MINUTES OF 291st MEETING OF REGISTRATION BOARD HELD ON 2nd, 3rd & 4th SEPTEMBER, 2019

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

291st meeting of Registration Board was held on 2-4th September, 2019 in the Committee Room, Drug Regulatory Authority of Pakistan, G-9/4, Islamabad. The meeting was chaired by Dr.Obaidullah, Director, Pharmaceutical Evaluation & Registration Division, DRAP. The meeting started with recitation of the Holy Verses and was attended by following:-

1.	Dr. Rafeeq Alam Khan, Meritorious Professor/ Dean, Faculty of Pharmacy, Dow University of Health Sciences.	Member
2.	Prof. Dr. Ghulam Sarwar, Dean, Faculty of Pharmacy, Jinnah University for Women, Karachi	Member
3.	Dr. Aslam Shah, Senior Manager (Pharmacy & Purchase), The Indus Hospital, Karachi	Member
4.	Dr. Qurban Ali, Ex-Director General, National Veterinary Laboratory, Islamabad	Member
5.	Dr. Amanullah Khan, Director, Drugs Testing Laboratory, Quetta. Government of Balochistan	Member
6.	Mr. Abid Saeed Baig, Director, Drugs Testing Laboratory, Rawalpindi, Government of Punjab	Member
7.	Syed Adnan Rizvi, Director, Drugs Testing Laboratory, Karachi, Government of Sindh	Member
8.	Dr. Muhammad Khalid Jawed, Director, Drugs Testing Laboratory, Peshawar Government of Khyber Pakhtunkhwa	Member
9.	Mr. Muhammad Aslam, Deputy Draftsman-II, Representative of Ministry of Law & Justice, Islamabad	Member
10.	Dr. Noor-us-Saba, Director, Biological Evaluation & Research Division, DRAP	Member
11.	Dr. Hafsa Karam Ellahi, Additional Director, Representative of QA&LT Division, DRAP	Member
12.	Mr. Abdullah, Additional Director (PE&R), DRAP.	Member / Secretary
13.	Dr.Muhammad Akram, Representative of Animal Husbandry Commissioner, M/o National Food Security & Research, Islamabad.	Co-opted Member

Ms.Tahreem Sara (Dy.Director-RRR), Assistant Directors of Reg-I, Reg-II, Post Reg-I, Post Reg-II, I&V-I, I&V-II and Mr. Asif Jalil, Incharge PEC with respective Assistant Directors presented the agenda of PE&R Division. Director, BE&R assisted by respective Assistant Directors presented the agenda of BE&R Division. Mr. Abdul Sattar Sohrani Additional Director, QA&LT assisted by respective Assistant Director presented the agenda of QA & LT Division.

Mr. Shamim Ahmed, Mr.Arshad Mehmood, Mr.Iftakhar (PPMA), Mr. Nadeem Alamgir (Pharma Bureau) and Mr. Kamran Anwar (PCDA) attended the meeting as observers on behalf of their respective associations.

Item No. I: Confirmation of Minutes of 290th Meeting of Registration Board.

290th meeting of Registration Board was held on 3rd & 4th July, 2019. Draft minutes of 290th meeting of Registration Board were circulated among the members of the Board on 29th July, 2019 for perusal/approval within five days. None of the members disagreed the draft minutes. Accordingly, minutes were approved by the Chairman Registration Board and circulated to all concerned for necessary action.

Decision: Registration Board confirmed the minutes of 290th meeting.

Item No. II **Division of Pharmaceutical Evaluation and Registration**

Pharmaceutical Evaluation Cell (PEC)

Agenda of Evaluator PEC-II

Agenda of Evaluator PEC-III

Agenda of Evaluator PEC-IV

Agenda of Evaluator PEC-V

Agenda of Evaluator PEC-VI

Agenda of Evaluator PEC-VIII

Agenda of Evaluator PEC-IX

Agenda of Evaluator PEC-X

Agenda of Evaluator PEC-XIII

Agenda of Evaluator PEC-XIV

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**

Total Cases: 1503

Following points were deliberated and decided in addition to routine agenda.

a. Correction / revision in submitted applications on form 5 / 5A / 5D for registration of drugs.

Registration Board clarified that any correction required in Form 5, 5A or 5D submitted before 7th March shall be done by submitting corrected version of same form accordingly.

b. Quality Assessment of various formulations including Simvastatin/ Ezetimibe, linezolid, fexofanidine and ticagrelor

Registration Board deliberated the matter regarding specialized manufacturing and testing requirements for simvastatin / ezetimibe tablets and requirement of specific polymorphic forms of linezolid, fexofanidine and ticagrelor. The Board advised Pharmaceutical Evaluation Cell (PEC) to prepare agenda regarding the scientific requirements of above mentioned formulations for the upcoming meeting.

c. MRP fixation for new formulations

Registration Board deliberated that it has been already decided in its 278th meeting that manufacturer can submit product development data with 3 months stability studies for initial assessment by respective division. The Board further decided that such data shall be presented before registration board for consideration. Incase of satisfactory results, case shall be referred to Costing & Pricing Division for fixation of MRP simultaneously. However, registration application shall be again placed before Registration Board after submission of required stability data of 6 months by the manufacturer for decision (approval / rejection).

Evaluator PEC-II

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

a. New cases

Routine applications for local manufacture (Human)

1.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Nalfon 10mg/ml Injection
	Composition	"Each Ampoule (1ml) Contains: Nalbuphine hydrochloride ……10mg"
	Diary No. Date of R& I & fee	Dy. No 24727 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	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	Approved by USFDA
	Me-too status (with strength and dosage form)	Nalbufin Injection of M/s Mass Pharma (Pvt) Ltd, 17 KM, Ferozepur Road, Lahore (Reg.# 025543)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specifications.	
2.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Devenda 500mg/5ml Injection
	Composition	"Each Ampoule (5ml) Contains: Levetiracetam…..500mg"
	Diary No. Date of R& I & fee	Dy.No.24728 dated 17-07-2018 Rs.20,000/- 17-07-2018
	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)	Eplipsa 500mg/5ml Injection of M/s Helix Karachi (Reg.#075918)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved.	
3.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Xevolac 10mg/ml Injection
	Composition	Each Ampoule (1ml) Contains: Ketorolac Tromethamine……10mg
	Diary No. Date of R& I & fee	Dy. No 24729 dated 17-07-2018 Rs.20,000/- 17-07-2018
	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	US-FDA Approved.

	Regulatory Authorities	
	Me-too status (with strength/dosage form)	Tromit Injection of Standpharm (Reg.# 049959)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved.	
4.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Xevolac 30mg/ml Injection
	Composition	"Each Ampoule (1ml) Contains: Ketorolac Tromethamine.....30mg"
	Diary No. Date of R& I & fee	Dy. No 24730 dated 17-07-2018 Rs.20,000/- 17-07-2018
	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	US-FDA Approved.
	Me-too status (with strength/dosage form)	Tromit Injection of Standpharm (Reg.# 049960)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved.	
5.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd. 312, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Xevolac 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ketorolac Tromethamine…10mg"
	Diary No. Date of R& I & fee	Dy. No 24731 dated 17-07-2018 Rs.20,000/- 17-07-2018
	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	USFDA Approved
	Me-too status (with strength/dosage form)	Kelac 10mg tablet of M/s Rotex Pharma (Reg.# 060804)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 03-10-2017 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved.	
6.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Pinext 500mg IV/IM Injection
	Composition	"Each Vial Contains: Cefepime as HCl (with L-Arginine)….500mg"
	Diary No. Date of R& I & fee	Dy. No 17619 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial

	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/dosage form)	Nuxipim 500mg Injection of Bosch
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
7.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore. **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Pinext 1000mg IV/IM Injection
	Composition	"Each Vial Contains: Cefepime as HCl (with L-Arginine)….1000mg"
	Diary No. Date of R& I & fee	Dy. No 17659 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	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/dosage form)	Nuxipim 1g Injection of Bosch
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore.	

8.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Sulbanext 1g IV/IM Injection
	Composition	"Each Vial Contains: Cefoperazone Sodium eq. to Cefoperazone …… 500mg Sulbactum Sodium eq. to Sulbactum ……..…500mg"
	Diary No. Date of R& I & fee	Dy.No 17656 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA-Japan
	Me-too status (with strength and dosage form)	2Sum Injection 1g of M/s Sami Pharmaceuticals, Karachi (Reg.# 047002)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
9.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Cefinext 100mg/5ml Suspension
	Composition	"Each 5ml Contains: Cefixime as trihydrate…100mg"
	Diary No. Date of R& I & fee	Dy.No 17660 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	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 AEMPS of Spain
	Me-too status (with strength/dosage form)	Fasxime 100mg Suspension of M/s Fassgen Pharmaceuticals, (Reg.# 053526)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.

	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
10.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ferrostar 20mg IV Injection
	Composition	"Each ml Ampoule Contains: Iron Sucrose complex eq. to elemental Iron.…20mg"
	Diary No. Date of R& I & fee	Dy. No 17649 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	5ml, As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Iroject Injection by M/s Medley Pharmaceuticals (Reg#070173)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel—The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
11.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	D-Next 5mg/ml IV/IM Injection
	Composition	"Each 1ml Contains: Cholecalciferol (Vitamin D3)…5mg"
	Diary No. Date of R& I & fee	Dy. No 17650 dated 11-05-2018 Rs.20,000/- Dated 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Vitamin
	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 ANSM of France
	Me-too status (with strength/dosage form)	D-Tres 5mg/ml Injection by M/s Sami (Reg#076115)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel—The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products (Pvt) Ltd. 44 A-B, Sundar Industrial Estate, Lahore dated 25-7-2019. • Reference product is available in ampoule whereas firm has applied for vial.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore. Moreover clarification shall be submitted regarding container closure system, since reference product is available in ampoule whereas firm has applied for vial.	
12.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Diazol 500mg/100ml Infusion
	Composition	"Each 100ml vial Contains: Metronidazole……500mg"
	Diary No. Date of R& I & fee	Dy. No 17652 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Imidazole derivative
	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)	Dyrid-P 500mg Injection by M/s Medicraft Pharmaceuticals (Pvt) Ltd. (Reg#051092)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel —The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products (Pvt) Ltd 44 A-B, Sundar Industrial Estate, Lahore dated 25-7-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore.	

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

		Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore.	
15.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 500mg IV Injection
	Composition	"Each Vial Contains: Ceftriaxone Sodium eq. to ceftriaxone……500mg"
	Diary No. Date of R& I & fee	Dy.No 17667 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	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)	Rezone 500mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031982)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	
16.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Moxiflin 400mg/250ml Infusion
	Composition	"Each Vial Contains: Moxifloxacin HCl……400mg"
	Diary No. Date of R& I & fee	Dy.No 17648 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	250ml;As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Moxilox 400mg Infusion by M/s Spencer Karachi (Reg.#075988)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
17.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Painext 75mg/3ml IV/IM Injection
	Composition	"Each 3ml ampoule Contains: Diclofenac Sodium…75mg"
	Diary No. Date of R& I & fee	Dy. No 17651 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	NSAID
	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)	Adik 75mg/3ml Injection by M/s City Pharma, Karachi (Reg.#075932)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products (Pvt) Ltd 44 A-B, Sundar Industrial Estate, Lahore dated 25-7-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	

18.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Alacep 200mg/100ml Infusion
	Composition	"Each vial Contains: Ciprofloxacin as lactate……200mg"
	Diary No. Date of R& I & fee	Dy. No 17655 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	100ml;As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Cinoflox 200mg/100ml Infusion by M/s S.J & G Karachi . . (Reg#058541)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
19.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 250mg IM Injection
	Composition	"Each vial Contains: Ceftriaxone as sodium……250mg"
	Diary No. Date of R& I & fee	Dy. No 17664 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	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.No. 075341)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e.

		M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	
20.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 1000mg IV Injection
	Composition	"Each vial Contains: Ceftriaxone as sodium……1000mg"
	Diary No. Date of R& I & fee	Dy.No 17668 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	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	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently, fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore	
21.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ceftronext 250mg IV Injection
	Composition	"Each vial Contains: Ceftriaxone as sodium……250mg"
	Diary No. Date of R& I & fee	Dy.No 17666 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	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)	Rezone 250mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031981)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products (Pvt) Ltd 44 A-B, Sundar Industrial Estate, Lahore dated 25-7-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
22.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tonext 500mcg IV/IM Injection
	Composition	"Each ml Contains: Mecobalamin……500mcg"
	Diary No. Date of R& I & fee	Dy.No 17653 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Coenzyme Type Vitamin B12
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA of Japan
	Me-too status (with strength and dosage form)	Mexamine 500mcg/ml Injection of M/s Asian Continental (Pvt.) Ltd, Karachi(Reg. # 057864)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products (Pvt) Ltd 44 A-B, Sundar Industrial Estate, Lahore dated 25-7-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
23.	Name and address of manufacturer / Applicant	"M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore **By:** M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km, Ferozepur Road, Lahore"

	Brand Name +Dosage Form + Strength	Sulbanext 2g IV/IM Injection
	Composition	Each Vial Contains: Cefoperazone Sodium eq. to Cefoperazone …… 1000mg Sulbactum Sodium eq. to Sulbactum ……..…1000mg
	Diary No. Date of R& I & fee	Dy.No 17657 dated 11-05-2018 Rs.20,000/- 11-05-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA-Japan
	Me-too status (with strength and dosage form)	2Sum Injection 1g of M/s Sami Pharmaceuticals, Karachi (Reg.# 047003)
	GMP status	Last GMP inspection dated 5th & 27th December, 2017 conclusion by Panel ―The firm (M/s NovaMed Pharmaceuticals Pvt. Ltd. Lahore) is compliant to Good cGMP guidelines at the time of inspection.
	Remarks of the Evaluator[II]	Form 5 was initially submitted from the manufacturer i.e. M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28-km, Ferozepur Road, Lahore. Subsequently fresh Form 5 has been submitted by the applicant i.e., M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore, dated 25-07-2019.
	Decision: Registration Board decided to defer all applied products of contract manufacturing from M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore, for assessment of manufacturing and quality control capacity of M/s Novamed Pharmaceuticals (Pvt) Ltd. 28-km,Ferozepur Road, Lahore	
24.	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	Metolar 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Metoprolol tartrate…50mg"
	Diary No. Date of R& I & fee	Dy. No 24703 dated 17-07-2018 Rs.20,000/- 17-07-2018 Rs. 30,000/- dated 27-06-2019
	Pharmacological Group	Beta blockers, selective
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Merol 50mg Tablet of M/s Atco Laboratories Limited (Reg.# 061338)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 29-01-2019 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved	
25.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi
	Brand Name +Dosage Form + Strength	Metolar 100mg Tablet

	Composition	"Each Film Coated Tablet Contains: Metoprolol tartrate…100mg"
	Diary No. Date of R& I & fee	Dy. No 24702 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Beta blockers, selective
	Type of Form	Form-5
	Finished product Specifications	BP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Metoscot Tablets of M/s Scotmann Pharmaceuticals (Reg.# 029912)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 29-01-2019 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved.	
26.	Name and address of manufacturer / Applicant	"M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Surexime 200mg Capsule
	Composition	"Each Capsule Contains: Cefixime as Cefixime Trihydrate…200mg"
	Diary No. Date of R& I & fee	Dy. No 24878 dated 18-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Cephalosporin, antibiotic
	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 AEMPS of Spain
	Me-too status (with strength and dosage form)	Xime 200 mg Capsules of M/s Fedro Pharmaceutical (Reg.# 075503)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 28-06-2018 concluded Good level of GMP compliance.
	Remarks of the Evaluator[II]	JP monograph is available for applied formulation.
	Decision: Approved with JP specifications.	
27.	Name and address of manufacturer / Applicant	M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Kloral 450/35mg Tablets
	Composition	"Each tablet contains: Paracetamol …… 450mg Orphenadrine Citrate ……35mg"
	Diary No. Date of R& I & fee	Dy. No 24931 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Norgesic of M/s iNova Pharmaceuticals Australia Pvt. Ltd.approved by TGA of Australia
	Me-too status (with strength/dosage form)	Rid-All Forte by M/s Stanley Pharma (Reg.#069786)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 06-03-2019 concluding GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	

28.	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	Diacin 50mg Capsule
	Composition	"Each Capsule Contains: Diacerein……50mg"
	Diary No. Date of R& I & fee	Dy. No 24927 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Other antiinflammatory and antirheumatic agents, nonsteroids
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As fixed by Govt.
	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	Firm has submitted copy of GMP inspection report conducted on 03-10-2018 & 19-12-2018 concluding GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
29.	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	Flocta 200mg Tablet
	Composition	"Each Tablet Contains: Floctafenine hemi fumarate…200mg"
	Diary No. Date of R& I & fee	Dy. No 24928 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength/dosage form)	Idaarac 200mg of m/s Sanofi Aventis (Reg.# 005322)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 03-10-2018 & 19-12-2018 concluding GMP compliance.
	Remarks of the Evaluator[II]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
30.	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	Qutec 50 Tablet
	Composition	"Each Tablet Contains: Diclofenac sodium (enteric coated)…..50mg Misoprostol…..200mcg"
	Diary No. Date of R& I & fee	Dy. No 24875 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	NSAID, Prostaglandin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's,20's,30's;As per leader price
	Approval status of product in Reference	Approved by MHRA of UK

	Regulatory Authorities	
	Me-too status (with strength/dosage form)	Misocot 50 Tablet by M/s Nabiqasim Karachi. (R#074965)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	• The submitted master formulation does not include ingredients for enteric coating. • It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise. • Manufacturing method has not been submitted. • In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.
	Decision: Deferred for following observations: • **The submitted master formulation does not include ingredients for enteric coating.** • **It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise.** • **Manufacturing method has not been submitted.** • **In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.**	
31.	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	Feburic 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Febuxostat…..40mg"
	Diary No. Date of R& I & fee	Dy. No 24885 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Xanthine oxidase inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10’s,20’s,30’s,45’s;As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Febuxin by M/s AGP, Karachi (Reg. No. 081104)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator’s specification.	
32.	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	Feburic 80mg Tablet
	Composition	"Each Film Coated Tablet Contains: Febuxostat……..80mg"
	Diary No. Date of R& I & fee	Dy.No 24886 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Xanthine oxidase inhibitor
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10’s,20’s,30’s,45’s;As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength/dosage form)	Febuxin by M/s AGP, Karachi (Reg. No. 081105)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
33.	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	Qutec 75 Tablet
	Composition	"Each Tablet Contains: Diclofenac sodium……75mg Misoprostol……200mcg"
	Diary No. Date of R& I & fee	Dy. No 24874 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	NSAID, Prostaglandin
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's,20's,30's;As per leader price
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength/dosage form)	Misocot 50 Tablet by M/s Nabiqasim, Karachi (R#074965)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	• The submitted master formulation does not include ingredients for enteric coating. • It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise. • Manufacturing method has not been submitted. • In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.
	Decision: Deferred for following: • **The submitted master formulation does not include ingredients for enteric coating.** • **It is not evident from the submitted master formulation that whether Misoprostol is in dispersion form or otherwise.** • **Manufacturing method has not been submitted.** • **In contrary to reference product which involves film coating over the misoprostol layer, no such details are mentioned in the dossier.**	
34.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan. contract manufacturing by M/s English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore"
	Brand Name +Dosage Form + Strength	Ruling 40mg Dry Powder Injection
	Composition	"Each Vial Contains: Omeprazole as Sodium…40mg"
	Diary No. Date of R& I & fee	Dy. No 24873 dated 18-07-2018 Rs.50,000/- 16-07-2018
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Nexum IV 40mg Injection by M/s Getz Pharma, Karachi, (Reg#050651)
	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products. Certificate of GMP Issued to M/s English Pharma on 16-01-2018
	Remarks of the Evaluator[II]	Form 5 has been submitted by manufacturer i.e. M/s English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore, Pakistan, instead of the applicant i.e. M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.
	Decision: Registration Board deferred the case since Form 5 has been submitted by manufacturer i.e. M/s English Pharmaceuticals Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore, Pakistan, instead of the applicant i.e. M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.	
35.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Rulcer 1gm Tablet
	Composition	"Each Tablet Contains: Sucralfate……1gm"
	Diary No. Date of R& I & fee	Dy. No 24872 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's; 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)	Sucralif Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg#054696)
	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	
	Decision: Approved with USP specifications.	
36.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Rulcer 500mg Tablet
	Composition	"Each Tablet Contains: Sucralfate……500mg"
	Diary No. Date of R& I & fee	Dy. No 24869 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Cytoprotective agent
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	10's; As per leader price
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Sucralif Tablets by M/s Alliance Pharmaceuticals (Pvt) Ltd, (Reg#054695)

	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
37.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Dremivate 12.5mg/4ml Syrup
	Composition	"Each 4ml Contains: Dimenhydrinate ……12.5mg"
	Diary No. Date of R& I & fee	Dy. No 24868 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Dymin Syrup by M/s Stanley Pharmaceuticals (Pvt) Ltd., (Reg#001718)
	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
38.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Stomacol-C Suspension
	Composition	Each 5ml Contains: Domperidone as Maleate…….5mg Cinnarizine..……10mg
	Diary No. Date of R& I & fee	Dy. No 24870 dated 18-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Pelton-C Suspension by M/s Vision Pharmaceuticals (Pvt.) Ltd., (Reg#047730)
	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.

	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
39.	Name and address of manufacturer / Applicant	"M/s The Schazoo Zaka Pvt Ltd. Lahore, Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura"
	Brand Name +Dosage Form + Strength	Dulax 20mg Capsule
	Composition	"Each Capsule Contains: Enteric Coated Pellets of Duloxetine hydrochloride Eq. to Duloxetine……20mg"
	Diary No. Date of R& I & fee	Dy. No 24916 dated 18-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Rs. 20per capsule
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dulan capsules of M/s Hilton Pharma (Pvt.) Limited Karachi (Reg.# 055446)
	GMP status	GMP Certificate issued on 24-07-2018
	Remarks of the Evaluator[II]	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad
	Decision: Approved.	
40.	Name and address of manufacturer / Applicant	"M/s The Schazoo Zaka Pvt Ltd. Lahore, Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura"
	Brand Name +Dosage Form + Strength	Dulax 30mg Capsule
	Composition	"Each Capsule Contains: Enteric Coated Pellets of Duloxetine hydrochloride Eq. to Duloxetine……30mg"
	Diary No. Date of R& I & fee	Dy. No 24917 dated 18-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Rs. 27 per capsule
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Dulan capsules of M/s Hilton Pharma (Pvt.) Limited Karachi (Reg.# 055447)
	GMP status	GMP Certificate issued on 24-07-2018
	Remarks of the Evaluator[II]	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad
	Decision: Approved.	
41.	Name and address of manufacturer / Applicant	M/s The Schazoo Zaka Pvt Ltd. Lahore, Kalalwala, Zaka ur Rehman State, Plot No.1, 20-km Lahore-Jaranwala Road, Shikhupura.
	Brand Name +Dosage Form + Strength	Dulax 60mg Capsule
	Composition	"Each Capsule Contains: Enteric Coated Pellets of Duloxetine hydrochloride Eq. to Duloxetine……60mg"
	Diary No. Date of R& I & fee	Dy. No 24918 dated 18-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Antidepressant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	Rs. 35 per capsule
	Approval status of product in Reference	Approved by USFDA

	Regulatory Authorities	
	Me-too status (with strength and dosage form)	Dulan capsules of M/s Hilton Pharma (Pvt.) Limited Karachi (Reg.# 055448)
	GMP status	GMP Certificate issued on 24-07-2018
	Remarks of the Evaluator[II]	**Source of pellets:** M/s Vision Pharmaceuticals, Islamabad
	Decision: Approved.	
42.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab.28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Medfene 50mg Tablet
	Composition	"Each Tablet Contains: Clomiphene Citrate…..50mg"
	Diary No. Date of R& I & fee	Dy. No 25115 dated 19-07-2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Gynofen 50mg Tablet. Reg No. 53337
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	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.	
43.	Name and address of manufacturer / Applicant	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Brand Name +Dosage Form + Strength	Solyxa 10mg Tablet
	Composition	"Each Film coated tablet contains: Solifenacin succinate…10mg"
	Diary No. Date of R& I & fee	Dy. No 25110 dated 19-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Solfine Tablet 10 mg of M/s Regal Pharmaceuticals (Reg. No.081959)
	GMP status	Last inspection report 10-1-2018, Panel recommended for the issuance of GMP Certificate.
	Remarks of the Evaluator[II]	The case was previously deferred in 289th meeting for consideration on its queue.
	Decision: Approved with innovator's specification.	
44.	Name and address of manufacturer / Applicant	"M/s Ferozsons Laboratories Ltd. P.O Ferozsons, Amangarh, Nowshera-Khyber Pakhtunkhwa"
	Brand Name +Dosage Form + Strength	Solyxa 5mg Tablet
	Composition	"Each Film coated tablet contains: Solifenacin succinate…5mg"
	Diary No. Date of R& I & fee	Dy. No 25110 dated 19-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Urinary antispasmodics
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications

	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Solfine Tablet 5 mg of M/s Regal Pharmaceuticals (Reg. No.081958)
	GMP status	Last inspection report 10-1-2018, Panel recommended for the issuance of GMP Certificate.
	Remarks of the Evaluator[II]	The case was previously deferred in 289th meeting for consideration on its queue.
	Decision: Approved with innovator's specification.	
45.	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	Taram-SR Tablet
	Composition	"Each Film Coated Sustained Release Tablet Contains: Tramadol HCl…100mg"
	Diary No. Date of R& I & fee	Dy. No 25104 dated 19-07-2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Opioid analogue
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Medifenac SR 100mg Tablet of M/s. Mediate Pharmaceuticals, Karachi (Reg.# 048703)
	GMP status	GMP Inspection conducted on 20-03-2018 concluded that firm is operating at acceptable level of compliance to the cGMP.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
46.	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	Adorner 20mcg Tablet
	Composition	"Each Film Coated Tablet Contains: Beraprost as Sodium…20mcg"
	Diary No. Date of R& I & fee	Dy. No 25103 dated 19-07-2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Vasodilator
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per PRC policy
	Approval status of product in Reference Regulatory Authorities	Approved by PMDA of Japan
	Me-too status (with strength and dosage form)	Benprost 20mcg tablet of M/s. NabiQasim, Karachi (Reg.# 061237)
	GMP status	GMP Inspection conducted on 20-03-2018 concluded that firm is operating at acceptable level of compliance to the cGMP.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
47.	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	Ampreg 100mg Capsule
	Composition	Each Capsule Contains: Pregabalin…….100mg

	Diary No. Date of R& I & fee	Dy. No 25101 dated 19-07-2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Vasodilator
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As per PRC policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Gabica 100mg Capsule by M/s Getz Pharma (Reg#047366)
	GMP status	GMP Inspection conducted on 20-03-2018 concluded that firm is operating at acceptable level of compliance to the cGMP.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
48.	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	Bamtural 10mg Tablet
	Composition	"Each Tablet Contains: Bambuterol HCl.…10mg"
	Diary No. Date of R& I & fee	Dy. No 25102 dated 19-07-2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Vasodilator
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC policy
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Bastrol 10mg Tablet by M/s Bosch Pharmaceuticals (Reg#055541)
	GMP status	GMP Inspection conducted on 20-03-2018 concluded that firm is operating at acceptable level of compliance to the cGMP.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
49.	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	Fixil Capsule 200mg
	Composition	"Each capsule contains: Cefixime Trihydrate eq. to Cefixime…200mg"
	Diary No. Date of R& I & fee	Dy.No. 25083 dated 19.07.2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Cephalosporin, antibiotic
	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 AEMPS of Spain
	Me-too status (with strength and dosage form)	Xime 200 mg Capsules of M/s Fedro Pharmaceutical (Reg.# 075503)
	GMP status	13-07-2017; Grant of new DML Panel recommends grant of new DML.
	Remarks of the Evaluator[II]	
	Decision: Approved with JP specifications.	

50.	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	Diasol Capsule 50mg
	Composition	"Each capsule contains: Diacerein …..50mg"
	Diary No. Date of R& I & fee	Dy. No.25082 dated 19.07.2018 Rs.20,000/- 19-07-2018
	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	13-07-2017; Grant of new DML Panel recommends grant of new DML.
	Remarks of the Evaluator[II]	
	Decision: Keeping in view the approval status of Diacerein capsule 50mg by Austrian Agency for Health and Food Safety (reference regulatory authority as per decision of Registration Board in 249th meeting), the Registration Board approved the formulation of Diacerein 50mg capsule only for the following clinical indication. • **Treatment of symptoms of osteoarthritis of the hip or knee joint.**	
51.	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	Novomit Injection 5mg/5ml
	Composition	"Each 5ml ampule contains: Tropisetron hydrochloride eq. to Tropisetron……5mg"
	Diary No. Date of R& I & fee	Dy. No.25082 dated 19.07.2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Serotonin 5-HTreceptor antagonist
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status (with strength/dosage form)	Tropiset Injection by M/s CCL Pharma (Reg#048023)
	GMP status	13-07-2017 for the Grant of new DML Panel recommends grant of new DML.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
52.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ebistate 10mg Tablet
	Composition	Each Film coated tablet contains: Ebastine……10mg
	Diary No. Date of R& I & fee	Dy. No 25113 dated 19-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by ANMS of France
	Me-too status (with strength/dosage form)	Clubex 10mg Tablets of M/s Welmark (Reg.# 056446)

	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
53.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Ebistate 20mg Tablet
	Composition	"Each Film coated tablet contains: Ebastine…20mg"
	Diary No. Date of R& I & fee	Dy.No 25114 dated 19-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form-5
	Finished product Specifications	JP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by Medicine Evaluation Board of Netherland.
	Me-too status (with strength/dosage form)	Lobastin Tablet 20mg of M/s Lowitt (Reg#080844)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
54.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Zemed 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Zolmitriptan……5mg"
	Diary No. Date of R& I & fee	Dy. No 24923 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Anti-migraine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK.
	Me-too status (with strength/dosage form)	Zoptan Tablets 5mg of M/s CCL Pharma (Reg.# 043870)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
55.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Cinitamed 1mg Tablet
	Composition	"Each Tablet Contains: Cinitapride as an acid Tartrate…..1mg"
	Diary No. Date of R& I & fee	Dy. No 25116 dated 19-07-2018 Rs.20,000/- 19-07-2018
	Pharmacological Group	Pro-kinetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifcations
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by AEMPS of Spain
	Me-too status (with strength/dosage form)	Sitip 1mg Tablet by M/s Sami Pharma. (Reg.No.076174)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
56.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Zemed 2.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Zolmitriptan.….2.5mg"
	Diary No. Date of R& I & fee	Dy. No 24922 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Anti-migraine
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK.
	Me-too status (with strength and dosage form)	Zoptan Tablets 2.5mg of M/s CCL Pharmaceuticals (Reg.# 043869)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
57.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Alemed Tablet
	Composition	"Each Film Coated Tablet Contains: Alendronate Sodium Eq. to Alendronic acid…70mg Cholecalciferol…70µg"
	Diary No. Date of R& I & fee	Dy. No 24924 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Drugs for treatment of bone diseases, Bisphosphonates, combinations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Osteopor-D Tablet of M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad. (Reg.# 068878)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
58.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Tilth 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Telithromycin…400mg"
	Diary No. Date of R& I & fee	Dy. No 24925 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Drugs for treatment of bone diseases, Bisphosphonates, combinations
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France

	Me-too status (with strength and dosage form)	Telrom 400mg Tablets of M/s Genome Pharmaceuticals. (Reg.# 056089)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
59.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Itomed 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Itopride hydrochloride…50mg"
	Diary No. Date of R& I & fee	Dy. No 24926 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Prokinetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved
	Me-too status (with strength/dosage form)	ITP of M/s Sami Pharmaceuticals
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
60.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	G-med 1mg Tablet
	Composition	"Each Film Coated Tablet Contains: Granisetron as hydrochloride……1mg"
	Diary No. Date of R& I & fee	Dy. No 24920 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Anti-emetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities	Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved
	Me-too status (with strength and dosage form)	Graniset Tablets of M/s CCL Pharmaceuticals (Reg.#048026)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved with USP specifications.	
61.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Brand Name +Dosage Form + Strength	Mecital 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Escitalopram as Oxalate…10mg"
	Diary No. Date of R& I & fee	Dy. No 24921 dated 18-07-2018 Rs.20,000/- 18-07-2018
	Pharmacological Group	Antidepressant
	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)	Zavesca tablet 10mg of Getz Pharma. (Reg.#045279)
	GMP status	GMP Inspection conducted on 12-12-2017 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
62.	Name and address of manufacturer / Applicant	"M/s Hudson Pharma Private Limited. Site-Plot No. D-93, North Western Industrial Zone, Port Qasim Authority, Pakistan" **contract manufacturing by** 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	Mecoson 500mcg Tablet
	Composition	"Each Sugar Coated Tablet Contains: Mecobalamin…….500mcg"
	Diary No. Date of R& I & fee	Dy. No 25065 dated 18-07-2018 Rs.50,000/- Dated 18-07-2018
	Pharmacological Group	Antianaemic agent
	Type of Form	Form-5
	Finished product Specifications	JP
	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/dosage form)	Mecomed 500mcg by Global Pharma (Reg. No . 041670)
	GMP status	Firm has submitted copy of GMP inspection report of M/s Hiranis, conducted on 29-01-2019 concluded satisfactory level of compliance with GMP guidelines
	Remarks of the Evaluator[II]	
	Decision: Approved.	
63.	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	Novomit Capsule 5mg
	Composition	"Each caspule contains: Tropisetron hydrochloride eq. to Tropisetron……5mg"
	Diary No. Date of R& I & fee	Dy. No.25084 dated 19.07.2018 Rs.20,000/-19-07-2018
	Pharmacological Group	Serotonin 5-HT receptor antagonist
	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 Sweden.
	Me-too status (with strength and dosage form)	Tropiset Capsules by M/s C.C.L Pharmaceuticals, (Pvt) Ltd; (Reg#048028)
	GMP status	13-07-2017 for the Grant of new DML Panel recommends grant of new DML.
	Remarks of the Evaluator[II]	
	Decision: Approved with innovator's specification.	
64.	Name and address of manufacturer / Applicant	"M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Stomacol-C Tablet
	Composition	"Each Tablet Contains: Domperidone as Maleate…5mg Cinnarizine…10mg"
	Diary No. Date of R& I & fee	Dy. No.24871 dated 18-07-2018 Rs.20,000/- 16-07-2018

	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per leader price
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Pelton-C Tablets by M/s Global Pharma Pharmaceuticals (Pvt.) Ltd., (Reg#032891)
	GMP status	Firm has submitted copy of GMP inspection report of M/s High-Q, conducted on 10/04/18 concluding an acceptable level of compliance with good manufacturing practices for Pharma products.
	Remarks of the Evaluator[II]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
65.	Name and address of manufacturer / Applicant	"M/s Inventor Pharma. Plot No. K/196, S.I.T.E. (SHW) Phase II, Karachi"
	Brand Name +Dosage Form + Strength	Inxime 200mg Capsule
	Composition	"Each Capsule Contains: Cefixime as Cefixime Trihydrate…200mg"
	Diary No. Date of R& I & fee	Dy. No 24891 dated 18-07-2018 Rs.20,000/- 17-07-2018
	Pharmacological Group	Cephalosporin, antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per Drap policy
	Approval status of product in Reference Regulatory Authorities	Approved by AEMPS of Spain
	Me-too status (with strength and dosage form)	Xime 200 mg Capsules of M/s Fedro Pharmaceutical (Reg.# 075503)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 05-07-2018 concluded Good level of GMP compliance.
	Remarks of the Evaluator[II]	JP monograph is available for applied formulation.
	Decision: Approved with JP specifications.	
66.	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	Q-Tine 200mg Tablet
	Composition	"Each Film Coated Tablet Contains: Quetiapine as hemi fumarate Eq. to Quetiapine…200mg"
	Diary No. Date of R& I & fee	Dy. No 25098 dated 19-07-2018 Rs.20,000/- 16-07-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength/dosage form)	Pine Table of M/s. Werrick Pharma (Reg.# 082046)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 12-11-2018 concluding as under: Conclusion: During the inspection, the facilities for manufacturing,

		quality and environmental control, documentation, SOP's compliance and qualified staff employed were evaluated. The firm has strengthened the quality control by providing instruments like Karl Fisher, air sampler, particle counter, TOC and liquid particle counter. They have also rectified the observations made in the previous GMP inspections, While some still need to be addressed, Based upon findings and observations of the inspection, the following sections of M/s Welwrd are considered to be operating at satisfactory level of GMP/ 1- Tablet section (general/antibiotic) 2- Liquid injectable section (general/antibiotic) 3- Dry injectable section (general/antibiotic) 4-Dry powder injectable (Cephalosporine) While the remaining sections viz capsule gen, dry powder suspension general and sachet sections were observed with certain short comings that need to be rectified. The firm will again be inspected in compliance to QA&LT Division letter f.4-7/2007-qa date 18-09-2018 for verification of the r emaining shortcomings by the panel constituted for conducting the panel GMP inspection of the firm for the grant of cGMP.
	Remarks of the Evaluator[II]	
	Decision: Approved.	

Following applications of M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi have been forwarded to Incharge PEC by DD-Reg II, vide file No. F.1-4/2013-Reg.II (Vol.I), for processing the cases against the "Adjustment of Extra fee Deposited", submitted for the 5 products as under:

i. Lopar Plus caplet
ii. Reltus n syrup
iii. Artefant DS Tablet
iv. Artefant DS Plus tablet
v. Artefant suspension.

As per forwarded record, the request of the firm for fee adjustment has been approved by concerned authority on 27-09-2016, and legal affairs division has also opined that PE&R division may entertain the applications for fee adjustment.

67.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Lopar plus caplets
	Composition	"Each caplet Contains: Loperamide HCl …..…2mg Simethicone……125mg"
	Diary No. Date of R& I & fee	Dy.No.253333 dated 20-12-2017, Rs.150,000/- 4-12-2013
	Pharmacological Group	Antiperistaltic & Antiflatulent
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	60's;As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration

		number, brand name and name of firm.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
68.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Reltus N Syrup
	Composition	"Each 5ml Contains: Ammonium chloride …..… 100mg Chlorpheniramine maleate……2mg Phenylephrine HCl ……. 5mg"
	Diary No. Date of R& I & fee	Dy.No.253333 dated 20-12-2017, Rs.60,000/- 23-12-2013
	Pharmacological Group	Expectorant
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	120ml;As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
69.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Artefan DS tablet
	Composition	"Each tablet Contains: Artemether …..… 40mg Lumefantrine…..240mg"
	Diary No. Date of R& I & fee	Dy.No.253333 dated 20-12-2017, Rs.60,000/- 21-01-2014
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status (with strength and dosage form)	Artem -DS Plus Tablets of M/s Hilton Pharma, Karachi (Reg.# 044209)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	
	Decision: Approved.	

70.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Artefant Suspension
	Composition	"Each 5ml of reconstituted suspension Contains: Artemether …..… 15mg Lumefantrine…..90mg"
	Diary No. Date of R& I & fee	Dy. No 253333 dated 20-12-2017, Rs.60,000/- 21-1-2014
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished product Specifications	IP
	Pack size & Demanded Price	30ml;As per SRO
	Approval status of product in Reference Regulatory Authorities	WHO recommended formulation
	Me-too status (with strength and dosage form)	Astin Dry Suspension of M/s MBL Karachi (Reg.# 081013)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	
	Decision: Approved.	
71.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Axetine 40mg capsule
	Composition	"Each capsule Contains: Atomoxetine as HCl ……. 40mg
	Diary No. Date of R& I & fee	R&I dated 26-01-2012 Rs.8,000/- Dated 19-01-2012
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	ADS 40mg Capsule of M/s Wilshire Laboratories (Pvt.) Ltd; (Reg.# 054002)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Assistant Director Reg-I vide letter No. F.1-2/2019-Reg-I dated 10-04-2019, has verified DRAP's receiving date from R& I section. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	
72.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Axetine 10mg capsule
	Composition	"Each capsule Contains: Atomoxetine as HCl ……. 10mg
	Diary No. Date of R& I & fee	R&I dated 26-01-2012, Rs.8,000/- Dated 19-01-2012
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK

	Me-too status (with strength/dosage form)	Moxitine capsules of M/s CCL Pharma; (Reg.# 045966)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Assistant Director Reg-I vide letter No. F.1-2/2019-Reg-I dated 10-04-2019, has verified DRAP's receiving date from R& I section. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	
73.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Axetine 25mg capsule
	Composition	"Each capsule Contains: Atomoxetine as HCl ……. 25mg
	Diary No. Date of R& I & fee	R&I dated 26-01-2012 , Rs.8,000/- Dated 19-01-2012
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's;Rs. 2900 per pack
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Autis 25mg Capsule of M/s Amarant Karachi (Reg.# 079957)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Assistant Director Reg-I vide letter No. F.1-2/2019-Reg-I dated 10-04-2019, has verified DRAP's receiving date from R& I section. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	
74.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Axetine 100mg capsule
	Composition	"Each capsule Contains: Atomoxetine as HCl ……. 100mg
	Diary No. Date of R& I & fee	R&I dated 26-01-2012 ,Rs.8,000/- Dated 19-01-2012
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Doqaz 100mg Capsule of M/s Hilton Pharma Karachi (Reg.# 079929)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Assistant Director Reg-I vide letter No. F.1-2/2019-Reg-I dated 10-04-2019, has verified DRAP's receiving date from R& I section. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	

75.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Montec-Fexo tablet
	Composition	"Each film coated tablet Contains: Montelukast as sodium …….. 10mg Fexodenadine HCl ……. 120mg
	Diary No. Date of R& I & fee	Dy. No dated 10-02-2012 Rs.8,000/- Dated 10-02-2012
	Pharmacological Group	Anti-asthamatic drug
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	14's;Rs. 3250 per pack
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength/dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Assistant Director Reg-I vide letter No. F.1-2/2019-Reg-I dated 10-04-2019, has verified DRAP's receiving date from R& I section. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data.	
76.	Name and address of manufacturer / Applicant	M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Axetine 18mg capsule
	Composition	"Each capsule Contains: Atomoxetine as HCl ……. 18mg
	Diary No. Date of R& I & fee	Dy. No 147 dated 26-01-2012 Rs.80,000/- 19-01-2012
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength/dosage form)	Moxitine capsules of M/s CCL Pharma; (Reg.# 045964)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	
77.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Reltus PH Expectorant
	Composition	"Each 5ml Contains: Ammonium chloride ……. 100mg Chliorpheniramine maleate …. 2mg

		Phenylephrine hydrochloride …… 5mg
	Diary No. Date of R& I & fee	Dy. No 932, dated 08-06-2012 Rs.8,000/- 08-06-2012
	Pharmacological Group	Cough expectorant
	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 (with strength/dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	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.**	
78.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Darif XR 15mg Tablet
	Composition	"Each film coated tablet contains: Darifenacin as hydrobromide ……. 15mg
	Diary No. Date of R& I & fee	Dy. No 136 dated 26-01-2012 Rs.8,000/- 19-01-2012
	Pharmacological Group	Antimuscarinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's;Rs. 2700 per pack
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength/dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Clarification shall be submitted whether applied formulation is prolonged release or otherwise. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	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.	
79.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Axetine 60mg capsule
	Composition	"Each capsule Contains: Atomoxetine as HCl ……. 60mg

	Diary No. Date of R& I & fee	Dy. No 138 dated 26-01-2012 Rs.8,000/- 19-01-2012
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's;Rs. 3060/-
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength/dosage form)	Moxitine capsules of M/s CCL Pharma; (Reg.# 045965)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	
80.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Darif XR 7.5mg Tablet
	Composition	"Each film coated tablet contains: Darifenacin as hydrobromide ……. 7.5mg
	Diary No. Date of R& I & fee	Dy. No 144 dated 26-01-2012 Rs.8,000/- 19-01-2012
	Pharmacological Group	Antimuscarinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	10's;Rs. 1970 per pack
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength/dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	• Clarification shall be submitted whether applied formulation is prolonged release or otherwise. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Assistant Director Reg-I vide letter No.F.1-2/ 2019-Reg-I dated 10-04-2019, has verified DRAP's receiving date from R & I section. • The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	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. Moreover clarification shall be submitted whether applied formulation is prolonged release or otherwise.	
81.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Axetine 80mg capsule
	Composition	"Each capsule Contains: Atomoxetine as HCl ……. 80mg
	Diary No. Date of R& I & fee	Dy. No 134 dated 26-01-2012 Rs.8,000/- 19-01-2012
	Pharmacological Group	Psychoanaleptics
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's;Rs. 3060/-
	Approval status of product in Reference	Approved by MHRA of UK

	Regulatory Authorities	
	Me-too status (with strength and dosage form)	Doqaz 80mg Capsule of M/s Hilton Pharma Karachi; (Reg.# 079928)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	
82.	Name and address of manufacturer / Applicant	"M/s Pharmatec Pak Ltd, B-86/A, SITE, Karachi."
	Brand Name +Dosage Form + Strength	Viren tablets
	Composition	"Each film coated tablet Contains: `Tenofovir Disoproxil fumarate 300mg eq. to 245mg of Tenofovir Disoproxil
	Diary No. Date of R& I & fee	Dy. No 630 dated 07-05-2012 Rs.8,000/- 07-05-2012
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	14's;Rs. 3060/-
	Approval status of product in Reference Regulatory Authorities	Tenofovir by Teva Pharma (USFDA Approved)
	Me-too status (with strength/dosage form)	Tenofo-B by Getz
	GMP status	Firm has submitted copy of GMP inspection report conducted on 30-04-18 concluding Good GMP compliance
	Remarks of the Evaluator[II]	The differential fee of 12,000/- has been processed as adjustment of extra fee paid of above cited products.
	Decision: Approved.	
83.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboreatories (Pvt) Ltd, Sheihupur
	Brand Name +Dosage Form + Strength	Areson 40/240 Tablets
	Composition	Each tablet contains:- Artesunate……..40mg Lumefantrine……240mg
	Diary No. Date of R& I & fee	Dy No.1434, 15-01-11; 8000/, Rs.12000/- 24-11-2014
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specifications	Manufacture specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength/dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 15-02-2018concluding as under: Last GMP inspection report dated 15-02-2018 declaring following " General Observations": "HVAC system is properly installed and functional in all production areas. Overall cleanliness of the plant is good. Flow of personal movement, material movement and process is as per cGMP. The firm has sufficient production capacities for manufacturing of different products in all sections. However the firm was advised to improve documentation system regarding validation of testing procedure and manufacturing procedure.

