UAC) **Electrophoretic Patterns** Electrophoretic Patterns i. Characterization by Electrophoresis in SDS-PAGE

	ii. Western Blot **Isoform Patterns** Isoform Patterns i. Isoelectric Focusing (IEF) and Capillary Isoelectric Focusing (cIEF) ii. Capillary Zone Electrophoresis (CZE) iii. Ion Exchange Chromatography (IEX) **Liquid Chromatography Patterns** Liquid Chromatography Patterns i. Characterization by Reversed-Phase HPLC ii. Characterization by Size Exclusion Chromatography (SEC) **Glycosylation Analysis** Glycosylation i. Sialic Acid Content (Including Protein Quantification by Amino Acid Analysis (AAA)) ii. Determination of Glycosylation Sites by MALDI and LC-ESI-MS and MS/MS iii. N-Glycosylation Analysis by MALDI- and LC-ESI-MS and MS/MS iv. O-Glycosylation Analysis by Mass-Spectrometry v. Glycan Linkage Analysis by GC-MS vi. Glycan Profiling by HPAEC-PAD and by MALDI-MS (Permethylated Glycans)
2. Biological Activity	Stimulation of Reticulocyte Production in Normozytic Mice after Subcutaneous Dosing (*in-vivo*Assay)
3. Immunochemical properties	Western Blot Technique with Direct Antibodies against Human Epoetin
4. Impurities	Product-related Impurities i. Forced Degradation ii. Natural Degradation iii. Dimers and Related Substances of High-Molecular Weight by SE-HPLC iv. Dimers and Related Substances of High-Molecular Weight by Western Blot Process-derived Impurities i. Absence of Host DNA (CHO cells) ii. Absence of Host Proteins (CHO cells) iii. Content Bacterial Endotoxin
5. Stability Studies	The firm has submitted the stability study. <u>The reference product has a shelf life of 18 Months (2-8^{o}C) while the product under consideration has a shelf life 24 Months (below 30^{o}C)</u>
Non-clinicalComparison i. In-vitro Studies ii. In-vivo Studies a. Biological/ Pharmacodynamic activity b. Non- clinical toxicity as determined in one repeat dose toxicity study	Primary Pharmacodynamics *In-vitro* (Receptor-binding Studies or Cell Proliferating Assays) *In-vivo* (Animal assay, e.g. Polycythemic or Normocythemic Assays) Secondary Pharmacodynamics Pharmacokinetic Studies Toxicology Studies a. Single-Dose Toxicity b. Repeat-Dose Toxicity Biosimilarity as per WHO requirements; <u>Phase-I Immunogenicity in Rats</u> <u>Phase II Bioavailability in Rats</u>
Clinical Comparison	No Phase I, II or III studies have been provided

<u>Remarks of the evaluator:</u>

Following biosimilarity data has been provided;

i. Comparative Quality data (Provided as per above mentioned details)
ii. Comparative Pre-clinical/ Non-clinical (Provided as per above mentioned details)
iii. Comparative clinical data is not provided.

1. Clarification is required regarding validity of CoPP as the dry seal of the ANVISA is not present on it.
2. Registration board decided following guidelines in 278th meeting held on 29-31st January 2017.

Biological Drugs, finished form/ Naked Vials

a) The importer shall provide the complete bio similarity studies including analytical studies (Physicochemical, Biological), animal studies and clinical studies (immunogenicity studies, PK, PD) of the finished product from the exporter.

b) The importer shall provide the guidelines for evaluation of biotherapeutics in the country of export (Non-reference authorities) as evidence that the submitted data is in accordance with the said guidelines.

c) The importer shall provide the lot release certificate of the country of export for the same drug (if applicable).

Decision: Keeping in view the biosimilarity data and CoPPs submitted by the firm indicating products availability in country of origin; Registration Board approved the products subject to compliance of current Import Policy for finished drugs and submission of valid legalized CoPPs.

C: Imported Veterinary Biologicals from Reference countries.

1.	Name of Importer	M/s Vety Care (Pvt.) Ltd. Plot No. 77, Street No.6, I-10/3 Islamabad.
	DSL details	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
	Name of Manufacturer	M/s Intervet Inc. 29160 Intervet Lane, P.O. Box 318, Millsboro, DE 19966-0318, USA
	Brand Name +Dosage Form + Strength	Nobilis MG Inac Mycoplasma Gallisepticum Bactein
	Composition	Each dose (0.5ml) contains: M. Gallisepticum antigen, bacterial concentrate……≥0.23OD
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	36 months (2^0C -8^0C)
	International availability	USA
	Products already registered in Pakistan	GPVAC-MG Bacterin Injection (Reg. No. 084595) of M/s Grand Pharma.
	Type of Form Dy. No & Date of application, Fee submitted	Form-5A Dy. No. 29782, 1611 & 10717 Dated: 05-09-2018, 14-01-2019 & 04-07-2019 Rs. 100000/- dated 05-09-2018
	Demanded Price / Pack size	500ml (1000 doses)/ De-controlled.
	General documentation	Certificate of Licensing and Inspection No. 18-01369 dated 17-4-2018
	Remarks of Evaluator	• Initially the firm submitted the Certificate of Licensing and Inspection (CLI) without legalization, the firm was asked to submit legalized CLI, in response of which the firm only submitted the legalization while no document was annexed to it. The firm further submitted that original legalization is attached and Certificate of

		Licensing and Inspection is already submitted. • In real time stability data, only potency test is performed for 3 batches at following time points: Batch No. Time Points (months) 117-901 0,7.5,47 117-902 0,7.5,28, 47 117-2001 0, 49 The firm submitted that during stability testing we only test on parameters which influence the stability of the product. Therefore, not all the final product tests are performed during a stability study. Hence we cannot provide you with other data as we did. The said statement is issued by M/s Intervet International, B.V., Netherlands while the above product is of M/s Intervet Inc., 29160 Intervet Lane, P.O. Box 318, Millsboro, DE 19966-0318, USA. • The said product with the same name is already registered in name of the firm under registration number 017145 from another manufacturer M/s Intervet, Netherland. • The firm has already been issued two deficiency letters.

Decision: Registration Board deferred the case for submission of following by the firm:

a. Valid legalized Certificate of Licensing and Inspection.

b. Clarification regarding already registered Nobilis MG Inac (Reg. No. 017145) in name of the firm.

D: Miscellaneous/ Deferred Cases

1. Change in manufacturing process and proportion of excipients of already registered Vaxapox vaccine (Reg. No. 074628) applied by M/s Sindh Medical Store, Karachi.

M/s Sindh Medical Store, Karachi applied for the change in manufacturing process and proportion of excipients of already registered Vaxapox vaccine as per following details:

Reg. No.	Name of Product	Current Manufacturing Process	Newly Applied Manufacturing process	Current Proportion of Excipients	Newly Applied Proportion of Excipients
074628	Vaxapox (Live Attenuated Varicella Vaccine, Lyophilized	Rolling Bottle Process	Cell Factory Process	Sucrose…5% Dextran….2.5% Trehalose….2% Sodium Glutamate..…0.8% Urea……..0.4% Arginine……0.18% Glucose……0.1% Mannitol…..1% Human Albumin…1%	Sucrose…0.76% Trehalose….4.5% Sodium Glutamate..…0.9% Urea……..0.18% Arginine…..0.18% Glucose……0.37% Human Albumin…..1%

The firm has submitted the following documents:

a. Application with Fee Challan of Rs. 5000/-
b. Copy of initial registration letter dated 02-01-2013
c. Copy of last renewal submission dated 29-01-2017
d. Legalized approval of said variations dated 20-03-2018 issued by China Food and Drug Administration.
e. Justification for said variation.
f. Real Time Stability data of 03 batches manufactured by Cell Factory Process for 42 months.

The original last renewal submission is available in this division.

Decision: Keeping in view the stability study data and approval of country of origin; Registration Board approved the above changes in Vaxapox Vaccine (Reg. No. 074628).

2. Imported veterinary biological applied by M/s Vet Line International, Lahore deferred in 291st meeting of Registration Board.

Following product of M/s Vet Line International, Lahore was deferred in 284th meeting of Registration Board as per following details:

Name and address of Importer	M/s Vet Line International, 55/S, 1st Floor Main Shadman Market, Lahore
Detail of DSL	No. 60-A/DGBT/11/2015 dated 12-02-2015 renewed upto 11-02-2019
Name and address of Manufacturer	Product License Holder: M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arche d'Oe 2,37390, Notre Dame D' Oe, France. Contract Manufacturer: M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
Brand Name +Dosage Form + Strength	Avi IB Var Lyophilisate for suspension for domestic fowl
Diary No. Date of R& I & fee	Dy. No. 15682 Dated 26-04-2018 Rs. 100000/- Dated 24-04-2018
Composition	Each dose contains: Live, attenuated infectious bronchitis (IB) virus, strain 1/96……. Maximum $4.3\log^{10}$ EID_{50}/dose
Pharmacological Group	Veterinary Vaccine
Type of Form	Form-5A
Finished Product Specification	Ph. Eur. Specs
Shelf Life	18 months (2^0C-8^0C)
Document Details	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/2397-3/2018 dated 20-04-2018 issued by Directorate of Veterinary Medicinal Products, Hungary iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
Pack size	20 x 1000 doses vials
International Availability	UEMOA(West African community including 8 countries)
Products already registered in Pakistan	Bioral H120 Neo of M/s Saadat International, Lahore.
Decision of RB in 284th meeting	Registration Board deferred the product for following: *a. Expert Opinion of following experts:* *i. Dr. Qurban Ali, Member Registration Board* *ii. Prof. Masood Rabbani, UVAS Lahore* *iii. Dr. Arshad Javed, NVL Islamabad* b. *Submission of accelerated stability data of 3 batches for six months*

Then two experts Dr. Qurban Ali and Dr. Arshad Javed provided their expert opinion as follows:

Expert opinion of Dr. Qurban Ali:

"Avian infectious bronchitis (IB) is a worldwide chicken disease, caused by avian infectious bronchitis virus (IBV) which infects all commercial poultry lines. Being a single–stranded RNA virus, IBV is highly susceptible to spontaneous mutation and genetic recombination, meaning that a large number of variants are circulating worldwide. IBV is extremely contagious and is easily transmitted by direct and indirect contact, due to its aerogenous spread, its high shedding titres and persistence in the environment.

IBV is the most economically important viral respiratory disease in the poultry industry also because biosecurity alone may not be sufficient for disease control. Therefore, vaccination is widely adopted to increase the protection of chickens against IBV strains, to reduce the damage cause by the pathogen and to decrease the infectious pressure at the epidemiological level.

Worldwide, both live attenuated and inactivated vaccine are in use. Live vaccines and used in young birds to achieve early protection and also for the priming of future layers and breeders, which are boosted by the inactive vaccines. Infectious bronchitis virus is characterized by an extreme degree of variability which deeply affects the first-choice control strategies against the disease. Each country tends to adopt its own protocols and even vaccine producers / distributors / suppliers themselves can also adopt different strategies in attempts to confront local epidemiological concerns.

In Pakistan, poultry is one of the most vibrant sub-sector of livestock yet challenged with the IB losses. The applied IB vaccine of variant strain 1/96 may help the sector in continued suppliers of an important vaccine for all types of poultry birds from Ceva, Hungary a reputable manufacturer of poultry vaccines. The under consideration 1/96 strain based vaccine is already is use and registered in many European countries.

The product is recommended for registration along with the advice of leaf-let in the vaccine pack for necessary specialized precautions for such vaccines.*"*

Expert Opinion of Dr. Arshad Javed:

"Avian infectious bronchitis (IB), a highly contagious viral respiratory infection of chicken, continues to be an economically important disease throughout the world including Pakistan. The infectious bronchitis virus (IBV), causative agent of IB, is associated with mortality in young chicks, marked drop in egg production, lying of soft, misshaped and poor quality eggs for long periods and incomplete recovery to the rate of laying to pre-infection levels. In addition, various IBV types are the cause of poor weight gains and feed conversions in broilers.

Even though the poultry industry extensively vaccinates against IBV, emergence of new serotypes and variant continually occur, making control of the disease difficult. Moreover, there is poor cross protection between different serotypes of IBV. Being an RNA virus, IBV has a huge capacity to change both by mutation and by genetic recombination if they occur in the hyper variable region. More specifically the spike protein gene mainly S1 subunit in this region is the most mutable component due to genetic drifts and recombination events happening in the environment.

Several IBV live and killed vaccines of classical Massachusetts strains especially M-41 and other European variant strains including applied IB vaccine of variant strain 1/96, are used for vaccine manufacturing for poultry industry in Pakistan. In the past few years, multiple IBV vaccination failures have been recorded in Pakistan, indicative of different IBV variants circulating in the country. Though vaccination is required to increase the immunity

of chickens against the circulating IBV strains, however, it has been made difficult to achieve this because of the lack of information regarding the type and number of existing IBV variants in Pakistan.

In a recent study conducted in Pakistan (Saba et al. 2018), showed that local isolate of IBV has close (99.1%) sequence identity with 793 / B. The applied vaccine strain (1/96) belongs to the variant IBV group 793 / B, so have high level of genetic homology with the recently isolated IBV in commercial poultry in Pakistan. In general there is a higher chance of good level of cross-protection between strains with a high level of genetic homology than between strain with a low homology. However, the vaccination-challenge experiments have shown that the relationship is not very strong. Therefore, a cross-immunization study has to be performed to be able to determine the cross-protective immunity of a strain. Moreover, the use of live vaccines carries a risk of residual pathogenicity associated with vaccine back-passage in flocks resulting in new IBV variants. Therefore, necessary specialized precautions for use of such vaccines should be provided to the users.

The product is recommended for registration subject to provision of data of cross-immunization study with local IBV circulating strains.*"*

The case was included in the agenda of 291st meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case and advised DBER to issue a reminder to the 3rd expert Prof. Masood Rabbani, UVAS Lahore."

The opinion of 3rd expert of Dr. Masood Rabbani has been received on 24-09-2019 wherein following has been submitted:

"It is submitted that I have gone through the dossiers of Veterinary Vaccine Avi IB Var Lyophilisate for domestic fowl. Each dose contains: Live attenuated infectious bronchitis (IB) virus, strain 1/96, Minimum 2.8log^{10}EID$_{50}$/dose, Maximum 4.3 log^{10}EID$_{50}$/dose. M/s Ceva-phylaxia Veterinary Biologicals Co. Ltd., 1107, Budapest, Szallass, Hungary submitted by Vet Line International. My comments are as follows:

S.#.	***Name of Manufacturer***	***Name of Drug/ Composition***	***Expert Opinion***
1.	*M/s Ceva-phylaxia Veterinary Biologicals Co. Ltd., 1107, Budapest, Szallass, Hungary*	*Avi IB Var Lyophilisate for suspension for domestic fowl. Each dose contains: Live, attenuated infectious bronchitis (IB) virus, strain 1/96, Minimum 2.8log^{10}EID$_{50}$/dose, Maximum 4.3 log^{10}EID$_{50}$/dose*	*The dossier indicates that the vaccine contains required level of immunogens of Avi IB Var Lyophilisate (IB virus Strain 1/96), it is monovalent freeze dried attenuated live virus variant vaccine. The dossier indicates that the vaccine is effective to control infection caused by variant virus of IB prevailing in Austria, Denmark, France and UK.*

Recommendations:

Taking into consideration the facts provided in the documents, ***it is recommended to register Avi IB Var Lyophilisate (IB Virus Strain 1/96) in Pakistan*** *in the best interest of the poultry sector especiall broiler and broiler breeder populations."*

Now, the firm has also applied for the same product in pack size of 2500 doses as per following details:

1.	Name of Importer	M/s Vet Line International, 939-A, Block-J, Phase-I, LDA, Lahore.
	DSL details	DSL No. 05-352-0066-040712D dated 09-02-2019 valid till 09-02-2021
	Name of Manufacturer	Product License Holder: M/s Laprovet Hungary Veterinary Pharmaceuticals Ltd., 1107 Budapest Horog u. 32-34. Hungary (the wholly owned subsidiary of Laprovet S.A.S. 7 rue du Tertreau, Arched'Oe 2,37390, Notre Dame D' Oe, France. Contract Manufacturer: M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., 1107 Budapest, Szallass u.5. Hungary.
	Brand Name +Dosage Form + Strength	Avi IB VAR
	Composition	Each dose contains: Live, attenuated infectious bronchitis (IB) virus, strain 1/96.....minimum 2.8$\log^{10}$ EID_{50}, maximum 4.3 $\log^{10}EID_{50}$
	Finished product specifications	Ph. Eur. Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	18 months (2^0C-8^0C)
	International availability	Iraq, UEMOA (West African Community)
	Products already registered in Pakistan	Not Available.
	Type of Form Dy. No & Date of application, Fee submitted	Form-5A Dy. No. 8269 Dated:13-06-2019 Rs. 100000/- dated 13-06-2019
	Demanded Price / Pack size	2500 doses/ De-controlled.
	General documentation	i. Legalized GMP certificate of M/s Ceva-Phylaxia Veterinary Biologicals Co. Ltd., Hungary No. 02.2/3807-2/2017 dated 17-08-2017 issued by Directorate of Veterinary Medicinal Products, Hungary ii. Legalized FSC No. 02.2/4870-4/2018 dated 26-09-2018 issued by Directorate of Veterinary Medicinal Products, Hungary. iii. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 issued by Directorate of Veterinary Medicinal Products, Hungary
	Remarks of Evaluator	The same product has already been applied by the firm in pack size of 20 x 1000 doses which was deferred in 291st meeting for expert opinion of 3rd expert which is also received now and the 3rd expert also recommended the product.

Decision: **Keeping in view the recommendations of veterinary experts and valid legalized GMP and Free Sale Certificates indicating availability of both pack sizes in country of origin; Registration Board approved both the pack sizes as per current Import Policy for finished drugs.**

3. Imported veterinary biologicals applied by M/s Vety-Care (Pvt.) Ltd., Islamabad deferred in 288th meeting of Registration Board.

Following products of M/s Vety-Care (Pvt.) Ltd., Islamabad were deferred in 288th meeting of Registration Board as per following details:

1.	**Name of Importer**	M/s Vety Care (Pvt.) Ltd. Plot No. 77, Street No.6, I-10/3 Islamabad.
	DSL details	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
	Name of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands.

	Brand Name +Dosage Form + Strength	Nobivac Tricat Trio Lyophilisate and solvent for suspension for injection
	Composition	<u>After Freeze-drying</u> Each dose contains: Live FCV strain F9……at least 4.6 log_{10} PFU Live FVR strain G2620A……at least 5.2 log_{10} PFU Live FPLV strain MW-1……at least 4.3 log_{10} $TCID_{50}$ <u>Nobivac Solvent:</u> Each ml contains: Disodium phosphate dihydrate.....0.31mg Potassium dihydrogen Phosphate ….0.21mg Water for injections to 999.16 mg
	Finished product specifications	Innovator Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	33 months (2-8^{0}C)
	International availability	Not Provided.
	Products already registered in Pakistan	Not Available as per record.
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 11336(R&I) Dated 28-03-2018 Rs. 100000/- 28-03-2018
	Demanded Price / Pack size	1's Vial Powder 1's Vial Solvent
	General documentation	Valid legalized CoPP No. 249028 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands.
	Remarks of Evaluator	• The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration. • Real time stability data provided is of 0,9,15,21,27,36 months instead of appropriate time intervals and **only titer and residual moisture** is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.

Decision of RB in 288th meeting:

"Registration Board deferred the case for submission of following by the firm:

a. Approval status of above product registration by reference regulatory authorities.

b. Complete stability data indicating all the parameters tested in COA."

The firm has now submitted the following:

a. Copy of modification approval in Nobivac Tricat Trio indicating registration number of said product issued by Ministry of Economic Affairs, Chief Veterinary Officer of The Netherlands, The Hague. However, as per submitted CoPP the product is not registered in country of origin.

b. As per Intervet the stability data already provided as per European Union Guidelines, and is

	being accepted all over the world. **Decision: Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.**	
2.	Name of Importer	M/s Vety Care (Pvt.) Ltd. Plot No. 77, Street No.6, I-10/3 Islamabad.
	DSL details	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
	Name of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands
	Brand Name +Dosage Form + Strength	Innovax ND-IBD
	Composition	Each dose(ml) contains: Live Herpesvirus of turkey strain HPV 360*….at least $10^{3.3}$PFU** * HPV 360 is a HVT-based recombinant encoding the NDV F protein and the IBDV VP2 protein. **Plaque Forming Units
	Finished product specifications	Innovator Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	36 months (Liquid Nitrogen)
	International availability	Not Provided.
	Products already registered in Pakistan	Not Available as per record.
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 11337(R&I) Dated 28-03-2018 Rs. 100000/- 28-03-2018
	Demanded Price / Pack size	1's Vial (2000 doses)
	General documentation	Valid legalized CoPP No. 249030 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands.
	Remarks of evaluator	• The product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration. • Real time stability data provided is of 0, 6, 12, 18, 24, 30, 36, 39 months instead of appropriate time intervals and only **titer** is tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.

Decision of RB in 288th meeting:

"Registration Board deferred the case for submission of following by the firm:

a. Approval status of above product registration by reference regulatory authorities.

b. Complete stability data indicating all the parameters tested in COA."

The firm has now submitted the following:

a. Copy of market authorization approval of product issued by Icelandic Medicine Agency.

b. As per Intervet the stability data already provided as per European Union Guidelines, and is being accepted all over the world.

Decision: Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit legalized evidence of product availability in reference regulatory authorities and European Union Guidelines regarding stability studies.

3.	Name of Importer	M/s Vety Care (Pvt.) Ltd. Plot No. 77, Street No.6, I-10/3 Islamabad.
	DSL details	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
	Name of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands
	Brand Name+ Strength	Nobilis MS Live
	Composition	Before Freeze-drying Each dose(ml) contains: Live attenuated *Mycoplasma synoviae strain* MS1……0.67ml After Freeze-drying Each dose contains: Live attenuated *Mycoplasma synoviae strain* MS1….$\geq 10^{6.5}$ CFU* and $\leq 10^{8.0}$ CFU *Colony Forming Units
	Finished product specifications	Innovator Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	24 months (2^0C-8^0C)
	International availability	Not Provided.
	Products already registered in Pakistan	Not Available as per record.
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 7302(R&I) Dated 26-02-2018 Rs. 100000/- 26-02-2018
	Demanded Price / Pack size	1's Vial (1000 doses)
	General documentation	Valid legalized CoPP No. 245782 dated 09-08-2016 issued by Ministry of Economic Affairs, The Netherlands.
	Remarks of Evaluator	• The firm then submitted another CoPP vide no. 249031 dated 21-03-2018 issued by Ministry of Agriculture Nature and Food, the Netherlands indicating that the product is not registered in country of origin. The firm submitted that some registrations in the Netherlands differ from the standard registration for a product. This does not mean that the product is in principle not registered or marketed in the Netherlands, but only with a deviation to the standard registration. • Real time stability data provided is of 0, 6, 9, 12,15, 21,24, 27 months instead of appropriate time intervals and **only titer and residual humidity** are tested instead of all controls of finished product. The firm submitted that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For

		veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.

Decision of RB in 288th meeting:

"Registration Board deferred the case for submission of following by the firm:

a. Approval status of above product registration by reference regulatory authorities.

b. Complete stability data indicating all the parameters tested in COA."

The firm has now submitted the following:

a. Copy of modification approval in Nobilis MS Live indicating registration number of said product issued by Ministry of Economic Affairs, Chief Veterinary Officer of The Netherlands, The Hague. However, as per submitted CoPP the product is not registered in country of origin.

b. As per Intervet the stability data already provided as per European Union Guidelines, and is being accepted all over the world.

Decision: Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit valid legalized CoPP indicating product availability in country of origin and European Union Guidelines regarding stability studies.

4.	Name of Importer	M/s Vety Care (Pvt.) Ltd. Plot No. 77, Street No.6, I-10/3 Islamabad.
	DSL details	DSL No. DSL-156 ICT/2013 dated 31-12-2014 valid till 30-12-2018. Copy of Renewal receipt dated 26-12-2018
	Name of Manufacturer	M/s Intervet International B.V. Wim de Korverstraat, 5831 AN Boxmeer, The Netherlands
	Brand Name +Dosage Form + Strength	Nobilis IB Primo QX Lyophilisate for suspension for spray
	Composition	Each dose of reconstituted vaccine contains: Live attenuated avian infectious bronchitis virus, strain D388…$10^{4.0}$-$10^{5.5}$ EID_{50}* *50% egg infective dose
	Finished product specifications	Innovator Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	15 months (2^0C-8^0C)
	International availability	Not Provided.
	Products already registered in Pakistan	Not Available as per record.
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 5721(R&I) Dated 16-02-2018 Rs. 100000/- 16-02-2018
	Demanded Price / Pack size	10Cupsx 10000 doses
	General documentation	Valid legalized CoPP No. 01/17/113770 dated 13-10-2017 issued by EMA indicating product availability in exporting region.
	Remarks of Evaluator	• Real time stability data provided is of 0, 6, 11, 18 months instead of appropriate time intervals and only **titer and residual humidity** are tested instead of all controls of finished product. The firm submitted

		that according to Ph. Eur. Monograph 0062, the test should be performed at regular intervals until 3 months beyond the end of shelf life. For veterinary vaccines the intervals at which the vaccines are tested for stability evaluation are not defined within European legislation. The monograph includes following tests in stability studies: Virus titrations, bacterial counts or potency tests carried out at regular intervals until 3 months beyond the end of the shelf life on not fewer than 3 representative consecutive batches of vaccine kept under recommended storage conditions together with results from studies of moisture content (for freeze-dried products), physical tests on the adjuvant, chemical tests on substances such as the adjuvant constituents and preservatives, and pH, as appropriate.
Decision of RB in 288th meeting: **"Registration Board deferred the case for submission of complete stability data indicating all the parameters tested in COA."**		
The firm has now submitted that as per Intervet the stability data already provided as per European Union Guidelines and is being accepted all over the world. **Decision: Registration Board decided to refer the case to expert working group on veterinary drugs regarding the prevalence of strains and advised the firm to submit the European Union Guidelines regarding stability studies.**		

4. Imported Human Biological applied by M/s Lab Diagnostic System Pvt. Ltd., Rawalpindi deferred in 291st meeting of Registration Board.

Following product of M/s Lab Diagnostic System Pvt. Ltd (LDS), Rawalpindi was deferred in 291st meeting of Registration Board as per following details:

Name of Applicant	M/s Lab Diagnostic System Pvt. Ltd (LDS) 111B, Hali Road, Westridge 1, Rawalpindi Cantt., 46000 Pakistan.
DSL details	DSL License No.01-374-0176-0415296D valid upto 07-03-2021.
Name of Manufacturer	Jiangsu Hengrui Medicine Co., Ltd Donglin Road, Port Industry Area, Economic and Technological Development Zone, Lianyungang, P.R. China.
Brand Name +Dosage Form + Strength	Pegaspargase (PEG-L-Asparaginase) Injection 5mL: 3750IU Single Dose Vial
Composition	Each 5mL vial contains Pegaspargase.....3750IU
Finished product specifications	In-house
Pharmacological Group	Anti-Neoplastic
Shelf life	18 Months (Store at 2ºC to 8ºC)
International availability	Oncaspar in US FDA
Alternate Products already registered in Pakistan	No Alternate available
Type of Form Dy. No. Date of Application, Fee submitted	Form-5 F Dy.No.5091(R&I)DRAP dated 03-5-2019 Dy. No.15920 (R&I) DRAP dated 28-08-2019. Fee of 50,000/- dated 3-5-2019.
Demanded Price / Pack size	PKR 250,000/- per each vial of 5mL /Single dose vial
General documentation	i. Copy of Certificate of Pharmaceutical Product (CoPP) No.JS20190296 issued by Jiangsu Food & Drug Administration, China valid upto 31-12-2020. ii. Legalized Authorization letter in the name of M/s LDS
Decision of 291st meeting of RB:	*Registration Board deferred the case for submission of following by the firm:* *a. Valid legalized CoPP issued by regulatory body of country of*

	origin. *b. Characterization of impurities of drug substance.* *Registration Board was apprised that Mr. Azhar Nazeer, Director Operation Shaukat Khanum Hospital, Lahore visited DRAP and held meeting with CEO, Director Biological and PE&R regarding non-availability of essential drugs used in treatment of cancer including Peg-L-asparaginase. He shared that aforementioned product has been imported under provision of special SRO for institutions but free availability is not assured and also resulted in treatment discontinuation invariably. He requested to consider instant registration application on priority.* *Keeping in view aforementioned situation, Registration Board advised DBER to simultaneously process the case for panel constitution for inspection of manufacturer abroad and for Price confirmation/ fixation from Pricing Division. However, the said decision shall not be used as precedent, as it is exclusive for this particular product due to its need and non-availability in Pakistan.*
Now the manufacturer of the substance i.e. Changzhou Qianhong Bio-pharma Co., Ltd China has forwarded DMF through email directly to DRAP which includes the Characterization of impurities of drug substance. The firm has not yet submitted the valid legalized CoPP.	
Decision: Keeping in view the above situation and copy of CoPP indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs. The firm will submit valid legalized CoPP and Chairman Registration Board is authorized for issuance of registration letter.	

5. Request of M/s. Hospital Services & Sales, Karachi for Change in Excipients (in-active ingredients) and Quality Standards for product Mevac-A Vaccine.

M/s. Hospital Services & Sales, Karachi has applied for Change in Excipients (in-active ingredients) and Quality Standards for product Mevac-A Vaccine. The said product has already been transferred to the firm in 258th meeting of Registration Board but during processing of the case the firm has submitted the said request. The details of the product is as under;

Manufacturer	Brand name & Composition	Decision of 258th meeting of Registration Board
M/s. Zhejiang Pukang Biotechnology Co. Ltd., - China	Mevac-A Vaccine (Freeze- dried Live Attenuated Hepatitis A Vaccine) Each 0.5ml dose contains: Live attenuated strain of HAV not less than 6.50 Lg $CCID_{50}$	Registration Board cancelled the Mevac-A Vaccine (072537) registration in name of M/s Hilton Pharma Karachi. The Registration registered the Mevac-A Vaccine (072537) in name of M/s M/s Hospital Services & Sales, Karachi manufactured by M/s. Zhejiang Pukang Biotechnology Co. Ltd.,- China as per valid legalized CoPP and as per import policy. The Registration Board also granted the shelf life extension from18 months to 24 months. Registration will be issued after seeking comments from Cost & Pricing division and verification of storage facility for the vaccines.

The firm has requested the following changes:

In-active ingredients FROM	In-active ingredients TO
The Previous Lactose, Gelatin, Amino Acid Equilibrium Solution, Magnesium Chloride, Magnesium Sulfate, Diluted Hydrochloric Acid and Trihydroxy Methyl Aminomethane Was Being Used	The New In-Active Ingredients are Trehalose, Dextran, Mannitol and Sorbitol

Change in quality standards:

Quality standards FROM	Quality Standard TO
a) The appearance: cream color solid b) The residual bovine serum album: ≤50ng/dose	a) The appearance: Opal solid b) The residual bovine serum album:

c) The effective period: The effective period is 18 months from the day when the virus titer inspection is qualified	≤30ng/dose c) The effective period: The effective period is 18 months from the production day

The firm has submitted the following documents;

i. Justification for the said change
ii. Legalized Approval of supplementary data from China FDA
iii. Legalized CoPP for the product
iv. Submitted on subject "Study on Immunogenicity and Immune Persistence of Freeze-dried Live Attenuated Hepatitis A Vaccine (Upgraded process in the new plant with new excipients) with the study objective to study the immune persistence of freeze-dried live attenuated hepatitis A vaccine after new/upgraded process is adopted.