	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data.	
84.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboreatories (Pvt) Ltd, Sheihupur
	Brand Name +Dosage Form + Strength	Legreat Suspension 125mg
	Composition	"Each 5ml after reconstitution contains: Levofloxacin (as hemihydrate) ……. 125mg
	Diary No. Date of R& I & fee	Dy. No. 2431 Dated 15-04-2013 Rs. 50,000/- 15-04-2013
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	60ml as per SRO
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too status (with strength and dosage form)	Levilox Dry Powder Suspension of M/s Nexus Pharma, Karachi (Reg.#075833)
	GMP status	
	Remarks of the Evaluator[II]	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	
85.	Name and address of manufacturer / Applicant	M/s Mcolson Research Laboreatories (Pvt) Ltd, Sheihupur
	Brand Name +Dosage Form + Strength	Magiplus Capsules 12/50mg
	Composition	" Each capsule contains:- Olanzapine…….12mg Fluoxetine (as HCl)……..50mg
	Diary No. Date of R& I & fee	Dated 15-01-2011 Rs. 8,000/ (Photocopy)- , Rs. 12,000/- dated 24-09-2014
	Pharmacological Group	Anti psychotic and a selective serotonin reuptake inhibitor
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Not verifiable
	Me-too status (with strength/dosage form)	--
	GMP status	
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.**	

	• **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
86.	Name and address of manufacturer / Applicant	M/s Lawari Interational, Gulkada Saidu Sharif, Swat
	Brand Name +Dosage Form + Strength	Memine 500mg Tablets
	Composition	"Each sugar coated tablet contains:- Mecobalamine……..500mcg"
	Diary No. Date of R& I & fee	Dy. No. 20 Dated 13-01-2011, Rs. 8,000/, Rs. 12,000/- dated 26-06-2014 (Dy. No 296)
	Pharmacological Group	Coenzyme type/Vitamin B12
	Type of Form	Form-5
	Finished product Specifications	JP
	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/dosage form)	Mecomed 500mcg by Global Pharma (Reg. No. 041670)
	GMP status	02-07-2016
	Remarks of the Evaluator[II]	
	Decision: Deferred for updated status of GMP.	
87.	Name and address of manufacturer / Applicant	M/s Welmed Pharmaceuticals Industries (Pvt.) Ltd., Plot No. 108, R-02, Industrial Estate Gadoon, Dist. Swabi.
	Brand Name +Dosage Form + Strength	Ferrimed capsule 150mg Other proposed brand names: Ferricam Feramed Ferrex
	Composition	Each capsule contains: Iron polysaccharide complex eq. to elemental iron……..……150mg
	Diary No. Date of R& I & fee	Dy. No.4829; 05-06-2017; Rs.20,000/- (05-06-2017)
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	Ferricure 150mg Capsule by M/s S.J & G Fazul Ellahie (Reg#050637)
	GMP status	12-12-2018 **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 to be operating in satisfactory level of cGMP 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.	
88.	Name and address of manufacturer / Applicant	M/s Ipram International, Plot # 26, S.S 3, National Industrial Zone Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Iprolac 10mg/ 1ml I/V I/M Injection
	Composition	Each ml contains: Ketorolac Tromethamol ……..10mg

	Diary No. Date of R& I & fee	Dy.No.8696;13-07-2017; Rs.20,000/- (13-07-2017)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	US-FDA Approved.
	Me-too status (with strength/dosage form)	Tromit Injection of M/s Standpharm (Reg.#049958)
	GMP status	16-02-2017 and grant of additional sections was granted in the report.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
89.	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 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Piracetam…400mg"
	Diary No. Date of R& I & fee	Dy. No 28181 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Psychostimulant
	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 ANSM of France
	Me-too status (with strength and dosage form)	Ceremin tablets 400mg of M/s Schazoo Pharma (Reg.#032599)
	GMP status	GMP Certificate issued on 10-12-2018
	Remarks of the Evaluator[II]	
	Decision: Approved.	
90.	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 80mg Tablet
	Composition	"Each Tablet Contains: Telmisartan……..80mg
	Diary No. Date of R& I & fee	Dy. No 28185 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Angiotensin 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)	Cardisan 80mg Tablet of M/s Schazoo Pharma (Reg.#065835)
	GMP status	GMP Certificate issued on 10-12-2018
	Remarks of the Evaluator[II]	
	Decision: Approved.	
91.	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	Piomin 15/500mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone…15mg Metformin HCl…500mg"
	Diary No. Date of R& I & fee	Dy. No 28168 dated 17-08-2018 Rs.20,000/- 07-08-2018

	Pharmacological Group	Anri-diabetic
	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)	Glet Tablet of M/s Brookes Pharmaceuticals, Karachi (Reg.#057726)
	GMP status	GMP Certificate issued on 10-12-2018
	Remarks of the Evaluator[II]	
	Decision: Approved.	
92.	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 40mg Tablet
	Composition	"Each Tablet Contains: Telmisartan…40mg"
	Diary No. Date of R& I & fee	Dy. No 28184 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Angiotensin 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)	Cardisan 40mg Tablet of M/s Schazoo Pharma (Reg.#065836)
	GMP status	GMP Certificate issued on 10-12-2018
	Remarks of the Evaluator[II]	
	Decision: Approved.	
93.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Clonaze 0.5mg Tablet
	Composition	"Each Tablet Contains: Clonazepam…0.5mg"
	Diary No. Date of R& I & fee	Dy. No 28475 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Cozepam 0.5mg Tablet of M/s Schazoo Pharma (Reg.#064716)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
94.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Comarin 0.625mg Tablet
	Composition	"Each Tablet Contains: Conjugated Estrogen…0.625mg"
	Diary No. Date of R& I & fee	Dy. No 28467 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Estrogen

	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Equin 0.6mg tablets approved by AEMPS of Spain
	Me-too status (with strength and dosage form)	PREMARINE TABLET 0.625 of M/s MULLER & PHIPPS KARACHI (Reg.#003619)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	The submitted reference product is suspended by AEMPS of Spain.
	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.	
95.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Olanex 10mg Tablet
	Composition	"Each Orodispersible Tablet Contains: Olanzapine……10mg"
	Diary No. Date of R& I & fee	Dy. No 28469 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Psycholeptics
	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)	Psyclan 10mg Mouth Dispersible Tablet of M/s PharmEvo Limited, Karachi (Reg.#039161)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
96.	Name and address of manufacturer / Applicant	M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Siteron 50mg Tablet
	Composition	Each Tablet Contains: Cyproterone Acetate……50mg
	Diary No. Date of R& I & fee	Dy. No 28470 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Anti-androgen
	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)	ANDROCUR TABLET of M/s ALI GOHAR & CO KARACHI (Reg.#010221)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
97.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Aripra 20mg Tablet

	Composition	"Each Tablet Contains: Aripiprazole……20mg"
	Diary No. Date of R& I & fee	Dy. No 28474 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Anti-psychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Apify 20mg Tablet of M/s Akhai Karachi (Reg.#076248)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
98.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Ferject 500mg/10ml Injection
	Composition	"Each 10ml Ampule Contains: Iron (as Ferric Carboxymaltose)…500mg"
	Diary No. Date of R& I & fee	Dy. No 28468 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Haematinic
	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	Ferinject Injection by Vifor Pharm (MHRA Approved)
	Me-too status (with strength/dosage form)	Ferinject 500mg/10ml by RG Pharma (Reg.# 072548)
	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 specifications. Regsitration letter will be issued after comments of Legal affairs divison, about patent issue of applied formulation.	
99.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Clonaze 2mg Tablet
	Composition	"Each Tablet Contains: Clonazepam…2mg"
	Diary No. Date of R& I & fee	Dy. No 28476 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Cozepam 0.5mg Tablet of M/s Schazoo Pharma (Reg.#064715)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
100.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Clonaze 2.5mg Drops

	Composition	"Each ml Contains: Clonazepam…2.5mg"
	Diary No. Date of R& I & fee	Dy. No 28477 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by AEMPS of Spain
	Me-too status (with strength and dosage form)	Naze Oral Drops of M/s Schazoo Laboratories (Reg.#053501)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	Submitted master formulation contains Ethanol (96%), whereas reference product does not contain Ethanol. Clarification shall be submitted in this regard.
	Decision: Deferred for clarification for the use of Ethanol (96%) in the applied formulation.	
101.	Name and address of manufacturer / Applicant	"M/s Aries Pharmaceuticals. 1-W, Industrial Estate, Hayatabad, Peshawar, k.p.k"
	Brand Name +Dosage Form + Strength	Aqvo 10ml Injection
	Composition	"Each Ampoule Contains: Sterile Water for Injection…10ml"
	Diary No. Date of R& I & fee	Dy.No 28473 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	Sterile pharmaceutical solvent & Diluting agent
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Water for Injection by M/s Pulse Pharmaceuticals (Reg#069217)
	GMP status	GMP certificate issued on the basis of inspection conducted on 10-03-2017.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
102.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Zorfix 10mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…10mg Atorvastatin (as calcium trihydrate) …10mg"
	Diary No. Date of R& I & fee	Dy. No 28143 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Combitrol 10/10 tablet by M/s Ferozsons Labs. (Reg#050815)
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.

	Remarks of the Evaluator[II]	
	Decision: Deferred for confirmation of valid DML status of the firm from Licensing Division.	
103.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Zorfix 5mg/10mg Tablet
	Composition	"Each film coated Tablet Contains: Amlodipine as besylate…5mg Atorvastatin (as calcium trihydrate) …10mg"
	Diary No. Date of R& I & fee	Dy. No 28142 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	Calcium channel blocker/ HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Atease 5+10mg Tablet by M/s PharmEvo (Reg#050559)
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	
	Decision: Deferred for confirmation of valid DML status of the firm from licensing division.	
104.	Name and address of manufacturer / Applicant	"M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi"
	Brand Name +Dosage Form + Strength	Expro 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Esomepraozle……40mg"
	Diary No. Date of R& I & fee	Dy. No 28140 dated 17-08-2018 Rs.20,000/- 17-08-2018
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	--
	Me-too status (with strength/dosage form)	--
	GMP status	GMP certificate issued on the basis of inspection conducted on 18-05-2017.
	Remarks of the Evaluator[II]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for confirmation of valid DML status of the firm from licensing division. Moreover following shall be submitted: • **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.**	
105.	Name and address of manufacturer / Applicant	"M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Omsect Insta 40/1680 mg Sachet
	Composition	"Each Sachet Contains:

		Omeprazole…..40mg Sodium Bicarbonate……1680mg"
	Diary No. Date of R& I & fee	Dy. No 28449 dated 20-08-2018 Rs.20,000/- 20-08-2018
	Pharmacological Group	PPI
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	Ruling + Sachet by M/s High-Q, Karachi. (Reg.# 070633)
	GMP status	Last inspection report dated 11-10-2017 & 16-10-2017 concluding as under: "Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Brookes Karachi was considered to be operating at Satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under."
	Remarks of the Evaluator[II]	
	Decision: Approved with USP specifications.	
106.	Name and address of manufacturer / Applicant	M/s Treat Pharmaceutical Industry Pvt Ltd. A-37, Small Industrial Estate, Township Kohat Road, Bannu.
	Brand Name +Dosage Form + Strength	Tricolin 1000mg/4ml Injection
	Composition	"Each 4ml ampoule Contains: Citicoline (as Citicoline Sodium)…1000mg"
	Diary No. Date of R& I & fee	Dy. No 1615 dated 11-01-2018 Rs. 20,000/- 10-01-2018
	Pharmacological Group	Psychostimulant
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by AEMPS of Spain
	Me-too status	Neurotec Injection of M/s Schazoo Laboratories. (Reg.#045995)
	GMP status	Last GMP inspection report dated 06-11-2018 concluding "The firm may be considered to be operating at satisfactory level of cGMP Compliance."
	Remarks of the Evaluator[2]	
	Decision: Approved with innovator's specification.	
107.	Name and address of manufacturer / Applicant	M/s Trigon Pharmaceuticals Pvt. Ltd., 8-Km Thoker Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Virogon 200mg tablet
	Composition	Each tablet contains: Acyclovir…….....200mg
	Diary No. Date of R& I & fee	Dy. No.11736; 30-03-2018; Rs.20,000/- (30-03-2018)
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's; Rs.170/-
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Zoraxin 200mg tablet of M/s Valor pharmaceuticals
	GMP status	Firm is GMP compliant as per inspection report dated 14-02-2018.

	Remarks of the Evaluator[2]	
	Decision: Approved.	
108.	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	Lezole tablet 2.5mg
	Composition	Each film coated tablet contains: Letrozole…….....2.5mg
	Diary No. Date of R& I & fee	Dy. No.16675; 07-05-2018; Rs.20,000/- (07-05-2018)
	Pharmacological Group	Aromatase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's and 30's; As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Femara tablet 2.5mg of M/s Novartis pharma
	GMP status	Assistant Director QA-II, vide letter no. F.4-5/2007-QA dated 26-08-2019, has communicated Incharge PEC that M/s Panacea Pharmaceuticals, Islamabad as per GMP inspection conducted on 14-05-2019.
	Remarks of the Evaluator[2]	
	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.	

b. Deferred cases

Evaluator PEC-II

109.	Name and address of manufacturer / Applicant	M/s Care Pharma Lahore., 8 KM, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Fevercare 6 Plus Syrup
	Composition	Each 5ml contains:- Paracetamol…….250mg
	Diary No. Date of R& I & fee	Dy.No :(Duplicate Dossier) 8000/-28-2-2011 12000/-30-7-2013
	Pharmacological Group	Antipyretic, Analgesic
	Type of Form	Form 5
	Finished product Specifications	USP spec
	Pack size & Demanded Price	60ml, 120ml, 450ml :As per SRO
	Approval status of product in Reference Regulatory Authorities	Paracetamol 250mg/5ml oral suspension (MHRA approved)
	Me-too status (with strength/dosage form)	Calpol-6 Plus of M/s GSK
	GMP status	Last inspection conducted on 06-08-2018 and report concludes that overall the cGMP compliance is saisfactory
	Previous remarks of the Evaluator.	• 1st Letter: 17th April , 2018 • Reminder Letter: 16th May, 2018 Latest GMP inspection report (which should have been conducted within the period of last one year). • Clarify pack size because in demanded price a different pack size and on covering letter different pack size.
	Previous decision(s)	**Deferred for following reasons:** Registration Board deferred the case for further deliberation **(M-284)**
	Evaluation by PEC	Certificate of current Good manufacturing practice on evaluation conducted on 13-03-2019 Pack size : 60ml, 120ml
	Decision: Approved with change of brand name.	

110.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Epsent 5mg Tablet
	Composition	Each Tablet Contains: Procyclidine Hydrochloride…5mg
	Diary No. Date of R& I & fee	Dy. No 21162 dated 15-11-2017 Rs. 20,000/- 13-11-2017
	Pharmacological Group	Anticholinergic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1000's, 500's & 100's
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Proclidine Tablets of M/s Shaheen Pharmaceuticals, 3Km Murghzar Road Saidu Sharif, Swat. (Reg.# 041018)
	GMP status	GMP dated 12-2-2018, the GMP compliance status of firm can't be verified because firm was not operational at the time of inspection however premises were found well maintained and at satisfactory level.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 287th meeting deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report, conducted on 29-03-2019, wherein the panel was of the opinion that the firm M/s Genetics Lahore was operating at satisfactory level of GMP compliance.
	Decision: Approved.	
111.	Name and address of manufacturer / Applicant	"M/s Wenovo Pharmaceuticals. Plot # 31& 32 Punjab Small Industrial Estate Taxila Pakistan"
	Brand Name +Dosage Form + Strength	Wenvax XR 75mg Capsule
	Composition	"Each Extended Release Capsule Contains: Venlafaxine as Hydrochloride…75mg"
	Diary No. Date of R& I & fee	Dy. No 12090 dated 02-04-2018 Rs.20,000/- 02-04-2018
	Pharmacological Group	Serotonin and nor epinephrine reuptake inhibitor
	Type of Form	Form-5
	Finished product 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	Venflax XR 75mg Capsule by M/s Regal Pharmaceuticals (Reg#081978)
	GMP status	GMP inspection dated 30-09-2018 & 29-10-2018 wherein panel unanimously recommends grant of GMP certificate.
	Remarks of the Evaluator.	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.
	Previous Decision:	Reg.Board in its 289th meeting deferred for source of pellets, along with stability studies data, GMP certificate of supplier & differential fee in case of import of pellets.
	Evaluation by PEC:	Firm has submitted requisite documents for "Venlafaxine HCl SR pellets 45.0%" from M/s Vision pharmaceuticals (Pvt.) Ltd., Islamabad.
	Decision: Approved.	

112.	Name and address of manufacturer / Applicant	"M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar"
	Brand Name +Dosage Form + Strength	Fribium 10mg Tablet
	Composition	"Each Tablet Contains: Clobazam ……10mg"
	Diary No. Date of R& I & fee	Dy. No 7987 dated 22-02-2019 Rs.20,000/- 22-02-2019
	Pharmacological Group	Benzodiazepine
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As PRC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Frisium tablet of M/s Sanofi-Aventis (Reg.# 002694)
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 289th meeting deferred for evidence of approval of required manufacturing facility of "Tablet (Psychotropic) Section" from CLB.
	Evaluation by PEC:	Firm has submitted copy of letter (No.F.3-10/2004-Lic (M-219)) issued by Deputy Director General (L&A), dated 05th October, 2009, declaring that Central Licensing Board, in its 219th meeting held on 7th September 2009, granted approval for change of Tablet (Antibiotic/ Quinolone) section into Tablet (Psychotropic) section to M/s Navegal Laboratories, Hattar.
	Decision: Approved.	
113.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals (Pvt.) Ltd, 13-Km Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Lowcost 4mg sachet
	Composition	Each sachet contains: Montelukast (as sodium) …… 4mg
	Diary No. Date of R& I & fee	Dy. No.3432; 21-12-2016; Rs.20,000/- (21-12-2016)
	Pharmacological Group	Leukotriene antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 14's; Rs. 182/-
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Aerotel Sachet of M/s Highnoon Laboratories. (Reg.#044768)
	GMP status	Last inspection dated 01-06-2016
	Remarks of the Evaluator.	Latest GMP inspection report conducted within a period of last 1 year by DRAP.
	Previous Decision:	Registration Board in its 278th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority. The Board also directed the firm to change the brand name.
	Evaluation by PEC:	Firm has submitted copy of panel inspection report conducted on 03-05-2019, wherein panel has recommended renewal of DML. Moreover firm has stated that they have another product with brand name of Lowcost 5mg tablet (Montelukast).
	Decision: Approved with change of brand name.	

114.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals (Pvt.) Ltd, 13-Km Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Pediawin sachet
	Composition	Each sachet contains: Sodium chloride …… 2.6gm Sodium citrate ……. 2.90gm Potassium chloride ….. 1.50gm Glucose anhydrous …… 13.5 gm
	Diary No. Date of R& I & fee	Dy. No.3433; 21-12-2016; Rs.20,000/- (21-12-2016)
	Pharmacological Group	ORS
	Type of Form	Form-5
	Finished product Specification	International Pharmacopoeia
	Pack size & Demanded Price	1 x 20 ’s: Rs. 300/-
	Approval status of product in Reference Regulatory Authorities.	WHO recommended Low osmolar ORS formulation
	Me-too status	Oragil Sachet of M/s Glitz Pharma (Reg.#038628)
	GMP status	Last inspection dated 01-06-2016
	Remarks of the Evaluator.	Latest GMP inspection report conducted within a period of last 1 year by DRAP.
	Previous Decision:	Registration Board in its 278th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of panel inspection report conducted on 03-05-2019, wherein panel has recommended renewal of DML.
	Decision: Approved.	
115.	Name and address of manufacturer / Applicant	"M/s Aspin Pharma Pvt Ltd. Plot # 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan"
	Brand Name +Dosage Form + Strength	Fosvac 20mg Tablet
	Composition	"Each Tablet Contains: Fosinopril Sodium…20mg"
	Diary No. Date of R& I & fee	Dy. No 10164 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Antihypertensive.
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 20-2-2018, concluding as under: “Based on the areas inspected the document reviewed and considering the finding of inspection M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012.”
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 289th meeting deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else apply on relevant Form along with stability data.
	Evaluation by PEC:	Following reference of me-too has been verified for applied formulation: “Monopril Tab 20mg (R.#013817).
	Decision: Approved.	

116.	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	Gefinib tablet 250mg
	Composition	Each film coated tablet contains: Gefitinib…… 250 mg
	Diary No. Date of R& I & fee	Dy. No 10164 dated 19-03-2018 Rs. 20,000/- 19-03-2018
	Pharmacological Group	Kinase inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by TGA
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted 30-03-2017. Wherein Panel recommends grant of Additional Sections, including the "Capsule (Oncology)".
	Remarks of the Evaluator.	Applied formulation is not present in available USP & BP
	Previous Decision:	Registration Board in its 282nd meeting deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC:	Following reference of me-too has been verified for applied formulation: "Gefticip Tab 250mg. of M/s AJ Mirza Pvt Ltd, (Reg.#088385)". It is pertinent to mention that the first generic was approved in 263rd meeting of registration Board hence, stability would be required for the applied formulation.
	Decision: Registration Board deferred the case for submission of stability studies data as per directions of 275th meeting of Registration Board.	
117.	Name and address of manufacturer / Applicant	M/S Pharma Lord (PVT.). 12 Km, Lahore Road. Layyah
	Brand Name +Dosage Form + Strength	Oxalid 100 mg/5 ml Dry powder suspension
	Composition	Each 5ml suspension contains: Linezolid ……100mg
	Diary No. Date of R& I & fee	Dy. No. 11913, 15-8-2017, Rs.20,000/=
	Pharmacological Group	Oxazolidinone
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60 ml/ As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyvox oral suspension of Pharmacia , USFDA
	Me-too status	Nezocin suspension of Brookes (Reg # 055003)
	GMP status	Last GMP inspection is conducted on 26- 05- 17 and the report concludes that firm was considered GMP compliant
	Remarks of the Evaluator.	No USP and BP monograph was found
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP certificate issued by Add. Director DRAP, Lahore on the basis of inspection conducted on 03-05-2019.
	Decision: Approved with innovator's specification.	

118.	Name and address of manufacturer / Applicant	M/s Pharma Lord (PVT.). 12 Km, Lahore Road. Layyah
	Brand Name +Dosage Form + Strength	Montelo 5 mg chewable tablet
	Composition	Each chewable tablet contains: Montelukast Sodium eq. to Montelukast …5mg
	Diary No. Date of R& I & fee	Dy.No. 11914, 15-8-2017, Rs.20,000/=
	Pharmacological Group	Bronchodilator
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2x7's , 1x10's, 10x10's /As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Singulair By M/S. Merck USFDA Approved
	Me-too status	Montekast 5mg Tablets of M/s Legacy Pharmaceuticals (Pvt) Ltd. (Reg.# 069785)
	GMP status	Last GMP inspection is conducted on 26- 05- 17 and the report concludes that firm was considered GMP compliant
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP certificate issued by Add. Director DRAP, Lahore on the basis of inspection conducted on 03-05-2019.
	Decision: Approved.	
119.	Name and address of manufacturer / Applicant	M/s Pharma Lord (PVT.). 12 Km, Lahore Road. Layyah
	Brand Name +Dosage Form + Strength	Montelo 10 mg tablet
	Composition	Each film coated tablet contains: Montelukast Sodium eq. to Montelukast……10mg
	Diary No. Date of R& I & fee	Dy.No. 11915, 15-8-2017, Rs.20,000/=
	Pharmacological Group	Bronchodilator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	10's, 14's, 100's /As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Singulair 10 mg film-coated tablet (MHRA Approved)
	Me-too status	Montiget 10mg by Getz
	GMP status	Last GMP inspection is conducted on 26- 05- 17 and the report concludes that firm was considered GMP compliant
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP certificate issued by Add. Director DRAP, Lahore on the basis of inspection conducted on 03-05-2019.
	Decision: Approved with USP specifications.	
120.	Name and address of manufacturer / Applicant	M/s Alfalah Pharma Pvt Ltd. 12 km, Sheikhupura Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Trama-P 325/37.5 mg Tablet
	Composition	Each film coated Tablet Contains: Tramadol hydrochloride…37.5mg Paracetamol…325mg
	Diary No. Date of R& I & fee	Dy. No 12906 dated 06-04-2018 Rs.20,000/- 06-04-2018

	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, by M/s Janssen Pharmaceuticals (USFDA Approved)
	Me-too status	Pacdol Plus Tablets by M/s Universal Pharmaceuticals (Reg#064066)
	GMP status	Not confirmed.
	Remarks of the Evaluator.	• Latest GMP status of the firm not confirmed.
	Previous Decision:	Registration Board in its 290th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report conducted on 27-04-2017, wherein the panel recommended the restoration of the DML 7 Production of the firm in the tablet section general only.
	Decision: Approved.	
121.	Name and address of Applicant	"M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore."
	Detail of Drug Sale License	N/A
	Name and address of manufacturer	M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam
	Name and address of marketing authorization holder	M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam. Number of product license and date of issue: VD-30864-18 dated 05th July, 2018.
	Name of exporting country	Vietnam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 35872 Dated 29-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 29-10-2018
	Brand Name +Dosage Form + Strength	Isotret 10mg Soft Gelatin capsule
	Composition	"Each softgel capsule contains: Isotretinoin…….10mg"
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Retinoic for treatment of acne
	Shelf life	3 years
	Demanded Price	As per brand leader
	Pack size	
	International availability	Approved by USFDA
	Me-too status	Acnotin 10 Soft Gelatin Capsules of M/s Ferozsons Laboratories Ltd, (Reg.# 070318)
	Stability studies	• Long term stability studies of 36 months and Accelerated stability studies of 6 months of three batches at Zone-IV A conditions.
	Detail of certificates attached	• **Original Legalized Free Sale certificate** issued by Ministry of Health Vietnam, Drug Administration valid upto 05-07-2023. • **Original Legalized CoPP (Certificate#. 692/GP-QLP)** issued on 14-08-2018 by Ministry of Health Vietnam, Drug Administration, declaring the free sale

		of applied product and GMP compliant status of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam • **Legalized copy of GMP certificate** issued by Ministry of Health Vietnam, Drug Administration, in the name of M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam valid for three years from date of approval. • **Copy of "Letter of Authorization" from** M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam authorising M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore to carry out registration process in Pakistan for applied product.

Remarks of the Evaluator:

Sr. #	Observations (Communicated vide letter No. F.1-1/2017/PEC-DRAP (AD PEC-II dated 11-04-2019))	Response of Firm (Received vide letter No. CCL/19/R-242 dated 06-05-2019)
i.	Clarification shall be submitted whether application is for "Finished pharmaceutical product import" or "Bulk import and local repack", since it is not evident form the submitted Form-5A.	Firm has submitted revised Form 5-A with following details: **Name and address of the indenter or agent:** "M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore." **Name and address of the manufacturer of drug:** "M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam" **Bulk Import and local repack at:** M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore. • The undertaking of Form 5-A endures scanned signature and stamp of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam. • The fee voucher has been submitted by the DML no. 000052, which is for the M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, whereas revised Form 5-A has been submitted by M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore
ii.	Manufacturer has referred finished product specifications as in-house, whereas USP and BP monograph is available for applied formulation. Clarification shall be submitted in this regard	Revised technical specifications of finished product have been submitted as per USP monograph for the Isotretinoin capsules. This revised document does not have any signatures or revision/effective date.
iii.	Finished product specifications submitted from manufacturer of applied formulation does not contain dissolution test. Clarification/Justification shall be submitted in this regard.	Revised finished product testing method has been submitted wherein dissolution test as per USP test 2 from USP monograph for the Isotretinoin capsules has been mentioned.

	iv.	Dissolution test has not been performed during the stability studies. Clarification/justification shall be submitted in this regard.	Revised stability study reports have been submitted for three batches as per Zone IV-b conditions wherein dissolution test and its results have been mentioned • It is pertinent to mention that revised stability study reports submitted by firm for the long term conditions contains the same results as presented in stability study reports submitted along with original dossier, in respect of various tests, batch numbers, test date etc, while the only difference is the inclusion of Dissolution tests and its results.

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

Decision: Deferred for following observations:

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

Reply of the firm:

- The firm has submitted revised original Form 5-A dated 23-07-2019 with correct address and sign and stamp from the authorized importer i.e., M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.
- Please be clarified that dissolution test is being performed by the manufacturer which inadvertently missed in earlier submitted stability studies. Upon highlighted by DRAP, dissolution test results incorporated in the stability studies of the same batches. That is the reason that there is no change in stability studies results other than addition of dissolution test and results.

Evaluation by PEC:

- It is pertinent to mention that in initial submission dissolution test was not mentioned at any stage of product development i.e., manufacturing process, Critical control steps during manufacturing and finished product specification.
- Also the previously submitted protocol does not include dissolution test.
- It is not evident whether stability studies have been performed as per USP method or in-house method since initially in-house method was only submitted.

Decision: The Registration Board after thorough deliberation approved the applied formulation with USP specifications, as per policy of inspections of manufacturer abroad. Moroever Registration Board decided to add following conditions in the registration letter:

- **The final quality control release of the applied formulation will be performed by M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, after blistering and packaging of imported soft gelatin Isotretinoin capsules.**
- **The first batch of the applied formulation has to be sampled by Area FID for quality release form CDL, before marketing of the product.**

122.	Name and address of Applicant	" M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore
	Detail of Drug Sale License	N/A
	Name and address of manufacturer	M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam
	Name and address of marketing authorization holder	M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam.

	Number of product license and date of issue: VD-30864-18 dated 05th July, 2018.
Name of exporting country	Vietnam
Type of Form	Form 5-A
Diary No. & Date of R& I	Dy. No 35873 Dated 29-10-2018
Fee including differential fee	Rs. 100,000/- Dated 29-10-2018
Brand Name +Dosage Form + Strength	Isotret 20mg Soft Gelatin capsule
Composition	"Each softgel capsule contains: Isotretinoin…….20mg"
Finished Product Specification	Manufacturer specifications.
Pharmacological Group	Retinoic for treatment of acne
Shelf life	3 years
Demanded Price	
Pack size	As per brand leader
International availability	Approved by USFDA
Me-too status	Acnotin 20 Soft Gelatin Capsules of M/s Ferozsons Laboratories Ltd, (Reg.# 070319)
Stability studies	• Long term stability studies of 36 months and Accelerated stability studies of 6 months of three batches at Zone-IV A conditions.
Detail of certificates attached	• **Original Legalized Free Sale certificate** issued by Ministry of Health Vietnam, Drug Administration valid upto 05-07-2023. • **Original Legalized CoPP (Certificate#. 692/GP-QLP)** issued on 14-08-2018 by Ministry of Health Vietnam, Drug Administration, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam. • **Legalized copy of GMP certificate** issued by Ministry of Health Vietnam, Drug Administration, in the name of M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam valid for three years from date of approval. • **Copy of "Letter of Authorization" from** M/s Phil Inter Pharma Co. Ltd., No. 20, Huu Nghi Blvd., VSIP, Thuan An District, Binh Duong, Vietnam authorising M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore to carry out registration process in Pakistan for applied product.

Remarks of the Evaluator:

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

			8, VSIP, Thuan An District, Binh Duong, Vietnam" **Bulk Import and local repack at:** M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore. • The undertaking of Form 5-A endures scanned signature and stamp of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam. • The fee voucher has been submitted by the DML no. 000052, which is for the M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, whereas revised Form 5-A has been submitted by M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore
	ii.	Manufacturer has referred finished product specifications as in-house, whereas USP and BP monograph is available for applied formulation. Clarification shall be submitted in this regard	Revised technical specifications of finished product have been submitted as per USP monograph for the Isotretinoin capsules. This revised document does not have any signatures or revision/effective date.
	iii.	Finished product specifications submitted from manufacturer of applied formulation does not contain dissolution test. Clarification/ Justification shall be submitted in this regard.	Revised finished product testing method has been submitted wherein dissolution test as per USP test 2 from USP monograph for the Isotretinoin capsules has been mentioned.
	iv.	Dissolution test has not been performed during the stability studies. Clarification/justification shall be submitted in this regard.	Revised stability study reports have been submitted for three batches as per Zone IV-b conditions wherein dissolution test and its results have been mentioned • It is pertinent to mention that revised stability study reports submitted by firm for the long term conditions contains the same results as presented in stability study reports submitted along with original dossier, in respect of various tests, batch numbers, test date etc, while the only difference is the inclusion of Dissolution tests and its results.
	• Submitted data of stability studies submitted from manufacturer reveal that stability has been performed with packaging of 1000 capsules per aluminium poly bag-bulk packaging.		
	Decision: Deferred for following observations: • The undertaking of Form 5-A endures scanned signature and stamp of the manufacturer i.e., M/s Phil Inter Pharma Co. Ltd., No. 25, Street No. 8, VSIP, Thuan An District, Binh Duong, Vietnam. • The fee voucher has been submitted by the DML no. 000052, which is for the M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, whereas revised Form 5-A has been submitted by M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore. • Revised stability study reports submitted by firm for the long term conditions contains the same results as presented in stability study reports submitted along with original dossier, in respect of various tests, batch numbers, test date etc, while the only difference is the inclusion of Dissolution tests and its results.		

Reply of the firm:

- The firm has submitted revised original Form 5-A dated 23-07-2019 with correct address and sign and stamp from the authorized importer i.e., M/s CCL Pharmaceuticals Pvt Ltd. 62 Industrial Estate, Kot Lakhpat, Lahore.
- Please be clarified that dissolution test is being performed by the manufacturer which inadvertently missed in earlier submitted stability studies. Upon highlighted by DRAP, dissolution test results incorporated in the stability studies of the same batches. That is the reason that there is no change in stability studies results other than addition of dissolution test and results.

Evaluation by PEC:

- In initial submission, dissolution test was not mentioned at any stage of product development i.e., manufacturing process, Critical control steps during manufacturing and finished product specification.
- Also the previously submitted protocol does not include dissolution test.
- It is not evident whether stability studies have been performed as per USP method or in-house method since initially in-house method was only submitted.

Decision: The Registration Board after thorough deliberation approved the applied formulation with USP specifications, as per policy of inspections of manufacturer abroad. Moroever Registration Board decided to add following conditions in the registration letter:

- **The final quality control release of the applied formulation will be performed by M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore, after blistering and packaging of imported soft gelatin Isotretinoin capsules.**
- **The first batch of the applied formulation has to be sampled by Area FID for quality release form CDL, before marketing of the product.**

123.	Name and address of manufacturer / Applicant	M/s Trigon Pharmaceuticals Pvt. Ltd., 8-Km Thoker Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Tri-Vir 0.5mg tablet
	Composition	Each film coated tablet contains: Entecavir…….....0.5mg
	Diary No. Date of R& I & fee	Dy. No.11763; 30-03-2018; Rs.20,000/- (30-03-2018)
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's; Rs.10,000/-
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Envir 0.5mg tablet of M/s Highnoon Laboratories
	GMP status	Firm is GMP compliant as per inspection report dated 14-2-2018.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 283rd meeting deferred for confirmation of valid DML status of the firm.
	Evaluation by PEC:	Firm has referred to 267th meeting of CLB wherein after decision of PQCB decided that no further action is warranted. The decision of PQCB is as under: "The Board after considering the inspection report , due deliberation and discussion decoded to allow M/s Trigon Pharmaceuticals Pvt Limited Lahore to resume production operations in Cephalosporin dry Powder injection, Psychotropic Injectable , Steroidal Injections and General liquid Injections (vials, ampoules), strictly in accordance with law."
	Decision: Approved.	

124.	Name and address of manufacturer / Applicant	M/s Winbrains Research Laboratories, Plot No. 69/1, Block B, Phase I-II, Industrial Estate, Hattar. **Contract manufacturer** M/s Weather Folds Pharmaceuticals, Plot No. 69/2, Phase-II, Industrial Area, Hattar.
	Brand Name +Dosage Form + Strength	Dydobin tablet 10mg
	Composition	Each film coated tablet contains: Dydrogesterone…….....10mg
	Diary No. Date of R& I & fee	Dy. No.14888; 13-09-2017; Rs.50,000/- (13-09-2017)
	Pharmacological Group	Progestogen
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Not demanded; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Duphaston (ANSM approved)
	Me-too status	Dydrogest 10mg tablet of M/s OBS, Karachi
	GMP status	Last inspection report of M/s Weather Folds Pharmaceuticals dated 15-09-2017; firm is found GMP compliant.
	Remarks of the Evaluator.	M/s Weather Folds Pharmaceuticals has approved Tablet (hormone) section. **Shortcomings:** • Contract manufacturing application in the light of rule 20-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976 including contract manufacturing agreement, number of sections of applicant approved by Licensing Board and number of products already registered/approved on contract manufacturing in the name of applicant. • Methylene chloride is discontinued/banned excipient. For this reason, you have to revise the formulation and re-submit the same. • Clarification regarding isomer of API used. Upon communication of above cited shortcomings firm has submitted following: • Revised master formulation excluding methylene chloride as coating solvent. • Copy of section approval letters issued by secretary CLB declaring approval of 7 sections. • List of already approved products (07) registered for contract manufacturing from M/s Weather folds
	Previous Decision:	Registration Board in its 284th meeting deferred for further deliberation on cis/trans isomers of Dydrogesteron.
	Evaluation by PEC:	Firm has submitted that we will use the Trans Isomer in production of our product Dydrogesterone.
	Decision: Approved with USP Specifications.	

Following applications of M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore, applied against the new section of "External preparations/ Application/Aerosol section for human", were considered ion 287th meeting of registration board, wherein the Board deferred the cases for "Clarification from Licensing Division for details of dosage forms which could be manufactured in the approved section of "External preparations/ Application/Aerosol Section for Human".

Now Assistant Director (Lic) vide letter No. F.1-14/2002-Lic (Vol-I) dated 04th July, 2019 has forwarded the copy of inspection report of M/s International Pharma Labs. Lahore, conducted for inspection of "External preparations/ Application/Aerosol Section."

The List of Machinery attached as Annex-XI of the above cited inspection report includes following

machinery:

1. Bottle blowing machine
2. Batch manufacturing tank SS 5001
3. Storage tank SS 500L
4. Spray Bottle filling machine
5. Filteration assembly.
6. Bottle filling machine.
7. Table S.S
8. Packing Hall table.
9. Scope set for manufacturing area.
10. S.S pellets.
11. Liquid filling machine.
12. Weighing balance.

With reference to above information forwarded by Licensing divisions, following cases are reproduced for consideration of the Board.

125.	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	D-Nol Solution
	Diary No. Date of R& I & fee	Form-5 Dy.No 30859-M dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Composition	Each 100ml Contains: Chloroxylenol…4.8 w/v
	Pharmacological Group	Antiseptic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	60/50 ml; 100/100 ml; 600/1000 ml
	Approval status of product in Reference Regulatory Authorities.	DETTOL ANTISEPTIC solution chloroxylenol 48mg/mL bottle by M/s Reckitt Benckiser Pty Ltd (TGA Approved)
	Me-too status	Sharexol Solution 4.8%w/v by M/s Sharex Laboratories (Reg#025122)
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	
	Decision: Deferred for evidence of me-too and international status of the applied formulation, in plastic container closure system.	
126.	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	Hydrogen Peroxide Solution
	Diary No. Date of R& I & fee	Form-5 Dy.No 30859-O dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Composition	Each 5 ml Contains: Hydrogen Peroxide…6% w/v
	Pharmacological Group	Antiseptic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	20/30 ml 300/450 ml 80/120 ml 166/250 ml 330/450 ml 330/500 ml
	Approval status of product in Reference Regulatory Authorities.	UK MHRA approved
	Me-too status	Hydrogen Per Oxide of Pharmawise Labs. (Pvt) Ltd.
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	

	Decision: Approved with Innovator's specifications.	
127.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	I-Gen-V Plus Lotion
	Diary No. Date of R& I & fee	Form-5 Dy.No 30859-P dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Composition	Each 100ml Contains: Gentian Violet…1 gm
	Pharmacological Group	Antiseptic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	40/25 ml 192/120 ml ml 750/450 ml 400/500 ml 800/500 ml 1600/ lit
	Approval status of product in Reference Regulatory Authorities.	Gentian violet 1% (Canada)
	Me-too status	Gention violet lotion of M/s Prime labs. (Reg.#029359)
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications.	
128.	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	Tinc-Iodine
	Diary No. Date of R& I & fee	Form-5 Dy.No 30859-K dated 13-09-2018 Rs.20,000/- Dated 13-09-2018
	Composition	Each unit Contains: Tincture Iodine…2.5% Potassium Iodine…2.5%
	Pharmacological Group	Antiseptic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer
	Pack size & Demanded Price	45/30 ml 90/60 ml 180/120 ml 375/250 ml 675/450ml 750/500 ml
	Approval status of product in Reference Regulatory Authorities.	Iodine Tincture BP (MHRA)
	Me-too status	Tincture Iodine of Festel Lab
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Remarks of the Evaluator.	
	Decision: Approved with Innovator's specifications.	
129.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd., Plot#2, , Street # N-4, national Industrial Zone, Rawat, Pakistan
	Brand Name +Dosage Form + Strength	Faximed 200 Tablets
	Composition	Each film coated tablet contains: Rifaximin……200mg
	Diary No. Date of R& I & fee	Dy.No 21156 dated 15-11-2017 Rs. 20,000/- 15-11-2017
	Pharmacological Group	Antibiotics
	Type of Form	Form 5

	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Normix Tablets by M/s Sanital Pharmaceutical Rawalpindi. (Reg#022656)
	GMP status	Last GMP inspection 6-7-2017 The firm is found complying GMP as of today
	Remarks of the Evaluator.	• Firm has proposed following alternate brand name: Foxi 200 Tablets
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report conducted on 06-11-2018, concluding good GMP compliance.
	Decision: Approved with innovator's specification.	
130.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd., Plot#2, , Street # N-4, national Industrial Zone, Rawat, Pakistan
	Brand Name +Dosage Form + Strength	Faximed 550 Tablets
	Composition	Each film coated tablet Contains: Rifaximin……550mg
	Diary No. Date of R& I & fee	Dy.No 21157 dated 15-11-2017 Rs. 20,000/- 15-11-2017
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1 x 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Rixago 550mg Tablet by M/s OBS Pharma Karachi (Reg#081073)
	GMP status	Last GMP inspection 6-7-2017 The firm is found complying GMP as of today
	Remarks of the Evaluator.	• Firm has proposed following alternate brand name: Foxi 500 Tablets
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report conducted on 06-11-2018, concluding good GMP compliance.
	Decision: Approved with innovator's specification	
131.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd., Plot#2, , Street # N-4, national Industrial Zone, Rawat, Pakistan
	Brand Name +Dosage Form + Strength	Respimed 1mg Tablet
	Composition	Each Film Coated Tablet Contains: Risperidone……..1mg
	Diary No. Date of R& I & fee	Dy.No 21158 dated 15-11-2017 Rs. 20,000/- 15-11-2017
	Pharmacological Group	Antipsychotics
	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	Tablet Resjun -1 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081921)
	GMP status	Last GMP inspection 6-7-2017 The firm is found complying GMP as of today
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report conducted on 06-11-2018, concluding good GMP compliance.
	Decision: Approved.	
132.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd., Plot#2, , Street # N-4, national Industrial Zone, Rawat, Pakistan
	Brand Name +Dosage Form + Strength	Respimed 2mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….2mg"
	Diary No. Date of R& I & fee	Dy.No 21159 dated 15-11-2017 Rs. 20,000/- 15-11-2017
	Pharmacological Group	Antipsychotics
	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	Tablet Resjun -2 of M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad. (Reg.# 081922)
	GMP status	Last GMP inspection 6-7-2017 The firm is found complying GMP as of today
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report conducted on 06-11-2018, concluding good GMP compliance.
	Decision: Approved.	
133.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd., Plot#2, , Street # N-4, national Industrial Zone, Rawat, Pakistan
	Brand Name +Dosage Form + Strength	Respimed 3mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone…….3mg"
	Diary No. Date of R& I & fee	Dy.No 21160 dated 15-11-2017 Rs. 20,000/- 15-11-2017
	Pharmacological Group	Antipsychotics
	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	Becalm 3mg Tablet of M/s Maple Pharmaceuticals, Karachi (Reg.# 058206)
	GMP status	Last GMP inspection 6-7-2017 The firm is found complying GMP as of today
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 285th meeting referred the case to

		QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report conducted on 06-11-2018, concluding good GMP compliance.
	Decision: Approved.	
134.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd., Plot#2, , Street # N-4, national Industrial Zone, Rawat, Pakistan
	Brand Name +Dosage Form + Strength	Respimed 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Risperidone……..…4mg"
	Diary No. Date of R& I & fee	Dy.No 21161 dated 15-11-2017 Rs. 20,000/- 15-11-2017
	Pharmacological Group	Antipsychotics
	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	Riss 4mg Tablet of M/s M/s Shawan Pharmaceuticals, Islamabad (Reg.# 080376)
	GMP status	Last GMP inspection 6-7-2017 The firm is found complying GMP as of today
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 285th meeting referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC:	Firm has submitted copy of GMP inspection report conducted on 6-11-2018 concluding good GMP compliance
	Decision: Approved.	
135.	Name and address of manufacturer / Applicant	M/s Weather Folds Pharmaceuticals Plot No. 69/2, Phase-II, Industrial Area, Hattar
	Brand Name +Dosage Form + Strength	Dyfogest 10mg Tablet
	Composition	Each film coated tablet contains: Dydrogesterone …10mg
	Diary No. Date of R& I & fee	Dy No.14499; 11-09-2017; Rs.20,000/-
	Pharmacological Group	Progestogen
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Duphaston 10 mg film-coated tablet by M/s Mylan Medical SAS , ANSM approved
	Me-too status	Duphaston 10 mg tablet by M/s Abbott(Reg#006654)
	GMP status	17-06-2017; Inspection for grant of additional sections Panel recommends grant of additional sections.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 275th meeting deferred for further deliberation regarding cis/trans isomers of Dydrogesteron.
	Evaluation by PEC:	Firm has submitted that we will use the Trans Isomer in production of our product Dydrogesterone.
	Decision: Approved.	
136.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, Defence Road, 1-km Towards Kahna, Lahore.
	Brand Name +Dosage Form + Strength	I-Husk Sachet

	Composition	Each Sachet Contains: Psyllium Husk …600mg
	Diary No. Date of R& I & fee	Dy.No.31029-H dated 14-09-2018 Rs.20,000/- 14-09-2018
	Pharmacological Group	Mineral supplements
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	Rs. 110/-, 10's; Rs. 375, 30's.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Not confirmed.
	GMP status	Inspection conducted on 19th Dec., 2017 & 2nd March, 2018 Renewal of DML and grant of additional sections. Panel recommends renewal of DML and grant of additional sections.
	Remarks of the Evaluator.	• Firm has submitted Form 5 with revised composition as under: "Each Sachet Contains: Psyllium Husk ….. 6gm" • Firm has also submitted fee of Rs. 5,000/- vide deposit slip# 0807336 dated 24-12-2018, for revision of formulation. • Following references against revised formulation have been verified: i. Ispilax Oral Sachet of M/s WelMark Pharmaceutical (Reg.# 075514).
	Previous Decision:	Registration Board in its 287th meeting deferred for evidence of approval of applied formulation in reference regulatory authorities which were adopted by Registration Board in its 275th meeting is required.
	Evaluation by PEC:	Firm has submitted following reference from TGA of Australia: "BONVIT PSYLLIUM HUSK POWDER of M/s G & R Gerardis Pty Ltd." with following composition: "Psyllium Husk Powder 1 gm/gm"
	Decision: Deferred for clarification of applied dosage form since submitted reference is in powder form.	

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

a. New DML (Remaining molecules)

Evaluator PEC-II

The drugs manufacturing license of M/s. Rakaposhi Pharmaceuticals, Hayatabad Industrial Estate, Peshawar (DML NO.000386) was declared invalid by the Drug Licensing Division, DRAP, vide letter dated 26th May, 2015 as the application for renewal of DML from 21-6-2014 to 20-6-2019 was received seven months after due date of renewal i.e. 21-6-2014.

Subsequently the Licensing Division vide letter dated 5th August, 2015 Board informed that the Central Licensing Board in its 242nd meeting held on 8th July, 2015 has approved the grant (re-grant) the Drug Manufacturing License with same license number .i.e. (000386).

Subsequently the Registration board in its 271st meeting approved various applications of M/s Rakaposhi. And now the firm has got approval of 4 molecules on priority for the "Oral dry powder Suspension (cephalosporin) section. Now the firm has requested for the priority consideration of following one application against the available balance of priority consideration.

137.	Name and address of manufacturer / Applicant	M/s. Rakaposhi Pharmaceuticals, Hayatabad Industrial Estate, Peshawar
	Brand Name +Dosage Form + Strength	Radoxime 40mg/5ml Dry Suspension
	Composition	"Each 5ml After Reconstitution Contains: Cefpodoxime as Proxetil…40mg"
	Diary No. Date of R& I & fee	Dy.No 16247 dated 07-03-2019 Rs20,000/- 06-03-2019
	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 ANSM of France
	Me-too status (with strength and dosage form)	Ultradoxim Dry Powder Suspension of M/s The Schazoo Pharmaceuticals Laboratories (Pvt) Ltd, Kalalwala 20Km Lahore (Reg.# 069401)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 19-09-2018 recommending issuance of GMP certificate.
	Remarks of the Evaluator[II]	
	Decision: Approved.	

b. New/Additional section (Remaining molecule)

CLB in its 259th meeting held on 29th & 30th March 2018, has approved the following 3 additional sections of M/s Medisure Laboratories Pakistan.
Capsule (Cephalosporin)
Dry Powder Suspension(Cephalosporin)
Dry Powder Injection(Cephalosporin)Section

Now the Applicant has applied for following two products in "Dry powder Suspension (Cephalosporin) section", to be considered priority against the available balance. Details of already considered products in this section are as under:

Sr.No.	Section	Already considered molecule/ products	Balance Molecules
1.	Dry Powder Suspension (Cephalosporin) Section	2 Molecules/3 Products	8

138.	**Name and address of manufacturer / Applicant**	**"M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan"**
	Brand Name +Dosage Form + Strength	Cipoxime 40mg/5ml Oral Supension
	Composition	"Each 5ml Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…….40mg"
	Diary No. Date of R& I & fee	Dy. No 8528 dated 26-02-2019 Rs. 20,000/- 25-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Radox 40mg/5ml Dry Suspension of M/s ARP (Pvt) Ltd, Islamabad. (Reg.# 080393)
	GMP status	Last inspection of conducted on 28-06-2018, Good level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approverd.	
139.	Name and address of manufacturer / Applicant	"M/s Medisure Laboratories Pakistan Pvt Ltd. A-115, S.I.T.E, Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Cipoxime 100mg/5ml Oral Supension
	Composition	"Each 5ml Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…100mg"
	Diary No. Date of R& I & fee	Dy. No 8528 dated 26-02-2019 Rs. 20,000 Dated 25-02-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per latest DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	Qink Dry Suspension of M/s. Wilshire Laboratories (Pvt) Ltd. (Reg.# 053636)
	GMP status	Last inspection of conducted on 28-06-2018, Good level of GMP compliance.
	Remarks of the Evaluator[II]	
	Decision: Approved.	

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

a. New Cases

Evaluator PEC-II

140.	Name and address of manufacturer / Applicant	"M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan"
	Brand Name +Dosage Form + Strength	Ampro-20 Oral Powder
	Composition	"Each 1gm Contains: Amprolium HCl…200mg"
	Diary No. Date of R & I & fee	Dy. No 23027 dated 03-07-2018 Rs.20,000/- Dated 03-07-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg
	Me-too status (with strength and dosage form)	AMPROLE 200 Water Soluble Powder by M/s Pantex Pharmaceutica, Lahore (Reg.#039986)
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly.
	Remarks of the Evaluator[II]	
	Decision: Approved.	
141.	Name and address of manufacturer / Applicant	"M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan"
	Brand Name +Dosage Form + Strength	Amanta Forte 10/100 gm Oral Powder
	Composition	"Each 100gm Contains: Amantadine HCl…10gm"
	Diary No. Date of R & I & fee	Dy. No 23025 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg
	Me-too status (with strength and dosage form)	AMANTABAK 10% POWDER by M/s ATTABAK PHARMACEUTICALS (Reg.#075697)
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specifications.	
142.	Name and address of manufacturer / Applicant	"M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan"
	Brand Name +Dosage Form + Strength	Tylo Plus Oral Liquid
	Composition	"Each 1ml Contains: Tylosin Tartrate…50mg Sulphamethoxypyridazine…50mg Trimethoprim…10mg Bromhexine HCl…5mg
	Diary No. Date of R & I & fee	Dy. No 23024 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	Antibacterial, Mucolytic & Antipyretic
	Type of Form	Form-5

	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100ml, 250ml, 500ml, 1 liter, 5 liter, 10 liter, 25 liter
	Me-too status (with strength and dosage form)	COMPLIBAK CRD ORAL SOLUTION. by M/s ATTABAK PHARMACEUTICALS (Reg.#053903)
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specification	
143.	Name and address of manufacturer / Applicant	"M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan"
	Brand Name +Dosage Form + Strength	Tylomix-FP Granules
	Composition	"Each 100gm Contains: Tylosin Phosphate…10gm"
	Diary No. Date of R & I & fee	Dy. No 23023 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	
	Me-too status (with strength and dosage form)	SANNA TYLOSIN PREMIX. by M/s SANNA LABORATORIES FAISALABAD (Reg.#026505)
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specification.	
144.	Name and address of manufacturer / Applicant	"M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan"
	Brand Name +Dosage Form + Strength	Erythro-S Oral Powder
	Composition	"Each 1000gm Contains: Erythromycin Thiocyanate…100gm Trimethoprim…20gm Sulphadiazine…100gm"
	Diary No. Date of R & I & fee	Dy. No 23022 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50gm,100gm, 200gm, 500gm, 1Kg, 2.5Kg, 5Kg, 10Kg, 25Kg
	Me-too status (with strength and dosage form)	ERYSUL-T ORAL POWDER by M/s M/S. BIO-OXIME PHARMACEUTICALS (Reg.#080315)
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specification.	

145.	Name and address of manufacturer / Applicant	"M/s Ras Pharmaceuticals Pvt Ltd. 25-km, Lahore Road, Multan"
	Brand Name +Dosage Form + Strength	NCOl Oral powder
	Composition	"Each 100gm Contains: Oxytetracycline HCl……20.0gm Neomycin sulphate…….20.0gm Colistinsulphate……24MIU
	Diary No. Date of R & I & fee	Dy. No dated 04-10-2017, Rs.20,000/-(Photocopy) Dated 04-10-2017
	Pharmacological Group	Antibacterial
	Type of Form	Form-5 (Duplicate dossier)
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50gm,100gm,250gm,500gm,1Kg, 2.5Kg, 5kg, 10kg, 25Kg
	Me-too status (with strength and dosage form)	OXYNO PLUS WATER SOLUBLE POWDER by M/s ATTABAK PHARMACEUTICALS (Reg.#075682)
	GMP status	Date of Inspection: 16-10-2018 The firm is a small manufacturing unit (veterinary) and was operating at the fair level of GMP compliance. However it is advised to overcome the shortcomings and submit the compliance accordingly.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specification	

b. Deferred Cases

146.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	ICE-VIT Oral Powder
	Composition	Each Kg powder contains: Potassium chloride…4,000mg Sodium….1,000mg Chloride…….2,000mg Bioten….100mg Calcium D pantothenate….10.2mg Folic acid….850mg Vitamin A….2,025,000IU Vitamin D3…..1,850,000IU Vitamin E…5,500IU Vitamin K3…5000mg Vitamin B12…..20mg Thiamine HCl…….4,150mg Riboflavin ……1,110mg
	Diary No. Date of R& I & fee	Dy. No 5135 dated 12-08-15 , Rs. 20,000/-
	Pharmacological Group	Vitamin & Mineral
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	Decontrolled/ 100gm, 500gm,1kg, 2.5kg, 5kg & 25 kg
	Me-too status	Selectromin powder of sanna labs
	GMP status	GMP inspection dated 16-10-2018 concluding fair level of GMP compliance.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 253rd meeting deferred for confirmation of Me too status.

	Evaluation by PEC:	Firm has submitted that previously units of certain ingredients were mentioned erroneously and now the firm has submitted revised composition against the me-too reference of "Selectromin Forte powder of Sanna laboratories (Reg.#021500). The corrected composition has been replaced above. Firm has also submitted fee for revision of formulation vide deposit slip# 0714725 dated 28-08-2019.
	Decision: Deferred for clarification of declaring contents of "Sodium" and "Chloride" in elemental form in the applied composition.	
147.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	CARDISOL Oral Solution
	Composition	Each 100ml contains L-Carnitine….50mg Vitamin B6 (PyrodoxineHCL)….50mg Vitanmin B12 ….1.5mg Nicotinamide….150mg Calcium pantothenate….100mg Sorbitol….10gm dl-Methionine…1000mg L-Arginine …….300mg. L-Citruline …. …200mg. L-Glycine …. …...200mg. L-Aspartic Acid……..…150mg. L-Lysine ……..…100mg. L-Glutamic Acid …150mg. L-Ornithine ……200mg.
	Diary No. Date of R& I & fee	Dy. No dated 27-08-15 20000/-
	Pharmacological Group	Multi Vitamin
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	Decontrolled/ 100ml, 500ml,1L, 2.5 L , 5 L & 25 L
	Me-too status	
	GMP status	GMP inspection dated 16-10-2018 concluding fair level of GMP compliance.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 253rd meeting deferred for confirmation of Me too status.
	Evaluation by PEC:	Firm has submitted revised composition against the me-too reference of "MEGABOLASE SOLUTION of M/S. MEDIEXCEL PHARMA, ISLAMABAD (Reg.# 043231). The corrected composition has been replaced above. Firm has also submitted Rs. 20,000/- fee for revision of formulation vide deposit slip# 0714724 dated 28-08-2019.
	Decision: Approved with Innovator's specification	
148.	Name and address of manufacturer / Applicant	M/s Ras Pharmaceuticals, Lahore Road, Multan.
	Brand Name +Dosage Form + Strength	NOR-TS Oral Liquid
	Composition	Each 100ml contains: Norfloxacin…..5gm Sulphamethoxypyridazine…..5gm Trimethoprim….1gm Phenylbutazone…1.2gm Bomhexine…..0.2gm

	Diary No. Date of R& I & fee	Dy. No 5129 dated 12-08-1520000/-
	Pharmacological Group	Antibacterial/Expectorant
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	Decontrolled/ 100ml, 500ml,1L, 2.5 L , 5 L & 25 L
	Me-too status	
	GMP status	GMP inspection dated 16-10-2018 concluding fair level of GMP compliance.
	Remarks of the Evaluator.	
	Previous Decision:	Registration Board in its 253rd meeting deferred for confirmation of Me too status.
	Evaluation by PEC:	Firm has submitted revised composition against the me-too reference of "MEGABIOTIC SOLUTION of M/S. SELMORE PHARMACEUTICALS, LAHORE (Reg.# 057006). The corrected composition has been replaced above. Firm has also submitted Rs. 20,000/- fee for revision of formulation vide deposit slip# 0714727 dated 28-08-2019.
	Decision: Deferred for rationale of Phenylbutazone in applied formulation.	

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

a. New DML (Remaining molecules)

M/s. Majestic Pharma, Plot # 21, Phase-1A, M-3, Industrial City, Faisalabad.

The Central Licensing Board in its 256th meeting held on 9-10th November, 2017 has considered and approved the grant of Drug Manufacturing License by way of Formulation.

Accordingly, firm has applied following registration applications, the section wise details are as follows:

- Oral Liquid (General) Section
- Oral Powder (General) Section
- The firm has requested to consider following two applications in the section of "Oral Powder (General) Section", against the balance of two molecules for priority consideration for the New DML.

  Previously 8 molecules have been considered in this section.

	Oral Powder (General) Section (2 products/2 molecules)	
149.	Name and address of manufacturer / Applicant	"M/s Majestic Pharma, Plot # 21, phase 1-A, m-3, industrial City, Sahianwala, Faisalabad.
	Brand Name +Dosage Form + Strength	Maji Tylodin Plus
	Composition	"Each 100gm oral water soluble powder Contains: Doxycycline HCl …..…40gm Tylosine tartrate …… 20gm"
	Diary No. Date of R & I & fee	Dy. No 9750 dated 26-06-2019 Rs.20,000/- 26-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg
	Me-too status (with strength and dosage form)	TYL-D 600 ORAL POWDER by M/s. VANTAGE PHARMACEUTICAL (Reg.#081710)
	GMP status	Date of Inspection: 17-10-2017 recommended renewal of DML.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specifications.	

150.	Name and address of manufacturer / Applicant	"M/s Majestic Pharma, Plot # 21, phase 1-A, m-3, industrial City, Sahianwala, Faisalabad.
	Brand Name+Dosage Form+ Strength	Maji Neon 72
	Composition	"Each 1000gm oral powder contains: Neomycin sulphate …… 720gm"
	Diary No. Date of R & I & fee	Dy. No 9749 dated 26-06-2019 Rs.20,000/- 26-06-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	100gm, 250gm, 500gm, 1Kg, 5Kg, 10Kg, 25Kg
	Me-too status (with strength and dosage form)	NEMOBAR-72 WATER SOLUBLE POWDER. by M/s. BAARIQ PHARMACEUTICALS (Reg.#071100)
	GMP status	Date of Inspection: 17-10-2017 recommended renewal of DML.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specifications.	

Case No. 05: Registration Applications of Categories to be Considered on Priority.

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

i. Human

151.	Name and address of Applicant	"M/s A & Z Health Services. Suit No. 2, Block 27, Industrial & Trade Center, G-9/4, Islamabad, Pakistan."
	Detail of Drug Sale License	Address: A & Z Health Services. Suit No. 2, Block 27, Industrial & Trade Center, G-9/4, Islamabad Validity: 28-06-2020 Status: Drug License by way of WholeSale Distributor
	Name and address of manufacturer	M/s Guerbet 16-24 rue Jean Chaptal, 93600, Aulnay-Sous-Bois, France.
	Name address for batch release site	M/s Guerbet BP 57400, 95943, Roissy CdG cedex, France with Physical manufacturing site address at: 16-24 rue jean Chaptal, 93600, Aulnay-Sous-Bois, France.
	Name and address of marketing authorization holder	M/s Guerbet BP 57400, F-95943, Roissy CdG CEDEX"
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 38087 Dated 19-11-2018
	Fee including differential fee	Rs. 50,000/- Dated 19-11-2018
	Brand Name +Dosage Form + Strength	Lipiodol Ultra-Fluide (480mg I/ml) Solution for Injection
	Composition	"Each ml Contains: Ethyl Esters of Iodized Fatty Acids of Poppy Seed Oil corresponding to an iodine content of …..… 480mg"
	Finished Product Specification	BP
	Pharmacological Group	Non-water soluble X-ray contrast media
	Shelf life	3 years
	Demanded Price	$400USD
	Pack size	10ml Glass ampoule
	International availability	Approved by ANSM of France
	Me-too status	N/A
	Stability studies	Firm has submitted long term (36 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#. 15/09/0335)** issued on 11-09-2015 by ANSM , France, declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Guerbet 16-24 rue Jean Chaptal, 93600, Aulnay-Sous-Bois, France • **Legalized GMP certificate** issued by ANSM, France for M/s Guerbet 16-24 rue Jean Chaptal, 93600, Aulnay-Sous-Bois, France, valid till 15-11-2021. • **Original "Letter of Authority"** from M/s Guerbet Asia Pacific Limited ("GAP") in the name of M/s A & Z Health Services. Suit No. 2, Block 27, Industrial & Trade Center, G-9/4, Islamabad, Pakistan to transact business in the company's own name and at its sole risk in the territory of Pakistan for applied product.
	Remarks of the Evaluator.	As per statement submitted by the firm, from the M/s Guerbet, the manufacture is performed by "M/s Delpharm tours, Rue paul Langevin, 37170 Chambray les Tours while the batch release is performed by "M/s Guerbet 16-24 rue Jean Chaptal, 93600, Aulnay-Sous-Bois, France"
	Decision: Deferred for clarification of the following: • **Regulatory status of the applied product in exporting country, whether it is being regulated as drug or medical device.** • **Manufacturing site of the applied product, whether "M/s Delpharm tours, Rue paul Langevin, 37170 Chambray les Tours" or "M/s Guerbet 16-24 rue Jean Chaptal, 93600, Aulnay-Sous-Bois, France"**	

b. Priority consideration of formulations due to shortage in market.

I. DRAP has received a reference from Director General (C-I), President's Secretariat, with subject "Hydrocortisone to Register in Pakistan".

In this regard following registration applications have been identified from the available record and presented here for consideration for Board:

152.	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 Specifications	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 (with strength/dosage form)	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"
	Remarks of the Evaluator[II]	Evidence of section approval required for applied formulation is required.
	Decision: Deferred for evidence of approval of required manufacturing facility from Licensing Division.	

153.	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 44233 dated 28-12-2018 Rs.20,000/- 28-12-2018
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	Rs. 17.5 per tablet Pack 1 x 20's M.R.P: 350/-
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength/dosage form)	--
	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 the firm rectified all observations noted during last GMP Inspection"
	Remarks of the Evaluator[II]	Evidence of section approval required for applied formulation is required. Evidence of me-too is required.
	Decision: Deferred for evidence of approval of required manufacturing facility from Licensing Division. Moreover Stability study data as per directions of 271st Board meeting.	

II. Registration Board in its 286th meeting decided to process following on priority to ensure free availability of these drugs. Moreover DRAP has received references from following various Professionals requesting attention to shortage of the applied formulation:

i. Dr. Syed Farhat Abbas (Consultant nephrologist, head of Department, Shifa International Hospitals Ltd. Islamabad.)
ii. Salwa Ahsan (Chief of Pharmacy, Shifa International Hospitals Ltd. Islamabad.)
iii. Dr. Iqtidar A. Khan (Professor, Department of Pediatrics & Child Health & Interim Chairman, The Agha Khan University, Karachi)

154.	Name and address of manufacturer / Applicant	"M/s PharmEvo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Brand Name +Dosage Form + Strength	Kay Gone 10gm Sachet
	Composition	Each Sachet Contains: Sodium Polystyrene Sulfonate…10gm
	Diary No. Date of R& I & fee	Dy.No 24563 (16-07-2018) Rs.20,000/- Dated 16-07-2018
	Pharmacological Group	Ion-exchange resin
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA as 454gm per bottle
	Me-too status	-
	GMP status	Last GMP inspection report dated 23-02-2018 concluding as under: "Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Pharm Evo Pvt. Ltd. Karachi was considered to be operating at acceptable level of compliance with GMP standards as today."
	Remarks of the Evaluator[2]	Evidence of Me-too status required.
	Previous Decision of 286th meeting:	Deferred for evidence of applied formulation/drug already

		approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm or else application on Form 5-D along with submission of differential fee and stability study data as per the requirements of 278th meeting of Registration Board.
	Evaluation by PEC	• Firm has submitted 36 months long term & 6 months accelerated stability study reports of three batches of "Polystyrene Sulphonate" from the supplier i.e., M/s Phaex polymers Pvt. Ltd., Maharashtra, India. • Moreover firm has submitted following undertaking: "We, PharmEvo (Pvt) Limited do hereby undertake that we will provide real time stability studies of (Sodium Polystyrene Sulphonate USP according to stability protocol till assigned shelf life of the product."
	Decision of 288th meeting: Deferred for application on Form 5-D along with submission of differential fee and stability study data by the finished product manufacturer as per the requirements of 278th meeting of Registration Board.	

Firm's reply:

Firm has submitted 1 month stability data of 3 batches, at both accelerated and long term stability conditions.

Evaluation by PEC:

- Firm has not submitted Form 5-D and differential fee.
- Firm has submitted stability data for 100gm jar packing , wherein firm has applied for the 10gm sachet packing

Decision: Deferred for rectification of following shortcoings:

- **Submission of Form 5-D along with differential fee.**
- **Submission of complete stability studies at hoth accelerated and log term conditions.**
- **Clarification of submitting stability data for jar packaging whereas firm has applied for sachet packaging.**

Case No. 06: Registration Applications of Import Cases.

a. New Cases (Veterinary)

155.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmed Block, New Garden Town, Lahore
	Detail of Drug Sale License	**Address:** Tarobina Corporation 226-Ahmed Block, New Garden Town, Lahore **Validity:** 10-07-2020 **Status:** License to sell drugs as a distributor
	Name and address of manufacturer	M/s Handong Co., Ltd., **Head Office:** Handong Bldg., 535, Ogeumro, Songpa-gu, Seoul, Korea. **Factroy:** 235-26, Chusaro, Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea
	Name and address of marketing authorization holder	M/s Handong Co., Ltd., **Head Office:** Handong Bldg., 535, Ogeumro, Songpa-gu, Seoul, Korea. **Factroy:** 235-26, Chusaro, Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea
	Name of exporting country	The Republic of Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.390 Dated 13/10/2015
	Fee including differential fee	Rs. 100,000/- Dated 12/10//2015
	Brand Name +Dosage Form + Strength	AMOX 50 Powder Powder for to be used with water for oral administration
	Composition	Each 1kg of powder contains: Amoxicillin **hydrate**…… 500gm (titer)
	Target species	Calf, Chicken
	Finished Product Specification	In House
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Rs. 10575/-
	Pack size	1's (1kg)
	International availability	
	Me-too status	Amoxi 50 soluble powder M/s Symans Pharmaceuticals (Reg # 063848)
	Detail of certificates attached	• **Original legalized CoPP (certificate No. 25-263)** for applied formulation issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture food and Rural affairs, Korea on **12-04-2018** • **Free sale status in CoPP**; **No** • **Original legalized Certificate of Free Sales (certificate No. M1907273)** for applied formulation issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural affairs, Korea on **13-05-2019,** declaring that applied product is registered and permitted to be freely sold by Republic of Korea. • Scanned copy of **Certificate of Good manufacturing Practice** issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture food and Rural affairs, Korea on **27-07-2015,** for M/s HAN DONG Co., LTD. 235-26, Chusaro, Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea, declaring that manufacturer conforms to Korean Veterinary Good manufacturing Practice.

	Remarks of the Evaluator.	• Firm has submitted letter of Certification letter declaring as under: "M/s Tarobina Corporation**,** 226-Ahmed Block, New Garden Town, Lahore hereby certifies that Amox 50 powder is manufactured only in South Republic of Korea, by "M/s HAN DONG Co., LTD." Korea and will be import only from Korea and will distribute by Tarobina Corporation Lahore. • Firm has submitted 6months accelerated and 24 months long term stability data for three batches of applied formulation as per Zone IV-A conditions.
	Decision: Approved with innovator's specifications as per Import Policy for inspections of manufacturer abroad.	
156.	Name and address of Applicant	M/s Tarobina Corporation, 226-Ahmed Block, New Garden Town, Lahore
	Detail of Drug Sale License	**Address:** Tarobina Corporation 226-Ahmed Block, New Garden Town, Lahore **Validity:** 26/06/2016 **Status:** License to sell drugs as a distributor
	Name and address of manufacturer	M/s Handong Co., Ltd., **Head Office:** Handong Bldg., 535, Ogeumro, Songpa-gu, Seoul, Korea. **Factroy:** 235-26, Chusaro, Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea
	Name and address of marketing authorization holder	M/s Handong Co., Ltd., **Head Office:** Handong Bldg., 535, Ogeumro, Songpa-gu, Seoul, Korea. **Factroy:** 235-26, Chusaro, Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea
	Name of exporting country	The Republic of Korea
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.386 Dated 13/10/2015
	Fee including differential fee	Rs. 100,000/- Dated 12/10//2015
	Brand Name +Dosage Form + Strength	TYLODOX PRO Powder for oral administration
	Composition	Each 1kg contains: Tylosin tartrate…….. 100g Doxycycline…… 200g
	Target species	Poultry, Goats, Sheep, Calves
	Finished Product Specification	In House
	Pharmacological Group	Antibacterial
	Shelf life	24 months
	Demanded Price	Rs. 9729.75/-
	Pack size	1's (1kg)
	International availability	
	Me-too status	TYLO-DOX PLUS WATER SOLUBLE POWDER of M/s N.B SONS (PVT) LTD., LAHORE (Reg.#49585)
	Detail of certificates attached	• **Original legalized CoPP (certificate No. 25-267)** for applied formulation issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture food and Rural affairs, Korea on **12-04-2018** • **Free sale status in CoPP**; **No** • **Original legalized Certificate of Free Sales (certificate No. M1907267)** for applied formulation issued by

		Animal and Plant Quarantine Agency of the Ministry for Agriculture Food and Rural affairs, Korea on **13-05-2019,** declaring that applied product is registered and permitted to be freely sold by Republic of Korea. • Scanned copy of **Certificate of Good manufacturing Practice** issued by Animal and Plant Quarantine Agency of the Ministry for Agriculture food and Rural affairs, Korea on **27-07-2015,** for M/s HAN DONG Co., LTD. 235-26, Chusaro, Sinam-myeon, Yesan-gun, Chungcheongnam-do, Korea, declaring that manufacturer conforms to Korean Veterinary Good manufacturing Practice.
	Remarks of the Evaluator.	• Firm has submitted letter of Certification letter declaring as under: "M/s Tarobina Corporation**,** 226-Ahmed Block, New Garden Town, Lahore hereby certifies that Tylodox Pro Oral powder is manufactured only in South Republic of Korea, by "M/s HAN DONG Co., LTD." Korea and will be import only from Korea and will distribute by Tarobina Corporation Lahore. • Firm has submitted 6months accelerated and 24 months long term stability data for three batches of applied formulation as per Zone IV-A conditions.
	Decision: Approved with innovator's specifications as per Import Policy for inspections of manufacturer abroad.	
157.	Name and address of Applicant	"M/s Uranus Bio-Tech Private Limited. Office # 112, 1st Floor, Arooj Arcade, F10 Markaz, Islamabad, Pakistan"
	Detail of Drug Sale License	Address: M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad Status: License To Sell Drugs in a Whole Sale Distributor
	Name and address of manufacturer	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name and address of marketing authorization holder	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.10304 Dated 20-03-2018
	Fee including differential fee	Rs. 100,000/- Dated 14-03-2018
	Brand Name +Dosage Form + Strength	Oxytong 5% Injection
	Composition	Each ml contains: Oxytetracycline …… 50mg
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Tetracycline antibacterial
	Shelf life	36 months
	Demanded Price	De-controlled
	Pack size	50ml
	Me-too status	OXYREX-5 INJECTION of M/s BIOREX PHARMACEUTICALS, ISLAMABAD. (Reg.# 031556)
	Stability studies	Firm has submitted long term (36 months) accelerated (06 months) stability data for three batches as per Zone IV-a conditions.

	Detail of certificates attached	• **Legalized copy of free Sale Certificate** (Certificate# (2014) SYSCZ Zi 23003 issued by Chongqing Agricultural Committee, PR China issued on 1-12-2017 declaring that applied product has been officially approved to be manufactured legally, and freely sold in and exported from People's Republic of China by M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. • **Legalized copy of GMP certificate** issued by Minister of Agriculture of P.R. China in the name of M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, valid till 01-11-2019. • **Notarized copy of "Exclusive Distribution Agreement"** between M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing and : M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad.
	Remarks of the Evaluator.	• Salt form of API is not mentioned in Form 5-A and Free sale certificate.
	Decision: Deferred for clarification of salt form of "Oxytetracycline."	
158.	Name and address of Applicant	"M/s Uranus Bio-Tech Private Limited. Office # 112, 1st Floor, Arooj Arcade, F10 Markaz, Islamabad, Pakistan"
	Detail of Drug Sale License	Address: M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad Status: License To Sell Drugs in a Whole Sale Distributor
	Name and address of manufacturer	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name and address of marketing authorization holder	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.10305 Dated 20-03-2018
	Fee including differential fee	Rs. 100,000/- Dated 14-03-2018
	Brand Name +Dosage Form + Strength	ALBENTONG SUS 10 Oral suspension
	Composition	Each ml contains: Albendazole …… 100mg
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Anthelmintic
	Shelf life	36 months
	Demanded Price	De-controlled
	Pack size	100ml
	Me-too status	ALBABAK-10 ORAL SUSPENSION of M/s ATTABAK PHARMACEUTICAL INDUSTRIES, ISLAMABAD. (Reg.# 034536)
	Stability studies	Firm has submitted long term (36 months) accelerated (06 months) stability data for three batches as per Zone IV-a conditions.
	Detail of certificates attached	• **Legalized copy of free Sale Certificate** (Certificate# (2014) SYSCZ Zi 23003 issued by Chongqing Agricultural

		Committee, PR China issued on 1-12-2017 declaring that applied product has been officially approved to be manufactured legally, and freely sold in and exported from People's Republic of China by M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. • **Legalized copy of GMP certificate** issued by Minister of Agriculture of P.R. China in the name of M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, valid till 01-11-2019. • **Notarized copy of "Exclusive Distribution Agreement"** between M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing and : M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications as per Import Policy for inspections of manufacturer abroad.	
159.	Name and address of Applicant	"M/s Uranus Bio-Tech Private Limited. Office # 112, 1st Floor, Arooj Arcade, F10 Markaz, Islamabad, Pakistan"
	Detail of Drug Sale License	Address: M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad Status: License To Sell Drugs in a Whole Sale Distributor
	Name and address of manufacturer	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name and address of marketing authorization holder	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.10306 Dated 20-03-2018
	Fee including differential fee	Rs. 100,000/- Dated 14-03-2018
	Brand Name +Dosage Form + Strength	Ivertong 1% Injection
	Composition	Each ml contains: Ivermectin …… 10mg
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Anthelmintic
	Shelf life	36 months
	Demanded Price	De-controlled
	Pack size	10ml
	Me-too status	IVERMECTIN INJECTION. of M/s LAWRANCE PHARMA (PVT) LTD.,LAHORE. (Reg.# 035038)
	Stability studies	Firm has submitted long term (36 months) accelerated (06 months) stability data for three batches as per Zone IV-a conditions.
	Detail of certificates attached	• **Legalized copy of free Sale Certificate** (Certificate# (2014) SYSCZ Zi 23003 issued by Chongqing Agricultural Committee, PR China issued on 1-12-2017 declaring that applied product has been officially approved to be manufactured legally, and freely sold in and exported from

		People's Republic of China by M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. • **Legalized copy of GMP certificate** issued by Minister of Agriculture of P.R. China in the name of M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, valid till 01-11-2019. • **Notarized copy of "Exclusive Distribution Agreement"** between M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing and : M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications as per Import Policy for inspections of manufacturer abroad.	
160.	Name and address of Applicant	"M/s Uranus Bio-Tech Private Limited. Office # 112, 1st Floor, Arooj Arcade, F10 Markaz, Islamabad, Pakistan"
	Detail of Drug Sale License	Address: M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad Status: License To Sell Drugs in a Whole Sale Distributor
	Name and address of manufacturer	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No.80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name and address of marketing authorization holder	M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd.No.80, East Part of Changzhou Road, Rongchang District, Chongqing, P.R. China"
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.10303 Dated 20-03-2018
	Fee including differential fee	Rs. 100,000/- Dated 14-03-2018
	Brand Name +Dosage Form + Strength	Flortong 30 Injection
	Composition	Each ml contains: Florfenicol …… 300mg
	Finished Product Specification	Manufacturer specifications.
	Pharmacological Group	Anibacterial
	Shelf life	36 months
	Demanded Price	De-controlled
	Pack size	100ml
	Me-too status	FLOROFEN INJECTION of M/s LEADS PHARMA (PVT) LTD., ISLAMABAD. (Reg.# 043160)
	Stability studies	Firm has submitted long term (36 months) accelerated (06 months) stability data for three batches as per Zone IV-a conditions.
	Detail of certificates attached	• **Legalized copy of free Sale Certificate** (Certificate# (2014) SYSCZ Zi 23003 issued by Chongqing Agricultural Committee, PR China issued on 1-12-2017 declaring that applied product has been officially approved to be manufactured legally, and freely sold in and exported from People's Republic of China by M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. • **Legalized copy of GMP certificate** issued by Minister of

		Agriculture of P.R. China in the name of M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing, valid till 01-11-2019. • **Notarized copy of "Exclusive Distribution Agreement"** between M/s Chongqing Fangtong Animal Pharmaceutical Co. Ltd. No. 80, East Part of Changzhou Road, Rongchang District, Chongqing and : M/s Uranus Biotech (Pvt.) Ltd., Office No. 112, First floor, Arooj Arcade, Sector F-10 Markaz, Islamabad.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications as per Import Policy for inspections of manufacturer abroad.	

Case No. 07: Registration Applications of Drugs for Which Stability Study Data is Submitted.

a. Exemption from Onsite Verification of Stability Data.