Decision: Registration Board deferred the case for submission of safety, efficacy & stability data by the firm.

6. Change in address of importer of already registered human biologicals applied by M/s Galaxay Pharma (Private) Limited, Karachi

M/s Galaxy Pharma (Private) Limited Karachi has applied for transfer of registration letter on new address of importer as per DSL of below mentioned registered Biological products. Details of the products provided by the firm are given below: -

Sr. No.	Reg. No.	Brand name & Composition	Initial Reg. date	Last Renewal Date
1.	039811	IVF-C 5000IU Each vial contains: Human Chorionic Gonadotropin (hCG)…5000IU	03-06-2005	27-08-2015
2.	039812	IVF-C 1000IU Each vial contains: Human Chorionic Gonadotropin (hCG)……5000IU.	03-06-2005	27-08-2015
3.	039814	IVF-M150IU Each vial contains: Menotropin (hMG)……150IU	03-06-2005	27-08-2015
4.	039813	IVF-M75IU Each vial contains: Menotropin (hMG)…..75IU	03-06-2005	27-08-2015
5.	039810	Follimon Injection Each vial contains: Urofollitropin (FSH)…75IU	03-06-2005	27-08-2015
6.	039815	Solvet for Follimon, IVF-C 5000IU, IVF-C 1000 IU, IVF-M 150 IU Injections Each solvent vial contains: Isotonic Sodium Chloride injection for reconstitution…..1ml.	03-06-2005	27-08-2015
7.	069577	Follitrope 300IU Each Pre-filled Syringe Injection contains: Recombinant Human Follicle Stimulating Hormone….300IU	12-04-2011	04-04-2016
8.	069576	Follitrope 225IU Each Pre-filled Syringe Injection contains: Recombinant Human Follicle Stimulating Hormone…...225IU	12-04-2011	04-04-2016
9.	069575	Follitrope 150IU Each Pre-filled Syringe Injection contains: Recombinant Human Follicle Stimulating Hormone…..150IU	12-04-2011	04-04-2016

10.	069574	Follitrope 75IU Each Pre-filled Syringe Injection contains: Recombinant Human Follicle Stimulating Hormone…..75IU	12-04-2011	04-04-2016
11.	052258	Aromek 2.5mg 1's Each tablet contains: Letrozole……2.5mg	13-11-2008	27-1-2014
12.	052258	Aromek 2.5mg 30's Each tablet contains: Letrozole……2.5mg	13-11-2008	27-1-2014
13.	066122	Oestrodose Each pressure dose delivers: 17B Estradiol……1.25g of gel (80gm/64 doses / Canister)	28-10-2010	22-04-2015
14.	059079	Utrogestan 200mg Each capsule contains: Micronized Progesterone….200mg	16-10-2009	22-10-2014
15.	062214	Utrogestan 100mg Each capsule contains: Micronized Progesterone….100mg	27-04-2010	27-04-2015
16.	066123	Oestrogel Contains: 17 B Estradiol (expressed as anhydrous estradiol…..60mg	28-10-2010	22-04-2015

The firm has submitted following documents: -

(i) Application with Fee of Rs.5, 000 /- for each product
(ii) Copy of registration letter and last renewal status
(iii) Copy of DSL

There was a change in proprietor ship. Accordingly, details of the change is as under:

Previous address	New address
D-180, Roihan Street Block-5, Clifton, Karachi.	Basement Plot No.28-C Lane No. 09 Ittehad Commercial Phase VI DHA Karachi.

The case was taken in 291st meeting of Registration Board and board decided as under;

"Registration Board deferred the case for submission, of NOC from previous proprietor of Drug Sale License, by the firm".

Remarks of Evaluator:

i. The product from Sr. No 11 to 16 pertains to PER division and may please be referred.

ii. The firm has submitted new DSL which mentions the previous name of proprietor.

Decision: Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s Galaxay Pharma (Private) Limited, D-180, Roihan Street Block-5, Clifton, Karachi to M/s Galaxay Pharma (Private) Limited, Basement Plot No.28-C Lane No. 09 Ittehad Commercial Phase VI DHA Karachi for above products subject to storage facility verification report of new address and the Registration Board refer the products from Sr. No 11 to 16 to PER division being pharmaceutical products.

7. Request of M/s Marush Pvt Ltd Lahore regarding the permission to import below mentioned veterinary vaccines with "Standard International English Labels".

M/s Marush Pvt Ltd has submitted request regarding the permission to import vaccines with "Standard International English Labels". The firm has applied for import of

registered vaccines with "Standard International English Labels" instead of the regular DRAP approved Urdu Labels. The request of the firm is reproduced here:

"It is stated that the undersigned is applying for Import of Registered Vaccines with "Standard International English Labels" instead of the regular DRAP approved Urdu Labels.

It is also submitted to update your kind offices that our shipment containing 2 of the below mentioned products were discarded, due to cold chain breakage at Lahore Airport.

Our manufacturer / supplier requires a lead time of 16-20 weeks for producing and dispatching vaccines to Pakistan with "Pakistani Specific Labels". Since our registration renewal status was not confirmed in writing till 26-8-2019, we refrained from placing fresh orders with the manufacturer till the end of August, 2019. The order that we have placed in September, 2019 will only be ready for delivery in 1st week of February 2020.

Therefore, we request your kind office to allow us to import the following duly registered vaccines with "Standard International English Labels".

These products are for vaccination in hatcheries only and will not be sold in open market through traders.

Sr. No.	Products Name	Pack Size	Registration No.	Quantity
1.	Cevac Transmune IBD	5000ds	039910	20,000 vials
2.	Cevac BI L	2500ds	023401	40,000 vials
3.	Cevac Broiler ND K	5000ds	039911	20,000 vials

It is further submitted that the firm has requested for import of huge quantities of the above mentioned products with standard International English Label" whereas the consignment of two of these products imported/cleared by the concerned AD, DRAP Lahore comprised of low quantities comparison are given below.

Sr. No.	**Products Name**	**Pack Size**	**Reg. No.**	**Quantity Cleared by Concerned AD DRAP**	**Quantity as per above request**
1.	Cevac Transmune IBD	5000ds	039910	4300	20,000 vials
2.	Cevac BI L	2500ds	023401	Not included	40,000 vials
3.	Cevac Broiler ND K	5000ds	039911	1000	20,000 vials

Decision: Registration Board deferred the case for submission of clarification regarding local printing of Registration number, MRP and Urdu text.

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

- **a.** New cases
- **b.** Deferred cases

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

- **a.** New DML
- **b.** New/Additional section(s)

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

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

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

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

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

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

Case no. 06 **Registration applications of import cases**

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

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

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

Case no. 08 **Miscellaneous cases**

Sr. No	Name of Evaluator	Title
1.	Mr. Ammar Ashraf Awan	**Evaluator PEC-II**
2.	Mr. Muhammad Haseeb Tariq	**Evaluator PEC-III**
3.	Mst.Farzana Raja	**Evaluator PEC-IV**
4.	Mst. Iqra Aftab	**Evaluator PEC-V**
5.	Mr. Muhammad Umar Latif	**Evaluator PEC-VI**
6.	Mst. Haleema Sharif	**Evaluator PEC-VIII**
7.	Mr. Haneef Ullah	**Evaluator PEC-IX**
8.	Mr. Muhammad Sarfraz Nawaz	**Evaluator PEC-X**
9.	Mst. Mehwish Javed Khan	**Evaluator PEC-XIII**
10.	Mr. Muhammad Ahsan Hafiz	**Evaluator PEC-XIV**

M/s. Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.

The Central Licensing Board in its 271st meeting held on 12th September, 2019 has considered and approved the grant of DML by way of formulation with following four sections:

1. Oral Powder Section-I (Veterinary)
2. Oral Powder Section-II (Veterinary)
3. Oral Liquid Section-I (Veterinary)
4. Oral Liquid Section-II (Veterinary)

Oral Liquid Section-I (10molecules / 27products)		
1.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	FLOSTER-23 Oral Liquid
	Composition	Each 100ml contains:- Florfenicol …… 23g
	Diary No., Date of R & I & Fee	Dy. 19037, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Floral Plus (Nawal Pharma) 074090
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
2.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	FLOSTER-25 Oral Liquid
	Composition	Each 100ml contains:- Florfenicol …… 25g
	Diary No., Date of R & I & Fee	Dy. 19038, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Florfenicol (Attabk Pharma) 075707
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
3.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	FLOSTER-20 Oral Liquid
	Composition	Each 100ml contains:- Florfenicol …… 20g
	Diary No., Date of R & I & Fee	Dy. 19039, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Florfen-20% (Nawal Pharma) 074091
	GMP Status	Inspection for grant of license conducted on 05/09/2019

		wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
4.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMCOFLOR-23% Oral Liquid
	Composition	Each 100ml contains:- Florfenicol …… 23g Colistin sulphate …….. 50MIU
	Diary No., Date of R & I & Fee	Dy. 19026 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Fentin-23 (Nawal Pharma) 078257
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
5.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMCOFLOR-25% Oral Liquid
	Composition	Each 100ml contains:- Florfenicol …… 25g Colistin sulphate …….. 50MIU
	Diary No., Date of R & I & Fee	Dy. 19078 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Flocol (D-Maarson Pharma) 074082
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
6.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMCOFLOR-11% Oral Liquid
	Composition	Each 100ml contains:- Florfenicol …… 11g Colistin sulphate …….. 50MIU
	Diary No., Date of R & I & Fee	Dy. 19027 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Flo raft (Nawal Pharma) 078252
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	

7.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	TIMSTER Oral Liquid
	Composition	Each ml contains:- Tilmicosin as phosphate …… 250mg
	Diary No., Date of R & I & Fee	Dy. 19054 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Respitil Aqueous concentrate (Attabak Pharma) 048160
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
8.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	EGA-MULTI Oral Liquid
	Composition	Each ml contains:- Enrofloxacin …… 10g Aminophylline …….. 4g Guaifenesine …… 10g
	Diary No., Date of R & I & Fee	Dy. 19056, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic, Expectorant, Broncho dilator
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	EG Enro Plus (Elegance Pharma) 074099
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
9.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	COLI-Q10 Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin …… 10g Colistin sulphate …….. 50MIU
	Diary No., Date of R & I & Fee	Dy. 19046 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Amtin-C (D-Maarson Pharma) 074080
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
10.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	COLI-Q20 Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin …… 20g Colistin sulphate …….. 50MIU

	Diary No., Date of R & I & Fee	Dy. 19045 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Maxen (D-Maarson Pharma) 075749
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
11.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	COLI-Q25 Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin …… 25g Colistin sulphate …….. 50MIU
	Diary No., Date of R & I & Fee	Dy. 19044, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Era-27.5% Oral liquid (Attabak Pharma) 071055
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
12.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	COLI-Q Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin …… 20g Colistin sulphate …….. 3%
	Diary No., Date of R & I & Fee	Dy. 19043 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Enrosir-20 (Attabak Pharma) 071060
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
13.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	BROM VET-10 Oral Liquid
	Composition	Each ml contains:- Bromhexine HCl …… 10mg
	Diary No., Date of R & I & Fee	Dy. 19033 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Mucolytic / Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Wal-Bro-100 (Nawal Pharma) 097863
	GMP Status	Inspection for grant of license conducted on 05/09/2019

		wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
14.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	BROM VET-50 Oral Liquid
	Composition	Each ml contains:- Bromhexine HCl …… 50mg
	Diary No., Date of R & I & Fee	Dy. 19032, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Mucolytic / Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Wal-Bro-50 (Nawal Pharma) 097862
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
15.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	BROM VET-M90 Oral Liquid
	Composition	Each ml contains:- Bromhexine HCl …… 50mg Menthol ……. 40mg
	Diary No., Date of R & I & Fee	Dy. 19040 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Mucolytic / Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Hexthol (Nawal Pharma) 097984
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
16.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	BROM VET-M60 Oral Liquid
	Composition	Each ml contains:- Bromhexine HCl …… 20mg Menthol ……. 40mg
	Diary No., Date of R & I & Fee	Dy. 19042 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Mucolytic / Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	BRO MAN (D-Maarson Pharma) 073994
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
17.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	BROM VET-M30 Oral Liquid

	Composition	Each ml contains:- Bromhexine HCl …… 10mg Menthol ……. 20mg
	Diary No., Date of R & I & Fee	Dy. 19041 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Mucolytic / Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Bromotin (Elegance Pharma) 073999
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
18.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	SAM-E VET Oral Liquid
	Composition	Each 100ml contains:- Silymarin …… 2100mg Vitamin E ……. 1500mg
	Diary No., Date of R & I & Fee	Dy. 19055, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Hepato-protective agent, Vitamin
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Hepato Care (Attabak Pharma) 062167
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Deferred for further deliberation.	
19.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	MULTI DOX-10 Oral Liquid
	Composition	Each 1000ml contains:- Doxycycline HCl …… 200g Tylosin tartrate ……. 100g Colistin sulphate ……. 500MIU Bromhexine HCl ……. 10g
	Diary No., Date of R & I & Fee	Dy. 19047, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotics, Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	CRD (D-Maarson Pharma) 072678
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
20.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	MULTI DOX-T Oral Liquid
	Composition	Each 1000ml contains:- Doxycycline HCl …… 200g Tylosin tartrate ……. 200g Colistin sulphate ……. 500MIU

		Bromhexine HCl ……. 5g
	Diary No., Date of R & I & Fee	Dy. 19049, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotics, Mucolytic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	CRD Maars (D-Maarson Pharma) 072677
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
21.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	MULTI DOX-5 Oral Liquid
	Composition	Each ml contains:- Doxycycline HCl …… 200g Tylosin tartrate …….. 100g Colistin sulphate ……. 500MIU Bromhexine HCl ……. 5g
	Diary No., Date of R & I & Fee	Dy. 19048 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotics, Mucolytic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	CRD Col (D-Maarson Pharma) 058879
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
22.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	MULTI DOX-3 Oral Liquid
	Composition	Each ml contains:- Doxycycline HCl …… 200g Tylosin tartrate …….. 100g Colistin sulphate ……. 500MIU Bromhexine HCl ……. 3g
	Diary No., Date of R & I & Fee	Dy. 19050, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotics, Mucolytic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Respi Liquid (D-Maarson Pharma) **073995**
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
23.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	MULTI DOX-480 Oral Liquid
	Composition	Each ml contains:- Doxycycline HCl …… 200mg Tylosin tartrate …….. 100mg Colistin sulphate ……. 480,000IU

		Bromhexine HCl ……. 5mg
	Diary No., Date of R & I & Fee	Dy. 19051 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotics, Mucolytic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Nawa Dox Oral liquid (Nawal Pharma) 074097
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
24.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	MULTI DOX-450 Oral Liquid
	Composition	Each ml contains:- Doxycycline HCl …… 200mg Tylosin tartrate ……..…. 100mg Colistin sulphate ……. 450,000MIU Bromhexine HCl ……. 2.5mg
	Diary No., Date of R & I & Fee	Dy. 19052, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotics, Mucolytic
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	TDC (Attabak Pharma) 058885
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
25.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMROQUIN-10 Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin …… 10g
	Diary No., Date of R & I & Fee	Dy. 19034 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Enro wal-10 (Nawal Pharma) 072626
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with USP specifications.	
26.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMROQUIN-20 Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin …… 20g
	Diary No., Date of R & I & Fee	Dy. 19035, 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled

	Me-Too Status	Enro wal-20 (Nawal Pharma) 072627
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with USP specifications.	
27.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMROQUIN-25 Oral Liquid
	Composition	Each 100ml contains:- Enrofloxacin …… 25g
	Diary No., Date of R & I & Fee	Dy. 19036 , 30-09-2019, Rs.20,000, 27-09-2019,
	Pharmacological Group	Fluorquinolone
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Enrotin (Epla Pharma) 025789
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein Panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with USP specifications.	
Oral Liquid Section-II (Veterinary) (10 molecules/12 products)		
28.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	LEVA CLOZ Oral SUSP.
	Composition	Each 100ml contains:- Oxyclozanide …… 3g Levamisole HCl …… 1.5g Cobalt chloride …… 0.075g Sodium selenite …… 0.035g
	Diary No., Date of R & I & Fee	Dy.19069 , 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Nilzole (Attabak Pharma) 034545
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
29.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	LEVA CLOZ DS Oral SUSP.
	Composition	Each 100ml contains:- Oxyclozanide …… 6% Levamisole HCl …… 3% Cobalt chloride …… 0.15% Sodium selenite …… 0.07%
	Diary No., Date of R & I & Fee	Dy.19068, 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Paranil Gold (Breeze Pharma) 059143
	GMP Status	Inspection for grant of license conducted on 05/09/2019

		wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
30.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	WORMI STAT Oral SUSP.
	Composition	Each 100ml contains:- Oxyclozanide …… 3g Levamisole HCl …… 1.5g Cobalt Sulphate …… 0.05g Sodium selenite …… 0.03g
	Diary No., Date of R & I & Fee	Dy. 19025, 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Leva Ras (Attabak Pharma) 062186
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
31.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	LEVA TRICK PLUS Oral SUSP.
	Composition	Each ml contains:- Triclabendazole …… 50mg Levamisole HCl …… 37.5mg Cobalt Sulphate …… 1.67mg Sodium selenite …… 0.35mg
	Diary No., Date of R & I & Fee	Dy.19030 , 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Triclobak Plus (Attabak Pharma) 062168
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
32.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	LEVA TRICK Oral SUSP.
	Composition	Each 100ml contains:- Triclabendaole …… 5g Levamisole HCl …… 3.75g Cobalt chloride …… 0.075g Sodium selenite …… 0.035g
	Diary No., Date of R & I & Fee	Dy.19031, 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Tenex plus 8.75 Drench (Breeze Pharma) 059107
	GMP Status	Inspection for grant of license conducted on 05/09/2019

		wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
33.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMEZOLE FORTE Oral SUSP.
	Composition	Each 100ml contains:- Albendazole …… 2.5g Cobalt chloride ……. 0.075% Sodium selenite ……. 0.035%
	Diary No., Date of R & I & Fee	Dy. 19029, 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Alben Mars (D-Maarson Pharma) 075744
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
34.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMEZOLE 2.5% Oral SUSP.
	Composition	Each 100ml contains:- Albendazole …… 2.5g
	Diary No., Date of R & I & Fee	Dy. , 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Albabak-2.5 Oral suspension (Attabak Pharma) 034538
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
35.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSEFAX Oral SUSP.
	Composition	Each 100ml contains:- Oxfendazole …… 2.265g
	Diary No., Date of R & I & Fee	Dy. 19022 , 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Oxfabak (Attabak Pharma) 034537
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with BP specifications.	
36.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSEFAX-CS Oral SUSP.

	Composition	Each 100ml contains:- Oxfendazole …… 2.265g Cobalt chloride ……. 0.075g Sodium selenite ……. 0.030g
	Diary No., Date of R & I & Fee	Dy.19023, 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Fenzol-cs (Attabak Pharma) 058901
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
37.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSENIDE GOLD Oral SUSP.
	Composition	Each ml contains:- Oxyclozanide …….. 62.5mg Oxfendazole …… 22.65mg Cobalt Sulphate ……. 1.67mg Sodium selenite ……. 0.5mg
	Diary No., Date of R & I & Fee	Dy.19021 , 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic, Minerals
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	O2 Forte (D-Maarson Pharma) 078264
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	
38.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSENIDE-3.4% Oral SUSPENSION
	Composition	Each ml contains:- Oxyclozanide …… 34mg
	Diary No., Date of R & I & Fee	Dy. 19020 , 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmintic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Oxanil (Breeze Pharma) 059130
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with BP specifications.	
39.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	VERMI BEAT Oral SUSP.
	Composition	Each 100ml contains:- Triclabendazole …… 12g Albendazole ……..…. 10g Ivermectin ……. 0.2g

	Diary No., Date of R & I & Fee	Dy.19024, 27-09-2019, Rs.20,000
	Pharmacological Group	Anthelmentic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100ml, 250ml,500ml,1Litre,2.5Litre / Decontrolled
	Me-Too Status	Thunder (Star Labs.) 058941
	GMP Status	Inspection for grant of license conducted on 05/09/2019 wherein panel unanimously approved for the grant of License.
	Remarks of Evaluator	
	Decision: Approved with innovator's specifications.	

Case No.02: Registration Applications of Drugs for which Stability Study Data is Submitted.

a. Verification of Stability Study Data.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
40.	M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar	Dexibrain 60mg Capsule Each capsule contains: Dexlansoprazole as enteric coated granules (17%) ……60mg Proton Pump inhibitor Innovator's specifications	Form 5-D Dy. No.2911 dated 22-01-2019 Rs. 20,000/- dated 22-01-2019 As per SRO	DEXILANT by M/s Takeda Pharms, USFDA. Panel Inspection conducted on 03-02-2017 recommends renewal of DML and grant of four additional sections.

STABILITY STUDY DATA			
Drug	Dexibrain 60mg Capsule		
Name of Manufacturer	M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar		
Manufacturer of API	M/s Vision pharmaceuticals (Pvt) Ltd. Plot no.22-23, Industrial Triangle, Kahuta Road, Islamabad		
API Lot No.	DLP123T		
Description of Pack (Container closure system)	Alu-Alu Blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C/ 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated : 0,1,2,3,4,6 (6 months) Real Time: 0,3,6 (6 months)		
Batch No.	T-10	T-11	T-12
Batch Size	1200 capsules	1200 capsules	1200 capsules
Manufacturing Date	10-07-2018	10-07-2018	10-07-2018
Date of Initiation	10-07-2018	10-07-2018	10-07-2018
No. of Batches	03		

Date of Submission	9628 (26/06/2019)

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # DLP123T) from M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad issued by Additional Director (QA & LT), DRAP, Islamabad. The certificate is valid till 25-01-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of purchase of pellets from local vendor.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months accelerated and 6 months real time stability data of three batches.
Label claim is not as per reference formulation since pellets used for the development of this formulation are not enteric coated granules. Correction is required.

Sr. No.	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size**	**International Availability / Local Availability** **GMP Inspection Report Date & Remarks**
41.	M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar	Dexibrain 30mg Capsule Each capsule contains: Dexlansoprazole as dual delayed pellets (17%)……..….30mg Proton Pump inhibitor Innovator's specifications	Form 5-D Dy. No.2910 dated 22-01-2019 Rs. 20,000/- dated 22-01-2019 As per SRO	DEXILANT by M/s Takeda Pharms, USFDA. Panel Inspection conducted on 03-02-2017 recommends renewal of DML and grant of four additional sections.

STABILITY STUDY DATA

Drug	Dexibrain 30mg Capsule
Name of Manufacturer	M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar
Manufacturer of API	M/s Vision pharmaceuticals (Pvt) Ltd. Plot no.22-23, Industrial Triangle, Kahuta Road, Islamabad

API Lot No.	DLP123T		
Description of Pack (Container closure system)	Alu-Alu Blister Foil		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C/ 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated : 0,1,2,3,4,6 (6 months) Real Time: 0,3,6 (6 months)		
Batch No.	T-07	T-08	T-09
Batch Size	1200 capsules	1200 capsules	1200 capsules
Manufacturing Date	09-07-2018	09-07-2018	09-07-2018
Date of Initiation	09-07-2018	09-07-2018	09-07-2018
No. of Batches	03		
Date of Submission	9628 (26/06/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # DLP123T) from M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad issued by Additional Director (QA & LT), DRAP, Islamabad. The certificate is valid till 25-01-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of purchase of pellets from local vendor.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months accelerated and 6 months real time stability data of three batches.
Label claim is not as per reference formulation since pellets used for the development of this formulation are not enteric coated granules. Correction is required.

Scope of Inspection: Verification of authenticity of stability data(Dexibrain 60mg capsules)
Dexibrain 30mg capsules
Letter No. F.13-11/2017-PEC(Pt) dated 19-08-2019
Inspection date 27-09-2019

Sr.#	Question	Remarks
1	Do you have documents confirming the import of API?	Local purchase invoice of M/s Vision Pharma Islamabad, Shipment documents available.
2	What was the rationale behind selecting the particular manufacturer of API?	GMP compliant, local availability , approved source for other sister companies
3	Do you have documents confirming the import of API reference standard and impurity standards?	Only Working standard available.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Yes for Certificates of analysis for API and Working standard available
5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, GMP certificate issued y Additional Director QALT Isb available.
6	Do you use API manufacturer method of testing?	Yes,
7	Do you have stability studies reports on API?	Yes , stability studies report of API. Available.
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed as per SIM Method & degradation product has been quantified by the manufacturer of API as per record seen.
9	Do you have method for quantifying the impurities in the API?	Not performed
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Yes, have Remaining quantity of API, no for reference standards and Impurities.
11	Have you used pharmaceutical grade excipients?	Yes, used pharmaceutical grade excipients/ capsule shells available for already approved products.
12	Do you have documents confirming the import of the used excipients?	Local purchase
13	Do you have test reports and other records on the excipients used?	Yes,
14	Do you have written and authorized protocols for the development?	Yes, records seen of written and authorized protocols for the development of capsules dosage form.
15	Have you performed Drug-excipient compatibility studies?	Yes, record available
16	Whether firm has performed comparative dissolution studies?	Yes, record available of comparative dissolution vs DEXXO 30mg and 60mg
17	Do you have product development (R&D) section	No
18	Do you have necessary equipments available in product development section for product development>?	Batch processed in existing production department.
19	Are the equipments in product development section qualified	-DO-
20	Do you have proper maintenance / calibration /re-qualification program for the equipment used in PD section?	-DO-
21	Do you have qualified staff in product development section with proper knowledge and training in product development?	As per approved production and QC incharge.
22	Have you manufactured three stability batches for the stability studies of as required.	Yes, separate batches for both strength each three in number

23	What were the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of the stability batches is the quantity required for testing and number of testing Frequencies
24	Do you have complete record of production of stability batches?	Yes, BMR available.
25	Do you have protocols for stability testing of stability batches?	Yes
26	Do you have developed and validated the method for testing of stability batches?	Yes,
27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable
28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes, installation qualification record available
29	Do your method of analysis stability indicating?	Yes,
30	Do your HPLC software is 21CFR compliant?	Yes Empower1,waters , 600 series
31	Can you show Audit Trail reports on testing?	Yes , record checked randomly and found satisfactory
32	Do you have some remaining quantities of degradation products and stability batches?	Degradation products not available. Stability batches available
33	Do you have commitment batches kept on stability testing?	Yes
34	Do you have valid calibration status for the equipments used in production in analysis?	Yes
35	Do proper and continuous monitoring and control are available for stability chamber?	Yes, Manual records maintained. Two chambers of 500 lit capacity with digital display and 12 hrs UPS backup
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes

Dissolution data available and verified for both pH 5.5 and pH7 for confirmation of dual delayed release profile of finished product.

Conclusion:

On risk based approach the genuineness /authenticity of stability data submitted by the firm for registration of Dexibrain 60mg, Dexibrain 30mg capsules is verifiable to satisfactory level. And the panel recommends grant of registration for the above mentioned products.

Decision: Registration Board decided to approve registration of Dexibrain 30mg Capsule and Dexibrain 60mg Capsule (Dexlansoprazole) by M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

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

42.	M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar	Rofluwin 500mcg Tablet Each tablet contains: Roflumilast …...500mcg Phosphodiesterase inhibitors Innovator's specifications	Form-5D 37742 dated 15-11-2018, Rs. 50,000/- dated 13-11-2018 As per SRO, As per SRO	Roflumilast 500mcg Tablet by MSN Pharmaceuticals, (USFDA approved) Panel inspection conducted on 03-02-2017 recommends renewal of DML.	The firm has revised the label claim o.n original dossier as per reference with submission of fee challan of Rs. 5000/- (deposit slip # 1957707) dated 25-09-2019

STABILITY STUDY DATA			
Drug	Rofluwin 500mcg Tablet		
Name of Manufacturer	M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar		
Manufacturer of API	M/s Chongqing Huapont Pharm. Co., Ltd. China		
API Lot No.	ROF-20171001		
Description of Pack (Container closure system)	Alu-Alu Blister, 20's		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Accelerated: 0,1,2,3,4,6 (months) Real Time: 0,3,6 (months)		
Batch No.	T-13	T-14	T-15
Batch Size	2000 tablets	2000 tablets	2000 tablets
Manufacturing Date	11-2018	11-2018	11-2018
Date of Initiation	19-11-2018	19-11-2018	19-11-2018
No. of Batches	03		
Date of Submission	05-08-2019 (Dy. No. 14156)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA of Roflumilast from M/s Chongqing Huapont Pharm. Co., Ltd. China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP Certificate (Certificate#CQ20180013) for M/s Chongqing Huapont Pharm. Co., Ltd. China issued by China Food and Drug Administration, China. It is valid till 06-06-2023.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of invoice for the purchase of Roflumilast (100g). Invoice is not attested by ADC.

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months accelerated and 6 months real time stability studies of 3 trial batches.
The API manufacturer has conducted a test for particle size by using Malvern Zetasizer 2000 laser diffraction.
Scope of Inspection: Verification of authenticity of stability data ROFLUWIN 500mcg Tablets (ROFLUMILAST 500mcg)
Letter No. F.13-11/2017-PEC(Pt) dated 26-09-2019
Inspection date Friday: 27-09-2019

S.#	Question	Remarks
1	Do you have documents confirming the import of API?	Good declaration copy shown during inspection, ADC clearance invoice / certificate unavailable
2	What was the rationale behind selecting the particular manufacturer of API?	GMP compliant, and DMF availability
3	Do you have documents confirming the import of API reference standard and impurity standards?	Only 100mg Working standard available. Provided with API by supplier
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Yes for Certificates of analysis for API and Working standard available
5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, Plant GMP. DML available.
6	Do you use API manufacturer method of testing?	No, In-house method validated
7	Do you have stability studies reports on API?	Yes , stability studies report of API. Available.
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed as per SIM Method & no degradation product has been quantified by manufacturer of API as per record seen.
9	Do you have method for quantifying the impurities in the API?	Not performed
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Yes, have Remaining quantity of API 95gms, no for reference standards and Impurities.
11	Have you used pharmaceutical grade excipients?	Yes, used pharmaceutical grade excipients/ available for already approved products.
12	Do you have documents confirming the import of the used excipients?	Local purchase
13	Do you have test reports and other records on the excipients used?	Yes,
14	Do you have written and authorized protocols for the development of Tablets?	Yes, records seen of written and authorized protocols for the development of new products
15	Have you performed Drug-excipients compatibility studies?	Yes
16	Whether firm has performed comparative dissolution studies?	No
17	Do you have product development (R&D) section.	No

18	Do you have necessary equipments available in product development section for development of Tablets?	Batch processed in existing production department.
19	Are the equipments in product development section qualified	-DO-
20	Do you have proper maintenance / calibration /re-qualification program for the equipment used in PD section?	-DO-
21	Do you have qualified staff in product development section with proper knowledge and training in product development?	As per approved production and QC incharge.
22	Have you manufactured three stability batches for stability studies of as required	Yes, as T13, T14, and T15
23	What were the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of the stability batches is the quantity required for testing and number of testing Frequencies are attached.
24	Do you have complete record of production of stability batches?	Yes, BMR available.
25	Do you have protocols for stability testing of stability batches?	Yes
26	Do you have developed and validated the method for testing of stability batches?	Yes,
27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not applicable
28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes, installation qualification record available
29	Do your method of analysis stability indicating?	No
30	Do your HPLC software is 21CFR compliant?	Yes Empower1,waters , 600 series
31	Can you show Audit Trail reports testing?	Yes, record checked randomly & found satisfactory
32	Do you have some remaining quantities of degradation products and stability batches?	Degradation products not available. Stability batches available
33	Do you have commitment batches kept on stability testing?	Yes
34	Do you have valid calibration status for the equipments used in production in analysis?	Yes
35	Do proper and continuous monitoring and control are available for stability chamber?	Yes, Manual records maintained. 02 chambers 0f 500lit capacity
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes

i. Only Good declaration copy available for confirmation of API import.
ii. Content uniformity test record available and evaluated during inspection and found satisfactory as per USP general chapter.

Conclusion:

On risk based approach the genuineness /authenticity of stability data submitted by the firm for registration of ROFLUWIN 500mcg Tablets (ROFLUMILAST 500mcg) is verifiable to satisfactory level.

And the panel recommends grant of registration of the aforementioned product. ((The above information is identified / verified or not as herein above. The DRB may decide as per policy vogue)).

Decision: Registration Board decided to approve registration of Rofluwin 500mcg Tablet (Roflumilast) by M/s Winbrains Research laboratories, Plot No.69, Block B, phase I-II, Industrial Estate, Hattar. Manufacturer will place first three production batches of both products on long term stability studies

throughout proposed shelf life and on accelerated studies for six months.

Agenda of Evaluator PEC-XIII

43.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. Contract Manufacturer M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name + Dosage Form + Strength	M- Xone 250mg Injection I/M
	Composition	Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone...250mg
	Diary No. Date of R& I & fee	Dy.No.187,24-04-2017;Rs.50,000 (24-04-2017)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocephin 250mg powder for solution for Injection vials of M/s Roche, UK (MHRA Approved)
	Me-too status	Rocephin of M/s Roche
	GMP status	M/s Iceberg: Last inspection 04-11-2016. M/s Bio-Labs: Last inspection report dated 05 & 06-12-2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	• In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have not been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s Astellas Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on 05-12-2018 and the report concludes: "Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB."
	Second Evaluation by PEC:	

	1. In 279th DRB meeting, the Registration Board deferred the case due to capacity of the manufacturer firm i.e. M/s Biolabs Pharma. 2. In 289th DRB meeting, the Registration Board deferred the case due to suspension of products of applicant i.e. M/s Iceberg Pharma. 3. The firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma, 4. The firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. 5. The GMP report of the applicant i.e. M/s Iceberg is of 26-06-2019 with conclusion of resumption of production in all sections after observing rectification of observations. 6. The GMP report of manufacturer i.e. M/s Astellas is of 13-11-2018 with conclusion of good GMP compliance. 7. Applicant has approved sections and no any product has been granted registration to them on Contract basis.	
	Previous Decision: Deferred in 291st DRB meeting for submission of fee for change in contract manufacturer.	
	Third Evaluation: Firm has submitted Rs. 5000/- for change in contract manufacturer.	
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s. Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
44.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. Contract Manufacturer: M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	M-Xone 500mg Injection I/M
	Composition	Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone...500mg
	Diary No. Date of R& I & fee	Dy.No.186,24-04-2017;Rs.50,000(24-04-2017)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocephin powder for solution for Injection vials by Roche (MHRA Approved)
	Me-too status	Rocephin by Martin Dow
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs**:** Last inspection report dated 5 & 6th December, 2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	• In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have not been given registration of any product on contract manufacturing till date.

		• Manufacturer firm i.e. M/s Astellas Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018** and the report concludes: **"**Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB."
	Second Evaluation by PEC: 1. In 279th DRB meeting, the Registration Board deferred the case due to capacity of the manufacturer firm i.e. M/s Biolabs Pharma. 2. In 289th DRB meeting, the Registration Board deferred the case due to suspension of products of applicant i.e. M/s Iceberg Pharma. 3. The firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma, 4. The firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. 5. The GMP report of the applicant i.e. M/s Iceberg is of 26-06-2019 with conclusion of resumption of production in all sections after observing rectification of observations. 6. The GMP report of manufacturer i.e. M/s Astellas is of 13-11-2018 with conclusion of good GMP compliance. 7. Applicant has approved sections and no any product has been granted registration to them on Contract basis.	
	Previous Decision: Deferred in 291st DRB meeting for submission of fee for change in contract manufacturer.	
	Third Evaluation: Firm has submitted Rs. 5000/- for change in contract manufacturer.	
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s. Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
45.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. Contract Manufacturer: M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	M-Xone 1g Injection I/M
	Composition	Each vial contains:- Ceftriaxone Sodium eq. to Ceftriaxone…….1g
	Diary No. Date of R& I & fee	Dy.No.189,24-04-2017;Rs.50,000 (24-04-2017)
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's & as per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocephin powder for solution for Injection vials by Roche (MHRA Approved)
	Me-too status	Rocephin by Martin Dow
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs**:** Last inspection report dated 5 & 6th December, 2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date.

		• Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	• In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have not been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s Astellas Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018** and the report concludes: **"Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB."**
	Second Evaluation by PEC: 1. In 279th DRB meeting, the Registration Board deferred the case due to capacity of the manufacturer firm i.e. M/s Biolabs Pharma. 2. In 289th DRB meeting, the Registration Board deferred the case due to suspension of products of applicant i.e. M/s Iceberg Pharma. 3. The firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma, 4. The firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. 5. The GMP report of the applicant i.e. M/s Iceberg is of 26-06-2019 with conclusion of resumption of production in all sections after observing rectification of observations. 6. The GMP report of manufacturer i.e. M/s Astellas is of 13-11-2018 with conclusion of good GMP compliance. 7. Applicant has approved sections and no any product has been granted registration to them on Contract basis.	
	Previous Decision: Deferred in 291st DRB meeting for submission of fee for change in contract manufacturer.	
	Third Evaluation: Firm has submitted Rs. 5000/- for change in contract manufacturer.	
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s. Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
46.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. Contract Manufacturer: M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	Senofer 20mg/ml Injection

	Composition	Each ml ampoule contains:- Iron (as sucrose)…… 20 mg
	Diary No. Date of R& I & fee	Dy. No. 185, 24-04-2017; Rs.50,000/- (24-04-2017)
	Pharmacological Group	Replenishes Hgb and depleted iron stores
	Type of Form	Form- 5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	5ml x 5's & as per PRC
	Approval status of product in Reference Regulatory Authorities.	Venofer Injection by Vifor Pharma (UK MHRA Approved) (MHRA Approved)
	Me-too status	Ferotein-S by Getz/venofer of RG
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs: Last inspection report dated 05 & 06-12-2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted.
	Previous decision	• In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have not been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s Astellas Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance. • Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018** and the report concludes: "**Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB."**
	Second Evaluation by PEC: 1. In 279th DRB meeting, the Registration Board deferred the case due to capacity of the manufacturer firm i.e. M/s Biolabs Pharma. 2. In 289th DRB meeting, the Registration Board deferred the case due to suspension of products of applicant i.e. M/s Iceberg Pharma. 3. The firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma, 4. The firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. 5. The GMP report of the applicant i.e. M/s Iceberg is of 26-06-2019 with conclusion of resumption of production in all sections after observing rectification of observations.	

	6. The GMP report of manufacturer i.e. M/s Astellas is of 13-11-2018 with conclusion of good GMP compliance. 7. Applicant has approved sections and no any product has been granted registration to them on Contract basis.	
	Previous Decision: Deferred in 291st DRB meeting for submission of fee for change in contract manufacturer.	
	Third Evaluation: Firm has submitted Rs. 5000/- for change in contract manufacturer.	
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s. Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
47.	Name and address of manufacturer / Applicant	M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur. Contract Manufacturer: M/s Bio-Labs (Pvt) Ltd, Plot # 145, Industrial triangle, Islamabad.
	Brand Name +Dosage Form + Strength	LNTROP-D Injection I/M
	Composition	Each ml contains:- Cholecalciferol …… 5 mg (eq. to 2, 00,000 I.U.)
	Diary No. Date of R& I & fee	Dy. No. 188, 24-04-2017; Rs.50,000/- (24-04-2017)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	"1's, 5's" & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection (ANSM, France)
	Me-too status	Get D injection of M/s Getz Pharma
	GMP status	M/s Iceberg: Last inspection 04-11-2016 M/s Bio-Labs**:** Last inspection report dated 5 & 6-12-2017 concludes fair level of GMP compliance.
	Previous remarks of the Evaluator	• Firm has submitted that they have not registered any product for contract manufacturing till date. • Agreement between both the firms is submitted. • Relevant section in the manufacturer firm is confirmed as dry powder injection (Cephalosporin). • M/s Iceberg's GMP inspection needs to be conducted. • Strength is not mentioned on fee- challan. • Two pack sizes are applied on one injection□
	Previous decision	• In 279th DRB meeting, Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Biolabs by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.
	Evaluation by PEC	• Firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma. • Applicant i.e. M/s Iceberg has 5 sections and they have submitted that they have not been given registration of any product on contract manufacturing till date. • Manufacturer firm i.e. M/s Astellas Pharma has Dry Powder Injection (Cephalosporin) section as mentioned in the submitted section approval letter. • Firm has submitted a copy of agreement between both the firms. • GMP inspection of M/s Astellas was conducted on 02-10-2017 and the report concludes satisfactory level of GMP compliance.

		• Firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. • GMP inspection of M/s Iceberg was conducted on **05-12-2018** and the report concludes: "Production of the firm shall remain suspended till recommendation by panel and subsequent approval by the CLB."
	Second Evaluation by PEC: 1. In 279th DRB meeting, the Registration Board deferred the case due to capacity of the manufacturer firm i.e. M/s Biolabs Pharma. 2. In 289th DRB meeting, the Registration Board deferred the case due to suspension of products of applicant i.e. M/s Iceberg Pharma. 3. The firm has changed the Contract Manufacturer from M/s Biolabs to M/s Astellas Pharma, 4. The firm wants to apply these drugs on the same fees submitted earlier on M/s Biolabs Contract basis. 5. The GMP report of the applicant i.e. M/s Iceberg is of 26-06-2019 with conclusion of resumption of production in all sections after observing rectification of observations. 6. The GMP report of manufacturer i.e. M/s Astellas is of 13-11-2018 with conclusion of good GMP compliance. 7. Applicant has approved sections and no any product has been granted registration to them on Contract basis.	
	Previous Decision: Deferred in 291st DRB meeting for submission of fee for change in contract manufacturer.	
	Third Evaluation: Firm has submitted Rs. 5000/- for change in contract manufacturer.	
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s. Astellas by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	

Agenda of Evaluator PEC-X

Deferred cases of Human Pharmaceuticals in 289th meeting of Registration Board

M/s Novex Pharmaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad (New License)

Drug Manufacturing License (DML) to issue to M/s Novex Pharaceuticals **by way of formulation** and granted (04) new section to the firm. Accordingly, firm has applied for following products for consideration by Drug Registration Board.

Eye Drops Section (02 Products/02 Molecules Approved in 289th Meeting of RB)		
48.	Name and address of Manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Moxoflow 0.5% Sterile Ophthalmic Solution
	Composition	Each ml Opthalmic Solution contains: Moxifloxacin Hydrochloride 5.45mg equivalent to Moxifloxacin……..….5mg.
	Diary No, Date of R & I & fee	Dy. No 13667 dated 07-03-19 Rs20,000/-Dated 07-03-19
	Pharmacological Group	Quinolone antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Moxivig 0.5%w/v Eye Drops, Solution Marketing Authorisation Holder Novartis Pharmaceuticals UK Limited
	Me-too status	A-Mox M/S Atco Laboratories Ltd
	GMP Status	Panel inspection conducted on 12-02-2019 & 21-02-2019, and the report concludes that the panel unanimously

		Recommended M/s Novex Pharmaceuticals for the grant of DML for the following section: 1. Sterile SVP Liquid Infusion vial (General) 2. Sterile Liquid Ampoule (General) 3. Sterile Liquid Ampoule (Steroid) 4. Sterile Eye/Ear/Nasal Preparations (Steroid)
	Remarks of the Evaluator	
	Decision of 289th meeting of RB: Deferred for evidence of approval of requisite manufacturing facility from licensing division since the firm has Sterile Eye/Ear/Nasal Preparations (Steroid) section Firm reply as under: Registration Board in its 248th meeting deliberated on decision of Central Licensing Board regarding manufacturing requirement for steroidal drugs and decided as follows: a. Products containing steroidal topical preparations like eye/ear drops, sterile eye ointment, external preparations i.e. cream/ointment/gel, lotions, spray/aerosols, suppositories, vaginal preparation, intra oral preparations, nasal drops etc. shall be permitted for manufacturing in general facility/area provided that manufacturers shall have segregated dispensing booths, cleaning validation and controls studies for processes and adequate system to minimize the potential risk of cross contamination. We have segregated dispensing booth as well as cleaning validation. Our HVAC System is a state of art and Capable to maintain the positive pressure in manufacturing unit. **Decision: Approved**	
49.	Name and address of Manufacturer / Applicant	M/s Novex Phamaceuticals, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novaket 0.5% w/v Ophthalmic Solution
	Composition	Each ml Opthalmic Solution contains: Ketorolac Tromethamine ……..….5mg.
	Diary No, Date of R & I & fee	Dy. No. 13675 dated 07-03-19 Rs20,000/-Dated 07-03-19
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished Product Specification	As per Innovator
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Acular Allergan Ltd. United Kingdom
	Me-too status	Kats Sterile Ophthalmic Solution of Medicaids (Pak) (Reg. 058072)
	Remarks of the Evaluator	
	Decision of 289th meeting of RB: Deferred for evidence of approval of requisite manufacturing facility from licensing division since the firm has Sterile Eye/Ear/Nasal Preparations (Steroid) section Firm reply as under: Registration Board in its 248th meeting deliberated on decision of Central Licensing Board regarding manufacturing requirement for steroidal drugs and decided as follows: a. Products containing steroidal topical preparations like eye/ear drops, sterile eye ointment, external preparations i.e. cream/ointment/gel, lotions, spray/aerosols, suppositories, vaginal preparation, intra oral preparations, nasal drops etc. shall be permitted for manufacturing in general facility/area provided that manufacturers shall have segregated dispensing booths, cleaning validation and controls studies for processes and adequate system to minimize the potential risk of cross contamination. We have segregated dispensing booth as well as cleaning validation. Our HVAC System is a state of art and Capable to maintain the positive pressure in manufacturing unit. **Decision: Approved with innovator's specification**	
Sterile Liquid Ampoule (Steroid) 4 Products/ 4 Molecules approved in 289th meeting of RB		
50.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Progest 250mg/ml Injection
	Composition	Each ml contains: Progestrone……..250mg

	Diary No, Date of R & I & fee	Dy. No 14881 dated 07-03-19 Rs20,000/- 06-03-19
	Pharmacological Group	Hormone
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed. ii. Generic/me-too) not confirmed from available data.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board Firm reply above query was not verified. **Decision: Deferred for following:** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board**	
51.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Testone 250mg Injection
	Composition	Each ml contains: Testosterone Propionate …….250mg
	Diary No, Date of R & I & fee	Dy. No 13669 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	anabolic Steroid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Sustanon 250 is a solution in oil. Each ampoule contains 1 ml arachis oil containing the following active substances: - 30 mg Testosterone propionate - 60 mg Testosterone phenylpropionate - 60 mg Testosterone isocaproate - 100 mg Testosterone decanoate
	Me-too status	
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed. ii. Generic/me-too) not confirmed from available data.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board Firm reply above query was not verified. **Deferred for following:** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	

Sterile Liquid Ampoule (General) 5 Products/ 5 Molecules		
52.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nofever 150mg/5ml Injection
	Composition	Each ml ampoule contains: Paracetamol ……..150mg
	Diary No, Date of R & I & fee	Dy. No. 14864 dated 07-03-19 Rs 20,000/-Dated 06-03-19
	Pharmacological Group	Analgesic & antipyretic
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	Bofalgan 300mg/2ml Injection of M/s Bosch-II Karachi
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed. ii. Generic/me-too) not confirmed from available data.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board Firm reply above query and Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board was not verified. **Deferred for following:** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.**	
53.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Gentox 80mg/2ml Injection
	Composition	Each 2ml ampoule contains: Gentamycin as sulfate…….80mg
	Diary No, Date of R & I & fee	Dy. No 14865 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Cidomycin 80 mg/2 ml Solution for Injection(UK)
	Me-too status	Lirin 80mg Injection of Zinta Pharma (Reg. 040098)
	Remarks of the Evaluator	Approval Status of product in Reference Regulatory Authorities is not confirmed.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board Now the firm has submitted the Approval Status of product in Reference Regulatory Authorities. **Decision: Approved**	
54.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Renox 25mg Injection
	Composition	Each ml ampoule contains: Ranitidine HCl ……..25mg

	Diary No, Date of R & I & fee	Dy. No. 14874 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Zantac Injection Teligent Pharm Inc USA
	Me-too status	ZANTIC 2ML INJ of Gsk
	Remarks of the Evaluator	i. Composition showed that API is Nalbuphine HCL whereas applied product is Ranitidine HCL. ii. Generic/me-too) not confirmed from available data.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm • Composition showed that API is Nalbuphine HCL whereas applied product is Ranitidine HCL clarify. Now the firm has submitted the correct composition along with fee 20,000/- and me-too status. **Decision: Registration Board deferred for further deliberation regarding NDMA impurity**	
55.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novil 22.75mg/ml Injection
	Composition	Each ml contains: Pheniramine Maleate….22.75mg
	Diary No, Date of R & I & fee	Dy. No 14891 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Anti-Histamine
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	
	Me-too status	Avil (Reg. 000226)
	Remarks of the Evaluator	i. Approval Status of product in Reference Regulatory Authorities is not confirmed.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm Now the firm has submitted the reply which is not verified. **Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.**	
56.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novecin 300mg Injection IV/IM
	Composition	Each ml ampoule contains: Lincomycin as HCl ……..300mg
	Diary No, Date of R & I & fee	Dy. No. 14894 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Lincosamide antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Lincomycin Injection X-Gen Pharma Inc USA
	Me-too status	Mahacin Injection M/s Humayun International Pharma (Pvt) Ltd, 20 K M Satiana Road, Faisalabad

	Remarks of the Evaluator	Covering letter showing that applied product is methylprednisolone acetate) whereas in form-5A it is Lincomycin.
	Decision of 289th meeting of RB: Deferred due to Covering letter showing that applied product is methylprednisolone acetate) whereas in form-5A it is Lincomycin clarify. Firm has submitted the reply with applied product covering letter. **Decision: Approved**	
57.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Novafer 100mg/5ml Injection
	Composition	Each 5ml ampoule contains: Iron sucrose complex ……..100mg
	Diary No, Date of R & I & fee	Dy. No. 147871 dated 07-03-19 Rs20,000/- 06-03-19
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Vonefer Injection Vifor France.
	Me-too status	Bisleri-S 100mg/5ml Injection of M/s Sami Pharma
	Remarks of the Evaluator	i. Composition submitted in form-5A shows paracetamol whereas covering letter shows Iron sucrose complex. ii. Generic/me-too) not confirmed from available data.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm • Incorrect composition. Firm submitted response is evaluated and found still incomplete, without fee and again incorrect composition. **Decision: Deferred for submission of Correct composition along with full fee.**	
Sterile SVP Liquid Infusion vial (General) 7 Molecules / 7 Products approved in 289th meeting of RB		
58.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Nofever 500mg/50ml Injection
	Composition	Each 50ml vial contains: Paracetamol……..….500mg
	Diary No, Date of R & I & fee	Dy. No 14869 dated 07-03-19 Rs20,000/-Dated 0-03-19
	Pharmacological Group	analgesics and antipyretics
	Type of Form	Form-5
	Finished Product Specification	Innovator's
	Pack Size & Demanded Price	50ml x1's , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	Paracetamol Injection Accord Healthcare Ltd UK UK emc Approved
	Me-too status	
	Remarks of the Evaluator	Generic/me-too) not confirmed from available data.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Firm reply as under: Our product in 500mg/50ml packing will be the first packing in Pakistan to be registered. **Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board along with submission of Form 5D and differential fee of Rs. 30,000/-.**	

59.	Name and address of Manufacturer / Applicant	M/s Novex Pharmaceuticlas, Plot No 54, S6 National Industrial Zone Rawat Islamabad
	Brand Name + Dosage Form + Strength	Flucoz 200mg/100ml Injection
	Composition	Each 100ml vial contains: Fluconazole……..….200mg
	Diary No, Date of R & I & fee	Dy. No 14868 dated 07-03-19 Rs20,000/-Dated 06-03-19
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	100ml x1's , As per SRO
	Approval Status of product in Reference Regulatory Authorities.	**Diflucon 200mg/100ml Injection** Pfizer Pharms USA
	Me-too status	
	Remarks of the Evaluator	Generic/me-too) not confirmed from available data.
	Decision of 289th meeting of RB: Deferred for following: • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm Firm submitted reply not verified. **Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

Locally manufactured veterinary pharmaceuticals (New DML)

CLB in its 271st meeting held on 12th September 2019 approved the grant of Drug Manufacturing License (Formulation) with following section: Oral Powder Section-I(Veterinary)		
60.	Name and address of Manufacturer/ Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	CHESTY LYTE Oral W/S Powder
	Composition	Each g contains:- Doxycycline HCl ……. 200mg Tylosin tartrate …….. 100mg Colistin sulphate ……. 0.5MIU Bromhexine HCl …….. 5mg Streptomycin sulphate …… 20mg
	Diary No., Date of R & I & Fee	Dy. 19065, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Riz Wan-S (Nawal Pharma) 078296
	Remarks of Evaluator	
	Decision: Approved with innovator's specification	
61.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	BRONCO FAST Oral W/S Powder
	Composition	Each 1000g contains:- Doxycycline HCl ……. 200g Tylosin tartrate …….. 100g Colistin sulphate ……. 450MIU Bromhexine HCl …….. 5g Streptomycin sulphate …… 36g
	Diary No., Date of R & I & Fee	Dy. 19086, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification

	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Pulmodox-S (Attabak Pharma) 071069
	Remarks of Evaluator	
	Decision: Deferred for clarification as both BRONCO FAST and BRONCO PLUS strengths shows very small difference.	
62.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	BRONCO PLUS Oral W/S Powder
	Composition	Each 1000g contains:- Doxycycline HCl ……. 20% Tylosin tartrate …….. 10% Colistin sulphate ……. 450MIU Bromhexine HCl …….. 0.5% Streptomycin sulphate …… 3.5%
	Diary No., Date of R & I & Fee	Dy. 19086, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic, Mucolytic, Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Becto-5 (Noble Pharma) 075609
	Remarks of Evaluator	
	Decision: Deferred as both BRONCO FAST and BRONCO PLUS strengths shows very small difference.	
63.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSEFLOR FORTE Oral W/S Powder
	Composition	Each g contains:- Oxytetracycline HCl……300mg Florfenicol ……..……. 100mg Neomycin sulphate ……. 150mg
	Diary No., Date of R & I & Fee	Dy. 19070, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotics
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Vety flor mix powder (reg. 094484)
	Remarks of Evaluator	
	Decision: Approved with innovator's specification	
64.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSEFLOR Oral W/S Powder
	Composition	Each 100g contains: - Oxytetracycline HCl……300mg Florfenicol ……..……. 100mg Neomycin sulphate ……. 150mg
	Diary No., Date of R & I & Fee	Dy. 19071, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotics
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	
	Remarks of Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
65.	Name and address of Manufacturer/ Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSE-COF Oral W/S Powder

	Composition	Each 100g contains:- Bromhexine HCl……..……0.5g
	Diary No., Date of R & I & Fee	Dy. 19053, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Mucolytic, Expectorant
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Brombak (Attabak Pharma) 063820
	Remarks of Evaluator	
	Decision: Approved with innovator's specification	
66.	Name and address of Manufacturer/ Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSEFON-985 Oral W/S Powder
	Composition	Each g contains:- Trichlorfon …… 985mg
	Diary No., Date of R & I & Fee	Dy. 19094, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Anthelmentic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	
	Remarks of Evaluator	
	Decision: Deferred for clarification and scientific justification as AMSEFON-985, AMSEFON-960 and AMSEFON-980 strengths shows very small difference.	
67.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSEFON-960 Oral W/S Powder
	Composition	Each 1000g contains: - Trichlorfon …… 960g
	Diary No., Date of R & I & Fee	Dy. 19096, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Anthelmentic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Nawagan (Attabak Pharma) 053922
	Remarks of Evaluator	
	Decision: Deferred for clarification and scientific justification as AMSEFON-985, AMSEFON-960 and AMSEFON-980 strengths shows very small difference.	
68.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMSEFON-980 Oral W/S Powder
	Composition	Each 1000g contains:- Trichlorfon …… 980g
	Diary No., Date of R & I & Fee	Dy. 19096, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Anthelmentic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Tri Gold (Attabak Pharma) 049700
	Remarks of Evaluator	
	Decision: Deferred for clarification and scientific justification as AMSEFON-985, AMSEFON-960 and AMSEFON-980 strengths shows very small difference.	
69.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMEDOX-T20 Oral W/S Powder

	Composition	Each 100g contains:- Doxycycline HCl …… 40mg Tylosin tartrate …….. 20g
	Diary No., Date of R & I & Fee	Dy. 19081, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Doxityl water soluble powder (059115)
	Remarks of Evaluator	
	Decision: Approved with innovator's specification	
70.	Name and address of Manufacturer/Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	AMEDOX-T60 Oral W/S Powder
	Composition	Each 100g contains:- Doxycycline HCl …… 40g Tylosin tartrate …….. 20g
	Diary No., Date of R & I & Fee	Dy. 19080, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	DOT (Attabak Pharma) 069628
	Remarks of Evaluator	Provided me-too composition Each 100g contains:- Doxycycline HCl …… 400g Tylosin tartrate …….. 200g
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
71.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	ANTIWORM-R15 Oral W/S Powder
	Composition	Each 500g contains:- Levamisole HCl …… 15%
	Diary No., Date of R & I & Fee	Dy. 19088, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	
	Remarks of Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
72.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	ANTIWORM-R20 Oral W/S Powder
	Composition	Each 100g contains:- Levamisole HCl …… 20g
	Diary No., Date of R & I & Fee	Dy. 19089, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Levabak (Attabak Pharma) 053902
	Remarks of Evaluator	
	Decision: Approved with innovator's specification and change of brand name	

73.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	ANTIWORM-R50 Oral W/S Powder
	Composition	Each 100g contains:- Levamisole HCl …….…… 50g
	Diary No., Date of R & I & Fee	Dy. 19090, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Deworm (Attabak Pharma) 053927
	Remarks of Evaluator	
	Decision: Approved with innovator's specification and change of brand name	
74.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	ENROVET-R20 Oral W/S Powder
	Composition	Each 100g contains:- Enrofloxacin HCl …….…… 20g
	Diary No., Date of R & I & Fee	Dy. 19057, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Enrocin (Attabak Pharma) 053919
	Remarks of Evaluator	
	Decision: Approved with innovator's specification and change of brand name	
75.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	FEBROL-C Oral W/S Powder
	Composition	Each 100g contains:- Vitamin C …….…… 20g Paracetamol …….…… 2g Potassium chloride …….. 4g Calcium carbonate …….. 45g Magnesium sulphate …….. 3.5g
	Diary No., Date of R & I & Fee	Dy. 19059, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Paravit-C (D-Maarson Pharma) 074081
	Remarks of Evaluator	
	Decision: Registration Board referred the case regarding the composition to the expert working group on veterinary drugs.	
76.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	URI CARE Oral W/S Powder
	Composition	Each 100g contains:- Methenamine ……. 98g Vitamin B1 ……. 800mg Vitamin B2 …… 920mg Vitamin K3 ……200mg
	Diary No., Date of R & I & Fee	Dy. 19064, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotics
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification

	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Urimin(Attabak Pharma) 034527
	Remarks of Evaluator	
	Decision: Approved with innovator's specification and change of brand name	
77.	Name and address of Manufacturer / Applicant	Aamster Laboratories Plot No. 18 St#SS-2, National Industrial Zone Rawat, Islamabad.
	Brand Name, Dosage Form, Strength	NEO PHEN-C Oral W/S Powder
	Composition	Each 1000g contains:- Oxytetracycline …….. 300g Chloramphenicol …… 300g Neomycin sulphate …… 150g Salicylic acid …… 50g
	Diary No., Date of R & I & Fee	Dy. 19063, 30-09-2019, Rs.20,000/- dated 27-09-2019
	Pharmacological Group	Antibiotic, Keratolytic
	Type Of Form	Form 5
	Finished product Specification	Manufacturers Specification
	Pack Size and Demanded Price	100gm,250gm,500gm,1Kg,5Kg,10Kg,25Kg / Decontrolled
	Me-Too Status	Neo-Oxy Chlor (Farm Aid Group)033224
	Remarks of Evaluator	
	Decision: Approved with innovator's specification	

78. M/s Ahsan Pharma Importer and exporter Karachi, applied for registration of Pemetrexed on Form 5-F

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 4024 Dated 18-04-2019 (Rs. 100,000/- Dated 08-03-2019) Dy. No 4025 Dated 18-04-2019 (Rs. 100,000/- Dated 08-03-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Ahsan Pharma Importer and exporter address: Zeenat Medicine market, A-5, 1st Floor Napier Road Karachi, Pakistan
	1.3.2	Name, address and contact details of Manufacturing site. Manufacturer: M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China Marketing Authorization Holder: M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	1.3.3	Specify whether the Applicant is: Importer will import from?
	1.3.4	**Drug Sale License** M/s Ahsan Pharma address: A-5, 1st Floor Zeenat Medicine market Karachi License No. 1318 valid till 30-Jul-2019
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted

	1.5.1	Generic name with chemical name & synonyms of the applied drug. Pemetrexed
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each injection (vial) contains: Pemetrexed (as pemetrexed disodium) ….100mg Each injection (vial) contains: Pemetrexed (as pemetrexed disodium)….500mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Pemetrexed Seacross 100mg Pemetrexed Seacross 500mg
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 10ml vial/ as per brand leader 50ml vial/ as per brand leader
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Folic acid analogues ATC code: L01BA04
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration concentrate for solution for infusion
	1.5.8	For Generic Drug Product, reference of other similar approved medicines with information pertaining to Manufacturer name, brand name, strength, composition, registration number & dosage form, Pack size and Price. ALIMTA 100MG INJECTION & ALIMTA 500MG INJECTABLE. of M/s ELI LILLY
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Pemetrexed Seacross 100 mg powder for concentrate for solution for infusion of Seacross Pharmaceuticals Limited United Kingdom Pemetrexed Seacross 500 mg powder for concentrate for solution for infusion of Seacross Pharmaceuticals Limited United Kingdom
	1.5.10	Dosage form of applied drug Powder for concentrate for solution for infusion
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the

		DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance does not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. **Submitted**
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer. M/s Chongqing Pharmaceutical Research Institute (Changshou) Co. Ltd. (CPRI Changshou) Address: No. 2, The Third Branch Road, Huanan Road, Changshou Economic & Technological Development District Chongqing 401220, People's Republic of China
	• Original Legalized CoPP for Pemetrexed Seacross 100mg (Certificate#. PP10156749) dated 20-08-2018 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer. • Original Legalized CoPP for Pemetrexed Seacross 500mg (Certificate#. PP10156675) dated 20-08-2018 by The **Medicines and Healthcare products Regulatory Agency**, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer. • Firm has submitted copy of exclusive distribution ship agreement (without products list) with manufacturer (from china) and Product license holder (from UK) • M/s Merixil Pharma Islamabad submit Original product specific Authorization letter by Marketing authorization holder M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom for two products, one of which is also applied by M/s Ahsan Pharma as well which has also distribution agreement with M/s Seacross Pharmaceutical Limited which is not product specific.	