161.	Name and address of manufacturer / Applicant	M/s Helix A/56, SITE, mangopir, Karachi
	Brand Name +Dosage Form + Strength	Brevi/vetam tablets 25mg
	Composition	"Each film coated tablet Contains: Brivaracetam…..…25mg"
	Diary No. Date of R& I & fee	Dy. No 6070A dated 14-06-2017 Rs.50,000/- 13-06-2017
	Pharmacological Group	Antiepileptics
	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 (with strength and dosage form)	
	GMP status	GMP inspection dated 05-01-018 concluding compliant as per CGMP requirement
	Remarks of the Evaluator[II]	
162.	Name and address of manufacturer / Applicant	M/s Helix A/56, SITE, mangopir, Karachi
	Brand Name+Dosage Form + Strength	Brevi/vetam tablets 75mg
	Composition	"Each film coated tablet Contains: Brivaracetam…..…75mg"
	Diary No. Date of R& I & fee	Dy. No 6066 dated 14-06-2017 Rs.50,000/- 13-06-2017
	Pharmacological Group	Antiepileptics
	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 (with strength and dosage form)	--
	GMP status	GMP inspection dated 05-01-018 concluding compliant as per CGMP requirement
	Remarks of the Evaluator[II]	
163.	Name and address of manufacturer / Applicant	M/s Helix A/56, SITE, mangopir, Karachi
	Brand Name+Dosage Form + Strength	Brevi/vetam tablets 50mg

	Composition	"Each film coated tablet Contains: Brivaracetam…..…50mg"
	Diary No. Date of R& I & fee	Dy. No 6069 dated 14-06-2017 Rs.50,000/- 13-06-2017
	Pharmacological Group	Antiepileptics
	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 (with strength and dosage form)	--
	GMP status	GMP inspection dated 05-01-018 concluding compliant as per CGMP requirement
	Remarks of the Evaluator[II]	
164.	Name and address of manufacturer / Applicant	M/s Helix A/56, SITE, mangopir, Karachi
	Brand Name+Dosage Form+ Strength	Brevi/vetam tablets 10mg
	Composition	"Each film coated tablet Contains: Brivaracetam…..…10mg"
	Diary No. Date of R& I & fee	Dy. No 6067 dated 14-06-2017 Rs.50,000/- 13-06-2017
	Pharmacological Group	Antiepileptics
	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 (with strength/dosage form)	--
	GMP status	GMP inspection dated 05-01-018 concluding compliant as per CGMP requirement
	Remarks of the Evaluator[II]	
165.	**Name and address of manufacturer / Applicant**	**M/s Helix A/56, SITE, mangopir, Karachi**
	Brand Name+Dosage Form+ Strength	Brevi/vetam tablets 100mg
	Composition	"Each film coated tablet Contains: Brivaracetam…..…100mg"
	Diary No. Date of R& I & fee	Dy. No 6068 dated 14-06-2017 Rs.50,000/- 13-06-2017
	Pharmacological Group	Antiepileptics
	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 (with strength/dosage form)	--
	GMP status	GMP inspection dated 05-01-018 concluding compliant as per CGMP requirement
	Remarks of the Evaluator[II]	

Now the firm has submitted stability data detailed as under:

STABILITY STUDY DATA

Drug	Brevi/Vetam Tablets
Name of Manufacturer	M/s Helix A/56, SITE, mangopir, Karachi

Manufacturer of API	Brivaracetam: M/s Chengda Pharmaceuticals Co., Ltd, Zhejiang.
API Lot No.	NP1713-1806001
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 initiation	Date of submission
Brevi/Vetam Tablets 75mg	TF001,TF002,TF003	900 tablets	16-08-2018	27-05-2019 (Dy.no 7305)
Brevi/Vetam Tablets 50mg	TF001,TF002,TF003	900 tablets	16-08-2018	27-05-2019 (Dy.no 7304)
Brevi/Vetam Tablets 10mg	TF001,TF002,TF003	900 tablets	16-08-2018	27-05-2019 (Dy.no 7302)
Brevi/ Vetam Tablets 100mg	TF001,TF002,TF003	900 tablets	16-08-2018	27-05-2019 (Dy.no 7306)
Brevi/Vetam Tablets 25mg	TF001,TF002,TF003	900 tablets	16-08-2018	27-05-2019 (Dy.no 7303)

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Brevi/Vetam 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 "Ramelton tablet 8mg (Ramelteont)", which was conducted on 18th August, 2017 and was presented in 273rd meeting of Registration Board. Registration Board decided to approve registration of "Ramelton tablet 8mg (Ramelteont)" by M/s helix 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 verifiable. 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 Brivaracetam from M/s Changda Pharmaceutical Co., Ltd. Jiashan, Zheijiang, China, issued by ADC, DRAP, Karachi has been submitted. Detailed as under:

Batch No.	**Invoice No.**	**Quantity Imported.**	**Date of approval by DRAP**
NP1713-1806001	C02S05ZEP180357	800gm	18-7-2018

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>• The firm has submitted that reference and impurity standards of “Brivaracetam” were received as FOC (free of Cost) samples in minute quantities i.e., in mgs with API “Brivaracetam”. Therefore, no procuring documents for reference & impurity standards is available.”</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of DML issued by CFDA for the M/s Chengda Pharmaceuticals Co., Ltd, Zhejiang. Valid upto 15-06-2020 has been submitted.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted photocopy of “Vendor Evaluation Questionnaire” filled for M/s Changda Pharmaceutical Co., Ltd. Jiashan, Zheijiang, China.</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 standard for Brivaracetam</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 2 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 Protocol for Development of New Product and SOP for Stability programme.</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">Brevi Tablets 75mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>06-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>06-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>06-08-2018</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 100mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>07-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>07-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>07-08-2018</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 25mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>02-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>02-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>02-08-2018</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 50mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>03-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>03-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>03-08-2018</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 10mg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
</table></td></tr>
</table>

<table>
<tr><td></td><td></td><td>
<table>
<tr><td>TF001</td><td>01-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>01-08-2018</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>01-08-2018</td><td>900 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">Brevi Tablets 75mg</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>350 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 100mg</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>350 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 50mg</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>350 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 10mg</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>350 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td colspan="3">Brevi Tablets 25mg</td></tr>
<tr><td>Batch No.</td><td>Remaining Quantity</td><td>Batch Size</td></tr>
<tr><td>TF001</td><td>350 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF002</td><td>480 tablets</td><td>900 Tablets</td></tr>
<tr><td>TF003</td><td>480 tablets</td><td>900 Tablets</td></tr>
</table>
</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of 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 Brivaracetam.</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 Brivaracetam 10mg,25mg,50mg,75mg & 100mg tablets.</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 Brivaracetam 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 Brevi tablet range.</td></tr>
</table>

<table>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has submitted that “we manufactured lab scale batches of our applied products by using same formulation of innovator’s product that was approved by FDA “Briviact tablets by “UCB, Inc.”</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><td colspan="3">Brevi Tablets 75mg</td></tr>
<tr><td>Feature</td><td>Reference product</td><td>Product of M/s Helix</td></tr>
<tr><td>Brand name</td><td>Briviact tablets 75mg tab</td><td>Brevi tablets 75mg</td></tr>
<tr><td>Batch No.</td><td>258600</td><td>TF001</td></tr>
<tr><td colspan="3">Brevi Tablets 50mg</td></tr>
<tr><td>Feature</td><td>Feature</td><td>Feature</td></tr>
<tr><td>Brand name</td><td>Briviact tablets 50mg tab</td><td>Brevi tablets 50mg</td></tr>
<tr><td>Batch No.</td><td>254253</td><td>TF001</td></tr>
<tr><td colspan="3">Brevi Tablets 25mg</td></tr>
<tr><td>Feature</td><td>Feature</td><td>Feature</td></tr>
<tr><td>Brand name</td><td>Briviact tablets 25mg tab</td><td>Brevi tablets 25mg</td></tr>
<tr><td>Batch No.</td><td>253106</td><td>TF001</td></tr>
<tr><td colspan="3">Brevi Tablets 100mg</td></tr>
<tr><td>Feature</td><td>Reference product</td><td>Product of M/s Helix</td></tr>
<tr><td>Brand name</td><td>Briviact tablets 100mg tab</td><td>Brevi tablets 100mg</td></tr>
<tr><td>Batch No.</td><td>256974</td><td>TF001</td></tr>
<tr><td colspan="3">Brevi Tablets 75mg</td></tr>
<tr><td>Feature</td><td>Reference product</td><td>Product of M/s Helix</td></tr>
<tr><td>Brand name</td><td>Briviact tablets 75mg tab</td><td>Brevi tablets 75mg</td></tr>
<tr><td>Batch No.</td><td>258600</td><td>TF001</td></tr>
</table>
• Comparative dissolution studies have been performed in following mediums:
a. pH 1.2 HCl buffer
b. pH 4.5 Acetate buffer
c. pH 6.4 Phosphate buffer
• F2 factor value has not been calculated since dissolution results were above 85% in 15 minutes
• Firm has submitted relevant chromatograms and raw data sheets for the CDP study.</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">• Firm has performed content uniformity test as per USP <905> for all the strengths.
• Firm has performed CDP in phosphate buffer at pH 6.4 while the recommended buffer is phosphate buffer of pH 6.8. Justification shall be submitted in this regard.
• CDP guidelines recommends analysis of 12 units each of reference and sample product while firm has performed study on 6 units each of reference and sample product. Justification shall be submitted in this regard.</td></tr>
</table>

Registration Board decided to approve registration of "Brevi/vetam tablets 10mg (Brivaracetam 10mg), Brevi/vetam tablets 25mg (Brivaracetam 25mg), Brevi/vetam tablets 50mg (Brivaracetam 50mg), Brevi/vetam tablets 75mg (Brivaracetam 75mg) and Brevi/vetam tablets 100mg (Brivaracetam 100mg) by M/s Helix A/56, SITE, Mangopir, Karachi. Manufacturer will place first three production batches of all products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.		
166.	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]	
167.	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]	
168.	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	Firm has referred to onsite inspection report of their product "Nista tablet 60mg (Daclatasvir)", which was conducted on

<table>
<tr><td></td><td>during last two years.</td><td>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.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>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:
<table><tr><th>Batch No.</th><th>Invoice No.</th><th>Quantity Imported</th><th>Date of approval by DRAP</th></tr><tr><td>57318060103</td><td>RIS18037</td><td>600gm</td><td>18-09-2018</td></tr></table></td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted 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
<table><tr><th>Material name</th><th>Batch#.</th><th>Quantity</th></tr><tr><td>VST Impurity A</td><td>180204</td><td>100mg</td></tr><tr><td>VST Impurity A</td><td>1808</td><td>100mg</td></tr><tr><td>VST Impurity A</td><td>180504</td><td>100mg</td></tr><tr><td>SCB Impurity 1</td><td>180503</td><td>100mg</td></tr><tr><td>SCB Impurity 1</td><td>171005</td><td>100mg</td></tr><tr><td>SCB Impurity 1</td><td>170903</td><td>100mg</td></tr><tr><td>SCB Impurity 1</td><td>180406</td><td>100mg</td></tr><tr><td>Sacubitril/Valsartan</td><td>180707</td><td>100mg</td></tr><tr><td>SCB (RS Standard)</td><td>170705</td><td>100mg</td></tr><tr><td>SCB (R.R)</td><td>170704</td><td>100mg</td></tr><tr><td>SCB (S.S)</td><td>170703</td><td>100mg</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>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.</td></tr>
<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>
</table>

<table>
<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>
<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 &</td><td>The firm has submitted photocopy of Specification/Testing</td></tr>
</table>

<table>
<tr><td></td><td>complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>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>
</table>

Following is the details of observations from PEC and the response of the firm:

Sr #	Observation from PEc	Response of the firm
	• Test method titled as “Stability indicating test method for Assay, Impurities and Degradation Product” in the recently submitted “Analytical Control Procedure for Stability studies”, does not mention the details for identification & quantification for impurities.	Analytical method with details of impurities enclosed
	• Scientific justification shall be	Stability indicating method was under development when 03

<table>
<tr><td></td><td>submitted for applying two different methods for Assay analysis during the stability studies.</td><td>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: 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.**
- **Clraification 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.**

Sr.#	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
169.	M/s Hilton Pharma (Pvt.) Ltd. Karachi	Sitaglu Met XR 50/500 mg tablet Each extended release tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin….50 mg Metformin hydrochloride (extended release)….500 mg (Anti-diabetic)	Form 5-D Dy. No. 1206 (06-07-2012) Rs: 15,000 (06-07-2012), Rs: 35000 (24-6-14) 10's, 14's, 20's, 28's As per DPC	Approved by USFDA
170.	M/s Hilton Pharma (Pvt.) Ltd. Karachi	Sitaglu Met XR 100/1000 mg tablet Each extended release tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin….100 mg Metformin hydrochloride (extended release)….1000 mg (Anti-diabetic)	Form 5-D Dy. No. 1204 (06-07-2012) Rs: 15,000 (06-07-2012), Rs: 35,000 (24-06-2014) 10's, 14's, 20's, 28's As per DPC	Approved by USFDA
171.	M/s Hilton Pharma (Pvt.) Ltd. Karachi	Sitaglu Met XR 50/1000 mg tablet Each extended release tablet contains: Each extended release tablet contains: Sitagliptin phosphate monohydrate eq. to Sitagliptin …. 50 mg Metformin hydrochloride (extended release)….1000 mg (Anti-diabetic)	Form 5-D Dy. No. 1204 (06-07-2012) Rs: 15,000 (06-07-2012), Rs: 35,000 (24-06-2014) 10's, 14's, 20's, 28's As per DPC	Approved by USFDA

Remarks:

Above applications were previously presented in various Registration Board meetings along with the stability data. Since the above products were formulated as bi-layered compressed tablets in contrary to reference product wherein Sitagliptin was incorporated via coating solution on the metformin extended release core. Hence the Board in its 284th meeting deliberated in detail that since with change in manufacturing method innovator's specifications could not be complied for applied formulation hence the Board did not accede to firm's request and directed the firm to re-submit the stability data of all the prodcust i.e. Sitaglu Met XR 50/500 mg tablet, Sitaglu Met XR 100/1000 mg tablet and Sitaglu Met XR 50/1000 mg tablet with formulation and manufacturing method as per reference product.

Now the firm has submitted fresh stability data with formulations as per reference product.

REQUEST OF EXEMPTION ROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Sitaglu Met XR 50/1000 mg tablet, Sitaglu Met XR 100/1000 mg tablet & Sitaglu Met XR 50/500 mg tablet vide Letter no. AQS/SK/190710-01, dated 10-07-2019 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:

(Date of submission: 12-07-2019 vide diary no. 11659).

<table>
<tr><th colspan="3">Administrative Portion</th></tr>
<tr><td>1.</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>Firm has referred to onsite inspection report of their product “HILVEL 400mg + 100mg (Sofosbuvir + Velpatasvir) ”, which was conducted on 14th December, 2017 and was presented in 277th meeting of Registration Board held on 27-29th December, 2017.
Registration Board decided to approve registration of “HILVEL 400mg / 100mg (Sofosbuvir + Velpatasvir” by M/s. Hilton Pharma (Pvt.) Ltd., Karachi. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months.
Following two observations were reported in the report:
i. The HPLC software is 21 CFR compliant.
ii. Audit trail on the testing reports of Hilvel Tablets 400mg+100mg is available.
iii. Adequate monitoring and control are available for stability chamber. Chamber are controlled and monitored through software having alarm system for alerts as well.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Sitagliptin phosphate monohydrate:
Commercial Invoices signed & stamped by ADC DRAP, Karachi dated 24-05-2018 for the import of Sitagliptin from M/s Zheijiang tianyu Pharmaceutical Co., Ltd, China has been attached.
<table>
<tr><th>Invoice No.</th><th>Quantity Imported.</th></tr>
<tr><td>TY118325</td><td>600Kg</td></tr>
</table>
Metformin hydrochloride:
Commercial Invoices signed & stamped by ADC DRAP, Karachi dated 27-06-2018 for the import of Sitagliptin from M/s Abhilash Chemicals & Pharmaceuticals has been attached</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted a delivery challan from M/s lab sciences addressing M/s Hilton Pharma (Pvt.) Ltd, Karachi for the submission of Reference standards of Sitagliptin & Metformin and impurity standards of impurity, dated 18-07-2016.
No document for the procurement of impurity standards of Sitagliptin has been submitted.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Sitagliptin: The firm has provided copy of Certificate (Certificate#ZJ20180033) of GMP compliance issued to M/s Zheijiang Tianyu Pharmaceutical Co., Ltd., Zheijiang province by CFDA valid Up to 14-03-2023.
Metformin HCl:
The firm has provided copy of Certificate (certificate# WC-0345) of GMP compliance issued to M/s Abhilash Chemicals & Pharmaceuticals Pvt. Ltd., Madurai District. issued by CDSCO, India valid Up to September,2021.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>• The firm has submitted photocopy of “SOP for Selection of manufacturer for API/Excipient and Procurement Procedure”,
SOP No: PDV-FM-068 with effective date 02-03-2018.
Version no: 01</td></tr>
</table>

<table>
<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, working standard and impurity standard for Sitagliptin & Metformin HCl. No COA of impurity standard of Sitagliptin has been submitted.
Analytical reports of APIs submitted from M/s Hilton are of different batches then the COAs of suppliers.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development & regulatory affairs comprising of 18 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted photocopy of Development Protocol for Lab scale batch manufacturing of Sitaglu Met XR 50/500mg, 50/1000mg & 100/1000mg Film coated tablets.
• Project code # HPL/10/18/SITM
• Issued on Ocotber, 2018
• The SOP mentions the details of master formulation & manufacturing method for both products. Copies of stability protocols have also been submitted for both products.
• Firm has also submitted stability protocols for all the stability batches.</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 Sitaglu Met XR tablets, such as.
<table>
<tr><th colspan="3">Sitaglu Met XR 50/500mg</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>SMX-297701-13</td><td>06-11-2018</td><td>1500 Tablets</td></tr>
<tr><td>SMX-297901-15</td><td>06-11-2018</td><td>3000 Tablets</td></tr>
<tr><td>SMX-298001-16</td><td>06-11-2018</td><td>3000 Tablets</td></tr>
<tr><th colspan="3">Sitaglu Met XR 50/1000mg</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>SMX-291311-3</td><td>19-09-2018</td><td>1500 Tablets</td></tr>
<tr><td>SMX-291511-4</td><td>19-09-2018</td><td>1500 Tablets</td></tr>
<tr><td>SMX-291611-5</td><td>19-09-2018</td><td>1500 Tablets</td></tr>
<tr><th colspan="3">Sitaglu Met XR 50/1000mg</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>SMX-293112-4</td><td>12-10-2018</td><td>1500 Tablets</td></tr>
<tr><td>SMX-293712-5</td><td>12-10-2018</td><td>1500 Tablets</td></tr>
<tr><td>SMX-293812-6</td><td>12-10-2018</td><td>1500 Tablets</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th colspan="2">Sitaglu Met XR 50/500mg</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>SMX-297701-13</td><td>130 Tablets</td></tr>
<tr><td>SMX-297901-15</td><td>130 Tablets</td></tr>
<tr><td>SMX-298001-16</td><td>130 Tablets</td></tr>
<tr><th colspan="2">Sitaglu Met XR 50/1000mg</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>SMX-291311-3</td><td>130 Tablets</td></tr>
<tr><td>SMX-291511-4</td><td>130 Tablets</td></tr>
<tr><td>SMX-291611-5</td><td>130 Tablets</td></tr>
<tr><th colspan="2">Sitaglu Met XR 50/1000mg</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>SMX-293112-4</td><td>130 Tablets</td></tr>
<tr><td>SMX-293712-5</td><td>130 Tablets</td></tr>
<tr><td>SMX-293812-6</td><td>130 Tablets</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical chart 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 and report for Sitagliptin (batch #.12301-171203) & Metformin HCl (batch#.MET/B/01/18060167)
• Relevant chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs have been submitted.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure PD-FPS/109/00) for Sitaglu Met XR 50/500 tablets, PD-FPS/75/00 for Sitaglu Met XR 100/1000 tablets & PD-FPS/77/00 for Sitaglu Met XR 100/1000 tablets along with Stability Study Report of stability batches & chromatograms, lab reports, raw data sheets etc.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>• The firm has submitted stability studies reports on Sitagliptin for both Accelerated (40˚C ± 2˚C / 75% ± 5%RH) & Long term (30˚C ± 2˚C / 65% ± 5%RH) conditions.
The firm has submitted stability studies reports on Metformin HCl for both Accelerated (40˚C ± 2˚C / 75% ± 5%RH) & Long term (30˚C ± 2˚C / 65% ± 5%RH) 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 Sitaglu Met XR tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not performed Drug-excipients compatibility studies and stated that the qualitative composition of their product is similar to that of innovator’s product tablet and also stability studies have not shown any significant change in quality attributes of the product.</td></tr>
</table>

<table>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>

Firm has submitted F2 factor protocol & reports. The details of reference product & Sample product are as follows:

<table>
<tr><th colspan="3">Sitaglu Met XR 50/500mg</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Janumet XR tablet</td><td>Sitaglu Met XR 50/500mg</td></tr>
<tr><td>Batch No.</td><td>M059630</td><td>SMX-297701-13</td></tr>
<tr><td>Expiry date</td><td>06-2020</td><td>--</td></tr>
<tr><th colspan="3">Sitaglu Met XR 50/1000mg</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Janumet XR tablet</td><td>Sitaglu Met XR 50/1000mg</td></tr>
<tr><td>Batch No.</td><td>M062584</td><td>SMX-291311-3</td></tr>
<tr><td>Expiry date</td><td>06-2020</td><td>--</td></tr>
<tr><th colspan="3">Sitaglu Met XR 100/1000mg</th></tr>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Hilton</th></tr>
<tr><td>Brand name</td><td>Janumet XR tablet</td><td>Sitaglu Met XR 50/1000mg</td></tr>
<tr><td>Batch No.</td><td>M058280</td><td>SMX-293112-4</td></tr>
<tr><td>Expiry date</td><td>01-2021</td><td>--</td></tr>
</table>

Comparative dissolution studies have been performed in following mediums:
<ol type="a">
pH 1.2 HCl buffer
pH 4.5 Acetate buffer
pH 6.8 Phosphate buffer

Submitted report shows comparable Dissolution profile of the reference and applied products.

</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">

Firm has applied Manufacturing method as that of the reference product wherein Sitagliptin has been deposited via coating on the metformin extended release core.

</td></tr>
<tr><td colspan="3">Registration Board decided to approve registration of “Sitaglu Met XR 50/1000 mg tablet, Sitaglu Met XR 100/1000 mg tablet and Sitaglu Met XR 50/500 mg tablet by M/s Hilton Pharma (Pvt.) Ltd. Karachi. Manufacturer will place first three production batches of all products on long term stability studies throughout proposed shelf life and on accelerated studies for six months</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	REMARKS (IF ANY)
172.	M/s Ferozsons Labs, Amangarh, Nowshera.	Sitagen-M 50/500 Tablets Each film coated tablet contains:- Sitagliptin phosphate monohydrate eq. to	Form-5 Dy. No: Dated. 25-01-2019 Rs.20,000/- dated 21-01-2019 14’s,28’s,30’s	Approved by USFDA Last GMP inspection conducted on 10-01-2018	

		Sitagliptin (Immediate release) ……... 50mg Metformin HCl (sustained release) ……500mg (Anti-diabetic)	As per SRO	recommending issuance of GMP certificate	

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data of Sitagen-M XR Tablets 50/500 mg vide Letter no. PDFLL-751517091, dated 15-07-2019 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
(Date of submission: 18-07-2019 vide diary no. 12410)

Sr. #	Question	Submission
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "INVICTA TABLETS" (Sofosbuvir 400mg and Velpatasvir 100mg), which was conducted on 16-March 2018 and was presented in 281st meeting of Registration board. Registration Board decided to approve registration of "INVICTA TABLETS" by M/s. Ferozsons Laboratories Limited. According to the report following points were confirmed • HPLC is 21 CFR compliant • Audit trails of the test reports were available. • Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted • Photocopy of ADC (Peshawar) attested commercial invoice for 300kg Sitagliptin phosphate monohydrate invoice # HN170727-C dated: 27/07/2017 lot No. M-20170112-D02-M06-01 from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China • Photocopy of ADC (Peshawar) attested commercial invoice for 1000kg Metformin HCl invoice # MEG1718/1631990 dated: 25/01/2018 lot No. 17127ML2ARM from M/s Ipca Laboratories Limited – India.
3.	Documents for the procurement of reference standard and impurity standards.	• Copy of NOC from DRAP Peshawar along with invoice for import of Sitagliptin Phosphate USP Reference Standard has been submitted. • Copy of P.O and invoice for import of Metformin HCl USP Reference Standard has been submitted. • No relevant document for procurement of impurity standards has been submitted.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sitagliptin:** • Copy of GMP Certificate issued on January 03, 2018 by Fuxin Food and Drug Administration People's Republic of China in the name of M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China, has been submitted. **Metformin:** • Copy of GMP Certificate issued on August 28, 2018 by Food and Drug Administration, M.S. Bandra (E), Mumbai, Maharashtra State, India is submitted.
5.	Mechanism for Vendor pre-qualification	Firm has submitted SOP "Procedure for induction of new vendor"

<table>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Sitagliptin
Photocopy of COA of Batch No. M-20170112-D02-M06-01 issued from Beijing Huikang Boyuan Chemical Tech Co, Ltd – China
• Metformin hydrochloride
Photocopy of COA of Batch No. 17127ML2ARM issued from M/s Ipca Laboratories Limited – India is submitted.
• Reference standards:
The firm has submitted the copy of COA’s of USP reference standard for Sitagliptin phosphate and Metformin HCl.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted documents for procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted list of 10 qualified persons</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted copy of SOP with the title ‘Product Development Protocol of Sitagen-M XR 50/500 mg Tablets (Sitagliptin + Metformin HCl)’.
Effective date 15-05-2018.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>• Firm has provided complete batch manufacturing record of all the three batches
<table>
<tr><th colspan="4">SITAGEN-M XR Tablets 50mg/500mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>SMXR-007</td><td>2500 Tabs</td><td>28-08-2018</td><td>05-09-2018</td></tr>
<tr><td>SMXR-008</td><td>2500 Tabs</td><td>28-08-2018</td><td>06-09-2018</td></tr>
<tr><td>SMXR-009</td><td>2500 Tabs</td><td>28-08-2018</td><td>07-09-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sitagen-M XR Tablet 50mg/500mg ; Stability Pack Size:2x5’s)
• SMXR-007: Batch Size : 2500 Tablets
Yield 2140 Tablets (214 Packs),
29 packs (Stability samples) For Accelerated (12 Packs) For Long Term (17 Packs)
185 packs (PD reference samples)
• SMXR-008: Batch Size : 2500 Tablets
Yield 2130 Tablets (213 Packs),
29 packs (Stability samples) For Accelerated (12 Packs) For Long Term (17 Packs)
184 packs (PD reference samples)
• SMXR-009: Batch Size : 2500 Tablets
Yield 2100 Tablets (210 Packs),
29 packs (Stability samples) For Accelerated (12 Packs) For Long Term (17 Packs)
181 packs (PD reference samples)</td></tr>
<tr><td colspan="3">QA/QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period from
27-08-2018 to 28-03-2019.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API</td><td>Firm has provided the method used for analysis of APIs along with</td></tr>
</table>

<table>
<tr><td></td><td>along with COA.</td><td>their certificate of analysis.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>• Firm has provided method used for analysis of FPP and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months stability data (Accelerated & Real Time).</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) , long term, 24 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Sitagliptin phosphate monohydrate from M/s Beijing Huikang Boyuan Chemical Tech Co, Ltd – China
And
Accelerated, 06 Months (40°C ± 2°C & 75±5%RH) , long term, 60 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of Metformin HCl from M/s Ipca Laboratories Limited – India</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of Manufacturer’s COAs and Firm analysis reports for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has not submitted Drug-excipients compatibility studies and has referred to the Innovator Product (Janumet XR Tablets).</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Janumet XR Tablets manufactured by MSD International GmbH.
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of Ferozsons Laboratories Ltd</th></tr>
<tr><td>Brand name</td><td>Janumet XR Tablets 50mg/ 500mg</td><td>Sitagen-M XR Tablets 50mg/500mg</td></tr>
<tr><td>Batch No.</td><td>N007489</td><td>SMXR-007</td></tr>
<tr><td>Mfg. date</td><td>01-2017</td><td>08-2018</td></tr>
</table></td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports</td></tr>
<tr><td colspan="3">Registration Board decided to approve registration of “Sitagen-M 50/500 Tablets by M/s Ferozsons Labs, Amangarh, Nowshera. Manufacturer will place first three production batches of product on long term stability studies throughout proposed shelf life and on accelerated studies for six months</td></tr>
</table>

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
173.	M/s Neutro Pharma (Pvt.) Ltd. Lahore, Pakistan.	Dacla 60mg tablets Each film coated tablet contains:- Daclatasvir dihydrochloride eq. to Daclatasvir …… 60mg (NS5A Inhibitor)	Form 5 Dy.# 35251 dated 23-10-2018 Rs. 20,000/- 23-10-2018 28's, As per SRO	Approved by USFDA Last GMP inspection report dated 18-07-2017 concluding that firm has maintained a fair level of GMP compliance.
	Evaluation by PEC: Firm has submitted 6 months accelerated and Long term stability studies detailed as under:			

STABILITY STUDY DATA			
Drug	Dacla 60mg tablets		
Name of Manufacturer	M/s Neutro Pharma (Pvt.) Ltd. Lahore, Pakistan.		
Manufacturer of APIs	M/s Ruyuan HEC Pharm, Guangdong, China.		
API Lot No.	DSV-RD20106101		
Description of Pack (Container closure system)	Unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,1,2,3,4 & 6 month Real Time: 0,3,6 month		
Batch No.	HTB 003	HTB 004	HTB 005
Batch Size	2222 tablets	2222 tablets	2222 tablets
Manufacturing Date	01-2018	01-2018	01-2018
Date of Initiation	02-2018	02-2018	02-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT	
Documents To Be Provided	**Status**
COA of API	Yes
Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Shaoguan Food and Drug Administration valid upto 17-06-2018.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory	Yes

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

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

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

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

<table>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COA of Daclatasivr dihydrochloride with Batch No. DSV-RD201706101 by M/s Ruyuan HEC Pharm Co., Ltd. China is submitted.
Reference standards: Qualification report of reference standard of Batch No. PRS-17023 R/RD/60121118 by M/s
Ruyuan HEC Pharm Co., Ltd. China is submitted.
No document for impurity standard has been submitted.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development.</td><td>Submitted</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development comprising of 5 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>• The firm has submitted photocopy of SOP for Real time & Accelerated Stability along with manufacturing protocol for all three trial batches of Dacla 60mg tablet.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record of three stability batches of Dacla 60mg tablet, such as.
<table>
<tr><th colspan="3">Dacla 60mg tablet</th></tr>
<tr><th>Batch No.</th><th>Date of Mfg.</th><th>Batch Size</th></tr>
<tr><td>HTB-003</td><td>01-2018</td><td>2222 Tablets</td></tr>
<tr><td>HTB-004</td><td>01-2018</td><td>2222 Tablets</td></tr>
<tr><td>HTB-005</td><td>01-2018</td><td>2222 Tablets</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th colspan="2">Dacla 60mg tablet</th></tr>
<tr><th>Batch No.</th><th>Remaining Quantity</th></tr>
<tr><td>HTB-003</td><td>280</td></tr>
<tr><td>HTB-004</td><td>252</td></tr>
<tr><td>HTB-005</td><td>308</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts for Accelerated Long term conditions for complete stability studies of applied formulations.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of COA & testing procedures for Daclatasvir dihydrochloride from M/s Ruyuan HEC Pharm, China, along with relevant FTIR spectrums and chromatograms for the API analysis.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure Dacla 60mg Tablet along with Stability Study Report of stability batches, chromatograms, lab reports, raw data sheets etc.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted stability studies reports for both Accelerated (40˚C ± 2˚C / 75% ± 5%RH) for 6 months & Long term (30˚C ± 2˚C / 65% ± 5%RH) conditions for 24 months from manufacturer.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients</td><td>The firm has submitted photocopies of its own Analytical reports</td></tr>
</table>

<table>
<tr><td></td><td>used.</td><td>for all excipients used in product development of Dacla tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has submitted analytical record for drug excipient compatibility studies.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative Dissolution reports. The details of reference product & Sample product are as follows:
<table>
<tr><th>Feature</th><th>Reference product</th><th>Product of M/s Neutro</th></tr>
<tr><td>Brand name</td><td>Mydacla 60mg of m/s Mylan India</td><td>Dacla 60mg tablet</td></tr>
</table>
• Comparative dissolution studies have been performed in 0.1M HCl buffer.
• Firm has submitted relevant UV spectrums and results for the CDP study.
• Firm has performed CDP in one buffer medium only for 6 tablets only, whereas as per guidelines CDP shall be performed in three dissolution mediums using 12 units each of reference and sample product.</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:

Observation	Response
Submitted digital data logging record of accelerated stability chamber shows fall in humidity measurement from 70% for the time period dated 06-03-2018 to 23-3-2018 as well as in the month of April, 2018 7 August, 2018. Clarification shall be submitted in this regard	Firm has replied as under: **"**It is clarified that the product was placed for accelerated stability studies at 40°C ± 2°C / 75% ± 5%RH. During the said period of time when humidity ranges were out of limit, the climate chamber of accelerated stability studies was out of order and the product was shifted to a parallel accelerated stability chamber which was being operated at the same conditions of temperature and humidity (40°C ± 2°C / 75% ± 5% RH) to avoid any effect on the study. So, it is assured that throughout the accelerated stability period, the product was exposed to optimum conditions of temperature and humidity for accelerated stability studies."
Relevant chromatograms, FTIR spectrum, lab reports, raw data sheets & COAs of API analysis by M/s Neutro Pharma (Pvt.) Ltd. Lahore shall be submitted.	As per submitted analytical record for API analysis, firm has not applied supplier's method of analysis for Assay analysis since the elution program mentioned in supplier's method of analysis is gradient with run time of 35 minutes, whereas submitted chromatograms show run time of only 10 minutes.
Relevant analytical record i.e., chromatograms, raw data sheets for dissolution analysis for the complete stability studies have not been submitted.	Firm has submitted UV spectrums and raw data sheets for the dissolution analysis for the complete stability studies.
Finished product testing method mentions HPLC method for dissolution analysis whereas CDP samples have been analysed by UV spectrophotometric method.	Firm has stated that "Practically we used UV method for dissolution test, but mistakenly not written in SOP while HPLC method was lodged. We have rectified and providing you UV method for dissolution test in SOP for Declatasvir 60mg tablet. Next time we shall try to avoid such mistakes.
Firm has performed CDP in one buffer medium only for 6 tablets only, whereas as per guidelines CDP shall be performed in three dissolution mediums using 12 units each of reference and sample product.	Firm has submitted new data for CDP in one buffer of 0.1N HCl, using 12 tablets each of both reference product (Mydacla) and the trial product. F2 factor = 78.42 has been calculated by firm for the said CDP study.

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

Decision of 289th meeting: Registration Board deferred the case for following reasons:

- Documeneted evidence for the activity of shifting the samples of applied product to a parallel accelerated stability chamber, during the period when humidity ranges were out of limit for the parent Accelerated stability studies chamber.
- Performance of dissolution test on the next time point of long term stability studies as per USFDA recommended method for all three stability batches.

Firm's reply: Firm has submitted a "Maintenance Work Order" dated 06-03-2018 for the "Stability chamber set at Accelerated Condition" with following conditions:

- Job description: Temperature & Humidity of stability chamber (memmert) is disturbed, kindly check it urgently.
- Action taken: All stability product of the chamber are shifted to parallel stability chamber till problems resolved.

Moreover, firm has submitted UV data for the performance of dissolution test for all three batches, along with raw data and test method as per USFDA.

Registration Board decided to approve registration of "Dacla 60mg tablets by M/s Neutro Pharma (Pvt.) Ltd. Lahore, Pakistan. **Manufacturer will place first three production batches of product on long term stability studies throughout proposed shelf life and on accelerated studies for six months**

b. Verification of stability study data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
174.	M/s Scilife Pharma (Pvt.) Ltd., Karachi.	B-Form Rotacaps 400mcg+12mcg Each capsule contains:- Budesonide…400mcg Formoterol fumarate dihydrate……. 12 mcg (Glucocorticosteroid/Selective β2 adrenoceptor agonist)	Form 5 dated 07-04-2017 Rs. 20,000/- 30's, As per Drug pricing policy	Symbicort Turbuhaler approved by Health Canada Venticort Rotacaps by M/s Macter Pharma, Karachi
	Evaluation by PEC: • Evidence of approval of applied formulation in similar dosage form as applied, by reference regulatory authorities/agencies, which were adopted by the Registration Board in its 275th meeting. • Budesonide is a glucocorticoid. Details of submitted data are as under: (Dy.# 34006 dated 12-10-2018)			

STABILITY STUDY DATA			
Drug	B-Form Rotacaps 400mcg+12mcg		
Name of Manufacturer	M/s Scilife Pharma (Pvt.) Ltd., Karachi.		
Manufacturer of APIs	M/s Vamsi labs Ltd., Maharashtra, India		
API Lot No.	Formoterol fumarate dihydrate: FF-0030317 Budesonide: BDS-0100517		
Description of Pack (Container closure system)	Alu –Alu blister with unit carton		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0,3,6 month Real Time: 0,3,6 month		
Batch No.	210B17	211B17	212B17
Batch Size	26000 rotacaps	26000 rotacaps	26000 rotacaps
Manufacturing Date	28-12-2017	28-12-2017	28-12-2017
Date of Initiation	19-01-2018	19-01-2018	19-01-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COAS of API	Yes.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate# NEW-WHO-GMP/CERT/PD/75003/2018/1/25587) issued by Food and Drug Administration Maharashtra to M/s Vamsi labs Ltd.,

		Maharashtra, India valid till 02-11-2021
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of Form 6 & commercial invoice has been submitted attested by ADC DRAP, Karachi
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Sr.#	Observation	Firm's Response
i.	Evidence of approval of applied formulation in similar dosage form as applied, by reference regulatory authorities/agencies, which were adopted by the Registration Board in its 275th meeting.	Firm has referred to product "Venticort" with similar composition of Macter International Karachi, approved by Registration Board in its 275th meeting. Moreover firm has referred that applied dosage form is a cost effective approach as compared to reference product.
ii.	Label claim for delivered dose shall be submitted, based upon the performance tests identified by USP in its general chapter <601>.	Firm has submitted results for "Uniformity of delivered dose" by Dose Uniformity Sampling Apparatus at 9th month long term stability time point. On the basis of above performance test firm has submitted following label claim: **"Each delivered dose (the dose that leaves the mouthpiece) contains: "Budesonide ……. 320mcg Formoterol fumarate dehydrate….. 9mcg"**
iii.	Following performance quality & specific tests as identified by USP in its general chapter <5> & <601> have not been performed during stability studies: • Aerodynamic size distribution. • Microbial Enumeration test • Test for specified microorganisms • Foreign particulate matter. • Uniformity of delivered dose	Firm has submitted results for following tests at 9th month long term stability time point: • Aerodynamic size distribution. • Microbial Enumeration test • Test for specified microorganisms • Foreign particulate matter. • Uniformity of delivered dose

Decision of 287th meeting: Deferred for further deliberation upon required manufacturing facility for applied formulation.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of B-Form Rotacaps 400mcg + 12mcg (Budesonide + Formoterol fumarate dehydate) by M/s. Scilife Pharma (Pvt). Ltd., Karachi.

Reference No: F.3-11/2017-PEC (Pt) dated 30th July, 2019.
Investigation Date and Time: 31st July, 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 B-Form Rotacaps 400mcg + 12mcg (Budesonide + Formoterol fumarate dehydrate) and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

1. Director, Drug Testing Laboratory, Government of Sindh, Karachi.
2. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
3. Mr. Asfandyar Ajab Khan, 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:

B-FORM ROTACAPS 400MCG + 12MCG

Sr.#	Question	Observation by panel
1.	Do you have documents confirming the import of API?	The firm has imported: 50g Budesonide API (Batch no: BSD-0100517) and 10g Formoterol Fumarate dihydrate API (Batch No. FF no: 0030317) from Vamsi Labs Ltd. India. Proper approval taken from DRAP dated 30.11.2017, and respectively
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 imported Budesonide + Formeterol Fumerate dihydrate working standard from the API manufacturer Vamsi Labs Ltd., India). Moreover the firm has imported reference standards and impurity standards from Eur. Ph. for both APIs.
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.
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 Budesonide API and Formoterol Fumarate dihydrate API issued by regulatory authority of their respective country of origin from Joint Commissioner (HQ) & controlling Authority, FDA administration, M.S. Bandra (E), Mumbai, Maharashtra state, India.
6.	Do you use API manufacturer method of testing?	The Firm used Eur. Ph compendial method for API which is the same as that of manufacturer`s
7.	Do you have stability studies reports on API?	The firm has stability studies report on APIs (Budesonide + formeterol fumerate dihydrate) conducted by API manufacturers.
8.	If whether the stability testing has been	The manufacturer of both APIs has performed the stability

	performed as per SIM method and degradation products have been quantified?	studies on APIs as per SIM method and the degradation products have been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying the impurities by Eur. Ph in the APIs
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of APIs, reference standards and impurities standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipient Lactose monohydrate (respitose).
12.	Do you have documents confirming the import of the used excipients?	The firm has relevant documents confirming the import of the used excipient. Proper approval taken from DRAP on invoice 9003327957 dated 07.11.2017
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 (Budesonide + formeterol fumerate dihydrate) 400+12 rotacaps.
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.
16.	Have you performed comparative studies?	The firm has conducted comparative studies with leading generic product of M/S. Incepta Pharma, Bangladesh (Budimat inhaler). Both the products have comparative profiles. The firm will also conduct studies with innovator product before commercial manufacturing.
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 available in product development section for development of the product?	The firm has necessary equipment's for production of (Budesonide + formeterol fumerate dihydrate) 400+12 rotacaps in product development section.
19.	Are the equipments in product development section qualified?	The equipment in product development section are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration / re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm 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 as follows; 1) 210B17, 2) 211B17 and 212B17
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 capsules per testing frequency and number of testing frequencies / intervals) and minimum working Capacity of the equipment.
24.	Do you have complete record of	firm has complete record of production of stability batches.

	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 developed and validated method for testing of stability batches of finish product i.e. B Form DS (Budesonide + formeterol fumerate dihydrate) 400/12 rotacaps. The method is stability indicating.
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?	Transfer studies 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?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of APIs and the finished product.
29.	Do your method of analysis stability indicating?	Firm's method of analysis was stability indicating and the record of testing of stability batches available.
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 and stability batches?	The firm has only remaining quantities of stability batches kept on real-time stability testing.
33.	Do you have stability batches kept on stability testing?	The firm has 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. First three validation batches to 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.