MODULE 2: CTD SUMMARIES

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

QUALITY OVERALL SUMMARY (QOS)

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

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

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Submitted
	3.2.S.2.4	Control of Critical steps and intermediates Submitted

	3.2.S.2.5	Process Validation and/or Evaluation Submitted
	3.2.S.2.6	Manufacturing process development Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.3	Validation of analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5	REFERENCE STANDARDS Submitted	
3.2.S.6	CONTAINER CLOSURE SYSTEMS Submitted	
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

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

	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 36 months at 30 ± 2^0C,75%RH and 6 months at 40^0C±75%RH for three batches for applied strengths separately

Remarks of Evaluators:

Provided Sole agency agreement with manufacturer M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China which is not Product License Holder, and applicant submit a copy of original letter from manufacturer CEO Zhao Ding which is as under:

"M/s Sichuan Huiyu Pharmaceutical Ltd. (No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China) confirms that M/s Seacross Pharmaceutical Limited, (Bedford Business centre, 61-63 st peters street, Bedford MK40 2PR, United Kingdom) is 100% subsidiary company of M/s Sichuan Huiyu
M/s Seacross Pharmaceutical Limited is the marketing company in UK, responsible for batch release. The centeralized pharmacovigilance & risk management, and quality, safety & efficacy of pharmaceutical products: and M/s Sichuan Huiyu Pharmaceutical Ltd. is the manufacturer in China, responsible for finished product manufacturing, primary & secondary packaging and batch control testing"

Decision: Registration Board deferred the case and decided to coordinate (email) M/s Seacross Pharmaceutical Limited (UK) (Marketing Authorization Holder) for declaration of their sole agent in Pakistan.

79. M/s Merixil Pharma, Islamabad Pakistan applied for registration of Bendamustine on Form5F

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 15314 Dated 22-08-2019 (Rs. 100,000/- Dated 18-06-2019)
1.2		Table of Contents (From Module 1 to Module 5) Submitted
1.3		Applicant Information Submitted
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder: M/s Merixil Pharma, Office 28, 2nd floor rose plaza, I-8 Markaz, Islamabad Pakistan.
	1.3.2	Name, address and contact details of Manufacturing site. Manufacturer: M/s Sichuan Huiyu Pharmaceutical Ltd. No. 5 Road Chengxi economic area, Neijiang, Sichuan-641000, China Marketing Authorization Holder: M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom
	1.3.3	Specify whether the Applicant is: Importer will import from UK
	1.3.4	**Drug Sale License** Copy of License to sell Drug by way of Wholesale/Distribution no. DSL-445-ICT/2013

		renewed upto 02-02-2020
	1.3.8	Manufacturer's Site Master File and Credential (for importer) Submitted
1.4		Type of Application Submitted
	1.4.1	Application is for the registration of: Generic Drug Product
	1.4.1	Pharmaceutical product is intended for: □ **Domestic sale**
	1.4.2	For imported products, please specify one of following: □ **Finished Pharmaceutical Product Import**
1.5		Detailed Information of Drug, Dosage From & Labelling Claims Submitted
	1.5.1	Generic name with chemical name & synonyms of the applied drug. Bendamustine
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Bendamustine HCl bendamustine hydrochloride (as bendamustine hydrochloride monohydrate) ……..100mg Powder for Injection
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Bendamustine Seacross 100mg for Injection
	1.5.4	Proposed Pack size and Proposed unit price of drug e.g., per tablet / capsule. Maximum Retail Price (MRP) per pack shall also be mentioned. 1's Injection
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Anticancer
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration IV (Bendamustine)
	1.5.9	The registration status of applied drug in same molecule and salt, strength, dosage form, container closure system, indications and route of administration etc. in other countries. The status in reference regulatory authorities is mandatory to mention. Bendamustine hydrochloride 2.5 mg/ml powder for concentrate for solution for infusion (UK)
	1.5.10	Dosage form of applied drug Lyophilized Dry Powder in vial
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens Submitted
	1.5.12	Description of Batch numbering system
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP). Submitted
	1.5.15	Commitment / Undertaking that after registration of applied drug, the Pharmacovigilance department of the applicant / manufacture is liable to impose similar restrictions, addition of any clinical information (like in Indications, Contra-indications, Side effects, Precautions, Dosage & A0dverse Drug Reactions etc. in Summary of Product Characteristics (SmPC), Labelling & Promotional material) or withdraw the drug from market in Pakistan within fourteen days after knowing that such information (which was not available or approved by the DRAP at the time of registration) / actions taken (for safety reasons) by any reference / stringent drug regulatory agency / authority & also inform the DRAP (Drug Regulatory Authority of Pakistan) for further action in this regard. **Submitted**
	1.5.16	Commitment / Undertaking that the applicant shall recall the defective Finished

		Pharmaceutical Products (FPP) and notify the compliance to the authority along with detail of actions taken by him as soon as possible but not more than ten days. The level of recall shall also be defined. **Submitted**
	1.5.17	Commitment / Undertaking that in case of any false claim / concealing of information, the DRAP has the right to reject the application at any time, before and even after approval or registration of the product in case if proved so. **Submitted**
	1.5.18	Commitment / Undertaking that the firm shall follow the official pharmacopoeia specifications for product / substance as published in the latest edition & shall update its specification as per latest editions of the same. In case, the specifications of product / substance not present in any official pharmacopoeia the firm shall establish the specifications. In both cases, the validation of specifications shall be done by the applicant. **Submitted**
	1.5.19	Commitment / Undertaking that in case of any post approval change, the applicant shall ensure that the product with both approvals shall not be available in the market at the same time. And the product with new approvals shall be marketed only after consumption / withdrawal of stock with previous approvals. The company shall be liable to inform the same regarding marketing status of product to the DRAP after getting such post-registration approvals. **Submitted**
	1.5.20	Other commitment e.g., regarding stability studies etc.
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.
1.6		Miscellaneous Information Submitted
	1.6.1	Information on Prior-related Applications
	1.6.2	Appendix
	1.6.3	Electronic Review Package
	1.6.4	QIS (Quality Information Summary)
	1.6.5	Drug Substance related Document including following: Name and address of API manufacturer: M/s Fujian South Pharmaceutical Co. Ltd. No. 98, Dongxin Road, xuefeng town mingxi country sanming city Fujian Province China (for Azacitidine Seacross 100mg for Injection)
	• Original Legalized CoPP for BENDAMUSTINE HCl 2.5mg/ml (Certificate#. PP10161088) dated 14-05-2019 by The Medicines and Healthcare products Regulatory Agency, 10 South Colonnade, Canary Wharf, London E14 4PU, United Kingdom declaring the free sale of applied product and GMP compliant status of the manufacturer. • GMP inspection dated 21-08-2017 of Manufacturer online verified dated 18-09-2019, link given below http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do • Original product specific Authorization letter by Marketing authorization holder M/s Seacross Pharmaceutical Limited, Bedford business centre, 61-63 st. peter's street, Bedford, Bedfordshire, MK40 2PR, United Kingdom to Importer M/s Merixil Pharma, Office 28, 2nd floor rose plaza, I-8 Markaz, Islamabad Pakistan to register and distribute AZACITIDINE 100mg INJECTION in Pakistan. • **M/s Ahsan Pharma Karachi has submitted copy of exclusive distribution ship agreement (without products list) with manufacturer (from china) and Product license holder (from UK)**	

MODULE 2: CTD SUMMARIES

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

QUALITY OVERALL SUMMARY (QOS)

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

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

3.2.S DRUG SUBSTANCE (API)

3.2.S.1	GENERAL INFORMATION (May not refer to DMF)	
	3.2.S.1.1	Nomenclature Submitted
	3.2.S.1.2	Structure Submitted
	3.2.S.1.3	General properties Submitted
3.2.S.2	MANUFACTURER	
	3.2.S.2.1	Manufacturer(s) Submitted
	3.2.S.2.2	Description of Manufacturing Process and Process Controls Submitted
	3.2.S.2.3	Control of Materials Submitted
	3.2.S.2.4	Control of Critical steps and intermediates Not Submitted

	3.2.S.2.5	Process Validation and/or Evaluation Not submitted
	3.2.S.2.6	Manufacturing process development not Submitted
3.2.S.3	CHARACTERIZATION	
	3.2.S.3.1	Elucidation of Structure and other Characteristics Submitted
	3.2.S.3.2	Impurities Submitted
3.2.S.4	CONTROL OF DRUG SUBSTANCE (API)	
	3.2.S.4.1	Specification Submitted
	3.2.S.4.2	Analytical procedures Submitted
	3.2.S.4.3	Validation of analytical procedures Submitted
	3.2.S.4.4	Batch analysis Certificate of analysis (COA) specifications and test results from drug substance (API) manufacturer(s) Drug product manufacturer's certificate of analysis with API lot numbers
	3.2.S.4.5	Justification of specifications Submitted
3.2.S.5	REFERENCE STANDARDS Submitted	
3.2.S.6	CONTAINER CLOSURE SYSTEMS Submitted	
3.2.S.7	STABILITY	
	3.2.S.7.1	Stability Summary and Conclusions Submitted
	3.2.S.7.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.S.7.3	Stability Data Submitted

3.2.P DRUG PRODUCT

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

	3.2.P.5.1	Specification(s) Submitted
	3.2.P.5.2	Analytical procedures Submitted
	3.2.P.5.3	Validation of analytical procedures Submitted
	3.2.P.5.4	Batch analysis Submitted
	3.2.P.5.5	Characterization of impurities Submitted
	3.2.P.5.6	Justification of specifications Submitted
3.2.P.6		Reference Standards or Materials Submitted
3.2.P.7		CONTAINER CLOSURE SYSTEM Submitted
3.2.P.8	STABILITY	
	3.2.P.8.1	Stability summary and conclusion (Finished Dosage Form) Submitted Stability protocol submitted
	3.2.P.8.2	Post-approval Stability Protocol and Stability Commitment Submitted
	3.2.P.8.3	Stability Submitted
		Firm has submitted three batches long term stability data 3 batches 24 months at 30 ± 2^0C,75%RH and 6 months at 40^0C±75%RH for three batches for applied strengths separately (Bendamustine Seacross 100mg for Injection)
Decision: Registration Board deferred the case and decided that Secretary Registration Board will contact M/s Seacross Pharmaceutical Limited (UK) (Marketing Authorization Holder) for declaration of sole agent in Pakistan.		

Imported application on Form-5A

a. New case

80.	**Name and address of Applicant**	M/s Graton Pharma office no. 102 first floor, the plaza block-9 clifton, Karachi
	Detail of Drug Sale License	
	Name and address of manufacturer	M/s Jodas Expoim Pvt. Ltd. Plot No. 55, Biotech Park, Phase III, Karkapatla (V), Markook (M) Siddipet (D), Telangana atate Pin-502 279 India
	Name and address of marketing authorization holder	M/s Jodas Expoim Pvt. Ltd. Plot No. 55, Biotech Park, Phase III, Karkapatla (V), Markook (M) Siddipet (D), Telangana atate Pin-502 279 India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7045 Dated 19-02-2019
	Fee including differential fee	Rs. 50,000/- Dated 19-02-2019
	Brand Name +Dosage Form + Strength	Ioxican 50ml I.V Solution
	Composition	Each ml contains: Iohexol USP……647mg
	Finished Product Specification	In-house
	Pharmacological Group	contrast media for diagnosis
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	50ml
	International availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Photocopy of CoPP issued by Drug Control Administration India. • Copy of Sole agency agreement with MAH valid upto 31st December 2021.
	Remarks of the Evaluator.	A letter dated 01st October 2019 from QA/LT Division DRAP Islamabad on subject "Shortage of ULTRAVIST in the market" and detailed as under: "M/s Bayer stated that due to technical issue at our Berlin supply

		center laid to 18% reduction in the volume of contrast agents produced by M/s Bayer last winter. Total impact of this has been amplified by current implantation of Regulatory decision related to contrast agents that steeply increased demand for specific agents. The results has been out of stock situations in practically all countries to which we deliver contrast agents. FID Karachi dated 07th August 2019 issued shortage notice to the company. There are also shortage report in the market. The alternate product Omnipack, the other competitors also not available in the market. It is therefore requested that registration of alternative brands may be expedited to ensure the availability of contrast media to meet the demands of the market for emergency cases" In review of above the application regarding contrast media was evaluated and following deficiencies were observed: i. Applied formulation composition as per FSC: Each ml vial Contains: Iohexol….755mg eq to iodine 350mg As per CoPP: Each ml contains: Iohexol USP……647mg eq. to iodine 300mg, Clarify. ii. Provided fee is 50,000/- while applied formulation is already approved in Pakistan. iii. Authority letter does not show the list of products for which you have been given authorization by manufacturer. iv. Copy of GMP issued by Drug Control Administration India dated **19-05-2018** and valid for one year from the date of issued. v. Copy of FSC issued by Drug Control Administration India dated **26-09-2018** and valid for one year from the date of issued. vi. Copy of CoPP issued by Drug Control Administration India valid upto 14-11-2021 vii. Copy of Drug Sales License is not provided. viii. Provided stability data is of Drug Substance.
	Decision: Registration Board deferred the case for following: **i. Clarification of composition of applied formulation since:** **Composition declared in FSC is: Each ml vial Contains: Iohexol….755mg eq to iodine 350mg** **And Composition declared in CoPP is: Each ml contains: Iohexol USP……647mg eq. to iodine 300mg, Clarify.** **ii. Submitted fee is 50,000/- while applied formulation is already approved in Pakistan.** **iii. Authority letter does not show the list of products for which importer have been given authorization by manufacturer.** **iv. Submission of original legalized and valid GMP certificate issued by Drug Control Administration India.** **v. Submissionof original legalized and valid FSC issued by Drug Control Administration India dated 26-09-2018 and valid for one year from the date of issued.** **vi. Submissionof original legalized and valid CoPP issued by Drug Control Administration India.** **vii. Copy of Drug Sales License is not provided.** viii. **Provided stability data is of Drug Substance.** ix. **Confirmation whether the applied drug is importable from India or not as per Imnopiort Policy Order.**	
81.	**Name and address of Applicant**	M/s Graton Pharma office no. 102 first floor, the plaza block-9 clifton, Karachi
	Detail of Drug Sale License	
	Name and address of manufacturer	M/s Jodas Expoim Pvt. Ltd. Plot No. 55, Biotech Park, Phase III, Karkapatla (V), Markook (M) Siddipet (D), Telangana atate Pin-502 279 India

	Name and address of marketing authorization holder	M/s Jodas Expoim Pvt. Ltd. Plot No. 55, Biotech Park, Phase III, Karkapatla (V), Markook (M) Siddipet (D), Telangana atate Pin-502 279 India
	Name of exporting country	India
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 7046 Dated 19-02-2019
	Fee including differential fee	Rs. 50,000/- Dated 19-02-2019
	Brand Name +Dosage Form + Strength	Ioxican 100ml I.V Solution
	Composition	Each ml contains: Iohexol USP……647mg
	Finished Product Specification	In-house
	Pharmacological Group	contrast media for diagnosis
	Shelf life	24 Months
	Demanded Price	As per SRO
	Pack size	100ml vial
	International availability	
	Me-too status	
	Stability studies	
	Detail of certificates attached	• Photocopy of CoPP issued by Drug Control Administration India. • Copy of Sole agency agreement with MAH valid upto 31st December 2021.
	Remarks of the Evaluator.	i. Applied formulation composition as per FSC: Each ml vial Contains: Iohexol….755mg eq to iodine 350mg As per CoPP: Each ml contains: Iohexol USP……647mg eq. to iodine 300mg, Clarify. ii. Provided fee is 50,000/- while applied formulation is already approved in Pakistan. iii. Authority letter does not show the list of products for which you have been given authorization by manufacturer. iv. Copy of GMP issued by Drug Control Administration India dated **19-05-2018** and valid for one year from the date of issued. v. Copy of FSC issued by Drug Control Administration India dated **26-09-2018** and valid for one year from the date of issued. vi. Copy of CoPP issued by Drug Control Administration India valid upto 14-11-2021 vii. Copy of Drug Sales License is not provided. viii. Provided stability data is of Drug Substance. ix. As per submitted copy Free Sales Certificate 100ml pack size is not registered in India.
	Decision: Registration Board deferred the case for following: **i. Clarification of composition of applied formulation since:** **Composition declared in FSC is: Each ml vial Contains: Iohexol….755mg eq to iodine 350mg** **And Composition declared in CoPP is: Each ml contains: Iohexol USP……647mg eq. to iodine 300mg, Clarify.** **ii. Submitted fee is 50,000/- while applied formulation is already approved in Pakistan.** **iii. Authority letter does not show the list of products for which importer have been given authorization by manufacturer.** **iv. Submission of original legalized and valid GMP certificate issued by Drug Control Administration India.** **v. Submissionof original legalized and valid FSC issued by Drug Control Administration India dated 26-09-2018 and valid for one year from the date of issued.** **vi. Submissionof original legalized and valid CoPP issued by Drug Control Administration**	

	India. **vii. Copy of Drug Sales License is not provided.** **viii. Provided stability data is of Drug Substance.** **ix. As per submitted copy Free Sales Certificate 100ml pack size is not registered in India, clarify.** **x. Confirmation whether the applied drug is importable from India or not as per Imnopiort Policy Order.**

Agenda of Evaluator PEC-VI

New Section:

M/s Aries Pharmaceuticals (Pvt) Ltd. (New Section):

Files received vide letter No. F.16-4/2013-Reg-IV, dated 15th May, 2017 and 6th June, 2017, stating following details:

The sections of the firm was approved vide Secretary Central Licensing Board Letter No.F.3-2/2000-Lic(Vol-II) dated, 11th April, 2017.

In 271st meeting, the Registration Board considered several products in DRY POWDER INJECTION (GENERAL) SECTION with following details:

- No. of molecules: 06
- No. of products: 07

The firm has applied for 02 more products in the same section. The final status of the products/molecules given below after consideration of 02 application dossiers.

- **No. of molecules: 08**
- **No. of products: 09**

60.	**Name and address of manufacturer / Applicant**	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad Peshawar KPK
	Brand Name +Dosage Form + Strength	LORNICA Injection 8mg IV/IM
	Composition	Each Lyophilized vial contains: Lornoxicam (lyophilized)…… 8mg
	Diary No. Date of R& I & fee	Dy No. 14398 dated 07/03/2019 PKR 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	MFG specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8 mg powder and solvent for solution for injection by M/s Takeda Austria GmbH, (TGA Austria Approved)
	Me-too status	Zafon 8mg injection by M/s Gez Pharma Reg # 58591
	GMP status	
	Remarks of the Evaluator.	The firm has applied for In-House manufacturing specifications and the product is not present in available pharmacopoeia.
	Decision: Deferred for evidence of availability of required manufacturing facility i.e., Lyophilizer.	
61.	**Name and address of manufacturer / Applicant**	M/s Aries Pharmaceuticals (Pvt) Ltd, 1-W, Industrial Estate, Hayatabad Peshawar KPK
	Brand Name +Dosage Form + Strength	ACE Injection 150mg IM
	Composition	Each Vial contains: Aceclofenac (Lyophilized)….. 150mg
	Diary No. Date of R& I & fee	Dy No. 14406 dated 07/03/2019 PKR 20,000/-
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	MFG specs
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	Could not be confirmed

	Regulatory Authorities.	
	Me-too status	Could not be confirmed
	GMP status	
	Remarks of the Evaluator.	Evidence of approval in reference regulatory authorities and me too status could not be confirmed.
	Decision of 284th meeting of RB	
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

Agenda of Evaluator PEC-IX

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

a. New cases

89.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name +Dosage Form + Strength	Citipride 1mg/5ml Oral Solution
	Composition	Each 5ml Contains: Cinitapride (as Acid Tartrate)…1mg
	Diary No. Date of R& I & fee	Dy No. 27778: 13.08.2018 PKR 20,000/-: 10.08.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders, Propulsives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovaotr's specifications.
	Pack size & Demanded Price	120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg / 5 ml Oral solution by ALMIRALL, SA CIMA Approved
	Me-too status	Cinipride 1mg/5ml Syrup. Reg No. 73656
	GMP status	The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	•
	Decision: Approved	
90.	**Name and address of manufacturer / Applicant**	**M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.**
	Brand Name +Dosage Form + Strength	Citipride 1mg Tablet
	Composition	Each tablet Contains: Cinitapride (as Acid Tartrate)…1mg
	Diary No. Date of R& I & fee	Dy No. 27778: 13.08.2018 PKR 20,000/-: 10.08.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders, Propulsives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	1x10's, 5x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Blaston 1 mg Tablets by LACER, SA. Approved by Spanish Agency of Medicines and Health Products
	Me-too status	Cint 1mg Tablet by High-Q Pharmaceuticals. Reg. No. 73888
	GMP status	The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC

		Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	•
	Decision: Approved	
91.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Monti 4mg Chewable Tablet
	Composition	Each Chewable Tablet Contains: Montelukast (as Sodium)…4mg
	Diary No. Date of R& I & fee	Dy No. 27780: 13.08.2018 PKR 20,000/-: 10.08.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders, Propulsives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	SINGULAIR® (montelukast sodium) Chewable Tablets (4mg, 5mg). USFDA approved
	Me-too status	Montewan 4mg Tablet. Reg No. 83930
	GMP status	The firm was inspected on 24.05.2019 with the following conclusion: The firm was evaluated for facilities like building, HVAC Sytem, quality control, quality assurance and production oerations. The Briell Pharma found to be operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved	
92.	Name and address of manufacturer / Applicant	Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Neotane Capsule 10mg
	Composition	Each capsule contains: Isotretinoin……10mg
	Diary No. Date of R& I & fee	Dy No. 7140: 23.02.2018 PKR 20,000/-: 23.02.2018
	Pharmacological Group	Retinoids for topical use in acne (Dermatological only)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10,s, 30,s; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ABSORICA® (isotretinoin) capsules, for oral use. USFDA approved
	Me-too status	No-Acne 10mg Capsules. Reg # 44013
	GMP status	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.
	Remarks of the Evaluator.	The brand, generic or strength has not been mentioned on the fee challan.
	Decision: Deferred for the following: • **Undertaking from the firm the challan shall not be used for any other dossier.** • **Submission of stability data of three batches as per zone-IV-A**	
93.	Name and address of manufacturer / Applicant	Relizon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Neotane Capsule 20mg
	Composition	Each capsule contains: Isotretinoin……20mg
	Diary No. Date of R& I & fee	Dy No. 7140: 23.02.2018 PKR 20,000/-: 23.02.2018

	Pharmacological Group	Retinoids for topical use in acne (Dermatological only)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10,s, 30,s; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ABSORICA® (isotretinoin) capsules, for oral use. USFDA approved
	Me-too status	No-Acne 20mg Capsules. Reg # 44014
	GMP status	The firm was inspected on 05.12.2017, wherein the panel recommended the grant of DML.
	Remarks of the Evaluator.	The brand, generic or strength has not been mentioned on the fee challan.
	Decision: Deferred for the following: • **Undertaking from the firm the challan shall not be used for any other dossier.** • **Submission of stability data of three batches as per zone-IV-A**	

b. Deferred cases

94.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Furox Powder for oral suspension 250mg/5ml
	Composition	Each 5ml contain: Cefuroxime as axetil…… 250mg
	Diary No. Date of R& I & fee	Dy No. 3373: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Kefzy Suspension 250mg/5ml. Reg. No. 82757
	GMP status	New DML
	Remarks of the Evaluator.	The reference product contains granules for oral suspension. However, the provided master formula and manufacturing outlines does not depict granule formation. The firm was asked for justification/ clarification. The firm provided another reference product, which could not be verified.
	Previous decision	The Board in its 289th meeting deferred the case for Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.
	Evaluation by PEC	The firm revised the manufacturing outlines to granules with submission of Rs. 5000/-.
	Previous decision	The Board in its 291st meeting deferred the case for Proof of International availability of same dosage form with same strength in reference regulatory authority as adopted in 275th meeting of the Registration Board.
	Evaluation by PEC	The product is available as "Zinnat granules for Suspension 250mg/5ml". **MHRA** approved.
	Decision: Approved	

Case no. 06 Registration applications of drugs for which stability study data is submitted

a. New cases

b. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
95.	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lukhpat, Lahore	Velbuvir tablet 400/100mg Each film-coated tablet contains: Sofosbuvir…400mg Velpatasvir……100 mg (Antiviral) (In-house specifications)	Form-5D Dy. No: 137 Dated 05.08.2016 Rs.50,000/- As per SRO (5's, 10's, 20's, 30's, 50's, 60's)	EPCLUSA® (sofosbuvir and velpatasvir) tablets, for oral use **USFDA** approved. Abriva forte by M/s CCL. The firm was inspected on 27-08-2018, 05-10-2018, 06-11-2018 with the following conclusion: "Based on observations the firm was found to be operating at satisfactory level of GMP compliance at the time of inspections."

STABILITY STUDY DATA			
Drug	Velbuvir tablet 400/100		
Name of Manufacturer	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lukhpat, Lahore		
Manufacturer of API	**Sofosbuvir:** Nantong Chanyoo Pharmatech Co., Ltd No. 2 Tonghai Si Road, Yangkou Chemical Industrial Park, Rudong Coastal Economic Development Zone, Nantong Province China **Velpatasvir**: Optrix Laboratories (Pvt) Ltd, Sy. No. 147, Ramilingampally Village Bommalaramaram, Yadadri-Bhuvanagiri District- 508 126		
API Lot No.	**Sofosbuvir:** RD-SFB(FORM VI)-201705161		
	Velpatasvir: OT-VCP002/67		
Description of Pack (Container closure system)	4x7's, in Alu Alu blister		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 (months) Real Time: 0,3,6 (months)		
Batch No.	T#001	T#002	T#003
Batch Size	2500	2500	2500
Manufacturing Date	04.2018	04.2018	04.2018
Date of Initiation	09.04.2018	09.04.2018	09.04.2018
No. of Batches	03		
Date of Submission	04.12.2018 (Dy. No. 39848)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API	**Sofosbuvir**; Yes **Velpatasvir;** Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sofosbuvir**; Copy of GMP certificate issued by Nantong Food & Drug Administration, valid upto 07-09-2020. **Velpatasvir;** Copy of GMP certificate issued by DCA Govt. of Telangana, valid upto 03-09-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Sofosbuvir:** Copy of commercial invoice attested by ADC DRAP Lahore, has been submitted
		Velpatasvir: Copy of commercial invoice attested by ADC DRAP Lahore, has been submitted
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	No
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcomings communicated	Response by the firm
In most of the chromatograms, the tailing factor is greater than 2.	• Upon Clarification, the firm submitted that "we had submitted our product specifications as 'Manufacturer's specifications'. Also attached are three USP reference monographs are attached herewith this letter for amoxicillin suspension (tailing factor = NMT 2.5), ceftriaxone injection (tailing factor = NMT 2) and Diclofenac potassium tablet (tailing factor not mentioned). So we humbly request to proceed our panel inspection of the product as **new column used in content uniformity test shows tailing factor less than 1.2** and also attached monograph, requirements vary from product to product and also in attached pharmacopeial monograph, requirements vary from product to product". However, some chromatograms of the new column have still tailing factor greater than 2.
The formulation requires content uniformity test as per USP general chapter.	• The firm mentioned weight variation test and determined average weight. Upon clarification, the firm submitted content (one time) uniformity test of the three batches. However, the summary sheets have average weight.

The results of disintegration time is 10-13 minutes and release in 15 minutes is 100% (CDP data).	Upon clarification, the firm submitted that DT and dissolution are totally different parameters as per pharmacopeia. Release profile can be available within very short time and it is not dependent upon disintegration time. Actual results of product for DT are 1-2 minutes and it was mistakenly as 10-12 minutes. This does not look appropriate justification. All the summary sheets have DT in the range of 10-13 minutes.
The assay has been performed and signed by Haidar Ali, but CoA depicts that the analyses are performed by Amna Basharat.	• Upon, clarification, the firm submitted that COA was signed by Ms Amna, because of her seniority and she supervises the analysis of Mr. Haider as well.
In almost all chromatograms, the theoretical plates are less than the pharmacopeial limit, i.e., 2000.	• Upon Clarification, the firm submitted that "we had submitted our product specifications as 'Manufacturer's specifications'. Also attached are three USP reference monographs are attached herewith this letter for amoxicillin suspension (theoretical plates not mentioned), ceftriaxone injection (theoretical plates = NLT 1500) and Diclofenac potassium tablet (theoretical plates not mentioned). So we humbly request to proceed our panel inspection of the product

The panel constituted for PSI by Chairman, Registration Board vide letter NO. F.13-11/2017-PEC (Vol.I) dated 06.03.2-2019 was advised to:

- Verify the method and data of content uniformity, performed for all three stability batches.
- Results of disintegration test.
- The date of initiation of stability studies from relevant log books.
- Raw data sheets (including information of sample, sample and standard weights, calculation formulae) for the whole stability studies.

The Board was appraised that the long term stability of APIs has been conducted at 25±2 °C / 60±5% RH. The Board was also appraised that the model of HPLC and software name have not been provided in the PSI.

Inspection report of M/s Wilshire Labs (Pvt.) Ltd., 124/1, Quaid e Azam Industrial Estate, Kot Lakhpat Lahore conducted on 23.05.2019.
Panel members: Dr. Shafiq ur Rahman (Director DTL, Lahore), Mrs. Aisha Irfan, (FID, DRAP, Lahore) and Ms. Maham Misbah (AD, DRAP Lahore)

Sr.#	Question	Observations
1	Whether the firm has documents confirming import of API?	Yes. Firm has imported 5Kgs Sofosbuvir from M/s. Nantong Chanyoo Pharmatech Co. Ltd., China vide invoice CY117221 dated 14.06.2017 and has clearance from DRAP, Lahore. Firm has imported Velpatasvir 1.5 Kgs from M/s Optrix Laboratories Pvt Ltd India vide invoice No. 011/EXP dated 13.05.2017 and has clearance from DRAP office Lahore.
2	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the manufacturer is its cGMP status, Drug Master File Study and study of API Specification. Firm has a complete protocol for vendor prequalification and evaluation (SOP reference No. WS/SC/SOP/G/04)
3	Whether documents confirm the import of API reference standard and impurity standards?	Firm had imported three impurities and working standards of Velpatasvir from principal manufacturer. Firm had also imported 15 impurities and Working standard of Sofosbuvir from principal manufacturer.
4	Whether the firm has certificate of Analysis of the API, reference standards and impurity standards from exporter?	Firm had certificates of analysis for the APIs, working standards and impurity standards
5	Whether the firm has any approval of API or GMP certificate of API	Firm had GMP certificate of Velpatasvir manufacturer issued by regulatory authority of India and GMP

	manufacturer issued by regulatory authority of country of origin?	certificate of Sofosbuvir manufacturer issued by regulatory authority of People 's Republic of China.
6	Whether firm use API manufacturer method of testing?	Firm had used API manufacturer's method for testing for API.
7	Whether firm has stability studies reports on API?	**Firm has accelerated and real time stability studies reports on API performed by manufacturer of API of Sofosbuvir and Velpatasvir**
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Stability testing has been performed as per SIM method and degradation products have been quantified by manufacturers of API of Velpatasvir and Sofosbuvir
9	Whether firm has method for quantifying the impurities in the API?	Firm has method for quantifying impurities in API obtained from both vendors of Sofosbuvir and Velpatasvir.
10	Whether firm has some remaining quantities of the API, its reference standard and impurities standards?	Firm had remaining quantities of working standards only.
11	Whether firm has used pharmaceutical grade excipients?	Excipients used are Croscarmellose Sodium, microcrystalline cellulose, magnesium stearate, Coating Material (Tabcoat). All Excipients are of Pharmaceutical Grade
12	Whether firm has documents confirming the import of the used excipients?	Yes.
13	Whether firm has test reports and other records on the excipients used?	Firm had certificates of analysis of API vendor and in-house Quality Control testing reports.
14	Whether firm has written and authorized protocols for the development of tablets?	Yes.
15	Whether firm has performed Drug-excipient compatibility studies?	Firm had not performed drug-excipient compatibility studies as the excipients used by the firm and innovator are the same.
16	Whether firm has performed comparative dissolution studies?	Firm had performed comparative dissolution studies with Ecplusa tablets manufactured by M/s Gilead Pharma. Equipments used for Comparative Dissolution Profile were weighing balance, Make/Model: Mettler Toledo MS 105 DU, Dissolution Tester, Make/Model: Guoming RC-8, HPLC, Made/Model: Agilent/1260.
17	Whether firm has product development (R&D) section	Yes.
18	Whether firm has necessary equipment available in product development section for development of finished product?	Firm has necessary equipment in product development section for manufacturing of Velpatasvir tablet 400/100mg. Rotary tablet compression machine, M/E-P-DPMG-029, Cone Mixer, L/E-PD-001, coating pan, L/E-PD-004 & Blister machine -02, M/E-P-DPPG-002 were used. Blistering machine of commercial production section was used.
19	Are the equipment in product development section qualified?	Yes.
20	Whether firm has proper maintenance / calibration / re- qualification program for the equipment used in PD section?	Yes.
21	Whether firm has qualified staff in product development section with proper knowledge and training in product development?	Yes.
22	Whether firm has manufactured three stability batches for the stability studies of finished product tablets as required?	Firm had manufactured three stability batches for the stability studies of Velbuvir tablet with batch number T001, T002 and T003 batch sizes of 2500 tablets, 2500 tablets and 2000 tablets, respectively.
23	What was the criteria for fixing the batch size of stability batches?	As stated by the firm's management, criteria for fixing batch size of stability batches was the number of tablets per testing and testing frequency provided by DRAP.

24	Whether firm has complete record of production of stability batches?	Firm had BMRs of all three stability batches.
25	Whether firm has protocols for stability testing of stability batches?	Yes. Stability Chamber with 1000L capacity having ID No: WS-QA-E-003 & WS-QA-E-006& Qualification Nos: WS-QA-E-PQR-001a &WS-QA-E-PQR-001b were used for accelerated & real time studies.
26	Whether firm has developed and validated the method for testing of stability batches?	Yes.
27	Whether firm has method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable.
28	Whether firm has documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes.
29	Whether firm has stability indicating method of analysis?	Yes.
30	Whether firm has HPLC software 21CFR compliant?	**Yes.**
31	Whether firm could you show Audit Trail reports on sofosbuvir testing?	Yes.
32	Whether firm has some remaining quantities of degradation products and stability batches?	Firm had remaining quantities of stability batches.
33	Whether firm has commitment batches kept on stability testing?	Firm had three commitment batches kept on stability testing.
34	Whether firm has valid calibration status for the equipment used in sofosbuvir tablets production and analysis?	Yes.
35	Do proper and continuous monitoring and control are available for stability chamber?	Firm's stability chambers were calibrated and equipped with digital data loggers and alarms. Firm was advised to effectively monitor the data to control excursions.
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Firm had cGMP compliance certificate from DRAP (Ref. No. 199/2018-DRAP (AD-619541-533 dated 15.11.2018 and valid for one year.)

Conclusion:-

With reference to DRAP, Islamabad letter No. F.13-11/2017-PEC (Vol.I) dated 06.03.2-2019 the inspection of M/s Wilshire Laboratories was conducted on 23-05-2019. Additional four points mentioned in above-mentioned letter were also verified during the inspection. On the basis of risk-based approach, the genuineness/authenticity of stability data submitted for registration of Velbuvir 400mg/100mg tablets is verifiable to satisfactory level and it seems that M/s Wilshire Laboratories have performed stability studies. Related manufacturing area, equipment, personnel and utilities are also rated as GMP compliant to satisfactory level.

Previous decision	The Board in its 290th meeting deferred the case for: i. Submission of stability data of API conducted in Zone IV, or **ii.** Conducting complete long term stability studies of finished product.
Evaluation by PEC	The panel submitted that "Firm had performed comparative dissolution studies with Ecplusa tablets manufactured by M/s Gilead Pharma. Equipments used for Comparative Dissolution Profile were weighing balance, Make/Model: Mettler Toledo MS 105 DU, Dissolution Tester, Make/Model: Guoming RC-8, HPLC, Made/Model: Agilent/1260'. However, it has been indetified that the firm has performed CDP on batch T002, wherein the disoolution/release trends in 0.1 N HCl go down with the passage of time in both the reference and test product. Moreover, the firm has performed CDP study at pH 5.0 in sodium acetate buffer. However, the medium specified by USFDA is 50 mM sodium acetate buffer, pH 5.0, with 0.5% w/v Cetyltrimethyl ammonium bromide (CTAB). USFDA has specified time point for sampling as 5, 10, 15, 20 and 30 min, however, the firm has performed CDP at 15, 30, 45 and 60 min. Justification is required.

	The CDP data is placed before the Board.
Decision	The Board discussed the following reply of the firm: ➢ **Dissolution trend of 0.1N HCl decline with the passage of time for both reference and test products** • Velbuvir tablet exhibit similar behavior as compared to reference product in 0.1 N HCl medium. Based on the this analogy, please refer to Dissolution Discussion Group web page http://www.dissolution.com/ddg/showthread.php?1032-decrease-in-dissolution *"we more or less experienced the same problem with an immediate release dose form. It seemed that, especially at the early time-points the distribution of our component in the dissolution medium was not homogeneous. At later time-points the medium is more homogeneous, resulting is a lower result than expected".* • The same decline behavior was discussed during WHO 2nd Quality workshop for manufacturer 3rd to 5th July 2019 Copenhagen with Lead PQTm Miss Lynde Paleshnuik, her opinion was that due to incompatibility of medium with API's, at initial time points higher release of contents will be achieved, while at higher time points the API will be degraded and results in lower content release. • One more aspect is Velpatasvir is 50% dispersion of Cross Povidone which when combine with Sofosbuvir exhibit uneven trend in 0.1N HCl medium, as our individual API Sofosbuvir in Ziqar 400mg tablet complies with USP criteria of more than 85% release in 15 minutes in same medium. ➢ **Medium of Choice pH 5.0 in sodium acetate buffer specified by USFDA is 5Mm sodium acetate with 0.5% w/v Cetyltrimethyl ammonium bromide (CTAB).** • Our Velbuvir tablet CDP Report document number WS-QC-CDR-030 on page 04 specifies; Buffer Solution Preparation: 0.05 M Sod Acetate buffer add (6.8039 g) of sodium acetate in 800 ml of water then maintain the pH 5.0 of this solution and add 0.5% of Cetyl trimethyl ammonium bromide CTAB i-e., (5g) and make up the volume to 1 Litre. ➢ **USFDA has specified time points for sampling as 5, 10, 15, 20 and 30 min, while firm has performed CDP at 15, 30, 45 and 60 minutes.** Please refer to the following guidelines; • https://www.drugfuture.com/Pharmacopoeia/USP32/pub/data/v32270/usp32nf27s0_c1092.html **Dissolution Chapter <1092> USP specifies "**Thus, dissolution time points in the range of 15, 20, 30, 45, and 60 minutes are usual for most immediate-release products". • https://www.fda.gov/media/70936/download Guidance for industry Dissolution testing of immediate release dosage form specifies at page # 09 "The dissolution measurements of the test and reference batches should be made under exactly the same conditions. The dissolution time points for both the profiles should be the same (e.g., 15, 30, 45, 60 minutes)". • https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence-rev1_en.pdf Doc. Ref.: CPMP/EWP/QWP/1401/98 Rev. 1 specifies at page 20 & 21 "Similarity of dissolution profiles, Dissolution profile similarity testing and any conclusions drawn from the results (e.g. justification for a bio-waiver) can be considered valid only if the dissolution profile has been satisfactorily characterized using a sufficient number of time points. For immediate release formulations, further to the guidance given in section 1 above, comparison at 15 min is essential to know if complete dissolution is reached before gastric emptying. Where more than 85% of the drug is dissolved within 15 minutes, dissolution profiles may be accepted as similar without further mathematical evaluation. In case more than 85% is not dissolved at 15 minutes but within 30 minutes, at least three time points are required: the first time point before 15 minutes, the second one at 15 minutes and the third time point when the release is close to 85%". • https://www.tga.gov.au/book/152-comparative-dissolution-profiles-biopharmaceutic-studies 15.2 Comparative dissolution profiles for biopharmaceutic studies specifies that "The percentage of nominal content released are measured at a minimum of three (3) suitably spaced time points (excluding zero-time point) to provide a profile for each batch (e.g. at 5, 15, 30 and 45 minutes, or as appropriate to achieve virtually complete dissolution)".
	Previous decision: The Board after thorough deliberation decided to defer the case for scientific justification from the firm regarding anomalous release profile of the formulation.
	Reply of the firm: In already submitted chromatograms with CDP report WS-QC-CDR-030 for Sofosbuvir API, One Peak observed in Standard and Sample chromatograms having retention time of 1.5 minutes and Peak height of 50 mAU observed at initial time point, at higher time points the same Peak height observed in Standard with Peak Height of 50 to 100mAU difference and at 60 minutes chromatogram, peak height reaches up to 450 mAU. ➢ *Literature review has revealed that Acid degradation in pure API leads to isolation of Sofosbuvir*

	impurity which was 2.5% after 06 hours and 22.5% after 24 Hours in 0.1N HCl. ➢ Scientific rationale for our product is that our CDP samples were exposed for long durations after sampling and during HPLC analysis in trays with continuous sequence running for multipoint and multimedia dissolution. Sampling for 0.1N HCl medium was started from 07-11-18 12:15 p.m. and ends at 07-11-18 02:35 p.m., as per USP bracketing sequence for standard and samples as 05 replicates for Standard and 06 samples consequently for whole dissolution sequence, HPLC Start date and time in medium of choice was 07-11-18 17:16 p.m., then results calculation of medium of choice, 0.1N HCl medium sequence start time 08-11-18 17:25 p.m. as well as end time for 0.1N HCl medium sequence was 10-11-18 07:19 a.m., means after lapse time of almost 24 hours sequence running from start standard of medium of choice to samples of 0.1N HCl Starts, and last sample withdrawn by Autosampler after about 60 hours, which leads to column overloading and anomalous behavior of API, this behavior was further studied on (dated 25th September 2019) with fresh sampling at 30 minutes and 60 minutes and the average results of Sofosbuvir API for reference product were 98% and 96% while Velbuvir tablet 100% and 98% respectively, with no Acid degradation peak as shown in CDP report WS-QC-CDR-030 for Sofosbuvir. We have concluded that, for Sofosbuvir API, Fresh 0.1 N HCl medium dissolution samples must be analyzed on HPLC and Analyst was trained for the same to analyze fresh samples for each medium, as compared to continuous sequence running for 02 to 03 days old samples on HPLC. ➢ Furthermore, as we are comparing Pilot Scale Velbuvir tablets with commercial lots of reference test products, in our scale up commercial batches, USP criteria of NLT 85% in 15 minutes will be achieved in Fresh Samples of 0.1N HCl medium and we will share our 1st commercial batch data with DRAP for the same.
Decision: Registration Board decided to approve registration of "Velbuvir tablet 400/100mg' by M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lukhpat, Lahore. Manufacturer will place first three production batches of both products on long term stability studies throughout the proposed shelf life and on accelerated studies for six months.	

Agenda of Evaluator PEC-V

Registration applications for local manufacturing of (veterinary) drugs

a. New Cases

96.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Bromovetz Oral Liquid 100ml
	Composition	Each 100ml Contains: Bromohexine HCl…2% Menthol…4%
	Diary No. Date of R&I & fee	Dy No. 26841; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Expectorant
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	100ml De-Controlled
	Me-too status	075611 ; "Mentobrom Oral Liquid M/s. Delux Chemicals Industries, Karachi "100ml,250ml,500ml,1000ml"
	GMP status	26 & 27-7-2019Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	
	Decision: Approved.	
97.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	Adevetz Oral Liquid
	Composition	Each ml Contains: Vitamin A…100,000 IU Vitamin D3…40,000 IU Vitamin E…40mg
	Diary No. Date of R&I & fee	Dy No. 26842; 06-08-2018 ; Rs.20,000
	Pharmacological Group	Multivitamin

	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	50ml,100ml,150ml,500ml,1000ml / De-Controlled
	Me-too status	058991; "Ade-Max Oral Solution of M/s. Nawan Lab, Karachi "100ml,500ml, 1 liter "
	GMP status	26 & 27-7-2019Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	----
	Decision: Approved.	
98.	Name and address of Manufacturer / Applicant	M/s Vetz Pharmaceutical (Pvt) Ltd. Plot # Q-1, S.I.T.E, Kotri, Sindh
	Brand Name+DosageForm+Strength	3D-Wormer Oral Liquid
	Composition	Each 100ml Contains: Albendazole…10gm Trichlabendazole…12gm Ivermectin…0.2gm
	Diary No. Date of R&I & fee	Dy No. 26843; 06-08-2018 ; Rs.20,000
	Pharmacological Group	N/A
	Type of Form	Form 5
	Finished Product Specification	Vetz Specs
	Pack Size & Demanded Price	N/A De-Controlled
	Me-too status	058941 "Thunder Drench "M/S. Star Labs, Lahore "50ml,100ml,200ml,250ml,500ml"
	GMP status	26 & 27-7-2019Conclusion: Based on the above observations their current GMP compliance level is rated as good.
	Remarks of Evaluator	----
	Decision: Approved.	
99.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtain Chowk Defence Road, 1 km towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Amoxi- CD Powder
	Composition	Each gram contains: Amoxicillin as Trihydrate ……...200gm Colistin Sulphate……800MIU
	Diary No. Date of R& I & fee	Dy.No.26772-B dated 03-08-2018 Rs.20,000/- DUPLICATE Dated 03-08-2018
	Pharmacological Group	Penicillin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5gm, 10gm, 25gm, 50gm, 100gm, 150gm, 200gm, 250gm, 500gm, 1kg, 2kg, 2.5kg, 5kg, 10kg, 15kg, 20kg and 25kg & Decontrolled
	Me-too status	Amoxicol Powder of M/s Farm Aid Group Pakistan Haripur (Reg. # 057106)
	GMP status	Last GMP inspection was conducted on 02-03-2018 and the report concludes renewal of DML.
	Remarks of the Evaluator	Oral Powder Penicillin Section (Veterinary) GMP report.
	Decision: Approved. Reference will be sent to Budget & Accounts Division for verification of challan and Board authorized its Chairman for the issuance of registration letter.	
100.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtain Chowk Defence Road, 1 km towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	Calcium Fortified Powder

	Composition	Each kg contains: Procaine Penicillin G…….30gm Penicillin- G Sodium……9.1gm Streptomyin Base (as Sulphate)……..…133gm Riboflavin……..1667mg Calcium Pantothenate (B-5)……..6667mg Niacin…….16.7mg Pyrodoxine HCl (VIT B6)……2.5gm VIT- B12 Activity……..……...25mg VIT- A……..……6666667Units VIT- D3……..……166667Units VIT- E.....25000 Nenadione Sodium Bisulfite (Source of VIT- K Activity)……...25000mg Folic Acid……....417mg Cholinc Bitartarate…….8333mg
	Diary No. Date of R& I & fee	Dy.No.26772-E dated 03-08-2018 Rs.20,000/- DUPLICATE Dated 03-08-2018
	Pharmacological Group	Penicillin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5gm, 10gm, 25gm, 50gm, 100gm, 150gm, 200gm, 250gm, 500gm, 1kg, 2kg, 2.5kg, 5kg, 10kg, 15kg, 20kg and 25kg & Decontrolled
	Me-too status	Flox Aid Fortified Powder of M/s MSD Karachi (Reg. # 002033)
	GMP status	Last GMP inspection was conducted on 02-03-2018 and the report concludes renewal of DML.
	Remarks of the Evaluator	Oral Powder Penicillin Section (Veterinary) GMP report.
	Decision: Approved with change of brand name. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board	
101.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtain Chowk Defence Road, 1 km towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	OPT Injection I/M, I/V, S/C
	Composition	Each 100ml contains: Oxytetracycline HCl……..5gm Prednisolone Acetate……..…500mg Tylosin Tartrate……...10gm
	Diary No. Date of R& I & fee	Dy.No.26771-A dated 03-08-2018 Rs.20,000/- Dated 03-08-2018
	Pharmacological Group	Anti-bacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50ml & Decontrolled
	Me-too status	Tylo OP Injection of M/s Leads Pharma (Pvt.) Ltd., Islamabad (Reg. # 041216)
	GMP status	Last GMP inspection was conducted on 02-03-2018 and the report concludes renewal of DML.
	Remarks of the Evaluator	Liquid injectable (Veterinary) is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Registration Board deferred the application for verification of section/manufacturing facility for "Liquid Injection (steriodal)" section.	

Registration applications for local manufacturing of (Human) drugs

Deferred cases

102.	Name and address of manufacturer / Applicant	M/s Glitz Pharma, Plot # 265, industrial triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Raze Tablet 4mg
	Diary No. Date of R& I & fee	Dy. No. 16975; 04-10-2017; Rs.20,000/- (02-10-2017)
	Composition	Each film coated tablet contains: Risperidone…..4mg
	Pharmacological Group	Antipsychotic ATC Code: N05AX08
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	6's,10's,20's;30's,28's,42's,50's, 100's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Risperdal Film Coated tablets MHRA approved
	Me-too status	Registration Number: 027656 Brand Name: Benzisox Tablets 4mg Manufacturer Name : Highnoon Laboratories Ltd,
	GMP status	GMP certificate granted on the basis of inspection conducted on 19-09-2017.
	Remarks of evaluation	Approved in USFDA with box warning.
	Previous Decision(285): Deferred for submission of latest GMP inspection report which should have been conducted within the period of last one year.	
	Evaluation by PEC: 16-01-2019 Conclusion: Keeping in view the observations noted during inspections as narrated above, the panel is of the opinion that the firm has rectified the observations noted in the previous panel inspection conducted on 16th January, 2019 and decided to recommend the issuance of GMP certificate.	
	Decision: Approved.	

103.	Name and address of manufacturer / Applicant	Hygeia Pharmaceuticals, Plot #295, industrial triangle Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Azitek tablets
	Diary No. Date of R& I & fee	Dyn:1049, 18-4-2016, Rs.20,000/-
	Composition	Each film coted tabled contains Azithromycin…….500mg
	Pharmacological Group	Macrolide, Antibiotics
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x6's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX by Pfizer (USFDA)
	Me-too status	Azitma by Sami
	GMP status	Last GMP Inspection dated 8-12-2015 with conclusive remarks of cGMP compliance.
	Remarks of the Evaluator.	Latest GMP inspection report (which should have been conducted within the period of last one year) missing
	Previous Decision (M-274)	Deferred for latest GMP inspection report conducted within past one year.
	Evaluation by PEC	Date of Inspection: 21-09-2017 Purpose: Routine GMP Inspection Conclusion: Satisfactory
	Previous Decision(277): Deferred for clarification of salt form of API	
	Fresh Evaluation: Firm has revised their formulation from "Each film coated tabled contains : Azithromycin…….500mg" to "Each film coated tabled contains: Azithromycin as	

	dihydrate…….500mg".	
	Decision: Approved.	
104.	Name and address of Manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name+DosageForm+Strength	Allernil Syrup 2mg/5ml
	Composition	Each 5ml Contains: Chlorpheniramine Maleate…2mg
	Diary No. Date of R&I & fee	Dy No.24904; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti allergic/ Arylalkylamine
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	60ml, As per DRAP policy.
	Approval status of product in Reference Regulatory Authorities	Chlorpheniramine Maleate 2mg/5ml Syrup Discontinued in USFDA.
	Me-too status	068446 "Colen Syrup "Alliance Pharmaceuticals (Pvt) Ltd, 112-A, Hayatabad Industrial Estate Jamrud Road Peshawar.
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of Evaluator	Chlorpheniramine oral solution is present in BP.
	Previous Decision (M-287):: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Justification for submitted finished product specifications, since firm has referred to BP monograph, which is "Chlorpheniramine oral solution" whereas firm has applied for "Chlorpheniramine Syrup".	
	Fresh Evaluation: i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. **Allernil 2ml/5ml by GSK** ii. Justification for submitted finished product specifications, since firm has referred to BP monograph, which is "Chlorpheniramine oral solution" whereas firm has applied for "Chlorpheniramine Syrup". F**irm has not provided justification.**	
	Decision: Deferred for the following reasons: **i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** ii. **Justification for submitted finished product specifications, since firm has referred to BP monograph, which is "Chlorpheniramine oral solution" whereas firm has applied for "Chlorpheniramine Syrup".**	
105.	Name and address of Manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name+DosageForm+Strength	Parkomef DS 100mg/5ml Syrup
	Composition	Each 5ml Contains: Mefenamic Acid…100mg
	Diary No. Date of R&I & fee	Dy. No.24907; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti Pyretic, Analgesic & Anti-Inflammatory
	Type of Form	Form 5
	Finished Product Specification	
	Pack Size & Demanded Price	60ml
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed.
	Me-too status	039179 Deemac Forte Suspension by Delux Chemical, Karachi
	GMP status	Grant of DML Approved dated:11-04-18

	Remarks of Evaluator	• Approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting could not be confirmed. • Applied formulation/drug me-too status could not be confirmed.
	Previous Decision(M-287): Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Fresh Evaluation i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. Mefenamic acid suspension by Chemidex Pharma (MHRA Approved) ii. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. Ponstel Suspension **Conclusion** The provided international availability and Me too is of suspension whereas, the applied formulation is syrup.	
	Decision Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
106.	Name and address of Manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name+DosageForm+Strength	Bactran Syrup (40/200 mg)/5ml
	Composition	Each 5ml Contains: Trimethoprim…40mg Sulphamethoxazole…200mg
	Diary No. Date of R&I & fee	Dy No.24903; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti-Bacterial
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	50ml
	Approval status of product in Reference Regulatory Authorities	Trimethoprim+Sulphamethoxazole 40+200mg By Teva , USA
	Me-too status	002322 "Lobact Paed Suspension By" " Leama Chemi Pharma (Pvt) Ltd,
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of Evaluator	• Sulfamethoxazole And Trimethoprim Oral Suspension is present in IP2018 and USP 2017. • International availability and Me too could not be confirmed.
	Previous Decision(M-287): Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
	Fresh Evaluation: Deferred for following: i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. USFDA ii. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status)	

	along with registration number, brand name and name of firm. 008752: SEPTRAN DS SUP by WELLCOME **Conclusion** The provided international availability and Me too is of suspension whereas, the applied formulation is syrup.	
	Decision Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	
107.	Name and address of Manufacturer / Applicant	M/s Parkar Pharma. Plot No. O/7-A, S.I.T.E Area Kotri, Sindh
	Brand Name+DosageForm+Strength	Bactran Syrup (80/400 mg)/5ml
	Composition	Each 5ml Contains: Trimethoprim…80mg Sulphamethoxazole…400mg
	Diary No. Date of R&I & fee	Dy No.24902; 18-07-2018 ; Rs.20,000
	Pharmacological Group	Anti Bacterial
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	50ml
	Approval status of product in Reference Regulatory Authorities	Sulfatrim Pediatri Sulfamethoxazole; Trimethoprim 200mg/5ml;40mg/5ml Suspension;Oral
	Me-too status	068292 "tran DS Suspension by "Imco Pharmaceutical Labs.,
	GMP status	Grant of DML Approved dated:11-04-18
	Remarks of Evaluator	• Sulfamethoxazole And Trimethoprim Oral Suspension is present in IP2018 and USP 2017. • International availability and Me too could not be confirmed.
	Decision (M-287): Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
	Fresh Evaluation: Deferred for following: i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. USFDA ii. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm. 008752: SEPTRAN DS SUP by WELLCOME **Conclusion** The provided international availability and Me too is of suspension whereas, the applied formulation is syrup.	
	Decision Deferred for following reasons: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.**	

Case no. 01 Registration applications of drugs for which stability study data is submitted

a. New cases

108.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Virata Tablet 60mg
	Composition	"Each film coated tablet Contains: Ticagrelor…..…60mg"
	Diary No. Date of R& I & fee	Dy. No dated 28-08-2017 Rs.50,000/- Dated 24-08-2017
	Pharmacological Group	Anti-platelet aggregation
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	
	Remarks of the Evaluator[II]	

Now the firm has submitted stability data detailed as under:

STABILITY STUDY DATA

Drug	Virata Tablet 60mg		
Name of Manufacturer	M/s CCL Pharmaceuticals Pvt. Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore.		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd., Jiangsu province, China.		
API Lot No.	RD-TG-201712111		
Description of Pack (Container closure system)	Alu-Alu foil in unit carton		
Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 months Real Time: 0,3,6 months		
Batch No.	T2/8	T3/8	T4/8
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	26-09-2018	26-09-2018	26-09-2018
No. of Batches	03		
Date of Submission	09-03-2019 (Dy. No. 5737)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Documents To Be Provided	Status
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP Certificate for M/s Nantong Chanyoo, China issued by Nantong Chemical & Medical Association has been submitted, valid upto 03-11-2020.
Protocols followed for conduction of stability study and details of tests.	Yes

Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	• Copy of invoice for Ticagrelor (60Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 16-01-2018 has been submitted.
All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
Commitment to continue real time stability study till assigned shelf life of the product.	Yes
Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Observations communicated	**Firm's response**	**Remarks by PEC**
Submit clarification regarding the polymorphic form of Ticagrelor as it is not evident from the submitted COA from supplier while the FDA chemistry review mentions four polymorphic firms and only one form is not converted into other form, on storage.	Crystalline form II of Ticagrelor was used. Drug Master File (DMF) of Ticagrelor contains the complete detail of its polymorphic form. Rationale behind selecting this form was the innovator i.e., AstraZeneca used Ticagrelor with CAS # [274693-27-5]. CCL also used Ticagrelor with same CAS # [274693-27-5] from Nantong Chanyoo Pharmatech, China source (document attached as	Registration Board has also specified Polymorphic form II for Ticagrelor.
The acceptance criteria of dissolution test submitted by firm for applied formulation is NLT 70% (Q) after 75 minutes. While the USP chapter <1092> (The Dissolution Procedure; Development and Validation) recommends Q values in the range of 75% - 80% for immediate release dosage forms and moreover the finished product specification of the innovator product i.e., "Brilinta", revealed in chemistry review by USFDA (Ref: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022433Orig1s000ChemR.pdf) specify the acceptance criteria of dissolution test as "Shall comply with requirements of USP for Q at 45 minutes and at 60 minutes. Hence justification shall be provided for the acceptance criteria of dissolution test, both in terms of the value of Q and sampling time, with reference to above cited references.	As per comparative dissolution profile performed for Virata showed that release of Ticagrelor in medium 0.2% w/v Polysorbate 80 in water after 45 minutes was 87% & at 60 minutes, the release was 90%. Initially, parameters for dissolution were taken from USFDA dissolution test method database that proposed sampling time of 75 minutes (copy attached as **Annexure-III**). As your good self-highlighted the document of chemistry review, which suggest sampling point of, 45 minutes & 60 minutes for Q value (based on comparison made with reference product during its CDP in medium 0.2% w/v Polysorbate (Tween) 80 in water) (document attached as **Annexure-III).** It is evident from profiling that changing in sampling point would have no significant impact on dissolution of Ticagrelor which can be verified during on-site inspection.	The comparative dissolution profile and dissolution studies at future long-term stability study time points could not be representative/alternate of the accelerated stability studies, hence these performance tests could not be relied upon to infer the accelerated stability study results.
In contrary to the reference product firm has not used "Dibasic calcium phosphate" in the master formulation. Clarification shall be	Initial formulation contains both diluents i.e., Mannitol and Dibasic calcium phosphate as per innovator. However, in initial trial, pitting and	Drug excipient compatibility study of API with Dibasic calcium phosphate shall

submitted in this regard.	poor powder flow at compression stage was observed. In next trial, we proceeded by excluding Dibasic calcium phosphate and trial compliance was observed both at physical & chemical stages. Stability studies of trial batches were performed and accordingly submitted to DRAP. Data can be verified during on-site inspection.	be established.
The submitted chromatograms for Assay test at "Zero time point" for all three stability batches declare that "Peak (s) manually integrated. Justify the reason for manually integrating the peak for Ticagrelor.	We assure that no major peak has been integrated which can be verified during on-site inspection. Moreover, this practice shall be discouraged from future onwards.	The draft "Good Chromatography practices guidelines" of WHO discourages the manual integration of peaks during chromatographic analysis and requires justification. Moreover the peak selection in the submitted chromatograms of initial time point is not uniform
The absorbance results for the dissolution test at "Zero time point" are in the range of "0.800 – 0.900", while the absorbance results for the dissolution test at 3rd and 6th time point are in the range of "0.100 – 0.200". Justify the variation in results of absorbance values, while following the same product testing method.	As per stability data sheet, the results of dissolution test are well within specified limits. The difference of absorbance range is due to preparation of standard and sample solutions at low concentration resulting in low absorbance value. Analysis of upcoming stability time points will be done as per testing method.	Firm has not submitted any raw data sheet from which the said dilution making could be confirmed. Moreover the clarification sub mitted by firm declares that they haven't followed their own finished product testing method.
Valid GMP certificate of M/s Nantong Chanyoo, Jiangsu province, China, issued by the relevant Provincial or state Regulatory authority shall be submitted since the submitted GMP certificate is issued by the Nantong Chemical & Medical Association.	Nantong Chemical & Medical Association is authorized to issue submitted GMP Certificate. In addition, M/s Nantong Chanyoo is authorized by Jiangsu FDA to export its materials to Europe USFDA also inspected M/s Nantong Chanyoo and considered said facility as cGMP compliant (document attached as	The Nantong Chemical & medical Association is not the relevant provincial regulatory authority for M/s Nantong Chanyoo.