Sr.#	**Question**	**Observation by panel**
36.	**Observations of PEC?**	

a)	Precautionary measures adopted to control of cross contamination of the steroidal preparation with the general products during the manufacturing of applied formulations	The firm has taken several steps to control the cross-contamination for steroidal preparation as below, i) Installed, Qualified and Maintained dedicated Sampling / Dispensing booth in the separate area for the handling of steroidal raw materials to avoid the cross contamination as Starting point of manufacturing. ii) Dedicated multi-directional mixer for the mixing of steroidal formulations available iii) Dedicated change parts available for the encapsulation of (Budesonide + Formoterol fumarate dihydrate) 400/12mcg that will ensure and minimize the risk cross contamination during filling process iv) Dedicated change parts along with auto feeder is installed and available for the blistering of (Budesonide + Formoterol fumarate dihydrate) 400/12mcg that will further ensure the control of cross contamination during blistering and primary packaging process. v) In addition to that, firm executed the PRE/POST cleaning validation studies on approved protocol for steroidal formulations based on worst-case scenario to make sure the prevention of cross contamination. vi) Isolation gowning has been provided for this product.
b)	Availability of specialized mixing facility to ensure the required particle size of formulation blend	The firm has executed and maintained the following steps for the obtaining required particle size of formulation blend as given below, i) The firm used both the APIs Budesonide and Formoterol fumarate dihydrate having controlled and special particle size required for inhaler preparation as less than 5µm. ii) The firm has also used inhaler grade excipients Lactose i.e. Respitose having required particle size. iii) Design and developed the Two stage mixing mechanism on multi-directional-mixer having 3D mixing capability to ensure the homogeneous mixing of APIs in blended formations having desired particle size. The same has been qualified through approved qualification protocol. iv) In addition to that the final blend of each batch will be tested on 10 point sampling method and checked on HPLC to make sure the equal and homogeneous distribution of both the APIs in formulation blend before start next step.
c)	Availability of necessary apparatus for the performance of uniformity of deliver dose and aerodynamic particle size	The firm has necessary apparatus for the performance of uniformity of deliver dose which is Dose Uniformity sampling apparatus and aerodynamic particle size distribution which is MSLI(Multistage Liquid Impinger) available and qualified to test the product.
d)	Detailed of the drug delivery device (Inhaler) intended to be marketed along with the applied formulation.	i) We are importing the DPI Device (SciAir) from TAIAN DALU MEDICAL INSTRUMENT CO., LTD. CHINA under import license **ELI-00187** for importing the inhaler device issue by Secretary Medical device board dated 19-10-2018 having 5 years expiry. ii) The device (DL-D02) bear the CE mark, showing Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the

		Notified Body **TÜV Rheinland LGA Products GmbH** following the procedure relating to the EC Declaration of Conformity set out in Annex V of Directive 93/42/EEC. iii) The SciAir device main structure and performance are as following: a. **Protection cap**: Contain and protect the inner parts and avoid pollution. b. **Mouthpiece:** For helping users to inhale the powder medication effectively. c. **Capsule cavity:** Contain capsule. d. **Push button:** For users to puncture the capsule to inhale the powder. e. **Back piece:** For seal the device bottom and supporting function. iv) SciAir DPI device enlistment with MD board having enlistment no. MDIE-0000028, dated v) 12/07/2019 vi) How to use: patient information leaflet attached for review.
e)	Results for uniformity of delivered dose by dose uniformity sampling apparatus performed at 9th month of long term stability time point	Results for uniformity of delivered dose by dose uniformity sampling apparatus performed at 9th month of long term stability time point has been checked and verified. Results are satisfactory.
f)	Results for the following tests performed at the 9th month of long term stability time point i) Aerodynamic size distribution ii) Micro enumeration test iii) Test for specified microorganisms iv) Foreign particulate matter	Results for the following tests performed at the 9th month of long term stability time point has been checked and verified. i) Aerodynamic size distribution ii) Micro enumeration test iii) Test for specified microorganism iv) Foreign particulate matter Results are satisfactory.

Conclusion and Recommendations:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of B-Form Rotacaps 400mcg + 12mcg (Budesonide/Formoterol Fumarate dehydrate) is verifiable to satisfactory level.
2. The firm has provided a number of measures and arrangements to minimize the risk of cross-contamination including specialized dedicated dispensing booth, 3D mixer, dedicated change parts on capsules filling machine, pre and post operation cleaning validation, work station exposure studies and special gowning in addition to effective HVAC system. **All the above mentioned measures / arrangements technically reduce the chances of cross-contamination to satisfactory level. The arrangements, controls and studies being made by the firm for manufacturing B-Form Rotacaps 400mcg / 12mcg of desired quality can be rated satisfactory. Any special arrangement or decision related to manufacturing of DPIs may kindly be rechecked by the board for uniform and effective compliance.**
3. Registration of the product (B-Form Rotacaps 400mcg / 12mcg) is recommended in the name of the manufacturer.

Decision: Registration Board deferred the case for the requirement of separate section of "Dry powder Inhaler Capsules" as decided by Board in its 290th meeting.

Sr.#	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	REMARKS (IF ANY)
175.	"M/s Martin Dow Ltd., Karachi"	Empator 10mg Tablets "Each film coated tablet contains: Empagliflozin …… 10mg (Antidiabetic)	Form-5D Dy.No 17716 dated 14-05-2018 Rs.50,000/- Dated 14-05-2018	Approved by USFDA Last GMP inspection conducted on 29-01-2018 concluding Good level of cGMP compliance..	

STABILITY STUDY DATA SUBMITTED INITIALLY

Drug	Empator 10mg Tablets		
Name of Manufacturer	M/s Martin Dow Ltd., Karachi		
Manufacturer of API	Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China		
API Lot No.	Empagliflozin: EGLZ-RD201801208		
Description of Pack (Container closure system)	Alu-Alu blister foil		
Stability Storage Condition	Accelerated: 40°C ± 2°C / 75% ± 5%RH Real Time: 30°C ± 2°C / 65% ± 5%RH		
Time Period	Accelerated: 6 Months Real Time: 6 Months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	NPD-T-307-L	NPD-T-314-P	NPD-T-313-P
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	08-09-2018	17-09-2018	14-09-2018
Date of Initiation	28-09-2018	28-09-2018	28-09-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Sr.#	Documents To Be Provided	Status
i.	COA of API	Yes
ii.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate (2018024) issued by M/s Shaoguan Food & Drug Administration, valid upto 18-12-2019 for M/s Ruyuan HEC Pharm Co., Ltd.
iii.	Protocols followed for conduction of stability study and details of tests.	Yes
iv.	Data of 03 batches will be supported by	Yes

	attested respective documents like chromatograms, laboratory reports, data sheets etc.	
v.	Documents confirming import of API etc.	**Empagliflozin:** Form 6 issued by DRAP has been submitted for quantity of 0.55Kg
vi.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
vii.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
viii.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[2]

- The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

Sr.#	**Name & Address of Manufacturer / Applicant**	**Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification**	**Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size**	**International Availability / Local Availability GMP Inspection Report Date & Remarks**	**REMARKS (IF ANY)**
176.	"M/s Martin Dow Ltd., Karachi"	Empator 25mg Tablets "Each film coated tablet contains: Empagliflozin …… 25mg (Antidiabetic)	Form-5D Dy.No 17717 dated 14-05-2018 Rs.50,000/- Dated 14-05-2018	Approved by USFDA Last GMP inspection conducted on 29-01-2018 concluding Good level of cGMP compliance..	

STABILITY STUDY DATA SUBMITTED INITIALLY

Drug	Empator 25mg Tablets
Name of Manufacturer	M/s Martin Dow Ltd., Karachi
Manufacturer of API	Empagliflozin: M/s Ruyuan HEC Pharm Co., Ltd. China
API Lot No.	Empagliflozin: EGLZ-RD201801208
Description of Pack (Container closure system)	Alu-Alu blister foil
Stability Storage Condition	Accelerated: 40˚C ± 2˚C / 75% ± 5%RH Real Time: 30˚C ± 2˚C / 65% ± 5%RH
Time Period	Accelerated: 6 Months Real Time: 6 Months

Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0,1,2,3,4 & 6 (months)		
Batch No.	NPD-T-316-P	NPD-T-315-P	NPD-T-303-L
Batch Size	2500 Tablets	2500 Tablets	2500 Tablets
Manufacturing Date	12-09-2018	12-09-2018	06-09-2018
Date of Initiation	28-09-2018	28-09-2018	28-09-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT INITIALLY

Sr.#	Documents To Be Provided	Status
i.	COA of API	Yes
ii.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Empagliflozin:** Copy of GMP certificate (2018024) issued by M/s Shaoguan Food & Drug Administration, valid upto 18-12-2019 for M/s Ruyuan HEC Pharm Co., Ltd.
iii.	Protocols followed for conduction of stability study and details of tests.	Yes
iv.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
v.	Documents confirming import of API etc.	**Empagliflozin:** Form 6 issued by DRAP has been submitted for quantity of 0.55Kg
vi.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
vii.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
viii.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR[2]

- The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Lab Scale Batches.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Empator 10mg and 25mg (Empagliflozin) by M/s. Martin Dow Ltd., Plot No. 37, Sector-19, Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 27th June, 2019.
Investigation Date and Time: 06th August, 2019 (Morning).
Investigation Site: Factory premises of M/s. Martin Dow Ltd., Plot No. 37, Sector-19, Korangi Industrial Area, Karachi.

Background:

Chairman Registration Board considered the applications of M/s. Martin Dow Ltd., Plot No. 37, Sector-19, Korangi Industrial Area, Karachi for registration of Empator 10mg and 25mg (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:

4. Dr. Saif ur Rehman Khattak, Director, CDL, DRAP, Karachi.
5. Dr. Rafeeq Alam Khan, Meritorious Professor, Department of Pharmacology, University of Karachi, Karachi, Member Registration Board, Islamabad.
6. Ms. Sanam Kausar, Assistant Director, CDL, DRAP, Karachi.

Sr. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API ?	The firm has imported 0.55kg API of Empagliflozin from M/s Ruyuan HEC Pharm. Co. Ltd., China Batch No. EGLZ-RD-201801202B and has taken approval from DRAP-Karachi for import.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor qualification being implemented by the firm which include a desktop audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF, reference standard, impurity standards etc. The firm was evaluated on above mentioned criteria and selected
3.	Do you have documents confirming the import of API reference standard and impurity standards?	The firm has documents confirming the import of API of said batches, working standards and their impurities standards.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, working standard and their impurities.
5.	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of Empagliflozin manufacturer issued by Shaoguan Food and Drug Administration, China.
6.	Do you use API manufacturer method of testing?	The firm has used API manufacturer method of testing for API.
7.	Do you have stability studies reports on API?	The firm has accelerated stability studies reports of six months and two years on real time on API stability studies reports on the Empagliflozin.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm has method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of API, reference standard & 02 impurities of Empagliflozin.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients.
12.	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the import of all excipients used.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.

14.	Do you have written and authorized protocols for the development of API tablets?	The firm has written and authorized protocols for the development of Empator (Empagliflozin 10mg and 25mg) tablets.
15.	Have you performed Drug-excipient compatibility studies?	Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies on both strengths of their products against innovator products (Jardiance 10mg & 25mg Tablets manufactured by M/s. Boehringer Pharma – Germany) and their products have shown comparable dissolution profiles.
17.	Do you have product development (R&D) section	The firm has product development (R&D) section with equipment for manufacturing of tablet dosage form. The analytical part is performed on equipment dedicated for R&D activities.
18.	Do you have necessary equipment available in product development section for development of API tablets?	The firm has necessary equipment for product development of API tablets. The product in question has been packed using packing machine of commercial packaging also. Furthermore, the analytical part has been performed via the dedicated quality control equipment & lab.
19.	Are the equipment in product development section qualified?	The available equipment in product development section are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has SOP for the maintenance / calibration / requalification of equipment used on PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has qualified staff which include One PhD Chemistry and six Pharmacists in product development section with relevant work experience.
22.	Have you manufactured three stability batches for the stability studies of API tablets as required?	The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Empator 10mg (NPD-T-307-L, NPD-T-314-P & NPD-T-313-P) and 25mg (NPD-T-316-P, NPD-T-315-P & NPD-T-303-L) tablet that are packed in Alu-Alu blisters of pack size 2 x 7's.
23.	What was the criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the number of tablets per testing and the number of tablets required for whole stability testing.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. Necessary log books of equipment used has been available with the firm.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocol for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated their own method for testing of stability batches based upon the API testing method. The method is supported by impurities standards spiking studies, hence capable of quantifying the degradation products in their tablets kept on stability testing.

27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters.
30.	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit Trail reports on API testing?	The firm showed the audit trail reports on API testing.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm does not have remaining quantities of stability batches for accelerated studies but has remaining quantities for real time stability studies.
33.	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 06 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the equipment used in API tablets production in analysis?	The firm has valid calibration status for the equipment used in Empator 10mg and 25mg tablet production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Continuous power supply and monitoring are available for stability chambers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Empator 10mg and 25mg (Empagliflozin) Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Empator 10mg and 25mg Tablets.

Recommendations:

1. The firm may kindly be granted necessary registration of Empator 10mg and 25mg tablets.

Decision: Registration Board decided to approve registration of "Empator 10mg Tablets (Empagliflozin) and Empator 25mg Tablets (Empagliflozin) by M/s Martin Dow Ltd., Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

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
177.	M/s Merck (Private) Limited 7, Jail, Road Quetta, Pakistan.	Glucovance Tablets 1000mg/5mg Tablet Each film coated tablet Contains: Metformin hydrochloride, ….1000mg Glibenclamide, ….5.00mg (Oral antidiabetic)	Form 5D Rs.8,000/- 20-01-2008 Dy. No. not mentioned Rs.52,000/- 31-01-2013 Dy. No. Not mentioned Rs. 90,000/- 21-02-2014 Dy. No. Not mentioned Rs.170/-30's	Approved by ANSM of France
	Previous DRB Decision / Remarks **Decision: Registration Board in its 263rd meeting deferred the case for submission of following documents:** **a. Confirmation of application diary numbers from record.** **b. Confirmation of approval status by reference regulatory authorities.** **c. Clarification for not conducting dissolution test in stability testing.** d. **Provision of complete data for stability including chromatograms/spectrums, lab reports, raw data sheets etc.**			
	Evaluation by PEC: Firm has submitted stability studies data, detail of which is as under:			

STABILITY STUDY DATA			
Drug	Glucovance Tablets 1000mg/5mg		
Name of Manufacturer	M/s Merck (Private) Limited, Pakistan		
Manufacturer of API	Metformin: M/s Merck Sante, France		
	Glibenclamide:		
API Lot No.	Metformin HCl: 118030174 Glibenclamide: 11711038		
Description of Pack (Container closure system)	PVC/PVDC-Alu foil in a 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.	T03	T04	T05
Batch Size	15000 tablets	15000 tablets	4152 tablets

Manufacturing Date	06-2018	06-2018	10-2018
Date of Initiation	06-2018	06-2018	10-2018
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	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 invoices have been attested by ADC, 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

- Firm has applied following limits for the dissolution test:
  Glibenclamide: NLT 63% in 45 minutes
  Metformin HCl: NLT 70% in 45 minutes

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Glucovance Tablets 1000mg/5mg by M/s. Martin Dow Ltd., Plot No. 37, Sector-19, Korangi Industrial Area, Karachi

The inspection was carried out as per DRAP letter No.F.13-11/2017-PEC (Pt) dated 01st August 2019 for on-site verification for authenticity/genuineness of the stability data of product Glucovance Tablets 1000mg/5mg manufactured by M/s Martin Dow Marker Limited Quetta. The panel was comprised of Dr. Aman Ullah Khan, Director Drug Testing Laboratory Quetta and Mr. Sajjad Ahmed Abbasi, Federal Inspector of Drugs Quetta stationed at Karachi.
Date of Inspection: 28th August 2019.

Sr.#	QUESTION	OBSERVATION BY PANEL
1.	Do you have documents confirming the import of API including approval from DRAP?	The firm has used Glibenclamide and imported from M/s Prudence Pharma Chem India and Metformin Hydrochloride imported from M/s Merck Sante S.A.S. France for the manufacturing of Trial batches of Glucovance Tablets 1000mg/5mg. 62.25gm of Glibenclamide and 12.45Kg of Metformin Hydrochloride have been used in the manufacturing of three trial batches of Glucovance Tablets 1000mg/5mg. The firm has proper approval for the import of the APIs from DRAP. Invoice No.

		PPC/041/18-19 dated 26th June 2018 approved by ADC Quetta for Gllibenclamide and Invoice No. 9515830181 dated 01/06/2018 approved by ADC Quetta for Metformin HCl.
2.	Do you have any rationale behind selecting the particular manufacturer	The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Supplier Qualification procedure which include the valid GMP status of the firm, Stability Data of APIs from source and capability to provide API reference standard and impurity standard.
3.	Do you have documents confirming the Import of Reference standard and Impurities standards?	Firm has documents confirming the import of API reference standards and impurities standard imported from Merck Vendor Lab Sciences dated 09 Nov. 2017.
4.	Do you have certificate of analysis of the API reference standard and impurities standards?	The firm has certificates of analysis of APIs, Reference standards and impurities standards.
5.	Do you have any approval of API or GMP certificate of manufacturer issued by regulatory authority of country of origin?	Firm has valid GMP certificates of APIs issued by the country of origin of manufacturer for Glibenclamide from Prudance India and Metformin HCl from Merck Sante France.
6.	Do you use API manufacturer method of Testing for testing of API?	The APIs manufacturer has used European Pharmacopeia (EP) method for testing the APIs. (Glibenclamide and Metformin HCl)
7.	Do you have stability Studies Report on API?	The firm has stability studies reports on both APIs (Glibenclamide and Metformin HCl). According to Zone IVA.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes, it is performed as per SIM method. The manufacturer of the API has performed testing as per SIM method.
9.	Do you have method for quantifying the impurities in the API?	The firm has used EP method for testing and has quantified the impurities in the APIs. 1) Metformin HCl Impurity only one impurity (1-Cyanoguanidine) has been identified by the API manufacturer as well as product manufactuer (Martin Dow Marker). 2) Glibenclamide impurity/Related Substances (Impurity A, Impurity B, Unknown Impurity-1, Unknown-2). Total impurities not more than 0.5% according to EP.
10.	Do you have some remaining quantities of the API, Its reference standard and impurities standard?	Firm has some quantities of the API, reference standard of the API and Impurities standards.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients which are imported from the following qualified excipients manufacturers: Croscarmellose Sodium (Mingtai Chemical Taiwan) Povidone 30 (BASF Germany) Cellulose Microcrystalline (Avicel PH-102) (Mingtai Chemical Taiwan) Magnesium Stearate (Dr. Paul Germany) All the consignments of excipients are approved by the ADC Quetta.

<table>
<tr><td>12.</td><td>Do you have documents confirming the import of the used excipients?</td><td>The firm has necessary documents confirming the import of the used excipients refer to Question No.11.</td></tr>
<tr><td>13.</td><td>Do you have test reports and other records on the excipients?</td><td>The firm has test reports and other records on the excipients used.
Croscarmellose Sodium (USP method)
Povidone 30 (USP Method)
Cellulose Microcrystalline (USP Method)
Magnesium Stearate (USP Method)</td></tr>
<tr><td>14.</td><td>Do you have written and authorized protocols for the development drug product?</td><td>The firm has written and authorized protocols for the development of Glucovance Tablets 1000mg/5mg. Furthermore, the firm is already manufacturing 03 strengths of the same product such as Glucovance 250mg/1.25mg, Glucovance 500mg/2.5mg & Glucovance 500mg/5mg since Feb. 2003.</td></tr>
<tr><td>15.</td><td>Have you performed Drug-Excipient compatibility studies?</td><td>The firm has not performed Drug-excipient compatibility studies as the product(s) of various strengths are already manufactured by the firm. Refer to Question No.14.</td></tr>
<tr><td>16.</td><td>Have you performed comparative dissolution studies?</td><td>The firm has performed comparative dissolution studies using Merck’s Specs with other strength of the same product (i.e. Glucovance 500mg/5mg Tablets. As per Martin Dow Marker (Formerly Merck Pvt. Limited) the dissolution limits:
1) Glibenclamide: NLT 63% in 45 minutes. However, the dissolution performed of the trial batches record shows by an average 90% in 45 minutes.
2) Metformin HCl: NLT 70% in 45 minutes, However, the dissolution performed of the trial batches record shows by an average 99.9% in 45 minutes.</td></tr>
<tr><td>17.</td><td>Do you have Product Development / R&D Section?</td><td>The firm has semi-developed R&D section which needs the required equipments. The firm has used the production area and quality control equipments for the development of the product. The firm has also deputed one full-time pharmacist (Mr.Rashid Altaf) strengthening the R&D section.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment’s available in product development section for development drug product?</td><td>Refer to Question No.17.</td></tr>
<tr><td>19.</td><td>Are the equipment’s in product development qualified?</td><td>The equipments used from the production area and quality control are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD?</td><td>Refer to Question Nos.17, 18 & 19.</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>Refer to Question No.17</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of drug product?</td><td>The firm has manufactured three stability batches for the stability studies of:
<table>
<tr><td>B.No.</td><td>Date Mfg.</td><td>06 Months Stability</td><td>Batch Size (Tablet)</td></tr>
<tr><td>Trial#3</td><td>24/05/2018</td><td>12/2018</td><td>4150</td></tr>
<tr><td>Trial#4</td><td>24/05/2018</td><td>12/2018</td><td>4150</td></tr>
</table>
</td></tr>
</table>

		Trial#5 | 13/10/2018 | 04/2019 | 4150 The tablets packed in Alu / PVC blisters with pack size of 3 x10's. The manufacturing process is wet granulation. The shelf life of the product is 03 years. The Trial batches were kept in the Stability Chamber for real time. The present quality control stability data shows the product is stable and there is no any substantial variation noted. Only 2% variation was noted among the batch.
23.	Do you have any criteria for fixing the batch size of stability of batches?	The batch size was fixed as per requirements of the testing.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm is already manufacturing three strengths of the same product. They have well developed and validated the testing of stability batches for the same as well.
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?	Method transfer was not applicable.
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has documents confirming the qualification of the equipment / instruments being used in the test and analysis of API and the finished drug (Glucovance Tablets 1000mg/5mg)
29.	Do your method of analysis stability Indicating?	Yes, it is stability indicating, already the impurities are performed by the product manufacturer.
30.	Do your HPLC Software 21CFR compliant.	The HPLC software is 21CFR Compliant. Total 09 HPLC are available among which 05 are 21 CFR compliant.
31.	Can you show Audit Trail reports on Glucovance tablets testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	As the degradation of the product was not found however the stability batches were available.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time.
34.	Do you have valid calibration status for the equipment used in Glucovance tablets production and analysis?	The firm has valid calibration status for the equipment used in the manufacturer of Glucovance 1000mg/5mg tablets.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 07 stability chambers, 02 for accelerated and 05 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipments and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.

Conclusion:
1. On the basis of risk based approach the genuineness / authenticity of stability data submitted by the firm for registration of Glucovance Tablets 1000mg/5mg is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Glucovance Tablets 1000mg/5mg.

Recommendations:
Glucovance Tablets 1000mg/5mg is recommended for registration in favor of M/s Martin Dow Marker Limited Quetta.
Moreover firm has requested to consider the registration of Glucovance 100mg/5mg tablets with the new name of company i.e., M/s Martin Dow marker Limited.

Decision: Deferred for submission of registration application on relevant Form with new title of the firm i.e., M/s Martin Dow Marker Limited Quetta along with submission of full fee.

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
178.	M/s CCL Pharmaceuticals Pvt. Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore.	Jardy-Met 5/1000 Tablet "Each film coated tablet contains: Empagliflozin ..…5mg Metformin hydrochloride..1000mg (Anti-diabetic)	Form-5-D Dy. No 6517 dated 14-02-2019 Rs.50,000/- Dated 14-02-2018 Pack size 10s;14s;20's,28s,30's; As per brand leader	Approved by USFDA
	Now the firm has submitted stability data detailed as under:			

STABILITY STUDY DATA

Drug	Jardy-Met 5/1000 Tablet		
Name of Manufacturer	M/s CCL Pharmaceuticals Pvt. Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore.		
Manufacturer of API	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province. Metformin hydrochloride: M/s Wanbury Ltd., Andhra Pradesh, India		
API Lot No.	Empagliflozin: E-20180604-D01-E Metformin hydrochloride: MT08890818		
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.	JMA-T2-18	JMA-T3-18	JMA-T4-18
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	14-11-2018	14-11-2018	14-11-2018
No. of Batches	03		

Date of Submission	13-06-2019 (Dy. No. 8373-B)

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 Drug manufacturing license (License no. Liao 20150233) for M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province issued by Liaoning Food and Drug Administration of the People's Republic of China is submitted, valid upto 20-12-2022. • Copy of GMP Certificate for M/s Wanbury Ltd., Andhra Pradesh, India issued by Drug Control Administration, Government Andhra Pradesh, India has been submitted, valid upto 05-02-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	• Copy of invoice for Empagliflozin (20Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 26-09-2018 has been submitted. • Copy of invoice for Metformin hydrochloride, attested by Assistant Director (I & E) DRAP, Lahore dated 12-09-2018 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

- 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.
- You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905> and innovator's product literature. Justification shall be submitted in this regard.
- Justification for value of Q=70% for both Empagliflozin & Metformin hydrochloride in the dissolution test shall be submitted since USP chapter <1092> (The Dissolution Procedure; Development and Validation) recommends Q values in the range of 75% - 80% for immediate release dosage forms.

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
179.	M/s CCL Pharmaceuticals Pvt.	Jardy-Met 5/500 Tablet "Each film coated tablet	Form-5-D Dy. No 6516 dated 14-02-2019	Approved by USFDA

	Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore.	contains: Empagliflozin .....5mg Metformin hydrochloride.... 500mg (Anti-diabetic)	Rs.50,000/- Dated 14-02-2018 Pack size 10s;14s;20's,28s,30's; As per brand leader	
	Now the firm has submitted stability data detailed as under:			

STABILITY STUDY DATA			
Drug	Jardy-Met 5/500 Tablet		
Name of Manufacturer	M/s CCL Pharmaceuticals Pvt. Ltd, 62. Industrial Estate, Kot Lakhpat, Lahore.		
Manufacturer of API	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province. Metformin hydrochloride: M/s Wanbury Ltd., Andhra Pradesh, India		
API Lot No.	Empagliflozin: E-20180604-D01-E Metformin hydrochloride: MT08890818		
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.	JMB-T2-18	JMB-T3-18	JMB-T4-18
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	14-11-2018	14-11-2018	14-11-2018
No. of Batches	03		
Date of Submission	13-06-2019 (Dy. No. 8373-A)		

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 Drug manufacturing license (License no. Liao 20150233) for M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province issued by Liaoning Food and Drug Administration of the People's Republic of China is submitted, valid upto 20-12-2022. • Copy of GMP Certificate for M/s Wanbury Ltd., Andhra Pradesh, India issued by Drug Control Administration, Government Andhra Pradesh, India has been submitted, valid upto 05-02-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes

Documents confirming import of API etc.	• Copy of invoice for Empagliflozin (20Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 26-09-2018 has been submitted. • Copy of invoice for Metformin hydrochloride, attested by Assistant Director (I & E) DRAP, Lahore dated 12-09-2018 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

- 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.
- The batch number mentioned in Stability study protocol of JardyMet 5/500mg tablet are different from that mentioned in Stability Study Data Sheets.
- You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905> and innovator's product literature. Justification shall be submitted in this regard.
- Justification for value of Q=70% for both Empagliflozin & Metformin hydrochloride in the dissolution test shall be submitted since USP chapter <1092> (The Dissolution Procedure; Development and Validation) recommends Q values in the range of 75% - 80% for immediate release dosage forms.

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
180.	M/s CCL Pharmaceuticals Pvt. Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore.	Jardy-Met 12.5/1000 Tablet Each film coated tablet contains: Empagliflozin…12.5mg Metformin hydrochloride..1000mg (Anti-diabetic)	Form-5-D Dy.No 6519 dated 14-02-2019 Rs.50,000/- Dated 23-11-2018 Pack size 10s;14s;20's,28s,30's; As per brand leader	Approved by USFDA
	Now the firm has submitted stability data detailed as under:			

STABILITY STUDY DATA

Drug	Jardy-Met 12.5/1000 Tablet
Name of Manufacturer	M/s CCL Pharmaceuticals Pvt. Ltd, 62. Industrial Estate, Kot Lakhpat, Lahore.
Manufacturer of API	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province. Metformin hydrochloride: M/s Wanbury Ltd., Andhra Pradesh, India
API Lot No.	Empagliflozin: E-20180604-D01-E Metformin hydrochloride: MT08890818
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	Real Time: 0,3,6 months Accelerated: 0,3,6 months		
Batch No.	JMD-T1-18	JMD-T2-18	JMD-T3-18
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	01-11-2018	01-11-2018	01-11-2018
No. of Batches	03		
Date of Submission	13-06-2019 (Dy. No. 8372-A)		

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 Drug manufacturing license (License no. Liao 20150233) for M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province issued by Liaoning Food and Drug Administration of the People's Republic of China is submitted, valid upto 20-12-2022. • Copy of GMP Certificate for M/s Wanbury Ltd., Andhra Pradesh, India issued by Drug Control Administration, Government Andhra Pradesh, India has been submitted, valid upto 05-02-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	• Copy of invoice for Empagliflozin (20Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 26-09-2018 has been submitted. • Copy of invoice for Metformin hydrochloride, attested by Assistant Director (I & E) DRAP, Lahore dated 12-09-2018 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

- 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.
- You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905> and innovator's product literature. Justification shall be submitted in this regard.
- Justification for value of Q=70% for both Empagliflozin & Metformin hydrochloride in the dissolution

test shall be submitted since USP chapter <1092> (The Dissolution Procedure; Development and Validation) recommends Q values in the range of 75% - 80% for immediate release dosage forms.

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
181.	M/s CCL Pharmaceuticals Pvt. Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore.	Jardy-Met 12.5/500 Tablet Each film coated tablet contains: Empagliflozin…12.5mg Metformin hydrochloride….500mg (Anti-diabetic)	Form-5-D Dy. No 6518 dated 14-02-2019 Rs.50,000/- Dated 23-11-2018 Pack size 10s;14s;20's,28s,30's; As per brand leader	Approved by USFDA
	Now the firm has submitted stability data detailed as under:			

STABILITY STUDY DATA

Drug	Jardy-Met 12.5/500 Tablet		
Name of Manufacturer	M/s CCL Pharmaceuticals Pvt. Ltd, 62. Industrial Estate, Kot Lakhpat, Lahore.		
Manufacturer of API	Empagliflozin: M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province. Metformin hydrochloride: M/s Wanbury Ltd., Andhra Pradesh, India		
API Lot No.	Empagliflozin: E-20180604-D01-E Metformin hydrochloride: MT08890818		
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.	JMC-T1-18	JMC-T2-18	JMC-T3-18
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	01-11-2018	01-11-2018	01-11-2018
No. of Batches	03		
Date of Submission	13-06-2019 (Dy. No. 8372-B)		

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 Drug manufacturing license (License no. Liao 20150233) for M/s Fuxin Long Rui Pharmaceutical Co. Ltd, Fluoride Industrial park, Fuxin City, Liaoning Province issued by Liaoning Food and Drug

	Administration of the People's Republic of China is submitted, valid upto 20-12-2022. • Copy of GMP Certificate for M/s Wanbury Ltd., Andhra Pradesh, India issued by Drug Control Administration, Government Andhra Pradesh, India has been submitted, valid upto 05-02-2022.
Protocols followed for conduction of stability study and details of tests.	Yes
Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
Documents confirming import of API etc.	• Copy of invoice for Empagliflozin (20Kg), attested by Assistant Director (I & E) DRAP, Lahore dated 26-09-2018 has been submitted. • Copy of invoice for Metformin hydrochloride, attested by Assistant Director (I & E) DRAP, Lahore dated 12-09-2018 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

- 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.
- You have not performed uniformity of dosage unit by content uniformity, as recommended by USP General Chapter <905> and innovator's product literature. Justification shall be submitted in this regard.
- Justification for value of Q=70% for both Empagliflozin & Metformin hydrochloride in the dissolution test shall be submitted since USP chapter <1092> (The Dissolution Procedure; Development and Validation) recommends Q values in the range of 75% - 80% for immediate release dosage forms.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Jardy-Met tablet range by M/s CCL Pharmaceuticals (Pvt.) Ltd., 62 Industrial Estate, Kot Lakhpat, Lahore.

Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt.) Ltd.
Physical Address	62 Industrial Estate, Kot Lakhpat, Lahore.
Drug Manufacturing License No. and validity	000052 by way of formulation Valid till 20-07-2020.
Contact Address	Mr. Irfan Sohail Senior Manager Regulatory Affairs 0308-8884984
Date of Inspection.	26-08-2019
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-PEC (Pt) dated 30-07-2019.
Name of Inspector	01. Mr. Shaheen Iqbal Director, DTL, Lahore. 02. Ms. Aisha Irfan

	Area FID, DRAP, Lahore. 03. Mr. Hafiz Ahsan Assistant Director, PEC (DRAP) Islamabad.
Name of firm Representatives	• Dr. Rizwan Mahmood Director Quality Operations • Mr. Kamran Atif Director Regulatory Affairs • Mr. Irfan Sohail Senior Manager Regulatory Affairs • Mr. Shahid Anwar General Manager R&D • Mr. Muhammad Fiaz Quality Control Manager • Mr. Farhan Qureshi Quality Assurance Manager

1.1 General Information about unit:

The firm is located in the industrial area at 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan. The firm was established in 1965 initially and shifted to the existing site in 1984. The firm has production facility, supply chain, engineering, quality control, quality assurance, research & development, regulatory and administrative departments. The production operations at firm involve manufacturing, packaging and distribution of finished pharmaceutical products. The firm is manufacturing generic products.

1.2 Focus of Inspection:

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

Sr. No.	Name / Composition of Drugs
01	Jardy-Met 5/500 Tablet Each film coated tablet contains: Empagliflozin……..5mg Metformin hydrochloride……...500mg
02	Jardy-Met 5/1000 Tablet Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……...1000mg
03	Jardy-Met 12.5/500 Tablet Each film coated tablet contains: Empagliflozin……..12.5mg Metformin hydrochloride……...500mg
04	Jardy-Met 12.5/1000 Tablet Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……...1000mg

Q.#	Questions	Observation by panel
1.	Do you have documents confirming the import of Empagliflozin + Metformin HCl APIs including approval from DRAP?	**Empagliflozin:** The firm has imported Empagliflozin raw material 20 kg from M/s Fuxin Long Rui, China on 26.09.2018. **Metformin HCL**: The firm has purchased Metformin HCl 10,000 kg from M/s Wanbury Ltd, India on 16.08.2018 through DRAP, Lahore.
2.	What was the rationale behind selecting the particular manufacturer of API?	Firm informed that they selected M/s Fuxin Long Rui, China and M/s Wanbury Limited, India based on their Vendor Evaluation mechanism.
3.	Do you have documents confirming the import of reference standard and impurity standards?	**Empagliflozin:** Firm had imported Empagliflozin working standard and impurity standard from API supplier. **Metformin HCL**: Firm had imported Metformin HCl working standard from Wanbury, India and Metformin related compound A from Wanbury, India invoice no. Wanbury/034/19-20 dated 28.05.2019.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm had certificates of analysis for APIs, working standards and impurities standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	**Empagliflozin:** Firm had provided valid GMP Certificate of M/s Fuxin Long Rui Pharmaceutical Co., Ltd, China issued by Fuxin Food and Drug Administration, China valid till 19-09-2019. **Metformin HCl:** Firm had provided valid GMP Certificate of M/s Wanbury Limited, issued by Drugs Control Administration, Government of Andhra Pardesh, India valid till 06-02-2022.
6.	Do you use API manufacturer method of testing for testing API?	The firm used API manufacturer's method of testing.
7.	Do you have stability studies reports on API?	The firm had stability studies reports on APIs of raw material manufacturers.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing had been performed as per SIM method.
9.	Do you have method for quantifying the impurities in the API?	Firm had testing method to quantify the impurities as per raw material manufacturers.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had some remaining quantities of the APIs and reference standards.
11.	Have you used pharmaceutical grade excipients?	The firm had used pharmaceutical grade excipients including Maize starch, Kollidon K-30, Kollidon CL, Aerosil 200, Magnesium stearate, Opadry purple, Opadry white and Opadry orange.
12.	Do you have documents confirming the import of the used excipients?	The firm had necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm had test reports and other records on the excipients used.

14.	Do you have written and authorized protocols for the development of Empagliflozin + Metformin HCl Tablets?	The firm had written and authorized protocols for the development of Empagliflozin + Metformin HCl Tablets. However, firm was advised to improve protocols.
15.	Have you performed Drug-excipient compatibility studies?	The firm had performed Drug-excipient compatibility studies by Tier approach under stress conditions of 60ºC ± 2ºC / 75%±5% RH.
16.	Have you performed comparative dissolution studies?	The firm had performed comparative dissolution studies for Jardy-Met 12.5mg/1000mg Tablet with Synjardy 12.5mg/1000mg Tablet, manufactured by M/s Boehringer Ingelheim and results were in acceptable limits. Out of four strengths applied, the firm had performed CDP with one strength of JardyMet 12.5mg/1000mg Tablet.
17.	Do you have product development (R&D) section	The firm had product development (R&D) section.
18.	Do you have necessary equipment available in product development section for development of Empagliflozin + Metformin HCl Tablets?	Product development section had necessary equipment to develop Empagliflozin + Metformin HCl Tablets.
19.	Are the equipment in product development section qualified?	The available equipment in product development section were qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm had proper maintenance / calibration / re-qualification program for the equipment used in product development section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm had 06 Pharmacists and 02 Chemists in product development section with suitable knowledge and training in product development.
22.	Have you manufactured three stability batches for the stability studies of Empagliflozin + Metformin HCl Tablets as required?	The firm had manufactured three stability batches for the stability studies of Empagliflozin + Metformin HCl Tablets (5/500mg, 5/1000mg, 12.5/500mg and 12.5/1000mg) with batch numbers i.e. JMA-T2-18, JMA-T3-18 and JMA-T4-18 for 5/500mg strength and JMB-T2-18, JMB-T3-18 and JMB-T4-18 for 5/1000mg strength and JMC-T1-18, JMC-T2-18 and JMC-T3-18 for 12.5/500mg strength and JMD-T1-18, JMD-T2-18 and JMD-T3-18 for 12.5/1000mg strength. The Batch size for these batches is 1,500 tablets each.
23.	Do you have any criteria for fixing the batch size of stability batches?	The firm had criteria for fixing the batch size of stability batches as per their in-house document CQP-004-H in the light of DRAP letter No. F.3-2/2014-I&E dated 08-12-2015.
24.	Do you have complete record of production of stability batches?	The firm had record of production of stability batches for which firm has provided Trial Forms.
25.	Do you have protocols for stability testing of stability batches?	The firm had protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm had developed and validated method of testing for finished product based on method of testing of API manufacturer. The firm has revised the dissolution specifications and updated the content uniformity test in product test method.

		Validation of assay method was completed in June, 2019 while first analysis of trial batches was performed in Nov, 2018. Dissolution method validation was not performed.
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?	NA
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Empagliflozin + Metformin HCl API and the finished drug?	The firm had proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Empagliflozin + Metformin HCl API and the finished drug.
29.	Do your method of analysis stability indicating?	The firm has referred to normalization factor method to demonstrate that their method is stability indicating.
30.	Do your HPLC software 21CFR Compliant?	HPLC used in the stability studies of current products was gradient and not 21CFR 11 compliant. However, now the firm has procured HPLC software 21CFR Compliant.
31.	Can you show Audit trail reports on Empagliflozin + Metformin HCl testing?	The audit trail was not active on the testing reports and log of data was available in the HPLCs. The data was also confirmed through record, chromatograms and logbooks.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm had remaining quantities (170 tablets of each batch) of stability batches.
33.	Do you have stability batches kept on stability testing?	The firm had stability batches kept on stability testing. The firm had commitment for stability studies of commercial batches.
34.	Do you have valid calibration status for the equipment used in Empagliflozin+Metformin HCl tablets production and analysis?	The firm had valid calibration status for the equipment used in Empagliflozin + Metformin HCl tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber ?	Adequate monitoring and control was available for stability chamber. The firm has provided uninterrupted power supply by UPS and generator (12000KV).
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Requisite facilities were satisfactory and GMP compliant.

CLARIFICATION:

(i) The firm has performed content uniformity of dosage unit by assay method on stability batches and incorporated in Product Test Method.

(ii) The firm has revised the dissolution specifications with value of Q=75% in Product Test Method and Stability Studies Protocol and commit to analyze in future points of long-term stability studies.

RECOMMENDATIONS:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, the panel is of the opinion that the data provided by the firm M/s. CCL Pharmaceuticals (Pvt.) Ltd., 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan regarding stability studies of following products was satisfactory and the stability studies were conducted by the firm.

Sr. No.	Name / Composition of Drugs
01	Jardy-Met 5/500 Tablet Each film coated tablet contains: Empagliflozin……..5mg Metformin hydrochloride……...500mg

02	Jardy-Met 5/1000 Tablet Each film coated tablet contains: Empagliflozin…….5mg Metformin hydrochloride……...1000mg
03	Jardy-Met 12.5/500 Tablet Each film coated tablet contains: Empagliflozin……..12.5mg Metformin hydrochloride……...500mg
04	Jardy-Met 12.5/1000 Tablet Each film coated tablet contains: Empagliflozin……12.5mg Metformin hydrochloride……...1000mg

Decision: Registration Board decided to approve registration of "Jardy-Met 5/500 Tablet, Jardy-Met 12.5/500 Tablet, Jardy-Met 12.5/1000 Tablet and Jardy-Met 5/1000 Tablet by M/s CCL Pharmaceuticals Pvt. Ltd, 62 Industrial Estate, Kot Lakhpat, Lahore. Manufacturer will place first three production batches of all products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
182.	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim Karachi	Solosin Capsule 8mg Each capsule contains: Silodosin…….8mg (Alpha-adrenoreceptor antagonists)	Form 5-D Dy No. 3303: 25.01.2018 PKR 50,000/-: 17.01.2018 10's, 914; 20's, 1828; 30's, 2742	RAPAFLO® (silodosin) 8mg Capsule for oral use. **USFDA** approved
	Evaluation by PEC: The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board. Details of submitted data are as under:			

STABILITY STUDY DATA			
Drug	Solosin Capsule 8mg		
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim Karachi		
Manufacturer of API	M/s Jilin Hukang Pharmaceutical Co., Ltd., Jilin Province, China.		
API Lot No.	170303		
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.	TF-01	TF-02	TF-03
Batch Size	1500 capsules	1500 capsules	1500 capsules

Manufacturing Date	18-12-2017	22-02-2018	22-02-2018
Date of Initiation	--	--	--
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COAS of APIs	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (Certificate# JL20180052) issued by China Food & Drug Administration valid upto 23-09-2023.
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.	• Firm has submitted FedEx Air Way Bill in the name of M/s Kaizen Pharmaceuticals, Pvt. Ltd. (FedEx tracking Number 8116062846090448). • Copy of commercial invoice (Invoice# 17068KAIJ) dated 27-07-2017 has been submitted. (Quantity: 55gm)
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- Submitted commercial invoices for import API has not been attested by ADC, DRAP. Documents of approval issued by DRAP for import of APIs shall be submitted.
- Clinical Pharmacology & Biopharmaceutics Review(s) of reference product "Rapaflo" (NDA 22-206) , approved by USFDA, declares as under:
  "Silodosin is formulated as immediate release capsules. The formulation is robust with rapid dissolution (>85% in 15 minutes)."
  Whereas you have mentioned limits of dissolution as NLT 75% (Q) of the labeled amount should dissolve in 30minutes. Clarification shall be submitted in this regard.
- Now firm has submitted data of 12th month time point of long term stability studies wherein dissolution results show more than 85% drug release in 15 minutes.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
183.	M/s Kaizen Pharmaceuticals (Pvt.)	Solosin Capsule 4mg Each capsule contains:	Form 5-D Dy No. 3302:	RAPAFLO® (silodosin) 4mg Capsule for oral use.