Decision: Registration Board deferred the case for following:

i. **Scientific justification that how comparative dissolution profile or dissolution studies (with revised limits as per reference product) at future long-term stability study time points could be representative/alternate of the accelerated stability studies which have been performed with the limits of NLT 70% (Q) after 75 minutes.**
ii. **Justification for manual integration of the chromatograms for Assay test at "Zero time point" for all three stability batches. Moreover the peak selection in the submitted chromatograms of initial time point is not uniform.**
iii. **Clarification for not following the product test method for dilution making, while performing the dissolution test in stability studies.**
iv. **Submission of raw data sheets from which the exact dilution making for dissolution test during stability studies is evident.**
v. **Valid GMP certificate of M/s Nantong Chanyoo, Jiangsu province, China, issued by the**

relevant Provincial or state Regulatory authority shall be submitted since The Nantong Chemical & medical Association is not the relevant provincial regulatory authority

c. Exemption from onsite verification of stability data

109.	Name and address of manufacturer / Applicant	M/s Wilson's pharmaceuticals, 387-388, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Sofvasc Trio Tablets 40/5/12.5mg
	Composition	Each film coated tablet contains: Olmesartan Medoxomil……..40mg Amlodipine as besylate…..…5mg Hydrochlorothiazide 12.5mg
	Diary No. Date of R& I & fee	Dy No.338 (11-12-2010/) Rs. 60,000 17-05-2013/
	Pharmacological Group	Antihypertensive agent, Diuretic
	Type of Form	Form-5D
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's ; Rs. 502 per tablet
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (Tribenzor tablets of Daiichi Sankyo, Germany)
	Me-too status	
	GMP status	GMP Inspection conducted on 24-01-2018 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.

STABILITY STUDY DATA

Drug	Sofvasc Trio Tablets 40/5/12.5mg		
Name of Manufacturer	M/s Wilson's pharmaceuticals, 387-388, Industrial Area, Islamabad.		
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd ,Maharashtra, India(Olmesartan Medoxomil) M/s Hetero Drugs Ltd (UNIT-IV) , Telangana, India(Amlodipine Besylate) M/s Suzhou Lixin Pharmaceuticals Co.Ltd ,China(Hydrochlorothiazide)		
API Lot No.	Lot #:83170554 (Olmesartan Medoxomil) Lot #:AM0331216 (Amlodipine Besylate) Lot #:C01-20170102 (Hydrochlorothiazide)		
Description of Pack (Container closure system)	Alu /Alu Blister Pack in Unit carton		
Stability Storage Condition	Accelerated:40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	Trial #01	Trial #02	Trial #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	22-02-2018	22-02-2018	22-02-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	• Copy of COA (batch #83170554) from M/s Glenmark Pharmaceuticals Ltd ,Maharashtra,

		India(Olmesartan Medoxomil) • Copy of COA (batch # AM0331216) from M/s Hetero Drugs Ltd(UNIT-IV) ,Telangana, India(Amlodipine Besylate) • Copy of COA (batch # C01-20170102) from M/s Suzhou Lixin Pharmaceuticals Co.Ltd ,China(Hydrochlorothiazide)
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	• Copy of GMP certificate (certificate No. 1708289) issued by Food & Drugs Administration, India. It is valid until 18-8-2019(Olmesartan Medoxomil) • Copy of GMP certificate (certificate No.1438/E(G)/TS/2018) issued by Drugs Control Administration, Telagana,India. It is valid until 04-04-2019(Amlodipine Besylate) • Copy of GMP certificate (certificate No.JS20140325) issued by Food & Drug Administration,China. It is valid until 25-8-2019(Hydrochlorothiazide)
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	• The firm has submitted copy of commercial invoice dated 18-09-2017(Olmesartan Medoxomil) attested by ADC, DRAP, Islamabad • The firm has submitted copy of commercial invoice dated 19-12-2016(Amlodipine Besylate) attested by ADC, DRAP, Islamabad • The firm has submitted copy of commercial invoice dated 09-03-2017(Hydrochlorothiazide) attested by ADC, DRAP, Islamabad
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 6months Accelerated and Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection reports of their product "Saferon tablets (Sofosbuvir 400 mg)", which was presented in 278th meeting of Registration Board held on 29-31st Jan, 2018 Observations: Software of HPLC present in the firm

		is 21 CFR compliant and audit trail on the testing reports was available and confirmed. Panel reviewed chromatograms for testing of API and trial batches at 0, 3 and 6 months for real time and accelerated stability testing. • **Decision:** Registration Board decided to approve registration of "Saferon (Sofosbuvir 400mg)" by M/s Wilson Pharmaceuticals, Islamabad. Manufacturer will place first three production batches on long term stability studies
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of commercial invoice dated 18-09-2017 declaring 10Kgs quantity of API (Olmesartan Medoxomil has been submitted which is attested by ADC, DRAP, Islamabad. Copy of commercial invoice dated 19-12-2016 declaring 300kgs quantity of API (Amlodipine Besylate) has been submitted which is attested by ADC, DRAP, Islamabad dated 29-12-2016. Copy of commercial invoice dated 09-03-2017 declaring 300Kgs quantity of API (Hydrochlorothiazide) has been submitted which is attested by ADC, DRAP, Islamabad dated 29-3-2017.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copies of invoices for working standard & impurity Standards regarding Amlodipine besylate, Olmesartan Medoxomil and Hydrochlorothiazide.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate declaring following information: **Certificate No**.1708289 **Issued to**: M/s Glenmark pharmaceuticals Ltd Plot No3109,GIDC.Industrial estate, Ankleshwar **Issued by**: Food & Drug Administration, Gandhagar Gujarat state India. **Validity**: Valid Till 18-08-2019. The firm has submitted copy of GMP certificate declaring following information: **Certificate No**.1438/E(G)/TS/2018 **Issued to**: M/s Hetero Drugs limited Unit IV Sy.No.599,Temple Road Bonthapally Village ,Gummadidala Mandal,Sangareddy District,Telangana State,India **Issued by**: Food & Drug Administration, Gandhagar Gujarat state India. **Validity**: Valid Till 04-04-2019. The firm has submitted copy of GMP certificate declaring following information: **Certificate No**.JS20140325 **Issued to**: M/s Suzhou Lixin Pharmaceuticals Co,Ltd No.21 Tangxi Road,Suzhou New District,Suzhou **Issued by**:Food & Drug Administration,China **Validity**: Valid Till 25-08-2019.
5.	Mechanism for Vendor pre-qualification	The firm has submitted SOP for Evaluation of Vendors.
6.	Certificate of analysis of the API, reference standards and impurity standards	Applicant has submitted following COAs: • Copy of COA olmesartan Medoxomil (batch #83170554) from M/s Glenmark Pharmaceuticals Ltd ,Maharashtra, India

<table>
<tr><td></td><td></td><td>

- Copy of COA of Amlodipine besylate (batch # AM0331216) from M/s Hetero Drugs Ltd(UNIT-IV) ,Telangana, India
- Copy of COA of Hydrochlorothiazide (batch # C01-20170102) from M/s Suzhou Lixin Pharmaceuticals Co.Ltd ,China
- Copy of COA of reference standard has been submitted
- Copy of COA impurity Standards Olmesartan olefinic, Olmesartan related compound A, Olmesartan impurity A, Olmesartan N-Alkyl impurity has been submitted.
- Copy of COA impurity Standards Hydrochorothiazide impurity A&B has been submitted.
- Copy of COA impurity Standards of Amlodipine impurity A, Amlodipine impurity D, Amlodipine impurity E, Amlodipine impurity F has been submitted.

</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of purchase order/Commercial invoices/COAs of all the excipients used in the formulation of applied product.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in R&D department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Sofvasc Trio Tablets 40/10/12.5mg”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 01</td><td>1500 tablets</td><td>02-2018</td></tr>
<tr><td>Trial # 02</td><td>1500 tablets</td><td>02-2018</td></tr>
<tr><td>Trial # 03</td><td>1500 tablets</td><td>02-2018</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th>Trial No</th><th colspan="2">Sofvasc Trio Tablets 40/5/12.5mg Remaining Quantity</th></tr>
<tr><th></th><th>Accelerated</th><th>Long Term</th></tr>
<tr><td>Trial # 01</td><td>110 tablets</td><td>216 tablets</td></tr>
<tr><td>Trial # 02</td><td>110 tablets</td><td>234 tablets</td></tr>
<tr><td>Trial # 03</td><td>110tablets</td><td>234 tablets</td></tr>
</table>
</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted photocopies of data logger record for chambers used in Real Time & Accelerated stability studies of applied product from 01-02-2018to 31-08-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopies of following:
Raw Material Test/Analysis Procedures & Raw Material Specifications of Amlodipine Besylate , Hydrochlorothiazide and Olmesartan Medoxomil (In-house+USP) & COAs for Olmesartan Medoxomil/Amlodipine Besylate/</td></tr>
</table>

		Hydrochorothiazide (Supplier/Manufacturer).
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopies of following: • FPP Test/Analysis Method & FPP Specifications (In-house) for Sofvasc Trio 40/10/12.5mg tablet along-with analytical record for complete stability studies.
15	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 60 Months Real Time Stability Study Data of 03 Batches of **Olmesartan Medoxomil** M/s Glenmark Pharmaceuticals Ltd ,Maharashtra, India , **Amlodipine besylate** 06 Months Accelerated and 36 Months Real Time Stability Study Data and **Hydrochorothiazide** 06month accelerated and 48 Months Real Time Stability Study M/s Suzhou Lixin Pharmaceuticals Co. Ltd ,China, as per Zone-IV a conditions.
16	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17	Drug-excipients compatibility studies.	Firm has declared that Drug-excipient compatibility studies is applicable since they have used similar qualitative formulation as that of innovator's product.
18	Record of comparative dissolution data.	The firm has performed comparative dissolution studies in three media including in 0.1NHCl, Acetate Buffer pH 4.5 and phosphate Buffer pH 6.8 with Tribenzor Tablets 40/10/12.5mg manufactured by M/s. Daiichi Sankyo, Germany Lot No: 0004213. The firm's product results are comparable to that of the comparator product.
19	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Audit trail on testing reports of applied formulation from 22-02-2018 to 22-08-2018 was submitted by the firm.

Remarks:

- Valid GMP certificates of all three API manufacturers shall be submitted.
- Protocol for stability testing has not been submitted.
- As per submitted batch manufacturing record, all the three trial batches have been compressed using single punch machine.
- You have not performed uniformity of dosage unit by content uniformity for in all the strengths, as recommended by USP General Chapter <905> throughout stability studies. Justification shall be submitted in this regard.
- Firm has performed CDP using 6 tablets each of the reference and applied product. Moreover f2 factor calculation has not been performed, although submitted results are comparable.
- Reference product literature declare the dissolution time as 30 minutes whereas firm has applied limit of 45 minutes for dissolution test

Decision: Registration Board deferred the case for justification of limits for Dissolution test in terms of time, since reference product literature declare the dissolution time as 30 minutes whereas firm has applied limit of 45 minutes for dissolution test.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Remarks
110.	M/s Wilson's Pharmaceuticals, I-9, Industrial Area Islamabad.	Sofvasc Trio Tablet Each Tablet contains: Olmesartan medoxomil USP 40mg Amlodipine besylate BP 10mg Hydrochlorothiazide BP 12.5mg. Anti-Hypertensive agent, Diuretic	Form-5-D Fast Track 10's, 20's&30's Rs.542/- Tablet 11-12-2010/3365. 17-05-2013/3125 Rs. 60,000/-	Tribenzor USFDA Approved 24-01-2018 Conclusion: "Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection."	

	Drug	Sofvasc Trio Tablet		
	Name of Manufacturer	M/s Wilson's Pharmaceuticals,I-9, Industrial Area Islamabad.		
	Manufacturer of API	Olmesartan medoxomil: M/s Glenmark Pharmaceuticals Ltd. India. Amlodipine besilate: M/s Hetero Drugs Limited (Unit-IV), India. Hydrochlorothiazide: M/s Suzhou Lixin Pharmaceutical Co.Ltd, China.		
	API Lot No.	Olmesartan medoxomil: 83170554 Amlodipine besilate: AM0321216, AM0331216 Hydrochlorothiazide: C01-20170102		
	Description of Pack (Container closure system)	Alu-Alu strip		
	Stability Storage Condition	Real Time: 30ºC ± 2ºC / 65% ± 5%RH Accelerated:40ºC ±2ºC / 75% ± 5%RH		
	Time Period	Real Time: 06 Months	Accelerated: 06 Months	
	Frequency	Real Time: 0,3,6 (Months)	Accelerated: 0,1,2,3,4,6 (Months)	
	Batch No.	Trial # 01	Trial # 02	Trial # 03
	Batch Size	1500 tablets	1500 tablets	1500 tablets
	Manufacturing Date	02-2018	02-2018	02-2018
	Date of Initiation	02-2018	02-2018	02-2018
	No. of Batches	03		
	Date of Submission	28-01-2019 (Dy. No. 3665)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	M/s Glenmark Pharmaceuticals Ltd. India: Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted. M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 1438/E(G)/TS/2018 issued by Drugs Control Administration (Telangana) India, valid up to

		04-04-2019 is submitted. M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. JS20140325 issued by Jiangsu Food and Drug Administration China, valid up to 25-08-2019 is submitted.
3.	Protocols followed for conduction of stability study and details of tests.	No
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Yes
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has provided 6 months Accelerated and 6 months Real Time Stability Study Data for 03 Batches.
- Dissolution parameters as submitted with Stability Study Data are as per USFDA recommended dissolution method.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection reports of their product "Saferon Tablets (Each film coated tablet contains Sofosbovir…..400mg) approved in 278th Meeting of Registration Board. 1. Firm presented test results of trial batches conducted at various time intervals (0, 3, 6 for both real time and accelerated stability testing) and real time testing at 9, 12, 18 and 24 months, which showed that trial batches were of standard quality during aforementioned test intervals. Moreover, both chambers have been provided with digital data loggers with record of test period since January, 2016. 2. Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed. Panel reviewed chromatograms for testing of API and trial batches at 0, 3 and 6 months for real time and accelerated stability testing.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**HYDROCHLORTHIAZIDE** ➢ **Details of ADC attested commercial Invoice** Invoice No. SZLX2017019A Quantity imported: 300 Kg ADC Attestation Date: 29-03-2017 Manufacturer: Suzhou Lixin Pharmaceutical Co. Ltd., No 21, Tangxi Road, Suzhou, New District, China Batch No.: C01-20170102 DOM: 19-12-2016 **AMLODIPINE BESYLATE** ➢ **Details of ADC attested commercial Invoice** Invoice No. 1000023678

		Quantity imported: 300 Kg ADC Attestation Date: 29-12-2016 Manufacturer: Hetero Drugs Limited,7-2-A2, Hetero Corporate, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, India Batch No.: AM0321216, AM0331216 DOM: 12-2016, **OLMESARTAN MEDOXOMIL** ➢ **Details of ADC attested commercial Invoice** Invoice No. 2007601342 Quantity imported: 10 Kg ADC Attestation Date: 16-10-2017 Manufacturer: M/s Glenmark Pharmaceuticals Ltd., Plot No. A-80, MIDC, Kurkumbh, Taluka-Daund, District- Pune, India. Batch No.: 83170554 DOM: 03-09-2017,
3.	Documents for the procurement of reference standard and impurity standards.	**HYDROCHLORTHIAZIDE** **Working Standard** 1g from 3J Diagnostic, TRC Canada **Impurities** Impurity A (Suzhou Lixin Pharmaceutical Co. Ltd) Impurity B (Suzhou Lixin Pharmaceutical Co. Ltd) Chlorthiazide Benzothiadiazine Related Compound A **AMLODIPINE BESYLATE WORKING STANDARD** **Working Standard** 25g from 3J Diagnostic, , TRC Canada **OLMESARTAN MEDOXOMIL WORKING STANDARD** **Working Standard** 1g from 3J Diagnostic, , TRC Canada **Olmesartan Impurity A (Synpure Labs)** **Olmesartan Olefenic Impurity (Synpure Labs)** **Olmesartan Related Compound A(Synpure Labs)** **Omlesartan Alkyl Impurity(Synpure Labs)**
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**HYDROCHLORTHIAZIDE** M/s Suzhou Lixin Pharmaceutical Co. Ltd, China: Photocopy of GMP Certificate No. JS20140325 issued by Jiangsu Food and Drug Administration China, valid up to 25-08-2019 is submitted. **AMLODIPINE BESYLATE** M/s Hetero Drugs Limited (Unit-IV), India: Photocopy of GMP Certificate No. 6208/E(G)/TS/2017 issued by Drugs Control Administration (Telangana) India, valid up to 21-04-2018 is submitted. **OLMESARTAN MEDOXOMIL** M/s Glenmark Pharmaceuticals Ltd. India: Photocopy of GMP Certificate No. 1708289 issued by Food & Drugs Control Administration (Gujarat) India, valid up to 18-08-2019 is submitted.
5.	Mechanism for Vendor pre-qualification	• The firm has submitted SOP for Mechanism for Vendor pre-qualification.

<table>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>
Photocopy of COAs of all three APIs, have been submitted. Detail is as under
<table>
<tr><th>API name</th><th>Batch No.</th><th>DOM</th></tr>
<tr><td>Olmesartan medoxomil</td><td>83170554 99.6%</td><td>09-2017</td></tr>
<tr><td>Olmesartan medoxomil Standard TRC Canada</td><td>27-SSR-73-1 98%</td><td></td></tr>
<tr><td colspan="3">Olmesartan Olefinic Impurity Synpure Labs</td></tr>
<tr><td colspan="3">Olmesartan Related Compund A Synpure Labs</td></tr>
<tr><td colspan="3">Olmesartan Impurity A</td></tr>
<tr><td colspan="3">Olmesartan N-Alkyl Impurity</td></tr>
<tr><td>Amlodipine besilate</td><td>AM0331216 99.37% Anhy.</td><td>12-2016</td></tr>
<tr><td>Amlodipine Working standard</td><td>5-SCC-113-1 98%</td><td></td></tr>
<tr><td>Hydrochlorthiazide</td><td>C01-20170102 101.2%</td><td>12-2016</td></tr>
<tr><td>Hydrochlorthiazide Working Standard</td><td>2-SCC-58-1 98%</td><td></td></tr>
<tr><td colspan="3">Impurity A Lixin</td></tr>
<tr><td colspan="3">Impurity B Lixin0</td></tr>
</table>
Amlodipine Working standard Storage Condition Freezer.
</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development comprising of 16 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>
The firm has submitted photocopy of “Authorized protocols/SOP for Development.
</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of the following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial No.01</td><td>1500 Tablets</td><td>02-2018</td></tr>
<tr><td>Trial No.02</td><td>1500 Tablets</td><td>02-2018</td></tr>
<tr><td>Trial No.03</td><td>1500 Tablets</td><td>02-2018</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Batch No.</th><th>Remaining tablets Accelerated</th><th>Remaining tablets Real time</th></tr>
<tr><td>Trial No.01</td><td>110</td><td>216</td></tr>
<tr><td>Trial No.02</td><td>110</td><td>234</td></tr>
<tr><td>Trial No.03</td><td>110</td><td>234</td></tr>
</table>
</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity</td><td>The firm has submitted photocopies of printouts of data logger charts for Real Time and Accelerated Conditions starting from 02-</td></tr>
</table>

<table>
<tr><td></td><td>monitoring of stability chambers (real time and accelerated)</td><td>2018 to 08-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>COA of supplier along with COA of manufacturer of finished product.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• The firm has submitted following documents:
Photocopy of Product Specifications & Method of analysis
• Stability Protocols.
• Analytical method validation report.
• Record of testing of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Olmesartan medoxomil
Accelerated: 6 month
Long term : 36 month.
Amlodipine Besilate
Accelerated: 6 month
Long term : 36 month.
Hydrochlorthiazide
Accelerated: 6 month
Long term : 36 month.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Sofvasc Trio Tablets.
<table>
<tr><th>Excipient</th><th>Batch No.</th><th>Supplier</th></tr>
<tr><td>Red Color 40 Lake</td><td>2016118</td><td>M.S. Corporation</td></tr>
<tr><td>Avicel pH 200</td><td>175012012</td><td>Blanver</td></tr>
<tr><td>Magnesium Stearate</td><td>MS-T-17015</td><td>S Kank Healthcare, India</td></tr>
<tr><td>Titanium Dioxide</td><td>170216</td><td>Al-Burque
Manufacturer:
Jiangsu Hongyuan</td></tr>
<tr><td>Pharmacoat 606</td><td>7078281</td><td>CBC Co. Ltd
Manufacturer
Shin Etsu Chemical</td></tr>
<tr><td>Croscarmellose Sodium</td><td>D205160059</td><td>Irfan Traders
Manufacturer
Accent Microcell, India</td></tr>
<tr><td>Starch</td><td>C7111618</td><td>Rafhan Maize</td></tr>
</table></td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not performed Drug-excipients compatibility studies and has referred to monographs of Hand-book of Pharmaceutical Excipients in this regard.
• Moreover, they have claimed that Ingredients of Sofvasc Trio and Tribenzor are same.
However, the coating material is not similar.
<table>
<tr><th>Tribenzor</th><th>Sofvasc Trio Tablet</th></tr>
<tr><td>Silicified MCC</td><td>MCC</td></tr>
<tr><td>Pregelatinized Starch</td><td>Starch</td></tr>
<tr><td>Croscarmellose Sodium</td><td>Croscarmellose Sodium</td></tr>
<tr><td>Magnesium Stearate</td><td>Magnesium Stearate</td></tr>
<tr><td>PVA</td><td>HPMC</td></tr>
<tr><td>PEG 3350</td><td>-</td></tr>
<tr><td>Titanium Dioxide</td><td>Titanium Dioxide</td></tr>
<tr><td>Talc</td><td>-</td></tr>
<tr><td>Iron Oxide Red</td><td>Iron Oxide Red</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted comparative Dissolution studies report. The details of reference product & Sample product are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Wilson</th></tr>
<tr><td>Brand name</td><td>Tribenzor 40/10/12.5mg</td><td>Sofvasc Trio Tablet</td></tr>
<tr><td>Batch No.</td><td>0004213</td><td>Trail 01</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
i. pH 1.2 HCl buffer
ii. Acetate buffer pH 4.5
iii. Phosphate Buffer pH 6.8</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulation</td></tr>
<tr><td colspan="3">
<table>
<tr><th>Deficiencies/ Short-comings</th><th>Firms Response</th></tr>
<tr><td>• Submit raw data sheets of all time points. Provide concentrations of standard and sample solution used in assay and dissolution, as it is not clear from the provided method.

• Impurities analysis not performed for finished product. Clarify and justify.

• Potency adjustment has not been done for API’s as evident in BMR. Clarify and justify.</td><td>• Firm has submitted raw data sheets mentioning potency of API instead of standard in the calculations having purity 100%.
Firm has submitted that stability studies of finished product percentage of all three APIs are found to be within limits i.e. no degradation in results observed uptil now nd committed if any variations in result observed we will perform degradation studies and will submit data.

Firm has submitted potency adjustment is not required as assay is 100% as per BMR.</td></tr>
</table>
The firms dissolution Specs are NLT 85% is dissolved in 45 minutes whereas, innovators specs mentions 30 minutes.
</td></tr>
<tr><td colspan="3">Decision: Registration Board deferred the case for justification of limits for Dissolution test in terms of time, since reference product literature declare the dissolution time as 30 minutes whereas firm has applied limit of 45 minutes for dissolution test.</td></tr>
</table>

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
111.	**Genix Pharma (Pvt.) Ltd.** Karachi	Diacan 100mg Tablets Each film coated tablet contains: - Canagliflozin ……100mg (Innovator's Specifications)	Form 5D 04-09-2014, Fee: 50,000/- As per SRO	EMC Invokana Tablets 100mg, Janssen-Cilag ltd England Firm is operating at acceptable level of GMP compliance as per inspection dated 10-04-2019	-

STABILITY STUDY DATA

Drug	Diacan 100mg Tablets		
Name of Manufacturer	Genix Pharma (Pvt.) Ltd.		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd. China		
API Lot No.	RD-CLF (hemihydrate)-201712031		
Description of Pack (Container closure system)	Alu-Alu Blister Pack		
Stability Storage Condition	**Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH **Real Time:** 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	**Accelerated:** 06 months **Real Time:** 06 months		
Frequency	**Accelerated:** 0, 1, 2,3,4 & 6 (Months) **Real Time:** 3,6 (Months)		
Batch No.	**18SB-193-01**	**18SB-194-02**	**18SB-195-03**
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Sr.#	Documents to Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Yes**
3.	Protocols followed for conduction of stability study and details of tests.	**Yes**
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	**Yes**

5.	Documents confirming import of API etc.	Copy of Commercial Invoice (invoice no. CY18019) dated attested by ADC (Karachi) dated 06-02-2018 has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	**Yes**
7.	Commitment to continue real time stability study till assigned shelf life of the product.	**Yes**
8.	Commitment to follow Drug Specification Rules, 1978.	**Yes**

REMARKS OF EVALUATOR
(AD PEC-I)

The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter no. RA/134/19, dated 15-07-2019 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following two observations were reported in the report: i. The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. ii. Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice (invoice no. CY18019) attested by ADC (Karachi) dated 19-02-2018 has been submitted for the import of Canagliflozin 2.5 Kg (batch# RD-CLF hemihydrate-201712031)
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copy of letters from M/s Changzhou Pharmaceutical Factory in the name of M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following reference standards on behalf of their principal i.e. M/s Nantong Chanyoo Pharmatech Co., Ltd, China.

Particulars	**Batch No.**	**Quantity**
Working standard	WCLF01-160501	3gm
Ring opening CLF	WCLF03-160501	10mg
Pentatomic ring CLF	WCLF04-160501	10mg

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>α CLF</td><td>WCLF05-160501</td><td>10mg</td></tr>
<tr><td>CLF-4</td><td>WCLF08-160501</td><td>10mg</td></tr>
<tr><td>Desflouro CLF</td><td>WCLF06-160501</td><td>10mg</td></tr>
</table>
</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has submitted GMP certificate issued by Nantong Chanyoo medical industry Association, which is not relevant regulatory authority.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy of “SOP for vendor certification”,
SOP No: QA/SOP/SY/037 with effective date 07-10-2016.
Version no: 01
Copy of “Vendor’s Audit form” filled for M/s Nantong Chanyoo Pharmatech Co., Ltd, China, dated 24-02-2017.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of Canagliflozin, working standards and impurity standards issued by M/s Nantong Chanyoo Pharmatech Co., Ltd, China.is submitted. Detail is as under
<table>
<tr><th>Particulars</th><th>Batch no</th></tr>
<tr><td>Canagliflozin</td><td>RD-CLF (hemihydrate)-201712031</td></tr>
<tr><td>Working standard</td><td>WCLF01-160501</td></tr>
<tr><td>Ring opening CLF</td><td>WCLF03-160501</td></tr>
<tr><td>Pentatomic ring CLF</td><td>WCLF04-160501</td></tr>
<tr><td>α CLF</td><td>WCLF05-160501</td></tr>
<tr><td>CLF-4</td><td>WCLF08-160501</td></tr>
<tr><td>Desflouro CLF</td><td>WCLF06-160501</td></tr>
</table>
</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 4 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for Lab scale batch manufacturing of Diacan 100mg Tablets. The SOP mentions the details of master formulation & manufacturing method for both Diacan 100mg Tablets. Copies of stability protocols have also been submitted for Diacan 100mg Tablets.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of the following 03 Batches:
<table>
<tr><th>BATCH NO</th><th>BATCH SIZE</th><th>MFG DATE</th></tr>
<tr><td>18SB-193-01</td><td>1500 Tablets</td><td>12-2018</td></tr>
<tr><td>18SB-194-02</td><td>1500 Tablets</td><td>12-2018</td></tr>
<tr><td>18SB-195-03</td><td>1500 Tablets</td><td>12-2018</td></tr>
</table>
</td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has attached Record of remaining quantities of stability batches according to which firm has sufficient number of tablets placed in stability chamber for completion of long-term stability studies till 24 months.</td></tr>
</table>

QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 01-12-2018 to 29-06-2019.
13.	Method used for analysis of API along with COA.	The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Canagliflozin (batch # RD-CLF (hemihydrate)-201712031) along with chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs for Canagliflozin from M/s Nantong Chanyoo Pharmatech Co., Ltd, China
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure (QC-FPNS-140 issued on 19-12-2018) for Diacan 100mg Tablet along with Stability Study Report of stability batches.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated and 24 Months Real Time Stability Study ($30_oC+2\ _oC$, 65+5%) Data of 03 Batches of Canagliflozin from M/s Nantong Chanyoo Pharmatech Co., Ltd, China
16.	Analysis reports for excipients used.	The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Diacan tablets.
17.	Drug-excipients compatibility studies.	The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product (Diacan Tablet) is similar to that of innovator's product i.e. Invokana tablet and also stability studies have not shown any incompatibility or significant degradation.
18.	Record of comparative dissolution data.	Firm has submitted F2 factor protocol (QC/PRO/CD/26) & dated 18-12-2018. The detail is as follows: Comparative dissolution studies have been performed in following mediums: i. pH 0.1N HCl buffer ii. pH 4.5 Acetate buffer iii. pH 6.8 Phosphate buffer In pH 1.2 N HCl buffer similarity factory is 84.530 In pH 4.5 Acetate buffer similarity factory is 75.995 In pH 6.8 Phosphate buffer similarity factory is 78.545
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports of stability studies of applied formulation

Remarks of Evaluator:

- Firm has submitted GMP certificate issued by Nantong Chanyoo Medical Industry Association, which is not relevant regulatory authority.
- Firm has added sodium lauryl sulphate as surfactant in all three dissolution mediums for the performance of comparative dissolution studies, while the Appendix 1 of WHO TRS No. 992, 2015 titled as "Recommendations for conducting and assessing comparative dissolution profiles" states as under:

  "Surfactants should be avoided in comparative dissolution testing.

  A statement that the API is not soluble in any of the media is not sufficient, and profiles in the absence of surfactant should be provided. The rationale for the choice and concentration of surfactant should be provided. The concentration of the surfactant should be such that the discriminatory power of the

test will not be compromised."

Decision: Registration Board deferred the case for submission of valid GMP certificate of API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co., Ltd. China from relevant Provincial or State regulatory authority since the Nantong Chanyoo Medical Industry Association is not the relevant regulatory authority for M/s Nantong Chanyoo Pharmatech Co., Ltd. China

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
112.	**Genix Pharma (Pvt.) Ltd.** Karachi	Diacan 300mg Tablets Each film coated tablet contains: - Canagliflozin ……300mg (Innovator's Specifications)	Form 5D 04-09-2014, Fee: 50,000/- As per SRO	EMC Invokana Tablets 300mg, Janssen-Cilag ltd England Firm is operating at acceptable level of GMP compliance as per inspection dated 10-04-2019	-

STABILITY STUDY DATA

Drug	Diacan 300mg Tablets		
Name of Manufacturer	Genix Pharma (Pvt.) Ltd.		
Manufacturer of API	Nantong Chanyoo Pharmatech Co., Ltd. China		
API Lot No.	RD-CLF (hemihydrate)-201712031		
Description of Pack (Container closure system)	Alu-Alu Blister Pack		
Stability Storage Condition	**Accelerated:** 40˚C ± 2˚C / 75% ± 5%RH **Real Time:** 30˚C ± 2˚C / 65% ± 5%RH		
Time Period	**Accelerated:** 06 months **Real Time:** 06 months		
Frequency	**Accelerated:** 0, 1, 2,3,4 & 6 (Months) **Real Time:** 3,6 (Months)		
Batch No.	**18SB-196-01**	**18SB-197-02**	**18SB-198-03**
Batch Size	1500 Tablets	1500 Tablets	1500 Tablets
Manufacturing Date	12-2018	12-2018	12-2018
Date of Initiation	12-2020	12-2020	12-2020
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Sr.#	Documents to Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Yes**
3.	Protocols followed for conduction of stability study and details of tests.	**Yes**

4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	**Yes**
5.	Documents confirming import of API etc.	Copy of Commercial Invoice (invoice no. CY18019) dated attested by ADC (Karachi) dated 06-02-2018 has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	**Yes**
7.	Commitment to continue real time stability study till assigned shelf life of the product.	**Yes**
8.	Commitment to follow Drug Specification Rules, 1978.	**Yes**

REMARKS OF EVALUATOR
(AD PEC-I)

1. The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter no. RA/134/19, dated 15-07-2019 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "WYMLY Tablets 25mg (Tenofovir Alafenamide)", which was conducted on 09-04-2018, and was presented in 281st meeting of Registration Board held on 11-13th April, 2018. Registration Board decided to approve registration of WYMLY Tablets 25mg (Tenofovir Alafenamide)", by M/s. Genix Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for 26 weeks. Following two observations were reported in the report: i. The HPLC software is 21CFR complaint and having certificates of compliance by USFDA. ii. Audit trail on the testing reports of WYMLY Tablets 25mg (Tenofovir Alafenamide) is available. iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Copy of Commercial Invoice (invoice no. CY18019) attested by ADC (Karachi) dated 19-02-2018 has been submitted for the import of Canagliflozin 2.5 Kg (batch# RD-CLF hemihydrate-201712031)
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copy of letters from M/s Changzhou Pharmaceutical Factory in the name of M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following reference standards on behalf of their principal i.e. M/s Nantong Chanyoo

<table>
<tr><td></td><td></td><td>Pharmatech Co., Ltd, China.<table><tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th></tr><tr><td>Working standard</td><td>WCLF01-160501</td><td>3gm</td></tr><tr><td>Ring opening CLF</td><td>WCLF03-160501</td><td>10mg</td></tr><tr><td>Pentatomic ring CLF</td><td>WCLF04-160501</td><td>10mg</td></tr><tr><td>α CLF</td><td>WCLF05-160501</td><td>10mg</td></tr><tr><td>CLF-4</td><td>WCLF08-160501</td><td>10mg</td></tr><tr><td>Desflouro CLF</td><td>WCLF06-160501</td><td>10mg</td></tr></table></td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has submitted GMP certificate issued by M/s Nantong Chanyoo medical industry Association, which is not relevant regulatory authority.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy of “SOP for vendor certification”,

SOP No: QA/SOP/SY/037 with effective date 07-10-2016.
Version no: 01
Copy of “Vendor’s Audit form” filled for M/s Nantong Chanyoo Pharmatech Co., Ltd, China, dated 24-02-2017.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of Canagliflozin, working standards and impurity standards issued by M/s Nantong Chanyoo Pharmatech Co., Ltd, China.is submitted. Detail is as under<table><tr><th>Particulars</th><th>Batch no</th></tr><tr><td>Canagliflozin</td><td>RD-CLF (hemihydrate)-201712031</td></tr><tr><td>Working standard</td><td>WCLF01-160501</td></tr><tr><td>Ring opening CLF</td><td>WCLF03-160501</td></tr><tr><td>Pentatomic ring CLF</td><td>WCLF04-160501</td></tr><tr><td>α CLF</td><td>WCLF05-160501</td></tr><tr><td>CLF-4</td><td>WCLF08-160501</td></tr><tr><td>Desflouro CLF</td><td>WCLF06-160501</td></tr></table></td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 4 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for Lab scale batch manufacturing of Diacan 300mg Tablets. The SOP mentions the details of master formulation & manufacturing method for both Diacan 300mg Tablets. Copies of stability protocols have also been submitted for Diacan 300mg Tablets.</td></tr>
</table>

<table>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of the following 03 Batches:<table><tr><th>BATCH NO</th><th>BATCH SIZE</th><th>MFG DATE</th></tr><tr><td>18SB-196-01</td><td>1500 Tablets</td><td>12-2018</td></tr><tr><td>18SB-197-02</td><td>1500 Tablets</td><td>12-2018</td></tr><tr><td>18SB-198-03</td><td>1500 Tablets</td><td>12-2018</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has attached Record of remaining quantities of stability batches according to which firm has sufficient number of tablets placed in stability chamber for completion of long-term stability studies till 24 months.</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 01-12-2018 to 29-06-2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Canagliflozin (batch # RD-CLF (hemihydrate)-201712031) along with chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs for Canagliflozin from M/s Nantong Chanyoo Pharmatech Co., Ltd, China</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure (QC-FPNS-141 issued on 19-12-2018) for Diacan 300mg Tablet along with Stability Study Report of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated and 24 Months Real Time Stability Study (30$_o$C+2 $_o$C, 65+5%) Data of 03 Batches of Canagliflozin from M/s Nantong Chanyoo Pharmatech Co., Ltd, China</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Diacan tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product (Diacan Tablet) is similar to that of innovator’s product i.e. Invokana tablet and also stability studies have not shown any incompatibility or significant degradation.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted F2 factor protocol (QC/PRO/CD/26) & dated 18-12-2018. The details is as follows:
Comparative dissolution studies have been performed in following mediums:
i. pH 0.1N HCl buffer
ii. pH 4.5 Acetate buffer
iii. pH 6.8 Phosphate buffer</td></tr>
</table>

		In pH 1.2 N HCl buffer similarity factory is 84.530 In pH 4.5 Acetate buffer similarity factory is 75.995 In pH 6.8 Phosphate buffer similarity factory is 78.545
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports of stability studies of applied formulation

Remarks of Evaluator:

- Firm has submitted GMP certificate issued by M/s Nantong Chanyoo medical industry Association, which is not relevant regulatory authority.
- Firm has added sodium lauryl sulphate as surfactant in all three dissolution mediums for the performance of comparative dissolution studies, while the Appendix 1 of WHO TRS No. 992, 2015 titled as "Recommendations for conducting and assessing comparative dissolution profiles" states as under:

  "Surfactants should be avoided in comparative dissolution testing.

  A statement that the API is not soluble in any of the media is not sufficient, and profiles in the absence of surfactant should be provided. The rationale for the choice and concentration of surfactant should be provided. The concentration of the surfactant should be such that the discriminatory power of the test will not be compromised."

Decision: Registration Board deferred the case for submission of valid GMP certificate of API manufacturer i.e., M/s Nantong Chanyoo Pharmatech Co., Ltd. China from relevant Provincial or State regulatory authority since the Nantong Chanyoo Medical Industry Association is not the relevant regulatory authority for M/s Nantong Chanyoo Pharmatech Co., Ltd. China

d. Deferred cases of stability studies.

Following cases were presented in 291st meeting of Registration Board

113.	Name and address of manufacturer / Applicant	M/s Tabros Pharma (Pvt.) Ltd., Karachi
	Brand Name +Dosage Form + Strength	Felixia 24/26mg tablet
	Composition	"Each film coated tablet Contains: Sacubitril…..… 24mg Valsartan …….. 26mg"
	Diary No. Date of R& I & fee	Dy. No 371 dated 09-09-2015, Rs.50,000/- 08-09-2015
	Pharmacological Group	antihypertensive
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	Rs. 1071.42 per tablet 2 x 14's:MRP Rs. 30,000
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	
	GMP status	GMP inspection dated 07-02-2018 concluding as under: "On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of the Evaluator[II]	
114.	Name and address of manufacturer / Applicant	M/s Tabros Pharma (Pvt.) Ltd., Karachi
	Brand Name +Dosage Form + Strength	Felixia 49/51mg tablet
	Composition	"Each film coated tablet Contains: Sacubitril…..… 24mg Valsartan …….. 26mg"
	Diary No. Date of R& I & fee	Dy. No 372 dated 09-09-2015, Rs.50,000/- 08-09-2015
	Pharmacological Group	antihypertensive
	Type of Form	Form-5

	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	Rs. 2142.85 per tablet 2 x 14's:MRP Rs. 60,000
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	
	GMP status	GMP inspection dated 07-02-2018 concluding as under: "On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of the Evaluator[II]	
115.	Name and address of manufacturer / Applicant	M/s Tabros Pharma (Pvt.) Ltd., Karachi
	Brand Name +Dosage Form + Strength	Felixia 97/103mg tablet
	Composition	"Each film coated tablet Contains: Sacubitril…..… 97mg Valsartan …….. 103mg"
	Diary No. Date of R& I & fee	Dy. No 373 dated 09-09-2015, Rs.50,000/- 08-09-2015
	Pharmacological Group	antihypertensive
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	Rs. 4285.71 per tablet 2 x 14's:MRP Rs. 120,000
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	
	GMP status	GMP inspection dated 07-02-2018 concluding as under: "On the basis of current inspection it was observed that the firm rectified all observations noted during last GMP Inspection."
	Remarks of the Evaluator[II]	

Now the firm has submitted stability data detailed as under:

STABILITY STUDY DATA

Drug	Felixia tablets
Name of Manufacturer	M/s Tabros Pharma (Pvt.) Ltd., Karachi
Manufacturer of API	M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Guangdong Province, China
API Lot No.	57318060103
Description of Pack (Container closure system)	Alu-Alu foil in unit carton
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH
Time Period	Real time: 6 months Accelerated: 6 months
Frequency	Accelerated: 0,1,2,3 & 6 months Real Time: 0,3,6 months

Product name	Batch Nos.	Batch size	Date of manufacture	Date of initiation of stability
Felixia 24/26mg tablet	TR001-1/FEL, TR002-1/FEL, TR003-1/FEL,	300 tablets 450 tablets 450 tablets	11-2018	

Felixia 49/51mg tablet	TR001-2/FEL TR002-2/FEL TR003-2/FEL	300 tablets 450 tablets 450 tablets	11-2018	
Felixia 97/103mg tablet	TR001-3/FEL TR002-3/FEL TR003-3/FEL	300 tablets 450 tablets 450 tablets	11-2018	

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of felixia tablet range and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

Administrative Portion

1. Reference of last onsite panel inspection for instant dosage form conducted during last two years.

Firm has referred to onsite inspection report of their product "Nista tablet 60mg (Daclatasvir)", which was conducted on 19th February, 2017 and was presented in 279th meeting of Registration Board.
Registration Board decided to approve registration of "Nista tablet 60mg (Daclatasvir)" by M/s Tabros Pharma. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Following two observations were reported in the report:

i. The HPLC software is 21 CFR compliant.
ii. Audit trail reports on the testing were available.
iii. Adequate monitoring and control are available for stability chambers.

2. Documents for the procurement of API with approval from DRAP (in case of import).

License to import Sacubitril/Valsartan from M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Guangdong Province, China, issued by ADC, DRAP, Karachi has been submitted. Detailed as under:

Batch No.	Invoice No.	Quantity Imported	Date of approval by DRAP
57318060103	RIS18037	600gm	18-09-2018

3. Documents for the procurement of reference standard and impurity standards.

Firm has submitted copy of letter from M/s Morgan Chemicals, declaring the submission of following reference standrads from the M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Guangdong Province, China

Material name	Batch#.	Quantity
VST Impurity A	180204	100mg
VST Impurity A	1808	100mg
VST Impurity A	180504	100mg
SCB Impurity 1	180503	100mg
SCB Impurity 1	171005	100mg
SCB Impurity 1	170903	100mg
SCB Impurity 1	180406	100mg
Sacubitril/Valsartan	180707	100mg
SCB (RS Standard)	170705	100mg
SCB (R.R)	170704	100mg
SCB (S.S)	170703	100mg

4. Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.

Copy of GMP certificate for M/s Zhuhai Rundu Pharmaceutical Co., Ltd., Guangdong Province, China issued by China Food and Drug Administration, valid upto 13-11-2021. The scope of inspection does not include the applied drug.

<table>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy of “SOP for Vendor Qualification of Raw and packaging materials”.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>The firm has submitted certificate of analysis for API, reference standard and impurity standards for Sacubitril/ Valsartan</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of R& D technical staff comprising of 5 technical members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted copy of “Product Development Protocol of Flexia tablet range” and SOP for Stability Study Protocols</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of three stability batches for the stability studies of Empagliflozin + Metformin HCl tablet range such as.
<table>
<tr><td colspan="3">Felixia 24/26mg tablet</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TR001-1/FEL</td><td>11-2018</td><td>300 Tablets</td></tr>
<tr><td>TR002-1/FEL</td><td>11-2018</td><td>450 Tablets</td></tr>
<tr><td>TR003-1/FEL</td><td>11-2018</td><td>450 Tablets</td></tr>
<tr><td colspan="3">Felixia 49/51mg tablet</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TR001-2/FEL</td><td>11-2018</td><td>300 Tablets</td></tr>
<tr><td>TR002-2/FEL</td><td>11-2018</td><td>450 Tablets</td></tr>
<tr><td>TR003-2/FEL</td><td>11-2018</td><td>450 Tablets</td></tr>
<tr><td colspan="3">Felixia 97/103mg tablet</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TR001-3/FEL</td><td>11-2018</td><td>300 Tablets</td></tr>
<tr><td>TR002-3/FEL</td><td>11-2018</td><td>450 Tablets</td></tr>
<tr><td>TR003-3/FEL</td><td>11-2018</td><td>450 Tablets</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><td colspan="3">Felixia 24/26mg tablet</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TR001-1/FEL</td><td>116 tablets</td><td>300 Tablets</td></tr>
<tr><td>TR002-1/FEL</td><td>256 tablets</td><td>450 Tablets</td></tr>
<tr><td>TR003-1/FEL</td><td>251 tablets</td><td>450 Tablets</td></tr>
<tr><td colspan="3">Felixia 49/51mg tablet</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TR001-2/FEL</td><td>131 tablets</td><td>300 Tablets</td></tr>
<tr><td>TR002-2/FEL</td><td>281 tablets</td><td>450 Tablets</td></tr>
<tr><td>TR003-2/FEL</td><td>286 tablets</td><td>450 Tablets</td></tr>
<tr><td colspan="3">Felixia 97/103mg tablet</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TR001-3/FEL</td><td>142 tablets</td><td>300 Tablets</td></tr>
<tr><td>TR002-3/FEL</td><td>281 tablets</td><td>450 Tablets</td></tr>
<tr><td>TR003-3/FEL</td><td>276 tablets</td><td>450 Tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
</table>

<table>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical charts and tables for Real Time and Accelerated Conditions for complete stability studies of applied formulations.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of raw material specifications, raw material testing procedures for Sacubitril/Valsartan.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Specification/Testing Method of Finished Product for Felixia tablets range. Relevant analytical record for complete stability studies has also been submitted.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports on Sacubitril/Valsartan as per Zone-IV-a conditions.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Felixia tablet range.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has submitted that “as same excipients used as used by innovator so compatibility studies with excipients are not required.”</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted comparative dissolution report. The details of reference product & Sample product are as follows:
<table>
<tr><th colspan="3">Felixia Tablets 24/26mg</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Helix</th></tr>
<tr><td>Brand name</td><td>Entresto tablet 24/26 mg</td><td>Felixia Tablets 24/26mg</td></tr>
<tr><td>Batch No.</td><td>TR634</td><td>TR001-1/FEL</td></tr>
<tr><th colspan="3">Felixia Tablets 49/51mg</th></tr>
<tr><th>Feature</th><th>Feature</th><th>Feature</th></tr>
<tr><td>Brand name</td><td>Uperio tablet 49/51 mg</td><td>Felixia Tablets 49/51mg</td></tr>
<tr><td>Batch No.</td><td>TT107</td><td>TR001-2/FEL</td></tr>
<tr><th colspan="3">Felixia Tablets 97/103mg</th></tr>
<tr><th>Feature</th><th>Feature</th><th>Feature</th></tr>
<tr><td>Brand name</td><td>Uperio tablet 97/103 mg</td><td>Felixia Tablets 97/103</td></tr>
<tr><td>Batch No.</td><td>TT213</td><td>TR001-3/FEL</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
a. 0.1N HCl buffer
b. pH 4.5 Acetate buffer
c. pH 6.8 Phosphate buffer
• F2 factor value has been calculated above 50 for all the three mediums.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>• Firm has submitted audit trail reports of stability studies of applied formulations.</td></tr>
<tr><td colspan="3">Following is the details of observations from PEC and the response of the firm:
<table>
<tr><th>Sr #</th><th>Observation from PEc</th><th>Response of the firm</th></tr>
<tr><td></td><td>• Test method titled as “Stability indicating test method for Assay, Impurities and Degradation Product” in the recently submitted “Analytical</td><td>Analytical method with details of impurities enclosed</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td>Control Procedure for Stability studies", does not mention the details for identification & quantification for impurities.</td><td></td></tr>
<tr><td></td><td>• Scientific justification shall be submitted for applying two different methods for Assay analysis during the stability studies.</td><td>Stability indicating method was under development when 03 months stability testing was performed so isocratic method was used for 03 months testing. After development of stability indicating gradient method the gradient test method was used for 06th month time point of stability testing</td></tr>
<tr><td></td><td>• Justify the yield of 270 tablets, 285 tablets & 296 tablets of the batch # TR001-1/FEL, TR001-2/FEL & TR001-3/FEL respectively while using the ZP-33 compression machine for the batch size of 300 tablets, since reported yield is not justifiable considering the operational requirements of the ZP-33 compression machine.</td><td>
<table>
<tr><th>Batch No.</th><th>Yield</th><th>Justification</th></tr>
<tr><td>TR001-01/FEL</td><td>270</td><td>Special precautions are taken during compression for small scale stability batches. The powder is directly fed manually in dies cavity to avoid losses so that complete powder is consumed and maximum number of tablets are available to perform real time stability studies. Tablets utilized in non destructive physical testing like friability and hardness test were crushed and used. Only 06 tablets were consumed for D.T testing.</td></tr>
<tr><td>TR001-02/FEL</td><td>285</td><td>The batch was not compressed on ZP-33.Compression was done on ZP-19 compression machine which can be verified through submitted BMR and PD reports. Please Refer PD report page no 20 & BMR page no. 04 of 06. On machine ZP-19 the losses are less than ZP-33. Only 06 tablets were consumed for D.T testing. Tablets utilized in non destructive physical testing like friability and hardness test were crushed and used.</td></tr>
<tr><td>TR001-03/FEL</td><td>296</td><td>The batch was not compressed on ZP-33.Compression was done on ZP-07 compression machine which can be verified through submitted BMR and PD reports. Please Refer PD report page no 20 & BMR page no. 04 of 06. On machine ZP-07 the losses are less than ZP-33 & ZP-19. Only 06 tablets were consumed for D.T testing. Tablets utilized in non-destructive physical testing like friability and hardness test were crushed and used</td></tr>
</table>
</td></tr>
</table>

- It is pertinent to mention that 36 tablets have also been utilized from each batch of TR001-01/FEL, TR001-02/FEL, TR001-03/FEL have also utilized in the Comparative dissolution studies.

Decision of 291st meeting: Registration Board deferred the case for following:

- Scientific justification for re-processing of tablets in product development studies already used in tests of "Friability" & "Hardness".
- Scientific justification for manually feeding the powder in dies cavity of ZP-33 machine for compressing the Batch# TR001-01/FEL.
- Clarification regarding the yield of Batch# TR001-03/FEL of Felixia Tablets 97/103mg, since the claimed yield of 296 tablets is not rationale considering the 6 tablets used for disintegration test.
- Clarification for conducting real time stability studies till claimed shelf life, since submitted record of tablets declare that firm does not have sufficient number of tablets to conduct real time stability studies till claimed shelf life, considering the tablets used in disintegration and Comparative Dissolution profile studies.

The firm vide its letter No. DRAP/TAB-REG/09-19 dated 24th September, 2019 has requested for a chance of personal hearing to explain their position with reference to above presented cases.

Proceedings:

The representatives of the firm appeared before the Board, and presented following submissions:

Sr. No.	Question by evaluator	Response by Tabros
1.	Scientific justification for re-processing of tablets already used in friability and hardness tests.	The scientific justification: • Manufacturing process used is a direct compression process in which slugging and deslugging is part of approved manufacturing steps. • Intragranular and extragranular excipients (used for blending after deslugging) are same. • Recycling of few inprocess tablets to deslugging stage (reprocessing of minor batch fraction) didn't reveal any impact on product quality attributes during physical and chemical testing at the time of release and during six month stability studies at accelerated and real time conditions. • Interchangeability studies (dissolution profile comparison studies) of this lot was also performed with the innovator brand and product found bioequivalent with the innovator brand.
2.	Scientific justification for manual feeding the powder in dies cavity of ZP-33 for compression.	• In very small size lab scale batches having batch size of 300 tablets,exact simulation with commercial scale manufacturing process is not evaluated during product development studies.Small quantity is manufactured for evaluation of product formulation and critical quality attributes of drug products.Feeding of powder through machine hopper is not possible and maximum powder will be lost as rejection.
3.	Clarification regarding the yield of 296 tablets(batch size 300 tablets) considering 06 tablets used in disintegration test.	• Normally ± 1-2% Manufacturing yield variations are observed during lab scale batches of tablets considering ±05% limits for weight variation at compression stage.In this batch yield obtained is appx + 1%. i.e. Total tablets = 302 ; For D.T = 06 Overall yield= 296 Tablets

<table>
<tr>
<td>4.</td>
<td>Clarification for conducting real time stability studies till claimed shelf life since submitted record of tablets declare that firm does not have sufficient number of tablets to conduct real time stability studies till claimed shelf life considering tablets used in disintegration and dissolution profile comparison.</td>
<td>Total tablets required for complete stability studies including D.T and Dissolution profile comparison till claimed shelf life

Tablet for stability studies for claimed shelf life= 22 x 11=242 Tablets
(22 Tablets for one time point and total 11 time points) (22=> 10 Assay and water content,06 DT,06 Dissolution test)
For Dissolution profile comparison= 36 tablets (one batch only)
Total tablets = 242+36=278 tablets (for bathes require dissolution profile comparison)
<table>
<tr><th>B.NO</th><th>YIELD</th><th>REMARKS</th></tr>
<tr><td>TR-001-01/FEL</td><td>270</td><td>In this batch we have used 36 tablets in dissolution profile comparison testing.Therefore now required tablets are 278 for claimed shelf life means there will be only 14 tablets left for final time point testing.

For this specific batch only we can consider following testing plan

Assay & water content with 05 tablets (Weight of one tablet is used for assay testing and rest can be used for water content)
Dissolution with 06 tablets
D.T with 03 Tablets (or skip D.T test) considering test results of other 02 trial batches of same strength i.e. TR-002-01/FEL,TR-003-01/FEL</td></tr>
<tr><td>TR-002-01/FEL</td><td>410</td><td>Enough tablets available for real stability studies till claimed shelf life</td></tr>
<tr><td>TR-003-01/FEL</td><td>405</td><td>Enough tablets available for real stability studies till claimed shelf life</td></tr>
<tr><td>TR-001-02/FEL</td><td>285</td><td>Enough tablets available for real stability studies till claimed shelf life with dissoluion profile comparison</td></tr>
<tr><td>TR-002-02/FEL</td><td>435</td><td>Enough tablets available for real stability studies till claimed shelf life</td></tr>
<tr><td>TR-003-02/FEL</td><td>440</td><td>Enough tablets available for real stability studies till claimed shelf life</td></tr>
<tr><td>TR-001-03/FEL</td><td>296</td><td>Enough tablets available for real stability studies till claimed shelf life with dissoluion profile comparison</td></tr>
<tr><td>TR-002-03/FEL</td><td>435</td><td>Enough tablets available for real stability studies till claimed shelf life</td></tr>
<tr><td>TR-003-03/FEL</td><td>430</td><td>Enough tablets available for real stability studies till claimed shelf life</td></tr>
</table>
</td>
</tr>
</table>

Decision: Registration Board after thorough deliberation rejected the applications of Felixia Tablets 97/103mg, Felixia Tablets 49/51mg, Felixia Tablets 24/26mg from M/s Tabros Pharma (Pvt.) Ltd., Karachi due to following reasons:

i. **Re-processing of tablets already used in tests of "Friability" & "Hardness" for compensating the batch yield, since firm could not submit any rationale for this practice to compensate the yield.**

ii. **Manual feeding of the powder in dies cavity of tablet compression machine, since this practice does not simulate the manufacture procedure applied for commercial production.**

iii. **Submitted record of tablets declare that firm does not have sufficient number of tablets to conduct real time stability studies till claimed shelf life.**

Case no. 02 Deferred cases Human Drugs

116.	Name and address of manufacturer / Applicant	"M/s Tabros Pharma Pvt Ltd. L-20/B,Sector-22, Federal B Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Hydrocort 10mg Tablet
	Composition	"Each Tablet Contains: Hydrocortisone……10mg"
	Diary No. Date of R& I & fee	Dy. No 44231 dated 28-12-2018 Rs.20,000/- 28-12-2018
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	Rs. 8.75 per tablet Pack 1 x 20's M.R.P: 175/-
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Cortab of M/s Platinum Pharma (Reg.# 037525)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 07/02/18 concluded as under: "On the basis of current inspection it was observed that firm rectified all observations noted during last GMP Inspection"
	Previous Remarks of the Evaluator.	Evidence of section approval required for applied formulation is required.
	Previous Decision	Registration board in its 291st meeting Deferred for evidence of approval of required manufacturing facility from Licensing Division.
	Evaluation by PEC	Firm has submitted copy of section approval letter issued by Secretary CLB dated 27-09-2019, declaring approval of following two sections for M/s Tabros Pharma. 497. Tablet General - Amendments (granulation area) 498. Tablet (Steroid) Regularization
	Decision: Registration Board approved the applied product for Tablet (Steroid) section.	

Extension in implementation timelines of SRO 713(I)/2018

Chairman registration board apprised the Board regarding following decision of DRAP Authority for the "Extension in implementation timelines of SRO 713(I)/2018":

The Authority decided as follows:-

1. Allowed those companies, for which panel for inspection has been constituted before 07-03-2019, to submit registration applications on Form 5 instead of Form 5F for initial 10 molecules per section only.
2. The exemption will remain valid till 31-12-2019.
3. No further exemption will be granted in any case.
4. Inspectors / panel members are advised to formally report every visit. Concerned Division were advised to specify a timelines for conducting/ concluding panel inspection.

Registration Board noted the above decision of DRAP authority and advised pharmaceutical Evaluation cell to present any cases of New DML/Additional section in context of this decision. Accordingly following cases of New DML were presented before the Registration Board.

Registration Applications of Newly Granted DML (Human)

Assistant Director (Licensing) vide letter No. F.3-1/2004-Lic dated 12-03-2018, has communicated Additional Director (E&M) DRAP, Peshawar, regarding constitution of panel by CLB.

CLB in its 270th meeting held on 23rd May, 2019 has approved grant of Drug manufacturing License (by way of formulation) for M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, with following three sections:

i. Capsule (Cephalosporin)
ii. Dry powder suspension (cephalosporin)
iii. Dry Powder injection (Cephalosporin)

Now the firm has applied following applications for priority consideration against the new DML.

Dry Powder injection (Cephalosporin) 1 Molecule/4 Products		
117.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Kmixone-500mg Injection
	Composition	"Each Vial of Dry Substance Contains: Sterile Ceftriaxone as Sodium……500mg"
	Diary No. Date of R& I & fee	Dy. No 19373 dated 01-10-2019 Rs. 20,000 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	El-cef Injection of M/s Linear Pharma Rawat (Reg.# 075342)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	IM or IV route of administration must be selected.
	Decision: Approved. Manufacturer will select one route of administration either IM or IV.	
118.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name +Dosage Form + Strength	Kmixone-2g Injection
	Composition	"Each Vial of Dry Substance Contains: Sterile Ceftriaxone as Sodium…2g"
	Diary No. Date of R& I & fee	Dy. No 19365 dated 01-10-2019 Rs. 20,000/- 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ceftriaxone 2 g powder for solution for injection/infusion. MHRA approved
	Me-too status (with strength and dosage form)	Cefast 2g Injection I.V. Reg. No. 82281
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	Applied strength is only available for IV route of administration.
	Decision: Approved for IV route of administration only.	
119.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Kmixone 250mg Injection
	Composition	"Each Vial of Dry Substance Contains: Sterile Ceftriaxone as Sodium……250mg"
	Diary No. Date of R& I & fee	Dy. No 19369 dated 01-10-2019 Rs. 20,000 01-10-2019
	Pharmacological Group	Antibiotic

	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	El-cef Injection of M/s Linear Pharma Rawat (Reg.# 075341)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	Applied strength is only available for IV route of administration.
	Decision: Approved. Manufacturer will select one route of administration either IM or IV.	
120.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Kmixone 1g Injection
	Composition	"Each Vial of Dry Substance Contains: Sterile Ceftriaxone as Sodium …….1gm"
	Diary No. Date of R& I & fee	Dy. No 19372 dated 01-10-2019 Rs. 20,000 Dated 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Triject IV 1gm Injection of M/s Nabiqasim Industries (Pvt) Ltd., Karachi (Reg.# 058374)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	Applied strength is only available for IV route of administration.
	Decision: Approved. Manufacturer will select one route of administration either IM or IV.	
Dry powder suspension (cephalosporin) 2 Molecules/4 Products		
121.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Maclor 125mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Cefaclor as Monohydrate……125mg"
	Diary No. Date of R& I & fee	Dy. No 19371 dated 01-10-2019 Rs. 20,000/- 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sac-Lor 125mg Dry Powder Suspension of M/s Semos Pharma. Karachi. (Reg.# 081617)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
122.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Maclor 250mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Cefaclor as monohydrate ……. 250mg"

	Diary No. Date of R& I & fee	Dy. No 19368 dated 01-10-2019 Rs. 20,000/- 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Sac-Lor 250mg Dry Powder Suspension of M/s Semos Pharma. Karachi. (Reg.# 081618)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
123.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Kmicef 200mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Cefixime as Trihydrate……200mg"
	Diary No. Date of R& I & fee	Dy. No 19366 dated 01-10-2019 Rs. 20,000 Dated 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Baxacim forte 200mg/5ml Dry Suspension of M/s Pliva Baluchistan (Reg.# 081029)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
124.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Kmicef 100mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Cefixime as Trihydrate…100mg"
	Diary No. Date of R& I & fee	Dy. No 19363 dated 01-10-2019 Rs. 20,000/- 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	X-Cef 100mg /5ml Dry Suspension of M/s Genix Pharma, Karachi (Reg.# 079915)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
Capsule (Cephalosporin) 2 Molecules/4 Products		
125.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Maclor 250mg Capsule
	Composition	"Each Capsule Contains: Cefaclor as Monohydrate…250mg"

	Diary No. Date of R& I & fee	Dy.No 19367 dated 01-10-2019 Rs. 20,000/- 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Misflor 250mg Capsules of M/s Mission Karachi (Reg.# 079182)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
126.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Maclor 500mg Capsule
	Composition	"Each Capsule Contains: Cefaclor as Monohydrate…500mg"
	Diary No. Date of R& I & fee	Dy. No 19364 dated 01-10-2019 Rs. 20,000/- 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Misflor 500mg Capsules of M/s Mission Karachi (Reg.# 079183)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
127.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Kmicef 400mg Capsule
	Composition	"Each Capsule Contains: Cefixime as Trihydrate……400mg"
	Diary No. Date of R& I & fee	Dy. No 19370 dated 01-10-2019 Rs. 20,000/- 01-10-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dispel Capsules 400 mg of M/s Fynk Pharmaceuticals (Reg.# 062702)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
128.	Name and address of manufacturer / Applicant	"M/s K.M. Int (Pvt) Ltd., Plot No 74-A, Hayatabad Industrial Estate, Peshawar, Pakistan"
	Brand Name+Dosage Form + Strength	Kmicef 200mg Capsule
	Composition	"Each Capsule Contains: Cefixime as Trihydrate…200mg"
	Diary No. Date of R& I & fee	Dy. No 19362 dated 01-10-2019 Rs. 20,000 Dated 01-10-

		2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Astexim 200mg Capsules of M/s Astellas Pharmaceuticals (Reg.# 062391)
	GMP status	New DML (No. 000903) issued on 24-06-2019 on the basis of inspection conducted on 14-05-2019.
	Remarks of the Evaluator[II]	
	Decision: Approved.	