	Ltd., E-127-129, North Western Industrial Zone, Bin Qasim Karachi	Silodosin…….4mg (Alpha-adrenoreceptor antagonists)	25.01.2018 PKR 50,000/-: 17.01.2018 10's, 562.5; 20's, 1125; 30's, 1687.5	**USFDA** approved
	Evaluation by PEC: The firm has submitted stability data along with documents as per checklist approved in 278th meeting of Registration Board. Details of submitted data are as under:			

STABILITY STUDY DATA			
Drug	Solosin Capsule 4mg		
Name of Manufacturer	M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim Karachi		
Manufacturer of API	M/s Jilin Hukang Pharmaceutical Co., Ltd., Jilin Province, China.		
API Lot No.	170303		
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.	TF-01	TF-02	TF-03
Batch Size	1500 capsules	1200 capsules	1200 capsules
Manufacturing Date	20-11-2017	16-02-2018	16-02-2018
Date of Initiation	--	--	--
No. of Batches	03		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COAS of APIs	Yes.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (Certificate# JL20180052) issued by China Food & Drug Administration valid upto 23-09-2023.
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.	Copy of commercial invoice (Invoice# 17068KAIJ) dated 27-07-2017 has been submitted. (Quantity: 55gm)
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes

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

REMARKS OF EVALUATOR

- Submitted commercial invoices for import API has not been attested by ADC, DRAP. Documents of approval issued by DRAP for import of APIs shall be submitted.
- Clinical Pharmacology & Biopharmaceutics Review(s) of reference product "Rapaflo" (NDA 22-206) , approved by USFDA, declares as under:
  "Silodosin is formulated as immediate release capsules. The formulation is robust with rapid dissolution (>85% in 15 minutes)."
  Whereas you have mentioned limits of dissolution as NLT 75% (Q) of the labeled amount should dissolve in 30minutes. Clarification shall be submitted in this regard.
- Now firm has submitted data of 12th month time point of long term stability studies wherein dissolution results show more than 85% drug release in 15 minutes.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Solosin (Silodosin) 4mg & 8mg Capsules by M/s Kaizen Pharmaceuticals (Pvt.) Limited, E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 25th April, 2019.
Investigation Date and Time: 25th June, 2019. (Afternoon)
Investigation Site: Factory premises of M/s Kaizen Pharmaceuticals (Pvt.) Limited, E-127-129, North Western Industrial Zone, Bin Qasim, Karachi.

Background:
Chairman Registration Board considered the applications of M/s Kaizen Pharmaceuticals (Pvt.) Limited, E-127-129, North Western Industrial Zone, Bin Qasim, Karachi for registration of Solosin (Silodosin) 4mg & 8mg Capsules and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration. It was also advised to verify:

a) Confirmation of import of API as the submitted commercial invoice for import of API has not been attested by ADC, DRAP.
b) Firm has submitted data of 12th month time point of long term stability studies wherein dissolution results show more than 85% drug release in 15 minutes.

Composition of Panel:

1. Dr. Rafeeq Alam Khan, Meritorious Professor, Dean Faculty of Pharmacy, Ziauddin University. (Member Registration Board).
2. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.
3. Dr. Mehwish Tanveer, Federal Inspector of Drugs, DRAP, Karachi.

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

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

Details of Investigation:
Solosin (Silodosin) 4mg & 8mg Capsules

Q.No.	Question	Observation by panel
1.	Do you have documents confirming the import of Silodosin API including approval from DRAP?	The firm has imported "Silodosin" from M/s Jilin Huikang Pharmaceuticals Co. Ltd, China through DHL on 01-04-17
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through Postal Audit checklist and availability of valid GMP approval by competent authority.
3.	Do you have documents confirming the import of Silodosin reference standard and impurity standards?	Firm has imported Silodosin working standard from M/s Jilin Huikang Pharmaceuticals Co. Ltd, China vide invoice No. 17-084 dated 27-07-17
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API and working standard. The DMF does not specify any impurity, however, limits for individual and total impurities are provided in CoA.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has provided copy of valid GMP certificate of M/s Jilin Huikang Pharmaceuticals Co. Ltd, China issued by China Food and Drug Administration.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer's method of testing.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm has gradient method for quantifying the impurities.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has some remaining quantities of the API, working standard only.
11.	Have you used pharmaceutical grade excipients?	The firm have used pharmaceutical grade excipients which include Mannitol, pregelatinized starch, Sodium Lauryl Sulphate, Magnesium Stearate and Hard Gelatin Capsule shells
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14.	Do you have written and authorized protocols for the development of Silodosin Capsules?	The firm has written and authorized protocols for the development of Silodosin 4mg & 8mg Capsules
15.	Have you performed Drug-excipient compatibility studies?	Since firm has used same excipients as used by the innovator. Therefore, compatibility studies not performed.
16.	Have you performed comparative dissolution studies?	The firm has performed Comparative Studies with Urorec 4mg — 17008 Urorec 8mg — 17051 Manufactured by Recordati iLac

<table>
<tr><td>17.</td><td>Do you have product development (R&D) section</td><td>The firm has dedicated product development (R&D) section with requisite manufacturing facilities.</td></tr>
<tr><td>18.</td><td>Do you have necessary equipment available in product development section for development of Silodosin Capsules?</td><td>The firm has necessary equipment available in product development section for development of Silodosin 4mg & 8mg Capsules.</td></tr>
<tr><td>19.</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section are qualified.</td></tr>
<tr><td>20.</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has proper maintenance / calibration with re-qualification program for the equipment used in PD section.</td></tr>
<tr><td>21.</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff in product development section with proper knowledge and training in product development. There are 8 Scientists (Pharmacist & Chemist) working only in R&D Section.</td></tr>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Silodosin Capsules as required?</td><td>The firm has manufactured three stability batches of Silodosin 4mg & 8mg Capsules. Packed in Alu-PVDC Opaque blisters:
<table>
<tr><td colspan="3">Silodosin 4mg Capsules</td></tr>
<tr><td>Batch No..</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TF # 01</td><td>11-17</td><td>1500 Capsules</td></tr>
<tr><td>TF # 02</td><td>02-18</td><td>1200 Capsules</td></tr>
<tr><td>TF # 03</td><td>02-18</td><td>1200 Capsules</td></tr>
</table>
<table>
<tr><td colspan="3">Silodosin 8mg Capsules</td></tr>
<tr><td>Batch No..</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>TF # 01</td><td>12-17</td><td>1500 Capsules</td></tr>
<tr><td>TF # 02</td><td>02-18</td><td>1500 Capsules</td></tr>
<tr><td>TF # 03</td><td>02-18</td><td>1500 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 is quantity of Capsules required per testing frequencies.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. All the Log Books are properly maintained.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocols for stability testing of stability batches.</td></tr>
<tr><td>26.</td><td>Do you have developed and validated method for testing of stability batches?</td><td>The firm has developed and validated the method for testing of stability batches.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has developed and validated method of testing for finished product and complete Method Validation Report is available. Therefore, method transfer studies are not applicable.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Silodosin API and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of Silodosin API and the finished drug.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm’s method of testing is stability indicating evident from forced degradation studies.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>The firm has Shimadzu’s LC 20A, with software “Lab solution DB” which is 21 CFR part 11 compliant with audit trail and date time stamped and with complete multi-level user authorization</td></tr>
<tr><td>31.</td><td>Can you show Audit trail reports on Silodosin testing?</td><td>Audit trail on the testing reports is available.</td></tr>
</table>

32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches kept on long term stability studies.
33.	Do you have stability batches kept on stability testing?	The firm has completed accelerated stability studies whereas 12 months studies have been completed for real time stability studies.
34.	Do you have valid calibration status for the equipment used in Silodosin Capsules production and analysis?	The firm has valid calibration status for the equipment used in production and analysis of Silodosin Capsules 4mg & 8mg.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are GMP compliant.
37.	Any other query raised y PE&R Division: a) Confirmation of import of API as the submitted commercial invoice for import of API has not been attested by ADC, DRAP. b) Firm has submitted data of 12th month time point of long term stability studies wherein dissolution results show more than 85% drug release in 15 minutes.	a) The submitted commercial invoice was not attested by ADC, DRAP, Karachi because the API was imported through DHL courier, which was verified by the panel. b) The firm has revised the specifications as per recommendations to No single capsule should dissolve less than Q + 5% = 85% in 15 mins.

Discussion:

1. **The panel observed significant change in "Assay" in accelerated stability studies of Silodosin 4mg batch # TF #03 at 6th month interval. The firm continued long term stability studies and completed 12 months stability studies as of today. Therefore, the proposed shelf life should be as per ICH Q1E for Silodosin 4mg which states that**

   "If significant change occurs between 3-6-months' testing at the accelerated storage condition, the proposed retest period or shelf life should be based on the long-term data. Extrapolation is not considered appropriate. In addition, a retest period or shelf life shorter than the period covered by long-term data could be called for. If the long-term data show variability, verification of the proposed retest period or shelf life by statistical analysis can be appropriate."

2. **Remaining batches of both strengths show no significant change at the accelerated conditions.**

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Solosin (Silodosin) 4mg & 8mg Capsules is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Solosin 4mg & 8mg Capsules.

Recommendations:

1. **The firm may kindly be granted necessary registration of Solosin 4mg & 8mg Capsules with the shelf life of:**
   a. 24 months for Solosin 8mg
   b. 12 months for Solosin 4mg until submission of complete data for 24 months.

Decision: Registration Board considering the recommendations of the panel decided to approve registration of "Solosin Capsule 8mg (Silodosin 8mg) with sheldf life of 24 months and Solosin Capsule 4mg (Silodosin 4mg) with shelf life of 12 months by M/s Kaizen Pharmaceuticals (Pvt.) Ltd., E-127-129, North Western Industrial Zone, Bin Qasim 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. 08: Miscellaneous Cases.

I. Contract manufacturing from M/s Bio Labs (Pvt.) Ltd, Islamabad.

Registration Board in its 286th meeting, while considering the report on assessment and confirmation of manufacturing capacity of M/s Bio Labs (Pvt.) Ltd, Islamabad and the subsequent measures taken by the firm, decided as under:

"Registration Board did not allow the contract manufacturing in Dry Vial (General) section till capacity assessment and Dry vial (Cephalosporin) till capacity enhancement however the Board allowed contract manufacturing for Infusion (non-antibiotic and antibiotic) and Ampoule (General) section."

Now, M/s Bio Labs (Pvt.) Ltd, Islamabad, has submitted a copy of letter (Letter No. F.1-12/89-Lic (Vol-III)) issued by Secretary CLB dated 27th June, 2019, wherein amendments in following sections have been granted by CLB in its 270th meeting.

1. Capsule (cephalosporin) section.
2. Oral Dry Powder Suspension (cephalosporin) section.
3. Dry powder Injection (cephalosporin) section.

With reference to above now firm has requested to allow for further contract manufacturing registration in the cephalosporin facility.

Decision: Registration Board decided that already constituted panel shall visit for the assessment and confirmation of manufacturing capacity of M/s Bio-labs for the sections Capsule (cephalosporin), Oral Dry Powder Suspension (cephalosporin) and Dry powder Injection (cephalosporin) sections.

II. Report On Assessment And Confirmation Of Manufacturing Capacity For Contract Manufacturing.

General Information

Name of Manufacturer	M/s English Pharmaceutical Industries
Physical Address	Link Kattar Band road, Thoker Niaz Beg, Lahore.
Drug Manufacturing License No. and Validity (Date of application for DML renewal)	DML by way of formulation, No: 000339 Renewed w.e.f. 19.07.2014
Contact Address	Mr. Chaudhary Muhammad Yousaf, CEO Tel: +92 03008422193
Date of inspection	14th June 2019
Purpose of inspection	Assessment and confirmation of manufacturing capacity regarding contract manufacturing of different products
Name of inspector (s)	i. Mr. Asim Rauf, Additional Director (E&M) DRAP Lahore. ii. Mr. Ajmal Sohail Asif, FID, Lahore.
Name of Firm's Representative (s) accompanying during inspection	i. Mr. Chaudhary Muhammad Yousaf, CEO ii. Mr. Shahid Riaz, Production Manager iii. Mr. Muhammad Shakeel, QC Incharge iv. Ms. Maddah, QA Manager

Scope of Inspection:

The inspection was conducted for assessment and confirmation of manufacturing capacity of M/s English Pharmaceutical Industries for following sections:

i. Dry powder Injectable (Penicillin)

ii. Liquid ampoule Injectable (General)
iii. Dry powder Lyophilized Injectable (General)
iv. Large Volume Vial Injectable (General)

Manufacturing record/data was evaluated from **January 2018 to December 2018** (1 year) for the said purpose. The details of capacity calculations are as under:

SECTION WISE CAPACITY CALCULATION

i. Capacity of dry powder injection (Penicillin) section:

STEP WISE CAPACITY OF EACH PROCESS							
Capacity - Washing of vials (per hour)	Capacity - Washing per month with single shift of 7 working hours (23 working Days)	Capacity – Dry heat sterilization - Single shift (Load per Day) **(2 Sterilizers)**	Capacity - Dry heat sterilization per month Single Shift (23 working Days) **(2 Sterilizers)**	Capacity - Filling (per hour)	Capacity - Filling per Month with single shift of 7 working hours (23 working Days)	Capacity – packing per hour	Capacity - packing per Month with Single shift of 7 working hours (23 working Days)
5000	805000	35000	805000	6000	966000	3000	**483000**

***Note: Limiting step in this process is packing of product.**

Capacity calculated with respect to the Packing process being capacity limiting step:

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity**	**Capacity utilized in %**
1st -2018	109800	1449000	7.57
2nd -2018	Nil	1449000	0
3rd -2018	108848	1449000	7.51
4th -2018	14900	1449000	1.02
Average Capacity Utilized in %			4.03

Manufacturing Capacity Utilized (average): ***4.03%***

Manufacturing Capacity Available (average): ***95.97%***

ii. Capacity of Dry powder Lyophilized Injectable (General) section:

STEP WISE CAPACITY OF EACH PROCESS							
Capacity - Washing of vials (per hour)	Capacity - Washing per month with single shift of 7 working hours (23 working Days)	Capacity – Dry heat sterilization - Single shift (Load per Day) **(2 Sterilizers)**	Capacity - Dry heat sterilization per month Single Shift (23 working Days) **(2 Sterilizers)**	Capacity - Filling (per hour)	Capacity - Filling per Month with single shift of 7 working hours (23 working Days)	Capacity – packing per hour	Capacity - packing per Month with Single shift of 7 working hours (23 working Days)
5000	805000	30000	690000	6000	966000	3500	**563500**

***Note: Limiting step in this process is packing of product.**

Capacity calculated with respect to the Packing being capacity limiting step:

QUARTER WISE CAPACITY UTILIZED			
Quarter	**Actual Production**	**Capacity**	**Capacity utilized in %**
1st -2018	68049	1690500	4.02
2nd -2018	198500	1690500	11.74
3rd -2018	80000	1690500	4.73
4th -2018	95500	1690500	5.64
Average Capacity Utilized in %			6.53

Manufacturing Capacity Utilized (average): ***6.53%***
Manufacturing Capacity Available (average): ***93.47%***

iii. Capacity of Liquid Ampoule Injectable (General) Section:

STEP WISE CAPACITY OF EACH PROCESS									
Capacity - Washing (per hour)	Capacity - Washing per month with single shift of 7 working hours (23 working Days)	Capacity – Dry heat sterilization - Single shift (Load per Day) **(2 Sterilizers)**	Capacity - Dry heat sterilization per month (23 working Days)	Capacity - Filling (per hour)	Capacity - Filling per Month with single shift of 7 working hours (23 working Days)	Capacity – Terminal sterilization per day in two cycles	Capacity- Terminal sterilization per month with single shift of 7 working hours (23 working Days)	Capacity – packing per hour	Capacity - packing per Month with Single shift of 7 working hours (23 working Days)
14300	**2300000**	200000	4600000	14400	2318400	200000	4600000	30000	4830000

***Note: Limiting step in this process is washing of product.**

Capacity calculated with respect to the washing process being capacity limiting step:

QUARTER WISE CAPACITY UTILIZED			
Quarter	Actual Production	Capacity	Capacity utilized in %
1st -2018	783733	6900000	11.35
2nd -2018	1075215	6900000	15.58
3rd -2018	1246999	6900000	18.07
4th -2018	285419	6900000	4.13
Average Capacity Utilized in %			12.28

Manufacturing Capacity Utilized (average): ***12.28%***
Manufacturing Capacity Available (average): ***87.72%***

iv. Capacity of Large Volume Vial Injectable (General) Section:

STEP WISE CAPACITY OF EACH PROCESS									
Capacity - Washing (per hour)	Capacity - Washing per month with single shift of 7 working hours (23 working Days)	Capacity – Dry heat sterilization - Single shift (Load per Day) **(2 Sterilizers)**	Capacity - Dry heat sterilization per month (23 working Days)	Capacity - Filling (per hour)	Capacity - Filling per Month with single shift of 7 working hours (23 working Days)	Capacity – Terminal sterilization per day in two cycles	Capacity- Terminal sterilization per month with single shift of 7 working hours (23 working Days)	Capacity – packing per hour	Capacity - packing per Month with Single shift of 7 working hours (23 working Days)
2000	**322000**	10000	230000	1800	289800	10000	230000	3000	483000

***<u>Note: Limiting step in this process is dry heat sterilization of product.</u>**

Capacity calculated with respect to the dry heat sterilization process being capacity limiting step:

QUARTER WISE CAPACITY UTILIZED			
Quarter	Actual Production	Capacity	Capacity utilized in %
1st -2018	16434	690000	2.38
2nd -2018	10500	690000	1.52
3rd -2018	129440	690000	18.75
4th -2018	0	690000	0
Average Capacity Utilized in %			5.66

Manufacturing Capacity Utilized (average): ***5.66%***
Manufacturing Capacity Available (average): ***94.34%***

CAPACITY OF QUALITY CONTROL DEPARTMENT

Quality Control Equipment Details			
S. #	Equipment	Quantity	Capacity per day
1	HPLC	4	Max 8
2	UV Spectrophotometer	1	20
3	pH Meter	2	50
4	Balance	4	80
5	Moisture Analyzer	1	30
6	Melting Point Apparatus	1	25
7	Incubators (hot and cool)	1 set	6
8	Filtration assembly	7	12
9	Stability chambers	2	--
10	Rafractometer	1	30
11	Hot sterilization oven	2	5
12	Autoclave	1	3

HPLC Capacity Calculation Quarter Wise (Max 2 tests/day) TOTAL 4 HPLCs				
QUARTER	Average Capacity of 4 HPLC	Performed	Capacity Utilized %	Capacity Available %
1st -2018	552	121	21.91	78.07
2nd -2018	552	123	22.28	77.71
3rd -2018	552	120	21.73	78.26
4th -2018	552	121	21.92	78.07
Average capacity Available:				**78.02%**

UV Spectrophotometer Capacity Calculation Quarter Wise (Average 20 tests/day)				
Quarter	Capacity	Performed	Capacity Utilized %	Capacity Available %
1st -2018	1380	141	10.21	89.78
2nd -2018	1380	155	11.23	88.76
3rd -2018	1380	152	11.01	88.98
4th -2018	1380	154	11.15	88.84
Average capacity Available:				**89.09%**

Capacity Calculation for sterility testing Quarter Wise depending on incubators (Average 5 tests/day)				
Quarter	Capacity	Test Performed	Capacity Utilized %	Capacity Available %
1st -2018	414	232	56.03	43.96
2nd -2018	414	230	55.55	44.44
3rd -2018	414	229	55.31	44.68
4th -2018	414	231	55.79	44.20
Average capacity available:				**44.32%**

CONCLUSION:

Production and QC capacity available for intended manufacturing sections is summarized in below table:

Section	English Pharma Registrations	English Pharma Pending applications	Contract Products Registrations	Contract products Pending applications	Manufacturing Capacity Available (average)
Dry Powder Injection (Penicillin)	8	0	0	4	**95.97%**
Dry Powder Lyophilized Injectable (General)	5	0	5	15	**93.47%**
Liquid Ampoule Injectable (General)	15	5	0	11	**87.72%**
Large Volume Vial Injectable (General)	4	0	0	6	**94.34 %**
HPLC	-	-	-	-	**78.02 %**
UV spectrophotometer	-	-	-	-	**89.09 %**
Sterility Testing	-	-	-	-	**44.32 %**

Name, Designation and Signatures of the Inspectors:

Sr. #	Name	Designation
1.	Mr. Asim Rauf	Additional Director (E&M), DRAP, Lahore
2.	Mr. Ajmal Sohail Asif	Federal Inspector of Drugs, DRAP, Lahore

Decision: **Registration Board upon considering the above presented report decided to allow contract manufacturing from M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore for the following sections:**

i. **Dry powder Injectable (Penicillin)**
ii. **Liquid ampoule Injectable (General)**
iii. **Dry powder Lyophilized Injectable (General)**
iv. **Large Volume Vial Injectable (General)**

III. Correction in minutes of 290th meeting.

Following case was presented in 290th meeting of Registration Board:

	Name and address of manufacturer / Applicant	"M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore."
	Brand Name +Dosage Form + Strength	Cloxam 50ml Injection
	Composition	"Each ml Contains: Cloxacillin as Sodium…50mg Amoxicillin as Trihydrate…….100mg"
	Diary No. Date of R & I & fee	Dy. No 10009 dated 16-03-2018 Rs.20,000/- Dated 14-03-2018
	Pharmacological Group	Penicillin
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	50ml glass vial
	Me-too status (with strength and dosage form)	Ampicox injection by M/s Alina Nawan Laboratories (Reg.#035061)
	GMP status	Last inspection report dated 05-03-2018, 17-08-2018 & 16-10-2018 recommending renewal of DML.
	Remarks of the Evaluator[II]	
	Decision: Approved with Innovator's specifications.	

It has been identified during processing of the minutes that inadvertently composition of product could not be written as applied, while the actual composition of the product is as follows:

"Cloxam 50ml Injection
Each ml Contains:
Ampicillin as Trihydrate…125mg
Cloxacillin as Sodium…125mg"

The me-too already referred in 290th meeting is valid for the above correct formulation. The case is presented before the Board for consideration.

Decision: Registration Board noted the correction in the composition as cited above.

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

a. New Cases

184.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Risdone 1mg Tablet
	Composition	Each film coated tablet contains: Risperidone……1mg
	Diary No. Date of R& I & fee	Dy No. 13045: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Antipsychotic agent
	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	Irosone Tablet by Evolution Pharma
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
185.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Risdone 3mg Tablet
	Composition	Each film coated tablet contains: Risperidone……3mg
	Diary No. Date of R& I & fee	Dy No. 13048: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Antipsychotic agent
	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	Irosone Tablet by Evolution Pharma
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
186.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Risdone 4mg Tablet
	Composition	Each film coated tablet contains: Risperidone……4mg
	Diary No. Date of R& I & fee	Dy No. 13045: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Antipsychotic agent
	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	Irosone Tablet by Evolution Pharma
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP

	Remarks of the Evaluator[3]	•
	Decision: Approved.	
187.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Montefr Tablet 4mg
	Composition	Each film coated tablet contains: Montelukast (as sodium)……4mg
	Diary No. Date of R& I & fee	Dy No. 13043: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Leukotriene receptor 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.	MHRA Approved but only as chewable tablet
	Me-too status	Astikast 4mg Chewable Tablet by Astellas Pharmaceutical
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	• Reference product is available as chewable tablet while firm has applied as film coated tablet.
	Decision: Deferred for revision of formulation to chewable tablet as per the reference product along with submission of fee for revision of formulation.	
188.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Montefr Tablet 5mg
	Composition	Each film coated tablet contains: Montelukast (as sodium)……5mg
	Diary No. Date of R& I & fee	Dy No. 13047: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Leukotriene receptor 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.	MHRA Approved but only as chewable tablet
	Me-too status	Astikast 5mg Chewable Tablet by Astellas Pharmaceutical
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	• Reference product is available as chewable tablet while firm has applied as film coated tablet.
	Decision: Deferred for revision of formulation to chewable tablet as per the reference product along with submission of fee for revision of formulation.	
189.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Galmet Tablet 50/850mg
	Composition	Each film coated tablet contains: Vildagliptin……50mg Metformin HCl……..850mg
	Diary No. Date of R& I & fee	Dy No. 13049: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Galvumet tablet (TGA Approved)
	Me-too status	Vilmetin 50/850mg Tablet by Aries Pharmaceuticals

	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	• Approved in TGA with shelf life of 18 months
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
190.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Clinda V 2% Cream
	Composition	Each gram contains: Clindamycin (as phosphate)……20mg
	Diary No. Date of R& I & fee	Dy No. 13042: 22-08-2017 PKR 20,000/-: 22-08-2017
	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.	Dalacin 2% cream (MHRA Approved)
	Me-too status	Dalacin vaginal cream by pfizer
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
191.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals Plot # 07, S6, National Industrial Zone RCCI Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Oromic 2% Gel
	Composition	Each gram contains: Miconazole nitrate……20mg
	Diary No. Date of R& I & fee	Dy No. 13044: 22-08-2017 PKR 20,000/-: 22-08-2017
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	DAKTARINT Oral Gel (MHRA Approved)
	Me-too status	Mecroz 2% Oral Gel by Tabros
	GMP status	Last inspection report dated 9-5-2017 specifies good compliance to GMP
	Remarks of the Evaluator[3]	• The formulation is a mucoadhesive oral gel in BP • The reference formulation contains miconazole 20mg while the applied formulation contains miconazole nitrate 20mg.
	Decision: Deferred for correction of salt form and revision of formulation along with submission of fee for correction of salt form since the reference product contains miconazole base.	
192.	Name and address of manufacturer / Applicant	M/s Caliph Pharmaceuticals, Plot No. 17, Special Industrial Zone (EPZ), Risalpur, KPK.
	Brand Name +Dosage Form + Strength	Vastan Tablet 160mg
	Composition	Each film coated tablet contains: Valsartan……160mg
	Diary No. Date of R& I & fee	27-12-2017, PKR 20,000/-: 27-12-2017
	Pharmacological Group	Antihypertensive
	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	Valid 160mg Tablet Scilife Pharma
	GMP status	GMP certificate issued on the basis of report dated 6-11-2018
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
193.	Name and address of manufacturer / Applicant	M/s Caliph Pharmaceuticals, Plot No. 17, Special Industrial Zone (EPZ), Risalpur, KPK.
	Brand Name +Dosage Form + Strength	Valsa 10mg/160mg Tablet
	Composition	Each film coated tablet contains: Amlodipine (as besylate)……10mg Valsartan……160mg
	Diary No. Date of R& I & fee	27-12-2017, PKR 20,000/-: 27-12-2017
	Pharmacological Group	Antihypertensive
	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 Tablets (USFDA Approved)
	Me-too status	Exforge Tablets by Novartis
	GMP status	GMP certificate issued on the basis of report dated 06-11-2018
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
194.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggain Bypass Road Lahore. Manufactured by: M/s Shawan Pharmaceuticals Plot # 37, Road NS-01, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Cefotel 250mg Injection IM
	Composition	Each vial contains: Ceftriaxone (as sodium)…..250mg
	Diary No. Date of R& I & fee	Dy No. 26253: 31-07-2018 PKR 50,000/-: 31-07-2018
	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.	(MHRA Approved)
	Me-too status	Rocephin Injection by Roche
	GMP status	Last inspection report of Shawan Pharma dated 24-03-2019, panel recommended renewal of DML.
	Remarks of the Evaluator[3]	• Applicant firm M/s Hoover Pharma has 8 approved sections and have submitted an undertaking that they are do not have any product registered for contract manufacturing. • The manufacturer firm M/s Shawan pharma has Sterile powder injection vial (cephalosporin) section.
	Decision: Approved.	
195.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggain Bypass Road Lahore. Manufactured by: M/s Shawan Pharmaceuticals Plot # 37, Road NS-01, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Cefotel 500mg Injection IM
	Composition	Each vial contains: Ceftriaxone (as sodium)…..500mg
	Diary No. Date of R& I & fee	Dy No. 26254: 31-07-2018 PKR 50,000/-: 31-07-2018
	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.	(MHRA Approved)
	Me-too status	Rocephin Injection by Roche
	GMP status	Last inspection report of Shawan Pharma dated 24-03-2019, panel recommended renewal of DML.
	Remarks of the Evaluator[3]	• Applicant firm M/s Hoover Pharma has 8 approved sections and have submitted an undertaking that they are do not have any product registered for contract manufacturing. • The manufacturer firm M/s Shawan pharma has Sterile powder injection vial (cephalosporin) section.
	Decision: Approved.	
196.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggain Bypass Road Lahore. Manufactured by: M/s Shawan Pharmaceuticals Plot # 37, Road NS-01, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Cefotel 1g Injection IV
	Composition	Each vial contains: Ceftriaxone (as sodium)…..1g
	Diary No. Date of R& I & fee	Dy No. 26255: 31-07-2018 PKR 50,000/-: 31-07-2018
	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.	(MHRA Approved)
	Me-too status	Rocephin Injection by Roche
	GMP status	Last inspection report of Shawan Pharma dated 24-03-2019, panel recommended renewal of DML.
	Remarks of the Evaluator[3]	• Applicant firm M/s Hoover Pharma has 8 approved sections and have submitted an undertaking that they are do not have any product registered for contract manufacturing. • The manufacturer firm M/s Shawan pharma has Sterile powder injection vial (cephalosporin) section.
	Decision: Approved.	
197.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggain Bypass Road Lahore. Manufactured by: M/s Shawan Pharmaceuticals Plot # 37, Road NS-01, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Cefobactum 1g Injection
	Composition	Each vial contains: Cefoperazone (as sodium)…..500mg Sulbactum (as sodium)……..500mg
	Diary No. Date of R& I & fee	Dy No. 26256: 31-07-2018 PKR 50,000/-: 31-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Q- Bact 1gm Injection M/s High-Q
	GMP status	Last inspection report of Shawan Pharma dated 24-03-2019,

		panel recommended renewal of DML.
	Remarks of the Evaluator[3]	• Applicant firm M/s Hoover Pharma has 8 approved sections and have submitted an undertaking that they are do not have any product registered for contract manufacturing. • The manufacturer firm M/s Shawan pharma has Sterile powder injection vial (cephalosporin) section.
	Decision: Approved.	
198.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggain Bypass Road Lahore. Manufactured by: M/s Shawan Pharmaceuticals Plot # 37, Road NS-01, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Cefobactum 2g Injection
	Composition	Each vial contains: Cefoperazone (as sodium)…..1g Sulbactum (as sodium)……..1g
	Diary No. Date of R& I & fee	Dy No. 26257: 31-07-2018 PKR 50,000/-: 31-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by 3 European countries Czech, Slovakia, Poland
	Me-too status	Bezone Injection of M/s Medisave
	GMP status	Last inspection report of Shawan Pharma dated 24-03-2019, panel recommended renewal of DML.
	Remarks of the Evaluator[3]	• Applicant firm M/s Hoover Pharma has 8 approved sections and have submitted an undertaking that they are do not have any product registered for contract manufacturing. • The manufacturer firm M/s Shawan pharma has Sterile powder injection vial (cephalosporin) section.
	Decision: Approved.	
199.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals (Pvt) Ltd. Plot No. 16, Zain Park, Industrial Area, Saggain Bypass Road Lahore. Manufactured by: M/s Mass Pharma (Pvt) Ltd., 17-Km, Foerozepur Road Lahore.
	Brand Name +Dosage Form + Strength	Tretigen soft gelatin capsule 20mg
	Composition	Each soft gelatin capsule contains: Isotretinoin….20mg
	Diary No. Date of R& I & fee	Dy No. 26246: 31-07-2018 PKR 50,000/-: 31-07-2018
	Pharmacological Group	Retinoic acid derivative
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	Rs. 59.83/Capsule, Rs 1795/pack
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Oratane 20mg Soft Capsule by Crystolite
	GMP status	GMP certificate of Mass Pharma issued on the basis of inspection dated 20-05-2019
	Remarks of the Evaluator[3]	• Applicant firm M/s Hoover Pharma has 8 approved sections and have submitted an undertaking that they are do not have any product registered for contract manufacturing. • The manufacturer firm M/s Mass pharma has soft gelatin capsule section.
	Decision: Approved.	

b. Deferred Cases.

200.	Name and address of manufacturer / Applicant	M/s Berlex Lab, International, 10Km Nangshah Chowk, Karachi Road, Multan.
	Brand Name +Dosage Form + Strength	Pantolex 40mg Tablet
	Diary No. Date of R& I & fee	29-3-2017: (DUPLICATE DOSSIER) PKR 20,000/-: 29-3-2017
	Composition	Each enteric coated tablet contains: Pantoprazole sodium sesquihydrate eq to pantoprazole……40mg
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP spec
	Pack size & Demanded Price	10's: 17 Pakistani rupees
	Approval status of product in Reference Regulatory Authorities.	Protonix Tablet byWyeth Pharms (USFDA Approved)
	Me-too status	Pantroz Tablet by ZJans Pharma
	GMP status	Not available.
	Remarks of the Evaluator.	• Latest GMP inspection report conducted within a period of last 1 year. Letter communicated dated: 9-5-2018 Firm has replied that their inspection is scheduled on 02-7-2018
	Decision of previous meeting of Registration Board:	Registration Board deferred the case for further deliberation. (M-284)
	Evaluation by PEC	• Firm has submitted panel inspection report dated 05-07-2018 recommending renewal of DML.
	Decision: Approved. Registration Board further decided that verification of fee challan may be done as per decision of 285th meeting of Registration Board.	
201.	Name and address of manufacturer / Applicant	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tribetanae 15gm Cream 1% w/w
	Composition	Each gram Contains: Betamethasone Dipropionate…10mg (1% w/w)
	Diary No. Date of R& I & fee	Dy. No 13050 dated 06-04-2018 Rs.20,000/- 06-04-2018
	Pharmacological Group	Corticosteroids, potent (group III)
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	15g / Rs.55/-
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	14-02-2018 Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Trigon Pharmaceuticals Pvt. Ltd Lahore was considered to be operating at Satisfactory level of compliance with cGMP guidelines as per DRUGS ACT, 1976 and rules framed there under at the time of inspection.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Decision of previous meeting of Registration Board	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 (**M-290)**
	Evaluation by PEC	Firm has requested to revise the formulation as per reference product. The updated composition applied by the firm is: Each gram contains: Betamethasone (as dipropionate)……0.05% w/w International Availability: Diprosone 0.05 % w/w Cream (MHRA Approved) Me-too status: Valisone 0.05% Cream by Crystollite (Reg#077635) Firm has also submitted fee Rs 20,000/- for revision of formulation.
	Decision: Registration Board decided to approved the case with USP specification and with following composition: **Each gram contains:** **Betamethasone (as dipropionate)……0.05% w/w**	
202.	Name and address of manufacturer / Applicant	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Tribetafusid 15gm Cream
	Composition	Each gram Contains: Betamethasone …10mg (1%w/w) Fusidic acid …20mg (2%w/w)
	Diary No. Date of R& I & fee	Dy.No 13049 dated 06-04-2018 Rs.20,000/- 06-04-2018
	Pharmacological Group	Corticosteroids, potent, combinations with antibiotics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	15g / Rs.165/-
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	14-02-2018 Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Trigon Pharmaceuticals Pvt. Ltd Lahore was considered to be operating at Satisfactory level of compliance with cGMP guidelines as per DRUGS ACT, 1976 and rules framed there under at the time of inspection.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Decision of previous meeting of Registration Board	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 (**M-290)**
	Evaluation by PEC	Firm has requested to revise the formulation as per reference product. The updated composition applied by the firm is: Each gram contains: Betamethasone (as valerate)……1mg Fusidic acid…….20mg

		International Availability: Xemacort 20 mg/g + 1 mg/g cream (**MHRA** Approved) Me-too status: Beta-F Cream by Atco Laboratories (Reg# 082104) Firm has also submitted fee Rs 20,000/- for revision of formulation.
	Decision: Registration Board decided to approved the case with Innovator's specification and with following composition: **Each gram contains:** **Betamethasone (as valerate)……1mg** **Fusidic acid…….20mg**	
203.	Name and address of manufacturer / Applicant	M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Isonine Cream 1%w/w
	Composition	Each gram Contains: Isotretinoin …10mg (1%w/w)
	Diary No. Date of R& I & fee	Form-5 Dy.No 13045 (06-04-2018) Rs.20,000/- 06-04-2018
	Pharmacological Group	Retinoids for treatment of acne
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10g / Rs.65/-
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Not confirmed
	GMP status	14-02-2018 Based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Trigon Pharmaceuticals Pvt. Ltd Lahore was considered to be operating at Satisfactory level of compliance with cGMP guidelines as per DRUGS ACT, 1976 and rules framed there under at the time of inspection.
	Remarks of the Evaluator.	• Approval status of product in Reference Regulatory Authorities not confirmed. • Me-too status not confirmed from available database.
	Decision of previous meeting of Registration Board	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 (**M-290)**
	Evaluation by PEC	Firm has requested to revise the formulation as per reference product. The updated composition applied by the firm is: Each gram contains: Isotretinoin……0.5mg International Availability: Isotrex 0.05% Cream (**MHRA** Approved) Me-too status: Silkit 0.05% Cream by Nabiqasim Industries (Reg# 085594) Firm has also submitted fee PKR 20,000/- for revision of formulation.
	Decision: Registration Board decided to approved the case with Innovator's specification and with following composition: **Each gram contains: Isotretinoin……0.5mg**	

204.	Name and address of Manufacturer / Applicant	M/s Caliph Pharmaceuticals (PVT) Ltd. Plot No.17, EPZ Risalpur, KPK.
	Brand Name +Dosage Form + Strength	Bicalutacal Tablet 50mg
	Composition	Each Film Coated Tablet Contains: Bicalutamide……50mg
	Diary No. Date of R& I & fee	Dy. No. 37906: 16.11.2018 PKR 20,000/-: 14.11.2018
	Pharmacological Group	Anti-androgens
	Type of Form	Form5
	Finished Product Specification	USP
	Pack size & Demanded Price	As Per SRO.
	Approval status of product in Reference Regulatory Authorities.	COSUDEX Bicalutamide 50mg tablet film coated (TGA Approved).
	Me-too status	Casodex Tablets 50mg By M/s ICI Pakistan Ltd, Karachi. Reg. No. 27380.
	GMP status	GMP inspection: 07.03.2017. Overall GMP was satisfactory.
	Remarks of the Evaluator.	
	Decision of previous meeting of Registration Board	Deferred for confirmation of manufacturing facility. (M-290)
	Evaluation by PEC	Firm has submitted sectional approval letter issued by Licensing Division dated 17-01-2019 specifying Tablet (General) Section. Firm has further submitted that they will manufacture this formulation in /tablet (general) section and that this formulation does not require any specific or dedicated manufacturing facility. The WHO ATC code for this product is "L02BB03" and the Board has also approved the same formulation in general tablet section in 282nd meeting
	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.	
205.	Name and address of Manufacturer / Applicant	M/s Caliph Pharmaceuticals (PVT) Ltd. Plot No.17, EPZ Risalpur, KPK.
	Brand Name +Dosage Form + Strength	Bicalutacal Tablet 150mg
	Composition	Each Film Coated Tablet Contains: Bicalutamide……150mg
	Diary No. Date of R& I & fee	Dy. No. 37909: 16.11.2018 PKR 20,000/-: 14.11.2018
	Pharmacological Group	Anti-androgens
	Type of Form	Form5
	Finished Product Specification	USP
	Pack size & Demanded Price	As Per SRO.
	Approval status of product in Reference Regulatory Authorities.	Casodex 150 mg Film-coated tablet Swedish Agency approved.
	Me-too status	Geperprostin 150mg film coated tablets by M/s by Salutas Pharma, Germany. Imported by Novartis Pharma (Pakistan).
	GMP status	GMP inspection: 07.03.2017. Overall GMP was satisfactory.
	Remarks of the Evaluator.	
	Decision of previous meeting of Registration Board	Deferred for confirmation of manufacturing facility. (**M-290)**
	Evaluation by PEC	Firm has submitted sectional approval letter issued by Licensing Division dated 17-01-2019 specifying Tablet (General) Section. Firm has further submitted that they will manufacture this formulation in /tablet (general) section and that this formulation does not require any specific or dedicated manufacturing facility.