Case.No.A:- Minutes of 08th meeting of Expert Working Group on Veterinary Drugs

The minutes of 8th meeting of Expert Working Group on veterinary drugs held on 30-09-2019 was presented before Registration Board for consideration of recommendations of working group on cases referred to by the Registration Board. The details are as follow;

Case.No.01:-

Sr. No.	Name and address of product manufacturer (Applicant)	M/s. Ottoman Pharma 10 Km, Raiwind Road, Lahore.
1.	Brand Name +Dosage Form + Strength	OTTO FLU PLUS + VAC Injectable Emulsion (For Veterinary use only) Each dose contains:- Inactivated AIV H7N3 [Not less than EID_{50} 10^9/ml……....0.06ml Inactivated AIV H5N1 [Not less than EID_{50} 10^9/ml……...…0.06ml
	Type of Form, Diary No. Date of R& I & fee	Form-5, Dy. No.7460(R&I) Date:27-02-2018 Rs.20,000/-.
	Composition	Quantity in 0.3ml Vaccine dose: Inactivated AIV H7N3 [Not less than EID_{50} 10^9/ml (**Active Substance**)……0.06ml Inactivated AIV H5N1 [Not less than EID50 10^9/ml (**Active Substance**)…….……0.06ml Thiomersal (**Preservative**)……0.0005ml Mineral Oil (Montanide oil) (**Excipient**)……...0.18ml
	Pharmacological Group	Biological (Vaccine for veterinary / poultry use only)
	Finished Product Specification	As per Innovators spec.
	Shelf Life	12 Months at 2-8^{0}C
	Document Details	i. Application on form 5 ii. Copy of DML No. 000502, Date of issue 05-08-2017 iii. Fee Challan Rs. 20,000/- iv. Panel inspection for renewal of DML dated 19-12-2017 wherein the panel rated the facility good and recommended the renewal.
	Pack size & Demanded Price	300ml/vial **Decontrolled**
	International Availability	N/A
	Products already registered in Pakistan	i. Bio-Avian ii. GPVAC Flu 5+7
	Previous Decision:	Registration Board referred the case regarding the use of H5N1 strain in Pakistan to the expert working group on veterinary drugs. (M-282)
	Decision of expert working group in 06th meeting : - The member from M/o Food, Security informed that Pakistan has been declared as H5N1 free country. After deliberation, the Group observed that at this stage it would be premature to restrict registration of such vaccines merely on this ground as availability of such vaccines for any possible outbreak of the disease in future has also to be taken in consideration. Moreover, being a killed vaccine, it may not carry the hazards associated with live vaccines. The Expert Working Group, therefore, recommended OTTO FLU PLUS + VAC vaccine for being me to product.	

Decision of Reg. Board in 289th meeting:

Registration Board in its 289th meeting referred the case to Expert Working Group on veterinary drugs for further deliberation with reference to H5N1 strain.

Decision of expert working group in 08th meeting : -

The working group re-evaluated the case and, keeping in view the fact of any possible outbreak of the disease in future and being a killed vaccine, decided to recommend the product OTTO FLU PLUS + VAC

of M/s. Ottoman Pharma 10 Km, Raiwind Road, Lahore. The working group also decided that member of M/o. Food Security will prepare a working paper on ***DIVA strategy*** for consideration of vaccines (particularly influenza vaccine) for the purpose of registration by Registration Board in future.
Decision of Reg. Board in 292nd meeting: **Registration Board endorsed the recommendation of the Expert Working group and approved the product " OTTO FLU PLUS + VAC vaccine".** **The Board further decided that M/o. Food Security will prepare a working paper on *DIVA strategy* for consideration of vaccines (particularly influenza vaccine) for the purpose of registration by Registration Board in future.**

Case.No.02

Sr. No	Name and address of manufacturer / Applicant	M/s. Vetz Pharmaceuticals (Private) Limited, Plot # Q-1, S.I.T.E. Kotri Sindh.
1	Brand Name +Dosage Form + Strength	Vetzazene injection
	Composition	Each ml contains:- Diminazine Aceturate……..……105mg Antipyrine…….……..……131mg
	Diary No. Date of R& I & fee	1016, 06-09-2016, 20,000/-, 02-09-2016
	Pharmacological Group	Antiprotozoa
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	10ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Pronil Injection of Selmore Pharma (Reg # 029609)
	GMP status	The inspection conducted on 24-10-2017 concluded as: ―Maintenance of required quality of air and temperature as well as cleanliness of the facility, its design to facilitate cleaning was found nicely managed. The implementation of quality oversight and control over the manufacturing of drugs was found well attended by the entire team under their best capacity. **The ability of management, enthusiasm to walk with scientific standards was visible and remarkable.** The exercise to understand the entire status of compliance with emerging regulatory expectations is **under way** and will be recorded accordingly‖.
	Remarks of the Evaluator.	
	Previous decision	Deferred for the clarification regarding chemical structure/nature of antipyrine in applied formulation **(M-277).** Registration Board referred the case to Expert working group on Veterinary Drugs for review of this formulation **(M-283).**
	Evaluation by PEC	□ The firm was communicated to provide rationale of antipyrine in applied formulation. In response firm has submitted that □ **―Diminazeneaceturate**is an antiprotozoal substance active against the following babesiosis (piroplasmosis) causing agents: Babesiabigemina, Babesiadivergens, Babesiabovis in cattle; Babesiacaballi and Babesiaequi in horses; Babesiaovis in sheep; Babesiacanis and Babesiagibsoni in dogs and Theileriaannulata in cattle. It is highly effective against Trypanosomacongolense and Trypanosomavivax and moderately active against Trypanosomabruceï, Trypanosomaevansi and Trypanosomaequiperdum.

		Antipyrine(phenazone) is an analgesic, a nonsteroidal anti- Inflammatory drug (NSAID) and an antipyretic. It reduces fever especially in case of babesiosis. • Reference: Plumb's veterinary drug hand book sixth edition (Donald.C Plumb, Pharm-D, USA) • Chemically, antipyrine is 1,2-Dihydro-1,5-dimethyl-2-phenyl-3H-pyrazol-3-one and synonyms are Phenazone and Analgesine. • The firm has submitted reference of literature which shows that antipyrine in the injection formulation acts as stabilizer and used for inflammation and fever.
	Previous Decision:	Registration Board referred the case to Expert Working Group on Veterinary drugs for review of formulation **(M-283)**.
Decision of Expert Working Group in its 5th meeting: Deferred for further evaluation with respect to withdrawal period and safety profile of antipyrine. **Decision of Expert Working Group in its 6th meeting:** *Fixed dose combination of Diminazene aceturate & Antipyrine (Phenazone) are available and marketed in countries having heamatozoons infections, where the principle of disease therapy intends requirement of 'antiprotozoal' and 'antipyratic' together for ease and convenience of use and therapeutic effect. However, withdrawal period is advised for strict observance on label when used in food producing animals. The combination is recommended for registration.*		
Decision of Registration Board in 289th meeting:- Registration Board in its 289th meeting deferred the case for further deliberation on the matter.		
Decision of Expert Working Group in its 08th meeting: The Committee deferred the case till getting the following information relating to the formulation; a. Evidence of availability of said formulation in any reference regulatory authority. b. Difference between chemical structure of antipyrine, metamizole and novaminsulfone. c. Confirmation of causing of "agranulocytosis" by antipyrine.		
Decision of Reg. Board in 292nd meeting: **Registration Board endorsed the decision of expert working group.**		

Case.No.03

1.	Name and address of manufacturer / Applicant	M/s. Inshal Pharmaceutical Industries, Plot # 2, Street SS2, National Industrial Zone, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	MINAPYRINE INJECTION
	Composition	Each ml contains:- Diminazene Aceturate……..105mg Antipyrine…..…….....131mg
	Diary No. Date of R& I & fee	560, 07-06-2012, Rs.12,000/-, 15-06-2015, 8000/-,
	(Photocopy attached) 07-06-2012	
	Pharmacological Group	Analgesic, Antipyretic, Antitrypansomiasis
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack size & Demanded Price	50ml amber colored glass vials; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	PRONIL INJECTION of Selmore Pharma (Reg # 029609)
	GMP status	Panel inspection conducted on 11-05-2018 recommended for the renewal of DML and two additional sections
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board referred the case to Expert working group on Veterinary Drugs for review of this formulation **(M-283)**.

Decision of Expert Working Group in its 5th meeting: Deferred for further evaluation with respect to withdrawal period and safety profile of antipyrine. **Decision of Expert Working Group in its 6th meeting:** *Fixed dose combination of Diminazene aceturate & Antipyrine (Phenazone) are available and marketed in countries having heamatozoons infections, where the principle of disease therapy intends requirement of 'antiprotozoal' and 'antipyratic' together for ease and convenience of use and therapeutic effect. However, withdrawal period is advised for strict observance on label when used in food producing animals. The combination is recommended for registration.*
Decision of Registration Board in 289th meeting:- Registration Board in its 289th meeting deferred the case for further deliberation on the matter.
Decision of Expert Working Group in its 08th meeting: The Committee deferred the case till getting the following information relating to the formulation; a. Evidence of availability of said formulation in any reference regulatory authority. b. Difference between chemical structure of antipyrine, metamizole and novaminsulfone. c. Confirmation of causing of "agranulocytosis" by antipyrine.
Decision of Reg. Board in 292nd meeting: **Registration Board endorsed the decision of expert working group.**

Case.No.04:-

1.	Name and address of Applicant	M/s. Mehran International, 498-C, Feroz Shah Mehta Road, Karachi.
	Detail of Drug Sale License	**Address:** M/s. Mehran International, 498-C, Feroz Shah Mehta Road, Karachi. **Validity: 0**1/08/2019 **Status:** Drug License by way of Wholesale
	Name and address of manufacturer	M/s Hebei New Century Pharmaceutical Co., Ltd. No.189 Taihang Street Hi-tech Zone Shijiazhuang City, Hebei China.
	Name and address of marketing authorization holder	M/s Hebei New Century Pharmaceutical Co., Ltd. No.189 Taihang Street Hi-tech Zone Shijiazhuang City, Hebei China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.2588 Dated 26/01/2017
	Fee including differential fee	Rs. 100,000/- Dated 25/01/2017
	Brand Name +Dosage Form + Strength	Diminazine and Antipyrine granules for injection
	Composition	Each 2.36g bag contains: Diminazene …….. 1.050gm Antipyrine …….. 1.31gm
	Target Species	(for horse, cattle and sheep use)
	Finished Product Specification	Manufacturer's specification
	Pharmacological Group	Antiprotozoal agent
	Shelf life	3 years
	Demanded Price	De-controlled
	Pack size	2.36g
	International availability	-
	Me-too status	Diminol powder for injection of M/s Star Labs (R.#017066)
	Detail of certificates attached	Original Legalized CoPP (certificate no. 2016030519) issued by *Shijiazhuang Animal Husbandry and Aquatic Product Bureau* confirms the free sale of the product in exporting country. The facilities and operations conform to GMP as recommended by WHO as per CoPP. The certificate remains valid until 04-03-2021
	Remarks of the Evaluator.	
	Previous Decision: **(M-283)**.	Registration Board referred the case to Expert Working Group on Veterinary drugs for review of formulation.
Decision of Expert Working Group in its 5th meeting: Deferred for further evaluation with respect to withdrawal period and safety profile of antipyrine. **Decision of Expert Working Group in its 6th meeting:** *Fixed dose combination of Diminazene aceturate*		

& Antipyrine (Phenazone) are available and marketed in countries having heamatozoons infections, where the principle of disease therapy intends requirement of 'antiprotozoal' and 'antipyratic' together for ease and convenience of use and therapeutic effect. However, withdrawal period is advised for strict observance on label when used in food producing animals. The combination is recommended for registration.
Decision of Registration Board in 289th meeting:- Registration Board in its 289th meeting deferred the case for further deliberation on the matter.
Decision of Expert Working Group in its 08th meeting: The Committee deferred the case till getting the following information relating to the formulation; a. Evidence of availability of said formulation in any reference regulatory authority. b. Difference between chemical structure of antipyrine, metamizole and novaminsulfone. c. Confirmation of causing of "agranulocytosis" by antipyrine.
Decision of Reg. Board in 292nd meeting: **Registration Board endorsed the decision of expert working group.**

ITEM NO. III: - <u>MISC. CASES</u>

Case No.01:- Request for grant of additional pack sizes for already registered Veterinary Drugs.

M/s. Wimits Pharmaceuticals, Lahore has applied for grant of additional packs for their registered veterinary drug as per details mentioned alongside:-

S.No.	Regn. No.	Name of Drug(s)/Composition	Already Granted Pack Size(s)	Demanded Additional Pack(s)	Justification
1.	087092	Minvet Granules Each Kg contains:- Vitamin A……0.8gm Vitamin D3…….0.16gm Vitamin E……0.38gm Vitamin B1……...1.0gm Vitamin B2…….1.25gm Vitamin B12…….0.001gm Vitamin B3…….6.25gm Copper Sulphate……0.25gm Magnesium Sulphate…….25gm Calcium Chloride…….....0.023gm Zinc Sulphate…….....2.17gm Manganese Sulphate…….....10gm Potassium Iodide…….....0.5gm Sodium Selenite…….....0.01gm Phosphorus…….....150mg Sodium Chloride…….....120gm Vitamin B6…….....4gm	500g 1Kg	5 Kg 10 Kg 20 Kg	Due to market packing 5 Kg, 10 Kg & 20 Kg granules.

M/s. Wimits Pharmaceuticals, Plot No.129, Sunder Industrial Estate (P.I.E) Raiwind Road, Lahore has deposited fee of Rs.5,000 x 3 = Rs.15,000/- and submitted following supporting documents:-

(i) Copy of registration letter.
(ii) Affidavit.
(iii) Copy of Drug Manufacturing License.
(iv) Copy of CRF.
(v) Label.

The demanded packs are not given to other firms.

Registration Board in its 283rd meeting decided to referred the case to Expert Working Group on Veterinary drugs for further consideration.

The Expert Working Group in its 5th meeting of Expert Working Group on Veterinary Drugs deferred the request of additional packs for getting additional information regarding target species and confirmation of availability of manufacturing facility for the product.

Accordingly letter was issued to M/s. Wimits Pharmaceuticals, Lahore. In response the firm has provided following details of manufacturing facility for Minvet Granules.

Sr. No.	Name	Code	Capacity
1.	Ribbon Blade Mixer	BL/VET/001	500Kg
2.	Rotary Granulator	BL/VET/002	500Kg
3.	Fluidized Bed Dryer	BL/VET/003	100Kg/2hrs
4.	Fluidized Bed Dryer	BL/VET/012	500Kg/2hrs
5.	Oscillating Granulator	BL/VET/004	500Kg
6.	Double Cone Mixer	BL/VET/005	500Kg
7.	Pouch Sealer	PW/VET/017	

The working group (in its 08th meeting) deferred the case for confirmation of batch size of the product.

Decision of Registration Board (292nd meeting):-

Registration Board endorsed the decision of expert working group.

ITEM.No.IV:- Cases Related to Biological Division (New cases)

Case No.1:-

M/s Hipra Pakistan (Private) Limited Lahore applied for transfer of registration of imported veterinary biological from M/s Marush (Pvt.) Limited Lahore to in their name. But the below mentioned Products are not available in country of origin as per provided CoPP and reason written on CoPP for marketing Authorization lacking is **"Commercial Reasons".**The case was discussed in 286th meeting of Registration Board and the Board decided as under;

Sr. No.	Name of Manufacturer	Brand Name & Composition as per CoPP	CoPP details	Decision of 286th meeting Registration Board
1.	M/S LABORATORIOS HIPRA, S.A. Avda. La Selva, 135 17170 Amer (Girona) Spain	**HIPRAVIAR-S/H120** Oral Lyophilisate Active ingredient(s) and amount(s) per unit dose including excipients: Live Newcastle Disease Virus, strain LaSota**>= 10exp.6.5 EID50** **Live** Infectious Bronchitis, strain H120 **>= 10exp.3.0 EID50** **Not available in country of origin**	CoPP No.23726/ 2017 Dated 18-12-2017	For products at sr. no. 20 & 21, Registration Board referred the case to **Expert Working Group on Veterinary drugs** regarding their opinion on non-availability in country of origin.
2.		**HIPRAVIAR-ND BROILERS** Emulsion for injection Active ingredient(s) and amount (s) per unit dose including excipients: DCI o DOE: Inactivated NDV, strain La Sota: **>/= 10exp.8 EID 50** **Product is not available in exporting countries**	CoPP No.23606/ 2017 Dated 15-12-2017	

The Working group after detail deliberation and keeping in view the prevalence of diseases in country of origin and decided as follow;

a. Reason for non-availability of the products in the country of origin by their concerned Regulatory Authority.
b. Evidence of availability of the same products in any other reference regulatory authority as prescribed by the Registration Board.
c. Evidence of availability of the same products with other brand names in country of origin or in any other reference regulatory.

Decision of Registration Board (292nd meeting):-

Registration Board endorsed the decision of expert working group.

Case No. 2:-

M/s. Ghazi Brothers Karachi has applied for Registration of below mentioned Veterinary vaccine and the case was discussed in 289th meeting of Registration Board and the Board decided as under;

Name of Manufacturer	**Name of Product**	**CoPP details**	**Decision of 288th meeting of RB**
M/s. IDT Biologika GmbH Address: Am Pharmapark D-06861 Dessau-Rosslau Germany.	**SALMOVAC 440** (Freeze-dried live Salmonella enteritidis Vaccine) Each Dose of vaccine contains (At least): Double-attenuated (adenine-histidine auxotrophic) Salmonella enteritidis mutant, strain 441/014 ≥ 1x 108CFU	CoPP No. 005/2018 dated 13-07-2018	Registration Board referred the case to Expert Working Group on Veterinary Drugs for evaluation of strain.

The Expert working evaluated the strain of the above product and accordingly recommended the use of said strain in veterinary.

Decision of Registration Board (292nd meeting):-

Registration Board endorsed the decision of expert working group.

Case No.3:-

The following case of M/s Forward Solutions 80-A,, Lahore were deferred in 258th meeting Registration Board due non-availability of the products in the country of origin.

Sr. No.	**Manufacturer**	**Brand Name and Composition**	**Remarks**	**Registration Board decision in 258th meeting**
1.	FATRO S.P.A – in Via Emili, 2–25030-Maclodio (BS) Italy	**IBA-VAC ST** (Lyophilized live vaccine against (Gumboro's Disease) Each dose contains: Moderately attenuated Live virus of Infectious Bursal Disease, 2512 strain: Titer: not less than 102 EID50	CoPP mentions that *"The product has been developed exclusively for the treatment of the conditions-particularly tropical diseases- not endemic in the country of export."*	Deferred for clarification by the firm for non-availability of the formulation by the regulatory authority in the country of the origin.
2.		**G-OLVAC** Inactivated vaccine in oil emulsion for injection against Newcastle Disease Virus and Infectious Bursal disease Virus Strength of active ingredient Per unit contains:		

		Inactivated Infectious bursal disease virus, NEV 39 strain and Newcastle Disease virus, LaSota strain Titer: Newcastle disease virus……not less than 108.5 EID50 Infectious Bursal disease Virus……not less than 105.5 EID50		
3.		**EDS – VAC** Inactivated vaccine in oil emulsion for injection against Egg drop syndrome 76. Inactivated EDS Titre/dose: Not less than 80 PD50/Dose for EDS Adeno like virus strain 127		

The Working group after detail deliberation and decided as follow;

a. Reason for non-availability of the products in the country of origin by their concerned Regulatory Authority.
b. Evidence of availability of the same products in any other reference regulatory authority as prescribed by the Registration Board.
c. Evidence of availability of the same products with other brand names in country of origin or in any other reference regulatory.

Decision of Registration Board (292nd meeting):-

Registration Board endorsed the decision of expert working group.

ITEM.No.V:- Cases related to Pharmaceutical Evaluation Cell (New cases)

499.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals Pvt Ltd, 25km, Lahore road, Multan
	Brand Name +Dosage Form + Strength	RZL-150 Fee Premix Powder
	Composition	Each 1kg contains: Zinc Bacitracin……100gm Lincomycin (Lincomycin as HCl)…..50gm
	Diary No. Date of R& I & fee	Dy. No. 57; 29-4-2016; Rs.20,000/- (29-4-2016)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	100gm, 500gm, 1kg, 2.5kg, 5kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	ZL-150 by Intervac Reg # 069663
	GMP status	16-10-2018 Firm was operating at the fair level of GMP Compliance.
	Previous remarks of the Evaluator.	Fee challan Photocopy attached.
	Previous decision(s)	Registration Board referred the applied formulation to Expert Working Group on Veterinary Drugs for review (M-288)
	Decision of Expert working group in 08th meeting: The Committee deferred the case for further evaluation regarding chemical compatibility and interaction of both APIs in the formulation. **Decision of Registration Board (292nd meeting):-** Registration Board endorsed the decision of expert working group.	
500.	Name and address of Applicant	M/s Mustafa Brothers 186-D Peoples Colony No.1 Faisalabad
	Detail of Drug Sale License	Address: P-1860-D, Peoples Colony No.1 Faisalabad Validity : 12/2/2019 Status: License to sell drugs as a distributor
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co. Ltd Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho City: Viet Nam.
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical Co. Ltd Address: No.130-1A Highway-Ba Lang Ward – Cai Rang District – CanTho City: Viet Nam.
	Name of exporting country	Viet Nam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No : 14758 Dated : 12/09/2017
	Fee including differential fee	Rs : 100,000 Dated : 12/09/2017
	Brand Name +Dosage Form + Strength	Analgin C Solution For Injection
	Composition	Each ml contains : Analgin……250mg Vitamin C……100mg
	Finished Product Specification	In-House
	Pharmacological Group	Antipyretic, Antiinflammatory
	Shelf life	3 Years (As packaged for sale) 14 days (After first opening the immediate packaging)
	Demanded Price	Decontrolled

	Pack size	100ml
	Me-too status	Could not be confirmed
	Detail of certificates attached	**Free sale Certificate:** Issued by Ministry of Agriculture and Rural development and is valid until 29-3-2019 **GMP certificate** Copy of GMP certificate issued from Ministry of Agriculture and Rural development/Socialist Republic of Viet Nam and is valid until 31 July 2022.
	Remarks of the Evaluator.	3 batches tested at Accelerated stability (40'C+-2'C and 75% RH +-5%) for 6 months and Long term stability (30'C+-2'C and 65% RH +-5%) for 3 years or 36 months a) 0111 Manufacturing date March 2011 b) 0211 Manufacturing date March 2011 c) 0311 Manufacturing date March 2011 Analgin is a synonym of metamizole (a banned drug)
	Previous Decision: Registration Board referred the case to expert Working Group of veterinary drugs for review of formulation (M-288). **Decision of Expert working group in 08th meeting:** The expert working group after thorough deliberation decided not to recommend the formulation due to the presence of banned ingredient "Analgin". **Decision of Registration Board (292nd meeting):-** **Registration Board endorsed the decision of expert working group.**	
501.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Oxy-G Plus Spray (vet)
	Composition	Form-5 Dy.No 30859-C dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Diary No. Date of R& I & fee	Each gm Contains: Oxytetracycline HCl…40mg Gentian violet…4mg
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	Price: 435/125 ml 700/200ml
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TERAGEN AEROSOL SPRAY
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for justification of applied dosage form in the section of "Oral Powder section (Penicillin) Veterinary" (M-287). Deferred for review of formulation & its drug delivery system as applied formulation is spray & its ingredients are mentioned in grams (M-288).
	Decision of Expert working group in 08th meeting: Expert working group decided to recommend the formulation with the clarification that unit of spray dosage form will be in grams or ml. **Decision of Registration Board (292nd meeting):-** **Registration Board endorsed the decision of expert working group.**	

502.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Oxy-G Plus Spray (vet)
	Composition	Form-5 Dy.No 30859-B dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Diary No. Date of R& I & fee	Each gm Contains: Oxytetracycline HCl……40mg Gentian violet…….4mg Citronella oil……..20 mg Permethrine…….10 mg
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	Price: 435/125 ml 700/200ml
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	TERAGEN Plus AEROSOL SPRAY
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for justification of applied dosage form in the section of "Oral Powder section (Penicillin) Veterinary" (M-287). Deferred for review of formulation & its drug delivery system as applied formulation is spray & its ingredients are mentioned in grams (M-288).
	Decision of Expert working group in 08th meeting: Deferred for further evaluation regarding chemical compatibility of citronella oil and permethrin and possible systemic effects of permethrin in the presence of oil. **Decision of Registration Board (292nd meeting):-** **Registration Board endorsed the decision of expert working group.**	
503.	Name and address of Applicant	Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No. 1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	Address: M/s. Ghazi Brothers, Gazi house d-35, KDA Scheme No.1. Miran Muhammad Shah Road, Karachi. Validity: 25 May, 2020 Status: License to sell drugs as a Distributor
	Name and address of manufacturer	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name and address of marketing authorization holder	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.1325 Dated 14/02/2017
	Fee including differential fee	Rs. 50,000/- Dated 20/12/2017
	Brand Name +Dosage Form + Strength	Sinomd 15% Powder (for oral use)
	Composition	Each 1kg of powder contains: Bacitracin (as methylene disalicylate)… 150g

		750g of bacitracin methylene disalicylate eq. to 150g of bacitracin base)
	Target Species	Chickens, Hen & growing turkeys
	Finished Product Specification	In House
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	De-Controlled
	Pack size	1kg, 2kg, 5kg & 10kg
	International availability	Could not be confirmed
	Me-too status	N/A
	Detail of certificates attached	*Original legalized free sale certificate:* Issued by: Pucheng administration of Animal Husbandry & Veterinary & Aquatic Products. Issued on: 14-01-2016. Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP Certificate (Copy): Issued by: Ministry of Agriculture of the People Republic of china, Fujian Province. Certificate No. (2015) S.Y.GMP Z.ZI, No.13003. Issued on: August 21, 2015 Valid till: August 20, 2020.
	Remarks of the Evaluator.	
	Previous Decision: Registration Board referred the case to the Expert committee on the veterinary drugs for their comments regarding need of this medicine within the country (M-286). **Decision of Expert working group in 08th meeting:** Deferred for confirmation of safety and rationality of Bacitracin and indications for applied formulation. **Decision of Registration Board (292nd meeting):-** **Registration Board endorsed the decision of expert working group.**	
504.	Name and address of Applicant	Ghazi Brothers, Ghazi House, D-35, K.D.A Scheme No. 1, Miran Muhammad Shah Road, Karachi-75350, Pakistan.
	Detail of Drug Sale License	Address: M/s. Ghazi Brothers, Gazi house d-35, KDA Scheme No.1. Miran Muhammad Shah Road, Karachi. Validity: 25 May, 2020 Status: License to sell drugs as a Distributor
	Name and address of manufacturer	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name and address of marketing authorization holder	Life Come Biochemistry Co., Ltd. No. 19 Nanpu Ecological Industrial Park, Pucheng, Fujian, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.1325 Dated 14/02/2017
	Fee including differential fee	Rs. 50,000/- Dated 20/12/2017
	Brand Name +Dosage Form + Strength	Sinobac 15% Powder (for oral use)
	Composition	Each 1kg of powder contains: Bacitracin (as zinc)… 150g (750g of bacitracin zinc eq. to 150g of bacitracin base)
	Target Species	Broiler, Hen , Cattle/Buffalo, Aquaculture

	Finished Product Specification	In House
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	De-Controlled
	Pack size	1kg, 2kg, 5kg & 10kg & 25kg
	International availability	Could not be confirmed
	Me-too status	N/A
	Detail of certificates attached	*Original legalized free sale certificate:* Issued by: Pucheng administration of Animal Husbandry & Veterinary & Aquatic Products. Issued on: 14-01-2016. Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP Certificate (Copy): Issued by: Ministry of Agriculture of the People Republic of china, Fujian Province. Certificate No. (2015) S.Y.GMP Z.ZI, No.13003. Issued on: August 21, 2015 Valid till: August 20, 2020.
	Remarks of the Evaluator.	
	Previous Decision: Registration Board referred the case to the Expert committee on the veterinary drugs for their comments regarding need of this medicine within the country (M-286). **Decision of Expert working group in 08th meeting:** Deferred for confirmation of safety and rationality of Bacitracin and indications for applied formulation. **Decision of Registration Board (292nd meeting):-** **Registration Board endorsed the decision of expert working group.**	

Case No.1 Mentioning of Generic Name on the Labeling Material with Equal Prominence as that of the Brand Name.

With reference to the subject cited herein-above, it has been noticed by DRAP that though the Drugs (Labeling and Packing) Rules, 1986 under the rule (3) clearly prescribe and command for mentioning both the Brand as well as Generic Name of a drug/medicine with equal prominence yet the pharmaceutical manufacturers are not complying with the commandment of law as prescribed which practice might be used as a tool for promotion of a Brand and may lead to aid unethical practices on the part of some manufacturers. The case is presented before the worthy Board for consideration and directions to manufacturers for strict compliance to the prescribed rules and regulations as set forth under the law.

Decision: The matter was considered at length by the Board and Board decided to direct all pharmaceutical manufacturers to strictly comply with the commandment of law (Rule 3 of Drugs (Labeling and Packing) Rules, 1986 in order to mention both the brand as well as generic names of drugs with equal prominence.

Case No.2 Mentioning of Exact Expiry Date on the Labeling Material.

Complaint has been received through Prime Minister's Pakistan Citizen's Portal bearing No. IS040919-4481555 dated 04th September 2019 whereby query has been raised about the expiry date of products which is mentioned on the labeling of Drugs/Medicines, as the firms mention expiry month which creates confusion whether it will be the beginning or end of the said month. The rule position was searched for which under sub-rule (g) of rule (3) of the Drugs (Labeling and Packing) Rules, 1986 direct that "Expiry Date" be mentioned while the manufacturers are mentioning the month of expiry which is not in accordance with the said law. The case is, therefore, presented before the worthy Board for consideration and directions, accordingly.

Decision: The matter was discussed and deliberated by the Board. The Board was of the opinion that internationally both the patterns I.e. (MM/YEAR or YEAR/MM) and date (DD/MM/YEAR or YEAR/MM/DD) are used while indicating towards the expiry of drugs. The Board decided to seek opinion of Legal Affairs Division of DRAP for further consideration by Registration Board.

Meeting ended with vote of thanks to and from the Chair.