		The WHO ATC code for this product is "L02BB03" and the Board has also approved the same formulation in general tablet section in 282nd meeting
	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. 02: Registration Applications of Categories to be Considered on Priority.

c. Export facilitation

M/s Efroze Chemical Industries (Pvt) Ltd, 146/23, Korangi Industrial Area Karachi. Following 3 files were received from section PR-I vide letter No. F.1-6/2019-PR.1 (EFD) dated 5th August 2019. As per the contents of the letter, M/s Efroze Chemical Industries (Pvt) Ltd have achieved the benchmark of USD $ 101,801.07 during fiscal year 2017-18. Now the firm has submitted 3 applications for 2 molecules.		
206.	Name and address of manufacturer / Applicant	M/s Efroze Chemical Industries (Pvt) Ltd, 146/23, Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Eflenticon Gel Oral Suspension
	Composition	Each 5ml suspension contains: Dicyclomine HCl…….2.5mg Dried aluminium hydroxide gel…..200mg Light magnesium oxide…….100mg Simethicone……..20mg
	Diary No. Date of R& I & fee	Dy No. 11396: 05-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	120ml: As per DPC
	Approval status of product in Reference Regulatory Authorities.	Kolanticon Gel by Peckforton Pharmaceuticals (MHRA Approved)
	Me-too status	Peptogel Suspension by Mediways International (Reg# 030280) Colenticon Gel by Pacific Pharma (Reg# 019294)
	GMP status	Last panel inspection was conducted on 19-03-2018 and the panel recommends renewal of DML.
	Remarks of the Evaluator[3]	• The shelf life of MHRA approved reference product is 18 months in amber glass bottle • The pack size of reference product is 200 and 500 ml since its dose is "Two to four 5ml spoonfuls every four hours as required" while the applied pack size is 120ml.
	Decision: Approved with Innovator's specifications with a shelf life of 18 months.	
207.	Name and address of manufacturer / Applicant	M/s Efroze Chemical Industries (Pvt) Ltd, 146/23, Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Tramafor 100mg SR Tablet
	Composition	Each sustained release tablet contains: Tramadol hydrochloride…….100mg
	Diary No. Date of R& I & fee	Dy No. 11402: 05-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Centrally acting analgesic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's: As per DPC
	Approval status of product in Reference Regulatory Authorities.	Larapam 100mg SR Tablets by Sandoz Limited (**MHRA** Approved)
	Me-too status	Tramal SR 100mg Tablet by Searle (Reg# 023317)

	GMP status	Last panel inspection was conducted on 19-03-2018 and the panel recommends renewal of DML.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
208.	Name and address of manufacturer / Applicant	M/s Efroze Chemical Industries (Pvt) Ltd, 146/23, Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Tramafor 50mg Capsule
	Composition	Each capsule contains: Tramadol hydrochloride……50mg
	Diary No. Date of R& I & fee	Dy No. 11401: 05-03-2019 PKR 20,000/-: 05-03-2019
	Pharmacological Group	Centrally acting analgesic
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's: As per DPC
	Approval status of product in Reference Regulatory Authorities.	Tramadol 50 mg capsules by Milpharm Limited (**MHRA** Approved)
	Me-too status	Newtra 50mg Capsule by Newton Health Care (Reg# 086582)
	GMP status	Last panel inspection was conducted on 19-03-2018 and the panel recommends renewal of DML.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
M/s Medisure Laboratories Pakistan (Pvt) Ltd, Karachi. Following 3 files were received from section Reg-I vide letter No. F.7-7/2017-Reg-II (Vol-II) dated 10th July 2019. As per the contents of the letter, Registration Board in its 289th meeting acceded to the request of the firm M/s Medisure Laboratories Pakistan (Pvt) Ltd, Karachi for consideration of one molecule i.e. lacosamide at 50, 100 and 200mg tablet in replacement of their already deferred product Ticalor Tablet 90mg. Now the firm has applied for lacosamide 50mg tablet, 100mg tablet and lacosamide 10mg/ml injection instead of lacosamide 200mg tablet (which the firm already mentioned in its request considered in 289th meeting of RB).		
209.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan (Pvt) Ltd, A-115, SITE Super Highway Karachi
	Brand Name +Dosage Form + Strength	Lacoste 50mg Tablet
	Composition	Each film coated tablet contains: Lacosamide……..50mg
	Diary No. Date of R& I & fee	Dy No. 9203: 28-02-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire tablet (**MHRA** Approved)
	Me-too status	Lalik Tablets by Medizan Laboratories
	GMP status	Last inspection dated 28-06-2018 confirms good compliance to GMP
	Remarks of the Evaluator[3]	•
	Decision: Approved with innovator's specification.	
210.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan (Pvt) Ltd, A-115, SITE Super Highway Karachi
	Brand Name +Dosage Form + Strength	Lacoste 100mg Tablet
	Composition	Each film coated tablet contains: Lacosamide……..100mg
	Diary No. Date of R& I & fee	Dy No. 9204: 28-02-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification

	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities.	Lacosamide Aspire tablet (**MHRA** Approved)
	Me-too status	Lalik Tablets by Medizan Laboratories
	GMP status	Last inspection dated 28-06-2018 confirms good compliance to GMP
	Remarks of the Evaluator[3]	•
	Decision: Approved with innovator's specification.	
211.	Name and address of manufacturer / Applicant	M/s Medisure Laboratories Pakistan (Pvt) Ltd, A-115, SITE Super Highway Karachi
	Brand Name +Dosage Form + Strength	Lacoste 10mg/ml Injection
	Composition	Each ml contains: Lacosamide……..10mg
	Diary No. Date of R& I & fee	Dy No. 9202: 28-02-2019 PKR 20,000/-: 28-02-2019
	Pharmacological Group	Antiepileptic
	Type of Form	Form 5
	Finished Product Specification	Firm has claimed in house specification
	Pack size & Demanded Price	20ml glass vials: As per DPC
	Approval status of product in Reference Regulatory Authorities.	Lacosamide G.L. Pharma GmbH 10 mg/ml solution for infusion (**MHRA** Approved)
	Me-too status	Lacosbar 200mg/20ml Injection by Barrett Hodgson
	GMP status	Last inspection dated 28-06-2018 confirms good compliance to GMP
	Remarks of the Evaluator[3]	
	Decision: Approved with innovator's specification.	

Case no. 03 Registration Applications of Import Cases.

a. Deferred cases

i. Veterinary

212.	Name and address of Applicant	M/s Chappal Enterprises, Office No. G8, Muhammadi Trade Tower, Opposite Adam Chamber, Altaf Hussain Road, New Challi, Karachi.
	Detail of Drug Sale License	**Address:** Suite No. 4/23 Arkay Square Extension New Chali Shahra e Liaquat, Karachi. **Validity:** 08-07-2019 **Status:** License to sell drugs by way of wholesale
	Name and address of manufacturer	ATCO Pharma for Pharmaceutical Industries, Industrial Quisna Zone-Part No. 1, Phase No. 3, Quisna-El Menofia, Egypt.
	Name and address of marketing authorization holder	ABO EL NAGA Trading Company (ATCO Pharma) 35 Emmarat El-Obour-Salah Salem Road, Appartment 8, floor 8, Heliopolis Cairo, Egypt..
	Name of exporting country	Egypt
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 19154: 25-05-2018
	Fee including differential fee	PKR 100,000/-: 25-05-2018
	Brand Name +Dosage Form + Strength	Neomycan 56% Water soluble powder
	Composition	Each 100g contains: Neomycin sulphate 81.25gm equivalent to Neomycin……56.875gm
	Finished Product Specification	Firm has claimed in house specification
	Pharmacological Group	Aminoglycoside Antibiotic

Shelf life	2 Years
Demanded Price	250gm: Rs. 2900/- 1kg: Rs. 9800/-
Pack size	250g, 1Kg
International availability	NA
Me-too status	Could not be confirmed.
Detail of certificates attached	Marketing authorization holder is neither manufacturer, nor involved in packaging, labelling dosage form manufactured by another company. • Original, legalized CoPP (No. 00031/2017/V) issued by General Directorate of Registration Ministry of Health dated 12 March 2017 confirms free sale status and GMP of the manufacturer. • Translated copy of Inspection report dated 12-07-2017 is submitted. • Copy of GMP certificate (No. 596/2017) valid till 12-7-2018 is also provided. • Legalized letter of authorization dated 28-09-2017 between M/s Atco Pharma for Pharmaceutcal Industries and M/s Chappal Enterprises is provided. • Original, legalized credentials of the manufacturer abroad are provided. • Original, legalized Free sale certificate (No. 00013/2016/V) dated 22-03-2016 issued by Ministry of Health, Central Administration for Pharmaceutical Affairs, General Directorate of Registration is provided.

Remarks of the Evaluator.

- Firm has submitted accelerated Stability studies data of 3 batches, moreover the firm has submitted that 1st production batch is sampled in 04/2015 for real time stability study data, while the other two batches are under stability testing and they will be submitted upon completion of 2 years data.
- The letter of authorization is between applicant in Pakistan and manufacturer in Egypt i.e. ATCO Pharma for Pharmaceutical Industries while the product license holder / marketing authorization holder is ABO EL NAGA Trading Company, upon query firm has submitted that "*Abo El-Naga trading company is a branch of ATCO Pharma for pharmaceutical industries and it is also manufacturing its products in ATCO pharma's factory and both authorized* ***CHAPPAL ENTERPRISES*** *for submission of registration documents*"
  Website of Atco Pharma for Pharmaceutical industries Egypt have been checked (http://atcopharma.com/history.aspx) and the history of the firm clarifies that Abo El-Naga Trading Company worked as distributor in Egypt in 1990 and they developed their own factory with name ATCO Pharma for Pharmaceutical Industries in 2007 which got GMP certificate in 2011.

Decision of previous meeting of Registration Board:

Deferred for submission of real time stability study data of 3 batches conducted as per the requirements of zone IV-A for the complete shelf life. (**M-285)**

Evaluation by PEC:

Firm has now submitted real time stability study data sheets of 3 batches as per conditions of Zone IV-A for the following batches

Batch No.	Duration of stability study data
150244	36 months
150245	36 months
150246	36 months

Decision: Approved with Innovator's specifications and shelf life of 24 months as per Policy for inspection of Manufacturer abroad.

213.	Name and address of Applicant	M/s Unicare Enterprises Plot No. 587/1-B, street No. 3, Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad.
	Detail of Drug Sale License	**Address:** Plot No. 587/1-BStreet No. 3 Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad **Validity:** 20-10-2018 **Status:** License to sell drugs as "distributor"
	Name and address of manufacturer	Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain
	Name and address of marketing authorization holder	Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 328: 23-01-2017
	Fee including differential fee	PKR 100,000/-: 16-1-2017
	Brand Name +Dosage Form + Strength	Karidox 500mg/g water soluble powder
	Composition	Each gram powder contains: Doxycycline (as hyclate)……..500mg
	Finished Product Specification	Firm has claimed in house specification
	Pharmacological Group	Semi synthetic tetracycline
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	200g, 1Kg thermosealed bag
	International availability	Approved and available in Spain
	Me-too status	Could not be confirmed
	Detail of certificates attached	**GMP Certificate:** Copy of GMP certificate (No. ES/189HV/16) is provided by the firm which states inspection conducted on 19-10-2016. The GMP certificate has been verified from Eudra GMP database as well. **COPP:** Original, legalized CoPP confirming free sale and GMP of the manufacturer issued by Departmento de medicamentos Veterinarios Parque Empresarial Madrid Spain dated 21 July 2016 is provided. **Sole Agency Agreement:** Copy of sole agency agreement between the MA holder in Spain and applicant in Pakistan is provided.

Remarks of the Evaluator.

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

Observations	Response by the firm
Justify the use of this product in calves and poultry for treatment of fowl cholera, coryza, infectious synovitis, avian spirochaetosis, colibacillosis, salmonellosis, necrotic enteritis, ornithosis, coli diarrhea and liver abscess. (as claimed in your label), since this drug is approved in country of origin and reference regulatory authority i.e. Spain for use in Porcine for the treatment of clinical respiratory infections caused by strains of *Mycoplasma hyopneumoniae* and *Pasteurella multocida* sensitive to doxycycline and in Birds (Chickens and turkeys) for the treatment of clinical	Firm has submitted that this is a generic product and widely used in poultry and cattle in Pakistan and international reference countries.

	respiratory infections associated with *Mycoplasma gallisepticum* sensitive to doxycycline.	
	Justify the claimed shelf life of 36 months, since the submitted stability data proposed a shelf life of 24 months while the shelf life approved by the country of origin for this product is 18months.	Firm has requested that the same shelf life as approved in country of origin may be granted. Firm has not submitted stability study data at the conditions of zone IV-A.
	Evidence of applied formulation/drug already approved by DRAP (generic/ me-too status) along with registration number, brand name and name of firm	Firm has submitted three references for me-too status, none of them could be verified from database.
	Decision of 288th meeting of Registration Board	Deferred for the submission of Long term stability studies conducted under the conditions of zone IV-A of 3 batches till shelf life.
	Evaluation by PEC	The firm has submitted real time and accelerated stability study data of 3 batches as per zone IV-A requirements for real time data up to 36 months. Firm has also submitted me-too status Doxyveto-50 S Soluble Powder of Orient traders Reg # 023470
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	
214.	Name and address of Applicant	M/s Unicare Enterprises Plot No. 587/1-B, street No. 3, Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad.
	Detail of Drug Sale License	**Address:** Plot No. 587/1-BStreet No. 3 Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad **Validity:** 20-10-2018 **Status:** License to sell drugs as "distributor"
	Name and address of manufacturer	Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain
	Name and address of marketing authorization holder	Laboratorios Karizoo S.A. Pol. Ind. La Borda, Mas Pujades, 11-12 08140 Caldes de Montbui Barcelona Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy No. 327: 23-01-2017
	Fee including differential fee	PKR 100,000/-: 16-1-2017
	Brand Name +Dosage Form + Strength	Flortek 100mg/ml (solution for oral administration)
	Composition	Each ml solution contains: Florfenicol……100mg
	Finished Product Specification	Firm has claimed in house specification
	Pharmacological Group	Antimicrobials for systemic use
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	500ml, 1L, 5L
	International availability	Approved and available in Spain
	Me-too status	Naflor 100mg/ml Oral solution by Nawan Pharma (049514)
	Detail of certificates attached	**GMP Certificate:** Copy of GMP certificate (No. ES/189HV/16) is provided by the firm which states inspection conducted on 19-10-2016. The GMP certificate has been verified from Eudra GMP database as well. **COPP:** Original, legalized CoPP confirming free sale and GMP of the manufacturer issued by Departmento de medicamentos

	Veterinarios Parque Empresarial Madrid Spain dated 21 July 2016 is provided. **Sole Agency Agreement:** Copy of sole agency agreement between the MA holder in Spain and applicant in Pakistan is provided.

Remarks of the Evaluator.

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

Observations	**Response by the firm**
Justify the use of this product in poultry (as claimed in your label), since this drug is approved in country of origin and reference regulatory authority i.e. Spain for use in pigs for the treatment and prevention at the group level where clinical signs of swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* sensitive to florfenicol are present.	Firm has submitted that this is a generic drug and following registered products are already being effectively used in poultry. 1. Naflore by Nawan Laboratories (049514) 2. Neflox by Selmore (049647) 3. Rivaflor 100 by Mylab (074100) Firm has submitted copy of EMA report of committee for veterinary medicinal products for extension of florfenicol to chicken. This reports concludes the recommendation of inclusion of florfenicol for chicken with following condition: ***Not for use in animals from which eggs are produced for human consumption***
Justify the claimed shelf life of 36 months, since the submitted stability data is not conducted as per the requirements of Zone IV-A, furthermore the submitted stability data concludes that the product is not within established limits when kept for accelerated stability testing and thus proposes a shelf life of 18 months with specific recommendation to not store product above 25ºC. The shelf life approved by the country of origin for this product is also 18 months.	Firm has requested that the same shelf life as approved in country of origin may be granted. Firm has not submitted stability study data at the conditions of zone IV-A.

Decision of 288th meeting of Registration Board	Deferred for the submission of Long term stability studies conducted under the conditions of zone IV-A of 3 batches till shelf life.
Evaluation by PEC	The firm has submitted real time and accelerated stability study data of 3 batches as per zone IV-A requirements for real time data up to 36 months.

Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.

Case No. 04: Registration Applications of Drugs for which Stability Study Data is Submitted.

a. New cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
215.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Tenova Plus Tablet Each film coated tablet contains: Tenofovir alfenamide (as fumarate) ….25mg (Anti-viral)	Form 5D 23-05-2017 PKR 50,000/- (22-05-2017) (DUPLICATE DOSSIER)	Vemlidy Tablet by Gilead Sciences (**USFDA** Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Tenova Plus Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Shanghai Desano Chemical Pharmaceutical Co. Ltd. No. 417 Binhai Road, Laogang Town Pudong New Area Shanghai China.		
API Lot No.	DBH251-B15A-180301		
Description of Pack (Container closure system)	Light yellow color round biconvex film coated tablet plain from both sides and packed into Alu Alu foil in printed 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 (Months)		
Batch No.	18PD-2437-02-T	18PD-2438-03-T	18PD-2439-04-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Oct-2018	Oct-2018	Oct-2018
Date of Initiation	30-10-2018	30-10-2018	30-10-2018
No. of Batches	03		
Date of Submission	Dy.# 6151 dated 15-05-2019		

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	Firm has submitted copy of GMP certificate (No. SH20170046) issued by China Food and Drug

	manufacturer issued by regulatory authority of country of origin.	Administration valid till 3-12-2022. The submitted certificate is not verifiable from sfda website.
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 22-03-2018 specifying import of 0.4Kg tenofovir alafenamide fumarate along with 100mg working standard.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcoming communicated	Response received by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 75% after 30 minutes without defining 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 "we have set dissolution specification NLT 75% (Q) as per USFDA and USP general chapter 1092. As per FDA dissolution database the end point is given 30 min so to comply this reference we have set dissolution specification NLT 75% in 30 minutes. In all provided stability reports the dissolution results are more than 85%. After receiving NOD we thoroughly reviewed the literature and found that the product is BCS Class-III so we have to revise our current specification to **NLT 80% (Q=75%) in 15 minutes**. We have performed 9th month testing of stability samples kept on long term stability studies on this revised specification and conducted dissolution testing the results found are more than 80% in 15 minutes. The dissolution results at 9th month at 15 minutes are as follows: Sample No. | % 1 | 86.67 2 | 86.85 3 | 87.07 4 | 87.16 5 | 86.98 6 | 87.25 Average | 87.00 The finished product has been tested at dissolution specifications NLT 75% in 30 minutes throughout the stability studies while the required

	specifications should be NLT 85% (Q=80%) in 15 minutes. Firm has conducted dissolution testing at 9th month for samples kept at real time stability conditions and the results are close to the acceptance criteria i.e. 85%. Furthermore, the results for accelerated stability studies are not available as per the revised specifications.
GMP certificate of the API manufacturer, since the submitted GMP certificate is not verifiable from China Food and Drug Administration (sfda) website.	Firm has submitted two GMP certificates 1. Certificate No. SH20170046 issued by China Food and Drug Administration 2. Certificate No. SH180005 issued by Shanghai Food and Drug Administration. **Both GMP certificates could not be confirmed from online database.**
Specify, where the API was stored after ADC clearance in March 2018 till the manufacturing of batches in October 2018.	The response submitted by the firm is as follows: *"Material was received in factory on dated 10-4-2018 and then tested according to specification, material found well within the specification, after testing material was transferred to Product development department on 14-05-2018 and their material was* ***stored below 25°C****.* *Due to excessive load of other priority products development of this product delayed and started in August 2018 and after successful formulation in October 2018 it was charged on real time and accelerated stability study"* The API Tenofovir alafenamide fumarate is to be stored between 2-8°C which is revealed in the reference product literature as well as mentioned in the CoA of the API manufacturer.

Decision: Deferred for following:

- **Submission of valid GMP certificate of API manufacturer from the relevant regulatory authority of China.**
- **Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=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 75% after 30 minutes].**
- **Clarification and scientific justification for storing the API below 25°C while the certificate of analysis as well as reference product literature specifies that the API should be stored between 2 – 8°C.**

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
216.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Omrax 12.5mg Tablet Each film coated tablet contains: Omarigliptin….12.5mg (Antidiabetic)	Form 5D 14-03-2016 PKR 50,000/- (14-03-2016) (DUPLICATE DOSSIER)	Marizeb Tablet by MSD (PMDA Japan Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Omrax 12.5mg Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Ruyuan HEC Pharm Co. Ltd, Ruyuan County, Shaoguan City Guandong Province PR China		
API Lot No.	RD201803001		
Description of Pack (Container closure system)	Yellow color round biconvex shape film coated tablet plain from both sides and packed into Alu Alu foil in printed 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 (Months)		
Batch No.	18PD-2460-01-T	18PD-2461-02-T	18PD-2462-03-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Nov-2018	Nov-2018	Nov-2018
Date of Initiation	31-12-2018	31-12-2018	31-12-2018
No. of Batches	03		
Date of Submission	Dy.# 6151 dated 15-05-2019		

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 (No. DE_BE_01_GMP_2016_0021) issued by Landesamt fur Gesundheit und Soziales, Germany dated 31-05-2016 • Copy of letter and establishment inspection report by FDA dated 13-11-2015
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 20-04-2018 specifying import of 0.5Kg Omarigliptin along with 20mg impurity A and B each.
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

<table>
<tr><th>Shortcoming communicated</th><th>Response received by the firm</th></tr>
<tr><td>Justify the acceptance criteria of dissolution test i.e. NLT 75% after 30 minutes without defining 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. Moreover 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.</td><td>Firm has submitted that we have set the dissolution specification NLT 75% as per USFDA and USP.
In all provided stability reports the dissolution results are more than 80% on all intervals and in both conditions which indicates that all results are meeting the USP criteria S1 i.e. Q+5.
Accelerated stability data dissolution results
<table>
<tr><th>Batch No.</th><th>0 month</th><th>3 month</th><th>6month</th></tr>
<tr><td>18PD-2460-01-T</td><td>99.37</td><td>92.26</td><td>98.58</td></tr>
<tr><td>18PD-2461-02-T</td><td>100.42</td><td>87.02</td><td>98.07</td></tr>
<tr><td>18PD-2462-03-T</td><td>89.4</td><td>87.1</td><td>97.9</td></tr>
</table>
Real time stability data dissolution results
<table>
<tr><th>Batch No.</th><th>0 month</th><th>3 month</th><th>6month</th></tr>
<tr><td>18PD-2460-01-T</td><td>99.37</td><td>87.35</td><td>89.01</td></tr>
<tr><td>18PD-2461-02-T</td><td>100.42</td><td>86.76</td><td>90.24</td></tr>
<tr><td>18PD-2462-03-T</td><td>89.4</td><td>92.7</td><td>97.01</td></tr>
</table>
The exact BCS class of Omarigliptin is not yet identified by PMDA Japan. As per the literature, the solubility of omarigliptin is 543mg/L which makes it an intermediate to high soluble drug. Other gliptins like sitagliptin, vildagliptin, trelagliptin etc are all BCS-III class drugs. As per the USFDA guidelines the value of Q for such drugs should be 80% and for dissolution testing at S-1 level the dissolution limit will become 85% (i.e. Q+5%).

Out of trend (OOT) results can be seen although all results are still within acceptable criteria / specifications.
Some results at the borderline of acceptance criteria with 6 months data makes it scientifically difficult to predict the shelf life for 24 months.
Since this is a once weekly antidiabetic drug and the drug release from each unit will help to control the glycemic levels for whole week that’s why the dissolution results of this particular drug plays very important role.
</td></tr>
<tr><td>Submit the latest GMP certificate of the API manufacturer by the relevant regulatory authority of the country of origin.</td><td>Firm has again submitted the same inspection report of FDA dated 13-11-2015 and
copy of GMP certificate (No. DE_BE_01_GMP_2016_0021) issued by</td></tr>
</table>

	Landesamt fur Gesundheit und Soziales, Germany dated **31-05-2016**.
Justify the finished product specification without the test for content uniformity.	Firm has submitted that they are not performing content uniformity test on new drug product at initial stage but after getting registration from DRAP after inspection on commercial batches we include the test of content uniformity as per guidelines.
Scientific justification for dissolution parameters including type of apparatus, speed and dissolution medium is required.	Firm has submitted that they have selected apparatus **2 paddle** method and for rpm the range value of 50 to 75 rpm given we have selected **50 rpm**. Time point for immediate release products in USP BP JP and also FDA is given as 30 miutes so we have adopted this **30 minute** end point for our study. Dissolution medium selection water and dilute hydrochloric acid, buffers in pH range of 1.2 to 7.5 are given. But as omarigliptin is Japanese product son we have considered **0.01N HCl** as dissolution medium. As results founded well within specification we have adopted this dissolution medium. Firm has not specified the pH of dissolution medium used. Further the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH while the firm has used 0.01N HCl which has pH 2.0.
Specify the exact crystal form of the drug substance / API used in the stability study, since the innovator product have revealed that this drug substance have 5 crystal forms with different stability and solubility	Firm has submitted that the exact crystal form of omarigliptin used in stability batches in Form-V. Firm has also submitted copy of declaration provided by API manufacturer. The review report / Deliberation result report of the PMDA Japan approved product Marizeb (http://www.pmda.go.jp/drugs/2015/P20151007002/170050000_22700AMX01014000_A100_2.pdf Accessed on 23-08-2019) specifies under the heading Quality materials/<Outline of submitted materials>/API/Characteristics as *"The drug substance is recognized in five crystal forms. The production method produces only crystalline form-I (anhydride) which is stable at room temperature"*

Decision: Deferred for following:

- **Submission of valid GMP certificate of API manufacturer from the relevant regulatory authority of China.**
- **Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 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 the reference product [i.e. NLT 75% after 30 minutes].**
- **Scientific justification of the Out of Trend (OOT) results of dissolution data.**
- **Scientific justification for selection of dissolution medium (i.e. 0.01N HCl having pH 2.0), since the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH.**
- **Scientific justification for the use of crystal form-V of the drug substance, since the innovator product has used crystal form-I which is more soluble and stable at room temperature.**

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
217.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Omrax 25mg Tablet Each film coated tablet contains: Omarigliptin….25mg (Antidiabetic)	Form 5D 14-03-2016 PKR 50,000/- (14-03-2016) (DUPLICATE DOSSIER)	Malizeb Tablet by MSD (PMDA Japan Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Omrax 25mg Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Ruyuan HEC Pharm Co. Ltd, Ruyuan County, Shaoguan City Guandong Province PR China		
API Lot No.	RD201803001		
Description of Pack (Container closure system)	Yellow color round biconvex shape film coated tablet plain from both sides and packed into Alu Alu foil in printed 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 (Months)		
Batch No.	18PD-2463-03-T	18PD-2464-04-T	18PD-2465-05-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Nov-2018	Nov-2018	Nov-2018
Date of Initiation	07-01-2019	07-01-2019	07-01-2019
No. of Batches	03		
Date of Submission	Dy.# 6481 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 (No. DE_BE_01_GMP_2016_0021) issued by Landesamt fur Gesundheit und Soziales, Germany dated 31-05-2016 • Copy of letter and establishment inspection report

		by FDA dated 13-11-2015
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 20-04-2018 specifying import of 0.5Kg Omarigliptin along with 20mg impurity A and B each.
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

<table>
<tr><th>Shortcoming communicated</th><th>Response received by the firm</th></tr>
<tr><td>Justify the acceptance criteria of dissolution test i.e. NLT 75% after 30 minutes without defining 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. Moreover 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.</td><td>Firm has submitted that we have set the dissolution specification NLT 75% as per USFDA and USP.
In all provided stability reports the dissolution results are more than 80% on all intervals and in both conditions which indicates that all results are meeting the USP criteria S1 i.e. Q+5.
Accelerated stability data dissolution results
<table>
<tr><th>Batch No.</th><th>0 month</th><th>3 month</th><th>6month</th></tr>
<tr><td>18PD-2463-03-T</td><td>93.40</td><td><u>86.60</u></td><td>100.65</td></tr>
<tr><td>18PD-2464-04-T</td><td>95.66</td><td><u>86.88</u></td><td>96.68</td></tr>
<tr><td>18PD-2465-05-T</td><td>90.80</td><td>87.02</td><td><u>85.80</u></td></tr>
</table>
Real time stability data dissolution results
<table>
<tr><th>Batch No.</th><th>0 month</th><th>3 month</th><th>6month</th></tr>
<tr><td>18PD-2463-03-T</td><td>93.40</td><td><u>86.53</u></td><td><u>85.17</u></td></tr>
<tr><td>18PD-2464-04-T</td><td>95.66</td><td><u>86.77</u></td><td><u>84.99</u></td></tr>
<tr><td>18PD-2465-05-T</td><td>90.80</td><td>87.05</td><td>97.33</td></tr>
</table>
The exact BCS class of Omarigliptin is not yet identified by PMDA Japan. As per the literature, the solubility of omarigliptin is 543mg/L which makes it an intermediate to high soluble drug. Other gliptins like sitagliptin, vildagliptin, trelagliptin etc are all BCS-III class drugs. As per the USFDA guidelines the value of Q for such drugs should be 80% and for dissolution testing at S-1 level the dissolution limit will become 85% (i.e. Q+5%).
• Out of trend (OOT) results can be seen although</td></tr>
</table>

	all results are still within acceptable criteria / specifications. • Some results at the borderline of acceptance criteria with 6 months data makes it scientifically difficult to predict the shelf life for 24 months. • Since this is a once weekly antidiabetic drug and the drug release from each unit will help to control the glycemic levels for whole week that's why the dissolution results of this particular drug plays very important role.
Submit the latest GMP certificate of the API manufacturer by the relevant regulatory authority of the country of origin.	Firm has again submitted the same inspection report of FDA dated **13-11-2015** and copy of GMP certificate (No. DE_BE_01_GMP_2016_0021) issued by Landesamt fur Gesundheit und Soziales, Germany dated **31-05-2016**.
Justify the finished product specification without the test for content uniformity.	Firm has submitted that they are not performing content uniformity test on new drug product at initial stage but after getting registration from DRAP after inspection on commercial batches we include the test of content uniformity as per guidelines.
Scientific justification for dissolution parameters including type of apparatus, speed and dissolution medium is required.	Firm has submitted that they have selected apparatus 2 paddle method and for rpm the range value of 50 to 75 rpm given we have selected 50 rpm. Time point for immediate release products in USP BP JP and also FDA is given as 30 miutes so we have adopted this 30 minute end point for our study. Dissolution medium selection water and dilute hydrochloric acid, buffers in pH range of 1.2 to 7.5 are given. But as omarigliptin is Japanese product son we have considered 0.01N HCl as dissolution medium. As results founded well within specification we have adopted this dissolution medium. Firm has not specified the pH of dissolution medium used. Further the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH while the firm has used 0.01N HCl which has pH 2.0.
Specify the exact crystal form of the drug substance / API used in the stability study, since the innovator product have revealed that this drug substance have 5 crystal forms with different stability and solubility	Firm has submitted that the exact crystal form of omarigliptin used in stability batches in Form-V. Firm has also submitted copy of declaration provided by API manufacturer. The review report / Deliberation result report of the PMDA Japan approved product Marizeb (http://www.pmda.go.jp/drugs/2015/P20151007002/170050000_22700AMX01014000_A100_2.pdf Accessed on 23-08-2019) specifies under the heading Quality materials/<Outline of submitted materials>/API/Characteristics as *"The drug substance is recognized in five crystal forms. The production method produces only crystalline form-I (anhydride) which is stable at room temperature"*

Decision: Deferred for following:

- **Submission of valid GMP certificate of API manufacturer from the relevant regulatory authority of China.**
- **Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 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 the reference product [i.e. NLT 75% after 30 minutes].**
- **Scientific justification of the Out of Trend (OOT) results of dissolution data.**
- **Scientific justification for selection of dissolution medium (i.e. 0.01N HCl having pH 2.0), since the pKa of the drug is 8.1 and as per pH pKa relationship, the drug is more soluble at higher pH.**
- **Scientific justification for the use of crystal form-V of the drug substance, since the innovator product has used crystal form-I which is more soluble and stable at room temperature.**

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
218.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Doxab 15mg Tablet Each film coated tablet contains: Edoxaban (as tosylate monohydrate)….15mg Anticoagulant	Form 5D 09-02-2018 PKR 50,000/- (09-02-2018) (DUPLICATE DOSSIER)	Savaysa Tablet (USFDA Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Doxab 15mg Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Jiangsu Yongan Pharmaceutical Co. Ltd. No. 18, 237 Provincial Road, Economic Development Zone, Huaian, Jiangsu China.		
API Lot No.	0300-201604001		
Description of Pack (Container closure system)	Large orange to orange color round shape film coated tablet having a bisect line on one side and plain from other side		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 3, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	18PD-2206-02-T	18PD-2207-03-T	18PD-2208-04-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Jan-2018	Jan-2018	Jan-2018
Date of Initiation	26-04-2018	26-04-2018	26-04-2018
No. of Batches	03		

Date of Submission	Dy.# 6653 dated 21-05-2019

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 (No. JS20160548) issued by China Food and Drug Administration valid till 03-03-2021
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 23-05-2016 specifying import of 1200gm edoxaban tosylate.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcoming communicated	Response received by the firm
Justify the acceptance criteria of dissolution test i.e. NLT 75% after 30 minutes without defining 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.	Firm has submitted that we have set the dissolution specification NLT 75% as per USFDA and USP general chapter 1092. As per the revised specifications provided by the firm the value of "Q" is 75% and the overall acceptance criteria at S1 level is NLT 80% in 30 minutes.
Justify the difference in initial testing conducted at 23-01-2018 and initiation of stability studies at 26-04-2018.	Firm has submitted that *"the initial testing of edoxaban was carried out on 23-01-2018 and then initial testing report was provided to product development department, but delayed due to delay in blistering of this product due to other priority products"* The firm has performed initial testing on 23-01-2018 and the samples were placed in stability chambers on 26-04-2018, the impact of delay in initiation of stability studies on the outcomes of stability results needs to be determined.
Provide the detail of quantities of API used in the development and testing of Doxab 15, 30 and 60mg strengths, since the same material (imported vide invoice No. ZY16050503G/W) has been used for the development of all strengths of Doxab.	Firm has submitted material stock record for edoxaban which specifis that 28.865gm API is still remaining. According to the submitted stock record, the manufacturer of API is Suzhou Biotechnology Co.

	Ltd, while as per the rest of documents API manufacturer is Jiangsu Yongan Pharmaceutical Co. Ltd
Justify the finished product specification without the test for content uniformity	Firm has submitted that they are not performing content uniformity test on new drug product at initial stage but after getting registration from DRAP after inspection on commercial batches we include the test of content uniformity as per guidelines.

Decision: Deferred for following:

- **Scientific justification for initiation of stability studies 3 months after the initial testing of the applied product.**
- **Clarification since the manufacturer of API mentioned on submitted stock report is Suzhou Biotechnology Co. Ltd, while as per the rest of documents along with stability data the API manufacturer is Jiangsu Yongan Pharmaceutical 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
219.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Denzol 30mg Capsule Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….30mg	Form 5 08-01-2015 PKR 20,000/- (08-01-2015) + PKR 100,000/- (08-01-2015)	Dexilant capsule (**USFDA** Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Denzol 30mg Capsule
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.
Manufacturer of API	Alphamed Formulations Private Limited. Sy No. 225, Sampanbole village Shamirpet Mandal, Medchal-Malkajgiri District Telangana India.
API Lot No.	AJ3A8010
Description of Pack (Container closure system)	White to off white coated pellets filled in size No. 3 gelatin capsule having off white cap and off white body and packed into Alu Alu foil in printed 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 (Months)

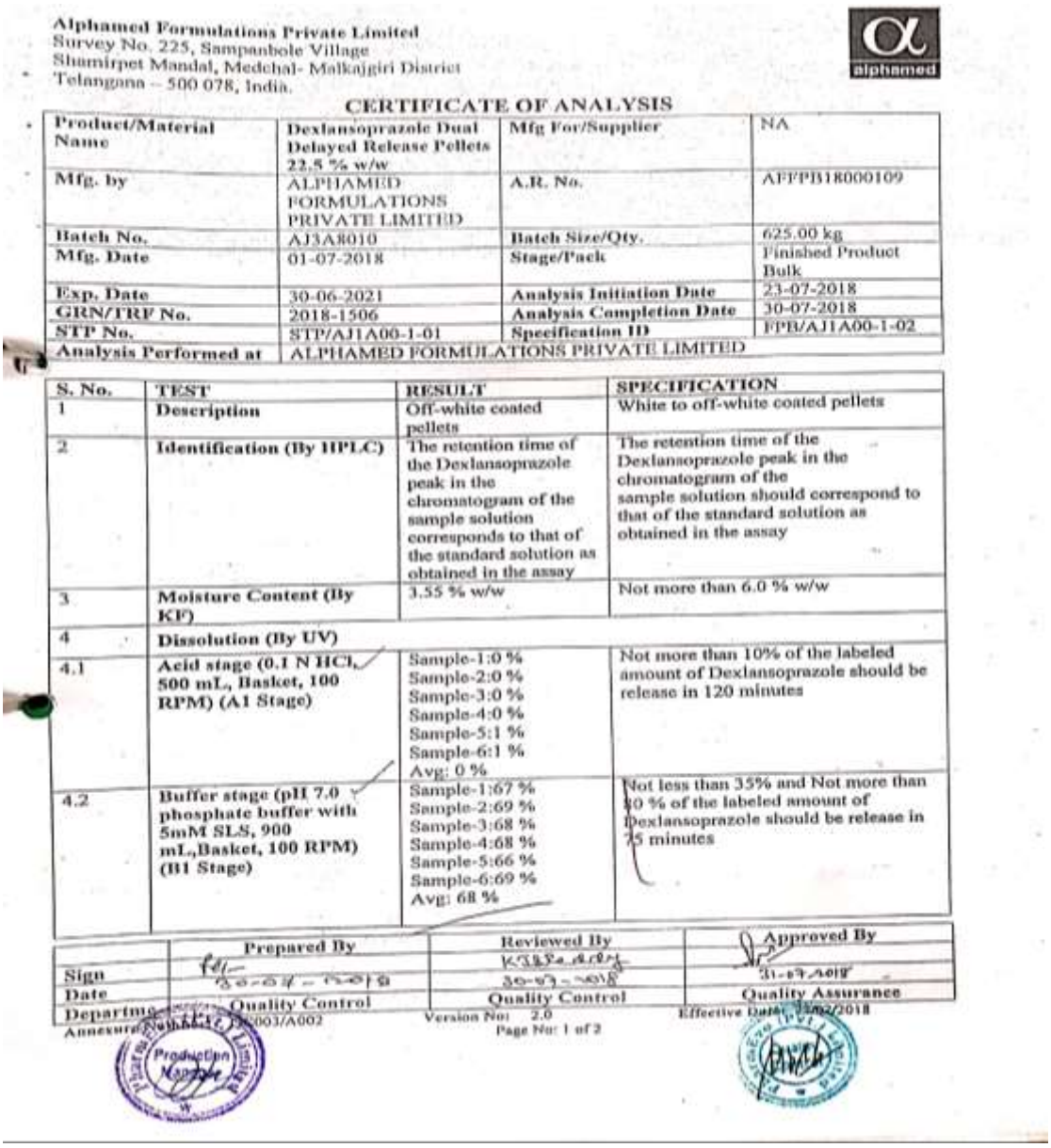
Batch No.	18PD-2428-01-T	18PD-2429-02-T	18PD-2430-03-T
Batch Size	2500 Capsule	2500 Capsule	2500 Capsule
Manufacturing Date	Oct-2018	Oct-2018	Oct-2018
Date of Initiation	20-10-2018	20-10-2018	20-10-2018
No. of Batches	03		
Date of Submission	Dy.# 7196 dated 27-05-2019		

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 Drugs Control Administration Government of Telangana dated 03-5-2017
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 08-08-2018 specifying import of 4Kg pellets
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- Firm has submitted two different COA from Alphamed which are totally contradictory with each other in terms of dissolution profiles.



Alphamed Formulations Private Limited
Survey No. 225, Sampanbole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

alphamed

CERTIFICATE OF ANALYSIS

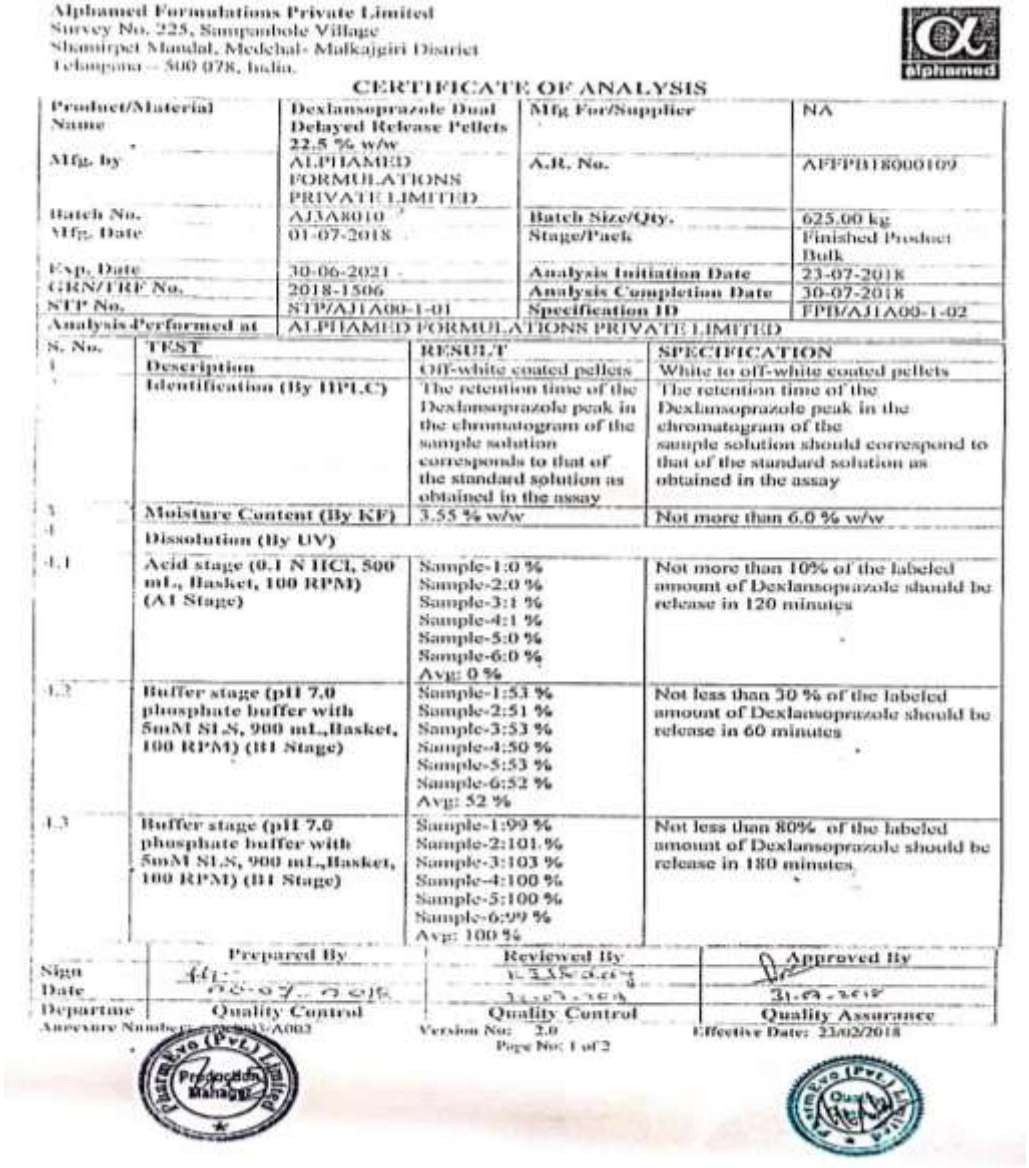
Product/Material Name	**Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w**	**Mfg For/Supplier**	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	**A.R. No.**	AFFPB18000109
Batch No.	AJ3A8010	**Batch Size/Qty.**	625.00 kg
Mfg. Date	01-07-2018	**Stage/Pack**	Finished Product Bulk
Exp. Date	30-06-2021	**Analysis Initiation Date**	23-07-2018
GRN/TRF No.	2018-1506	**Analysis Completion Date**	30-07-2018
STP No.	STP/AJ1A00-1-01	**Specification ID**	FPB/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	Off-white coated pellets	White to off-white coated pellets
2	**Identification (By HPLC)**	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	**Moisture Content (By KF)**	3.55 % w/w	Not more than 6.0 % w/w
4	**Dissolution (By UV)**		
4.1	**Acid stage (0.1 N HCl, 500 mL, Basket, 100 RPM) (A1 Stage)**	Sample-1:0 % Sample-2:0 % Sample-3:0 % Sample-4:0 % Sample-5:1 % Sample-6:1 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	**Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL,Basket, 100 RPM) (B1 Stage)**	Sample-1:67 % Sample-2:69 % Sample-3:68 % Sample-4:68 % Sample-5:66 % Sample-6:69 % Avg: 68 %	Not less than 35% and Not more than 80 % of the labeled amount of Dexlansoprazole should be release in 75 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date			31-07-2018
Departme	Quality Control	Quality Control	Quality Assurance

Annexure No: [illegible]/F/2003/A002 Version No: 2.0 Page No: 1 of 2 Effective Date: 15/02/2018

- As per the first COA (submitted along with stability data) attached above, the dissolution testing of pellets was carried out at acid stage and buffer stage at pH 7.0. At the buffer stage, the acceptance criteria are **NLT 35% and NMT 80% in 75 minutes.** As per the analytical report generated by the firm the acceptance criteria for buffer stage was **NLT 80% without specifying time**. Further the finished product specification of the firm NLT 75% in 75 minutes is also contradictory to the COA of pellets manufacturer. After letter of shortcoming, firm has submitted following COA



Alphamed Formulations Private Limited
Survey No. 225, Sampenbole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

alphamed

CERTIFICATE OF ANALYSIS

Product/Material Name	Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w	Mfg For/Supplier	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	A.R. No.	AFFPB18000109
Batch No.	AJ3A8010	Batch Size/Qty.	625.00 kg
Mfg. Date	01-07-2018	Stage/Pack	Finished Product Bulk
Exp. Date	30-06-2021	Analysis Initiation Date	23-07-2018
GRN/TRF No.	2018-1506	Analysis Completion Date	30-07-2018
STP No.	STP/AJ1A00-1-01	Specification ID	FPB/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Off-white coated pellets	White to off-white coated pellets
2	Identification (By HPLC)	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	Moisture Content (By KF)	3.55 % w/w	Not more than 6.0 % w/w
4	Dissolution (By UV)		
4.1	Acid stage (0.1 N HCl, 500 mL, Basket, 100 RPM) (A1 Stage)	Sample-1:0 % Sample-2:0 % Sample-3:1 % Sample-4:1 % Sample-5:0 % Sample-6:0 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL, Basket, 100 RPM) (B1 Stage)	Sample-1:53 % Sample-2:51 % Sample-3:53 % Sample-4:50 % Sample-5:53 % Sample-6:52 % Avg: 52 %	Not less than 30 % of the labeled amount of Dexlansoprazole should be release in 60 minutes
4.3	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL, Basket, 100 RPM) (B1 Stage)	Sample-1:99 % Sample-2:101 % Sample-3:103 % Sample-4:100 % Sample-5:100 % Sample-6:99 % Avg: 100 %	Not less than 80% of the labeled amount of Dexlansoprazole should be release in 180 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date	26-07-2018	30-07-2018	31-07-2018
Departme	Quality Control	Quality Control	Quality Assurance

Annexure Number: ANNEXURE/A003 Version No: 2.0 Effective Date: 23/02/2018
Page No: 1 of 2

Production Manager

- The second COA of alphamed submitted by the firm (Pharmevo) is of the same batch AJ3A8010 signed on the same dates but with totally different release specification. As per new COA the average release of pellets at pH 7.0 is 100% while that mentioned in previous COA was 68%. As per new COA the testing of pellets at pH 7.0 is conducted at two different stages at two specifications i.e. NLT 30% in 60 minutes and NLT 80% in 180 minutes.
- Further, since the firm has submitted that their finished product specifications is NLT 75% in 75 minutes and as per the response provided by firm, the release of pellets was more than 80% in 75 minutes, while as per the COA of pellets release is NLT 80% in 180 minutes.
- Further the firm has not performed testing of pellets at pH 5.5 as per the requirements of Registration Board.

Shortcoming communicated	Response received by the firm
Scientific justification is required for the adaptation of dissolution specification (NLT 75% in 75 minutes) in buffer stage for finished product in the light of general monographs of USP/BP and FDA guidance on "Dissolution Testing of Immediate Release Solid Oral Dosage Forms"	Firm has submitted that as per USFDA recommended dissolution method the end time point is 120 minutes for acid as well as buffer stage. We have set specification NLT 75% after 75 minutes in buffer stage as when we tested the pellets at initial stage the release was more than 80% in 75 minutes so we shortened the specified time point of 120 minutes to 75 minutes.

Decision: Deferred for following:

- **Scientific justification of submission of 2 different certificate of analysis from the pellets manufacturer Alphamed Formulations of the same batch with same analysis date and signature but with different limits and tests for dissolution of pellets.**
- **Scientific justification of adaptation of dissolution limits for the finished product in the buffer stage i.e. NLT 75% in 75 minutes which is contradictory to the dissolution of pellets (i.e. NLT 80% in 180 minutes) as well as the reference product. Furthermore clarification is required how the capsule can provide sustained release effect if the dissolution is not less than 75% in 75 minutes.**
- **Scientific justification of not performing dissolution testing of the pellets at buffer stage pH 5.5 before the filling of pellets for confirmation of dual delayed release action and to comply with the decision of Registration Board.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
220.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Denzol 60mg Capsule Each capsule contains: Dexlansoprazole (as dual delayed release pellets)…….60mg	Form 5 08-01-2015 PKR 20,000/- (08-01-2015) + PKR 100,000/- (08-01-2015) (DUPLICATE DOSSIER)	Dexilant capsule (USFDA Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Denzol 60mg Capsule		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Alphamed Formulations Private Limited. Sy No. 225, Sampanbole village Shamirpet Mandal, Medchal-Malkajgiri District Telangana India.		
API Lot No.	AJ3A8010		
Description of Pack (Container closure system)	White to off white coated pellets filled in size No. 3 gelatin capsule having off white cap and off white body and packed into Alu Alu foil in printed 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 (Months)		
Batch No.	18PD-2425-01-T	18PD-2426-02-T	18PD-2427-03-T
Batch Size	2500 Capsule	2500 Capsule	2500 Capsule

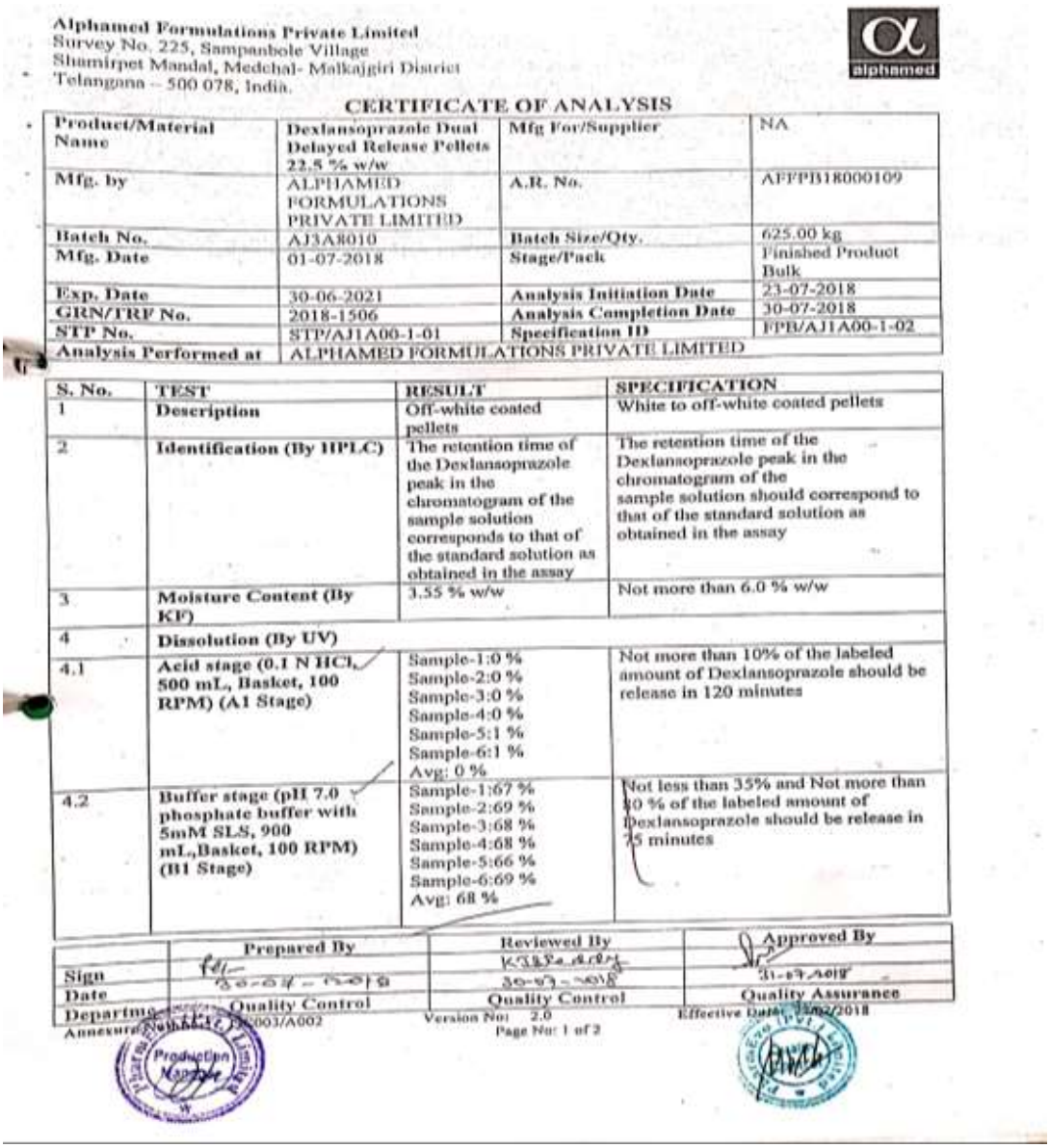
Manufacturing Date	Sep-2018	Sep-2018	Sep-2018
Date of Initiation	30-10-2018	30-10-2018	30-10-2018
No. of Batches	03		
Date of Submission	Dy.# 7195 dated 27-05-2019		

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 Drugs Control Administration Government of Telangana dated 03-5-2017
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted ADC attested invoice dated 08-08-2018 specifying import of 4Kg pellets
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- Firm has submitted two different COA from Alphamed which are totally contradictory with each other in terms of dissolution profiles.



Alphamed Formulations Private Limited
Survey No. 225, Sampanhole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

alphamed

CERTIFICATE OF ANALYSIS

Product/Material Name	**Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w**	**Mfg For/Supplier**	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	**A.R. No.**	APFPB18000109
Batch No.	AJ3A8010	**Batch Size/Qty.**	625.00 kg
Mfg. Date	01-07-2018	**Stage/Pack**	Finished Product Bulk
Exp. Date	30-06-2021	**Analysis Initiation Date**	23-07-2018
GRN/TRF No.	2018-1506	**Analysis Completion Date**	30-07-2018
STP No.	STP/AJ1A00-1-01	**Specification ID**	FPB/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	**Description**	Off-white coated pellets	White to off-white coated pellets
2	**Identification (By HPLC)**	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	**Moisture Content (By KF)**	3.55 % w/w	Not more than 6.0 % w/w
4	**Dissolution (By UV)**		
4.1	**Acid stage (0.1 N HCl, 500 mL, Basket, 100 RPM) (A1 Stage)**	Sample-1:0 % Sample-2:0 % Sample-3:0 % Sample-4:0 % Sample-5:1 % Sample-6:1 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	**Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL,Basket, 100 RPM) (B1 Stage)**	Sample-1:67 % Sample-2:69 % Sample-3:68 % Sample-4:68 % Sample-5:66 % Sample-6:69 % Avg: 68 %	Not less than 35% and Not more than 80 % of the labeled amount of Dexlansoprazole should be release in 75 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date	30-07-2018	30-07-2018	31-07-2018
Department	Quality Control	Quality Control	Quality Assurance

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- As per the first COA (submitted along with stability data) attached above, the dissolution testing of pellets was carried out at acid stage and buffer stage at pH 7.0. At the buffer stage, the acceptance criteria are **NLT 35% and NMT 80% in 75 minutes.** As per the analytical report generated by the firm the acceptance criteria for buffer stage was **NLT 80% without specifying time**. Further the finished product specification of the firm NLT 75% in 75 minutes is also contradictory to the COA of pellets manufacturer. After letter of shortcoming, firm has submitted following COA

Alphamed Formulations Private Limited
Survey No. 225, Sampanhole Village
Shamirpet Mandal, Medchal- Malkajgiri District
Telangana – 500 078, India.

CERTIFICATE OF ANALYSIS

Product/Material Name	Dexlansoprazole Dual Delayed Release Pellets 22.5 % w/w	Mfg For/Supplier	NA
Mfg. by	ALPHAMED FORMULATIONS PRIVATE LIMITED	A.R. No.	AFFPB18000109
Batch No.	AJ3A8010	Batch Size/Qty.	625.00 kg
Mfg. Date	01-07-2018	Stage/Pack	Finished Product Bulk
Exp. Date	30-06-2021	Analysis Initiation Date	23-07-2018
GRN/TRF No.	2018-1506	Analysis Completion Date	30-07-2018
STP No.	STP/AJ1A00-1-01	Specification ID	FPB/AJ1A00-1-02
Analysis Performed at	ALPHAMED FORMULATIONS PRIVATE LIMITED		

S. No.	TEST	RESULT	SPECIFICATION
1	Description	Off-white coated pellets	White to off-white coated pellets
2	Identification (By HPLC)	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution corresponds to that of the standard solution as obtained in the assay	The retention time of the Dexlansoprazole peak in the chromatogram of the sample solution should correspond to that of the standard solution as obtained in the assay
3	Moisture Content (By KF)	3.55 % w/w	Not more than 6.0 % w/w
4	Dissolution (By UV)		
4.1	Acid stage (0.1 N HCl, 500 mL, Basket, 100 RPM) (A1 Stage)	Sample-1:0 % Sample-2:0 % Sample-3:1 % Sample-4:1 % Sample-5:0 % Sample-6:0 % Avg: 0 %	Not more than 10% of the labeled amount of Dexlansoprazole should be release in 120 minutes
4.2	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL,Basket, 100 RPM) (B1 Stage)	Sample-1:53 % Sample-2:51 % Sample-3:53 % Sample-4:50 % Sample-5:53 % Sample-6:52 % Avg: 52 %	Not less than 30 % of the labeled amount of Dexlansoprazole should be release in 60 minutes
4.3	Buffer stage (pH 7.0 phosphate buffer with 5mM SLS, 900 mL,Basket, 100 RPM) (B1 Stage)	Sample-1:99 % Sample-2:101 % Sample-3:103 % Sample-4:100 % Sample-5:100 % Sample-6:99 % Avg: 100 %	Not less than 80% of the labeled amount of Dexlansoprazole should be release in 180 minutes

	Prepared By	Reviewed By	Approved By
Sign			
Date	26-07-2018	30-07-2018	31-07-2018
Departme	Quality Control	Quality Control	Quality Assurance

Annexure Number: QC/003/A003 Version No: 2.0 Effective Date: 23/02/2018
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- The second COA of alphamed submitted by the firm (Pharmevo) is of the same batch AJ3A8010 signed on the same dates but with totally different release specification. As per new COA the average release of pellets at pH 7.0 is 100% while that mentioned in previous COA was 68%. As per new COA the testing of pellets at pH 7.0 is conducted at two different stages at two specifications i.e. NLT 30% in 60 minutes and NLT 80% in 180 minutes.
- Further, since the firm has submitted that their finished product specifications is NLT 75% in 75 minutes and as per the response provided by firm, the release of pellets was more than 80% in 75 minutes, while as per the COA of pellets release is NLT 80% in 180 minutes.
- Further the firm has not performed testing of pellets at pH 5.5 as per the requirements of Registration Board.

Shortcoming communicated	Response received by the firm
Scientific justification is required for the adaptation of dissolution specification (NLT 75% in 75 minutes) in buffer stage for finished product in the light of general monographs of USP/BP and FDA guidance on "Dissolution Testing of Immediate Release Solid Oral Dosage Forms"	Firm has submitted that as per USFDA recommended dissolution method the end time point is 120 minutes for acid as well as buffer stage. We have set specification NLT 75% after 75 minutes in buffer stage as when we tested the pellets at initial stage the release was more than 80% in 75 minutes so we shortened the specified time point of 120 minutes to 75 minutes.

Decision: Deferred for following:

- **Scientific justification of submission of 2 different certificate of analysis from the pellets**

manufacturer Alphamed Formulations of the same batch with same analysis date and signature but with different limits and tests for dissolution of pellets.

- **Scientific justification of adaptation of dissolution limits for the finished product in the buffer stage i.e. NLT 75% in 75 minutes which is contradictory to the dissolution of pellets (i.e. NLT 80% in 180 minutes) as well as the reference product. Furthermore clarification is required how the capsule can provide sustained release effect if the dissolution is not less than 75% in 75 minutes.**
- **Scientific justification of not performing dissolution testing of the pellets at buffer stage pH 5.5 before the filling of pellets for confirmation of dual delayed release action and to comply with the decision of Registration Board.**

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
221.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.	Rofmast 250mcg Tablet Each tablet contains: Roflumilast ……..250mcg	Form 5-D (DUPLICATE) 22-12-2011 PKR 15,000/- 22-12-2011 + PKR 35,000/- 27-05-2016 As per SRO	Daliresp tablet by Astrazaneca (**USFDA** Approved) Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Rofmast 250mcg Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Glenmark Life Sciences Limited. A-80, MIDC, Kurkumbh 413802, Dist Pune-Zone 4.		
API Lot No.	83160631		
Description of Pack (Container closure system)	White color round biconvex core uncoated tablet plain from both sides and packed into Alu-Alu foil in printed 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 (Months)		
Batch No.	18PD-2399-05-T	18PD-2400-06-T	18PD-2401-07-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Aug-2018	Aug-2018	Aug-2018
Date of Initiation	27-09-2018	27-09-2018	27-09-2018

No. of Batches	03
Date of Submission	Dy.# 4994 dated 02-05-2019

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 (No. 6086071) issued by FDA Mahrashtra which is valid till28-01-2020
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.	Firm has submitted ADC attested invoice dated 01-12-2016 specifying import of 0.04Kg API
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Shortcoming communicated	Response by the firm
Particle size distribution of the drug substance needs to be submitted, since the USFDA approved innovator product (Daliresp tablet) has used API (roflumilast) micronized to a defined particle size distribution for formulation, due to its low water solubility (0.52-0.56 mg/L at 21-22°C). The FDA review further specifies that the particle size distribution of the roflumilast is observed to directly correlate with the dissolution or drug release from the dosage form (available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000ChemR.pdf).	Particle size distribution is performed by the manufacturer i.e. Glenmark India and the detailed COA from the manufacturer also reveals particle size distribution as: D(10) 3.7µ D(50) 11.1µ D(90) 22.9µ
• Justify the dissolution specification NLT 75% in 45 minutes, since the dissolution specification of the USFDA approved innovator product (Daliresp tablet) is NLT 85% in 30 minutes as revealed in administrative and correspondence documents section of NDA approval USFDA available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000AdmincorresR.pdf.	Firm has submitted that they have adapted dissolution specification (NLT 75% in 45 minutes) from FDA dissolution database. Further they inform that after receiving letter of shortcoming, they did literature review and found that the specification should be NLT 85% in 30 minutes. Firm has now revised the finished product specifications and also tested dissolution at 9th month time point. The results of dissolution at 9th month is as follows: Sample | Dissolution result (%)

	<table><tr><td>Sample 1</td><td>86.04</td></tr><tr><td>Sample 2</td><td>87.86</td></tr><tr><td>Sample 3</td><td>89.19</td></tr><tr><td>Sample 4</td><td>87.98</td></tr><tr><td>Sample 5</td><td>88.51</td></tr><tr><td>Sample 6</td><td>89.71</td></tr></table> • Whether dissolution test results close to acceptance criteria when tested only at 9th month without having dissolution data at accelerated conditions at the revised specification is scientifically justifiable for grant of 2 years shelf life.
• Justify the use of potency of standard as 99.44% in calculation of assay, since the assay (on anhydrous basis) mentioned in certificate of analysis is 99.34%.	Firm has submitted that the: Potency of COA by Glenmark India is as: Anhydrous basis: 99.50% As is basis: 99.44% Potency of COA by pharmevo Anhydrous basis: 99.34% As is basis: 98.6% Firm has submitted that they have used the as is basis potency from the COA of Glenmark in all the three stability batches. • The firm has submitted COA for testing of API, signed on 20-11-2016 while the same COA specifies that the material was received on 16-12-2016 and the ADC clearance was also granted on 01-12-2016. • Justification of use of assay values on as is basis from the COA of API manufacturer, while the firm has also tested the API and generated COA against their own test results.

Decision: Deferred for following:

- **Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 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 75% after 45 minutes].**
- **Clarification on how the firm has generated the certificate of analysis / analytical report for testing of API on 20.11.2016, while the material was cleared by AD, DRAP on 01.12.2016.**
- **Scientific justification on use of assay values on as is basis (i.e. 99.44%) mentioned on the certificate of analysis of API manufacturer, since the firm has also tested the API and generated analytical test report having slightly different values for assay (i.e. 98.60%).**

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
222.	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western	Rofmast 500mcg Tablet Each tablet contains:	Form 5-D (DUPLICATE) 22-12-2011	Daliresp tablet by Astrazaneca (**USFDA** Approved)

	Industrial zone, Port Qasim, Karachi.	Roflumilast…….500 mcg	PKR 15,000/- 22-12-2011 + PKR 35,000/- 27-05-2016 As per SRO	Last inspection dated 23-02-2018 confirms that the firm is operating at an acceptable 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	Rofmast 500mcg Tablet		
Name of Manufacturer	M/s Pharmevo (Pvt) Ltd., Plot # A-29, North Western Industrial zone, Port Qasim, Karachi.		
Manufacturer of API	Glenmark Life Sciences Limited. A-80, MIDC, Kurkumbh 413802, Dist Pune-Zone 4.		
API Lot No.	83160631		
Description of Pack (Container closure system)	White color round biconvex core uncoated tablet plain from both sides and packed into Alu-Alu foil in printed 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 (Months)		
Batch No.	18PD-2402-06-T	18PD-2403-07-T	18PD-2404-08-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	Aug-2018	Aug-2018	Aug-2018
Date of Initiation	27-09-2018	27-09-2018	27-09-2018
No. of Batches	03		
Date of Submission	Dy.# 5852 dated 09-05-2019		

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 (No. 6086071) issued by FDA Mahrashtra which is valid till28-01-2020
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.	Firm has submitted ADC attested invoice dated 01-12-2016 specifying import of 0.04Kg API
6.	All provided documents will be attested (name,	Yes

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

REMARKS OF EVALUATOR

Shortcoming communicated	Response by the firm
Particle size distribution of the drug substance needs to be submitted, since the USFDA approved innovator product (Daliresp tablet) has used API (roflumilast) micronized to a defined particle size distribution for formulation, due to its low water solubility (0.52-0.56 mg/L at 21-22°C). The FDA review further specifies that the particle size distribution of the roflumilast is observed to directly correlate with the dissolution or drug release from the dosage form (available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000ChemR.pdf).	Particle size distribution is performed by the manufacturer i.e. Glenmark India and the detailed COA from the manufacturer also reveals particle size distribution as: D(10) 3.7µ D(50) 11.1µ D(90) 22.9µ
• Justify the dissolution specification NLT 75% in 45 minutes, since the dissolution specification of the USFDA approved innovator product (Daliresp tablet) is NLT 85% in 30 minutes as revealed in administrative and correspondence documents section of NDA approval USFDA available at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2011/022522Orig1s000AdmincorresR.pdf.	Firm has submitted that they have adapted dissolution specification (NLT 75% in 45 minutes) from FDA dissolution database. Further they inform that after receiving letter of shortcoming, they did literature review and found that the specification should be NLT 85% in 30 minutes. Firm has now revised the finished product specifications and also tested dissolution at 9th month time point. The results of dissolution at 9th month is as follows: Sample 1: 86.04 Sample 2: 87.86 Sample 3: 89.19 Sample 4: 87.98 Sample 5: 88.51 Sample 6: 89.71 • Whether dissolution test results close to acceptance criteria when tested only at 9th month without having dissolution data at accelerated conditions at the revised specification is scientifically justifiable for grant of 2 years shelf life.
• Justify the use of potency of standard as 99.44% in calculation of assay, since the assay (on anhydrous basis) mentioned in certificate of analysis is 99.34%.	Firm has submitted that the: Potency of COA by Glenmark India is as: Anhydrous basis: 99.50% As is basis: 99.44% Potency of COA by pharmevo Anhydrous basis: 99.34% As is basis: 98.6% Firm has submitted that they have used the as is basis potency from the COA of Glenmark in all the three stability batches.

	• The firm has submitted COA for testing of API, signed on 20-11-2016 while the same COA specifies that the material was received on 16-12-2016 and the ADC clearance was also granted on 01-12-2016. • Justification of use of assay values on as is basis from the COA of API manufacturer, while the firm has also tested the API and generated COA against their own test results.

Decision: Deferred for following:

- **Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=80%) in 30 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 75% after 45 minutes].**
- **Clarification on how the firm has generated the certificate of analysis / analytical report for testing of API on 20.11.2016, while the material was cleared by AD, DRAP on 01.12.2016.**
- **Scientific justification on use of assay values on as is basis (i.e. 99.44%) mentioned on the certificate of analysis of API manufacturer, since the firm has also tested the API and generated analytical test report having slightly different values for assay (i.e. 98.60%).**

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
223.	M/s Wilson Pharmaceuticals 387-388, I-9 Industrial Area, Islamabad.	Nib-Sol AF Tablet 80mg Each tablet contains: Sotalol hydrochloride….80mg (anti-arrhythmic) USP Specs	Form 5 Dy No. 41801 07-12-2018 PKR 20,000/- 07-12-2018 10's, 20's, 100's: As per SRO	Betapace Tablet (**USFDA** Approved) Last GMP Inspection conducted on 23-01-2018 and report concludes that overall firm was found to be operating at a very good level of GMP compliance.
	Remarks of Evaluator: The firm has submitted stability study data along with required documents as per checklist approved in 251st meeting of Registration Board. Detailsof submitted data are as under: **(Dy.# 6165 dated 15-05-2019)**			

STABILITY STUDY DATA	
Drug	Nib-Sol AF Tablet 80mg
Name of Manufacturer	M/s Wilson Pharmaceuticals 387-388, I-9 Industrial Area, Islamabad.
Manufacturer of API	M/s Neuland Laboratories Limited, Bonthapally (V), Veerabhadraswamy Temple Road, Gummadidala (M) Sangareddey District Telangana India.
API Lot No.	SH10218023
Description of Pack (Container closure system)	Alu-Alu strips

Stability Storage Condition	Real time : 30°C ± 2°C / 65% ± 5%RH Accelerated: 40°C ± 2°C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial #1	Trial #2	Trial #3
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	05-2018	05-2018	05-2018
Date of Initiation	28-05-2018	28-05-2018	28-05-2018
No. of Batches	03		

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 Drugs Control Administration Govt of Telangana dated 14-06-2017
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of license to import dated 02-02-2018 Firm has also submitted copy of commercial invoice attested by ADC dated 3-3-2018 confirming import of 2Kg API
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

- The applied formulation is a generic drug as "SOTACOR TABLET" Registration number 001193 is already registered. The firm has submitted its stability study data and requested to consider it "out-of-queue" on the basis of stability study data.
- Registration Board in its 261st meeting decided as follows:
  "Those applicants who submit stability studies data, may be incentivized through preferential treatment for consideration for registration of the product"
- Firm has also applied exemption from onsite inspection, but since it is a generic drug and as per the practice product specific inspections are not conducted for such drugs, therefore the stability data is presented before the Board for further guidance.

Decision: Registration Board after reviewing the stability study data and keeping in view that the applied product is a generic drug decided to approve the product with USP specification.

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
224.	M/s Wilson Pharmaceuticals 387-388, I-9 Industrial Area, Islamabad.	Nib-Sol AF Tablet 160mg Each tablet contains: Sotalol hydrochloride….160mg (anti-arrhythmic) USP Specs	Form 5D Dy No. 16636 07-03-2019 PKR 50,000/- 07-03-2019 As per SRO	Betapace Tablet (**USFDA** Approved) Last GMP Inspection conducted on 23-01-2018 and report concludes that overall firm was found to be operating at a very good level of GMP compliance.
	Remarks of Evaluator: The firm has submitted stability study data along with required documents as per checklist approved in 251st meeting of Registration Board. Detailsof submitted data are as under: **(Dy.# 6165 dated 15-05-2019)**			

STABILITY STUDY DATA			
Drug	Nib-Sol AF Tablet 160mg		
Name of Manufacturer	M/s Wilson Pharmaceuticals 387-388, I-9 Industrial Area, Islamabad.		
Manufacturer of API	M/s Neuland Laboratories Limited, Bonthapally (V), Veerabhadraswamy Temple Road, Gummadidala (M) Sangareddey District Telangana India.		
API Lot No.	SH10218023		
Description of Pack (Container closure system)	Alu-Alu strips		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 65% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
Time Period	Real time: 6 months Accelerated: 6 months		
Frequency	Accelerated: 0, 1, 2, 3, 4, 6 (Months) Real Time: 0, 3, 6 (Months)		
Batch No.	Trial #1	Trial #2	Trial #3
Batch Size	1500 Tablet	1500 Tablet	1500 Tablet
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	08-06-2018	08-06-2018	08-06-2018
No. of Batches	03		

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 Drugs Control Administration Govt of Telangana dated 14-06-2017
3.	Protocols followed for conduction of stability study and details of tests.	Yes

4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Firm has submitted copy of license to import dated 02-02-2018 Firm has also submitted copy of commercial invoice attested by ADC dated 3-3-2018 confirming import of 2Kg API
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
DATA FOR EXEMPTION FROM ONSITE INVESTIGATION OF SUBMITTED STABILITY DATA		
ADMINISTRATIVE PORTION		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to their last inspection report for their product "saferon tablet " Registration Board in its 269 and 278th meeting decided to approve Registration of "Saferon (Sofosbuvir 400mg) tablets by M/s Wilson Pharmaceuticals, I-9 Industrial Area, Islamabad in its 278th Meeting. Date of Inspection: 10-12-2015 , 19-04-2017 & 20-01-2018 □ Software of HPLC present in the firm is 21CFR compliant and audit trail on the testing reports was available and confirmed.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	• Firm has submitted copy of license to import dated 02-02-2018 • Firm has also submitted copy of commercial invoice attested by ADC dated 3-3-2018 confirming import of 2Kg API
3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted copy of invoice for purchase of working standard.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted copy of GMP certificate issued by Drugs Control Administration Govt of Telangana dated 14-06-2017
5.	Mechanism for Vendor pre-qualification	Firm has submitted SOP for evaluation of suppliers and vendors
6.	Certificate of analysis of the API, reference standards and impurity standards	Firm has submitted COA of API and working standard.
7.	Documents for the procurement of excipients used in product development?	Firm has submitted documents for procurement of excipients.
8.	List of qualified staff involved in product development with relevant experience.	Firm has provided list of 12 technical staff of product development section.
PRODUCTION DATA		
9.	Authorized Protocols/SOP for the development &	Firm has submitted authorized protocols/SOPs for

	stability testing of trial batches.	the development & testing of trial batches.
10.	Complete batch manufacturing record of three stability batches.	Firm has provided Batch Manufacturing Record for all the three batches
11.	Record of remaining quantities of stability batches.	Firm has provided following remaining quantities for each batch • Trial # 02: 314 Tablets • Trial # 03: 314 Tablets • Trial # 04: 314 Tablets
QA/QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted record of Digital data logger for temperature and humidity monitoring of stability chambers.
13.	Method used for analysis of API along with COA.	Firm has submitted COA and method of analysis of API.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has submitted complete record of real time and accelerated stability testing of 3 batches of finished product. Firm has performed testing as per USP method since the finished product monograph is available in USP
15.	Reports of stability studies of API from manufacturer.	Firm has submitted both accelerated (40°C ± 2°C & 75±5%RH) stability studies & long term (30°C ± 2°C & 65±5%RH) stability studies reports of three batches.
16.	Analysis reports for excipients used.	Firm has submitted analysis reports for all excipients used.
17.	Drug-excipients compatibility studies.	Firm has submitted that their formulation is as per innovator product. No incompatibilities of excipients with drug substance are observed during accelerated stability.
18.	Record of comparative dissolution data.	Firm has not performed comparative dissolution profile and submitted that the reference product is not available in Pakistan
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted certificate of compliance and audit trail reports for HPLC analysis for all the three batches.
Evaluation by PEC:		
Decision: Registration Board decided to approve registration of "Nib-Sol AF Tablet 160mg (Sotalol hydrochloride 160mg)" with USP specifications by Wilson Pharmaceuticals 387-388, I-9 Industrial Area, Islamabad. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.		

Case No. 05: Miscellaneous Cases

M/s Shrooq Pharmaceuticals have applied for following two cases, wherein firm has requested that they have applied for registration of these drugs and their application were considered by Registration Board in its 239 meeting and were rejected with following decision

Rejected as the firm has no external liquid preparation section

Now, the firm has submitted fresh applications for the registration of same product on 03-09-2018 and requested to consider them on "Out of queue" basis since there products were rejected although they have external liquid section at the time of consideration and rejection by the Board.

The firm has submitted evidence of approval of section Topical (Cream, ointment, Lotion & Gel) Dated 14-05-2005. The evidence of sections is mentioned on the back side of original DML.

225.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21-Km, Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Cleroz liquid 1.5% w/w
	Composition	Each gram contains: Ciclopirox olamine……..15mg
	Diary No. Date of R& I & fee	Dy No. 29489: 03-09-2018 PKR 20,000/-: 03-09-2018
	Pharmacological Group	Antifungal
	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.	Stieprox 15mg/g Shampoo by M/s GlaxoSmithKline (Ireland) Limited (**HPRA** Ireland Approved)
	Me-too status	Stieprox Topical Liquid by M/s GSK
	GMP status	The firm was last inspected on 07-06-2017 & 30-08-2017, wherein the panel recommended renewal of DML.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	
226.	Name and address of manufacturer / Applicant	M/s Shrooq Pharmaceuticals (Pvt) Ltd. 21-Km, Ferozepur Road Lahore
	Brand Name +Dosage Form + Strength	Micin-T Lotion
	Composition	Each ml of lotion contains: Clindamycin (as phosphate)……..10mg
	Diary No. Date of R& I & fee	Dy No. 29488: 03-09-2018 PKR 20,000/-: 03-09-2018
	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.	Dalacin T 1% Topical Solution (**MHRA** Approved)
	Me-too status	Clinbet Lotion by Seraph
	GMP status	The firm was last inspected on 07-06-2017 & 30-08-2017, wherein the panel recommended renewal of DML.
	Remarks of the Evaluator[3]	•
	Decision: Approved.	

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

a. New Cases.

227.	Name and address of manufacturer / Applicant	M/s A.H. Pharmaceuticals Labs Pvt Ltd. Plot No. 865/A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad 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	Cycladol 20mg Tablet
	Composition	Each Tablet Contains: Piroxicam Beta Cyclodextrin eq to Piroxicam …….20mg
	Diary No. Date of R& I & fee	Dy.No. 17073 dated 09-05-2018 Rs.50,000/- 09-05-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs
	Pack size & Demanded Price	2 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Cycladol tablet (ANSM approved)
	Me-too status	Pirujin Tablet M/s Jupiter Pharma
	GMP status	Last GMP inspection of A.H Pharmaceuticals conducted on 04-07-2017 and report concludes that Panel recommends renewal of DML & overall Evalution of Inspection report rating is 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	• Number of sections of applicant approved by licensing Board:**02** • Number of products already registered/approved on contract manufacturing in the name of applicant**: 05 products approved in 290th DRB meeting**
	Decision: Approved with innovator's specification.	
228.	Name and address of manufacturer / Applicant	M/s A.H. Pharmaceuticals Labs Pvt Ltd. Plot No. 865/A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad 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	Demerol CF Tablet
	Composition	Each Tablet Contains: Paracetamol…500mg Caffeine…65mg Chlorpheniramine…2mg
	Diary No. Date of R& I & fee	Dy.No. 17074 dated 09-05-2018 Rs.50,000/- 09-05-2018
	Pharmacological Group	Narcotic, Analgesic, Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs
	Pack size & Demanded Price	10 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Hesmol Extra tablets of M/s Wisdom Pharmaceuticals Reg # 078571

	GMP status	Last GMP inspection of A.H Pharmaceuticals conducted on 04-07-2017 and report concludes that Panel recommends renewal of DML & overall Evaluation of Inspection report rating is 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	• Inspection report of M/s A.H. Pharmaceuticals • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Number of sections of applicant approved by licensing Board:**02** • Number of products already registered/approved on contract manufacturing in the name of applicant: 05 products approved in 290th DRB 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.	
229.	Name and address of manufacturer / Applicant	M/s A.H. Pharmaceuticals Labs Pvt Ltd. Plot No. 865/A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad 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	Calac-D 5mg/ml Injection
	Composition	Each ml Contains: Cholecalciferol……5mg
	Diary No. Date of R& I & fee	Dy.No. 17075 dated 09-05-2018 Rs.50,000/- 09-05-2018
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form 5
	Finished product Specification	BP Spec's
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities	Vitamin D3 Good 200,000 IU / 1 ml IM solution for injection of (ANSM France approved)
	Me-too status	Calciferol Injection M/s Global Pharmaceuticals
	GMP status	Last GMP inspection of A.H Pharmaceuticals conducted on 04-07-2017 and report concludes that Panel recommends renewal of DML & overall Evalution of Inspection report rating is 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	• Number of sections of applicant approved by licensing Board:**02** • Number of products already registered/approved on contract manufacturing in the name of applicant: **05 products approved in 290th DRB meeting**
	Decision: Approved with change of brand name.	
230.	Name and address of manufacturer / Applicant	M/s A.H. Pharmaceuticals Labs Pvt Ltd. Plot No. 865/A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad 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	Ketlur 30mg/ml Injection

	Composition	Each ml Contains: Ketorolac Tromethamine…30mg
	Diary No. Date of R& I & fee	Dy.No. 17076 dated 09-05-2018 Rs.50,000/- 09-05-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1ml x 5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ketorolac of USFDA approved
	Me-too status	Tolek injection by Regal Pharmaceuticals
	GMP status	Last GMP inspection of A.H Pharmaceuticals conducted on 04-07-2017 and report concludes that Panel recommends renewal of DML & overall Evalution of Inspection report rating is 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	• Number of sections of applicant approved by licensing Board:**02** • Number of products already registered/approved on contract manufacturing in the name of applicant: 05 products approved in 290th DRB meeting
	Decision: Approved.	
231.	Name and address of manufacturer / Applicant	M/s A.H. Pharmaceuticals Labs Pvt Ltd. Plot No. 865/A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad 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	Moxibay 400MG Tablet
	Composition	Each Tablet Contains: Moxifloxacin HCl Eq to Moxifloxacin 400mg
	Diary No. Date of R& I & fee	Dy.No. 17072 dated 09-05-2018 Rs.50,000/- Dated 09-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs
	Pack size & Demanded Price	5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Avelox 400 mg of (MHRA approved)
	Me-too status	Moxox 400mg of M/s Wellborne Pharmachem and Biologicals
	GMP status	Last GMP inspection of A.H Pharmaceuticals conducted on 04-07-2017 and report concludes that Panel recommends renewal of DML & overall Evalution of Inspection report rating is 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	• Number of sections of applicant approved by licensing Board:**02** • Number of products already registered/approved on

		contract manufacturing in the name of applicant: 05 products approved in 290th DRB meeting
	Decision: Approved with change of brand name & innovator's specification.	
232.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	CPS 500mg IV/IM Injection
	Composition	Each Vial Contains: Cefoperazone as Sodium…….250mg Sulbactum as Sodium……..250mg
	Diary No. Date of R& I & fee	Dy.No. 16937 dated 08-05-2018 Rs.20,000/- 08-05-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	1's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status	Ceflactam Injection 500mg M/s Barret Hodgson
	GMP status	Last GMP inspection conducted on 04-07-2018and report concludes that their current GMP compliance level is rated as GOOD.
	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.	
233.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Lorex 5mg/5ml Syrup
	Composition	Each 5ml Contains: Loratadine……5mg
	Diary No. Date of R& I & fee	Dy.No. 22885 dated 02-07-2018 Rs.20,000/- 02-07-201
	Pharmacological Group	Antihistamines
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 100ml, 120ml & 450ml RS: 100/- per 60ml bottle RS: 200/- per 90ml bottle RS: 220/- per 100ml bottle RS: 300/- per 120ml bottle RS: 500/- per 450ml bottle
	Approval status of product in Reference Regulatory Authorities	Lorapaed Allergy Relief 5 mg/5 ml Oral Solution of MHRA approved
	Me-too status	Loratic Syrup M/s Spencer Pharmaceutical
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved.	
234.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	E-Best 20mg Tablet

	Composition	Each film coated tablet Contains: Ebastine……20mg
	Diary No. Date of R& I & fee	Dy.No. 22886 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	10's, 14's, 20's, ; RS: 50/Tablet
	Approval status of product in Reference Regulatory Authorities	EBASTINE ARROW 10 mg film-coated tablets ANSM Approved
	Me-too status	Atmos Tablets 10mg of M/s Scotmann Pharmaceuticals
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved.	
235.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ketofix Syrup 1mg/5ml
	Composition	Each 5ml contains: Ketotifen as hydrogen fumarate.…1mg
	Diary No. Date of R& I & fee	Dy.No. 22889 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	30ml, 60ml, 90ml, 100ml, 120ml & 450ml RS: 100/- per 30ml bottle RS: 200/- per 60ml bottle RS: 250/- per 90ml bottle RS: 300/- per 100ml bottle RS: 350/- per 120ml bottle RS: 1000/- per 4500ml bottle
	Approval status of product in Reference Regulatory Authorities	Zaditen 1 mg / 5 ml oral solution of ANSM approved
	Me-too status	Asthonex Syrup M/s Global Pharmaceuticals
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
236.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Parapol Extra Tablet 500mg/65mg
	Composition	Each tablet cobtains: Paracetamol…….500mg Caffeine…..65mg
	Diary No. Date of R& I & fee	Dy.No. 22894 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Analgesic /Xanthine
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's,100's,200's 400's 500's ; RS:20/-tablet
	Approval status of product in Reference Regulatory Authorities	Panadol Extra Tablets. Of MHRA approved
	Me-too status	Paratol Extra tablet of M/s Highnoon

	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved.	
237.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Famous Dry Suspension 40mg/5ml
	Composition	Each 5ml after reconstitution contains: Famotidine…40mg
	Diary No. Date of R& I & fee	Dy.No. 22888 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	H2-receptor antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml, 60ml, 90ml, 100ml, 120ml & 450ml RS: 100/- per 30ml bottle RS: 200/- per 60ml bottle RS: 250/- per 90ml bottle RS: 300/- per 100ml bottle RS: 350/- per 120ml bottle RS: 1000/- per 4500ml bottle
	Approval status of product in Reference Regulatory Authorities	Pepcid 40 mg/5 ml of Salix Pharma Inc., USA (USFDA)
	Me-too status	Antidine Dry powder suspension 40 mg/5 ml of Fynk Pharmaceuticals
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved.	
238.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Roxit 150mg Tablet
	Composition	Each film coated tablet contains: Roxithromycin…150mg
	Diary No. Date of R& I & fee	Dy.No.22893 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	10's, 20's,30's,40's 50's 60's,70's, 80's, 90's, 100's ; RS:100/-tablet
	Approval status of product in Reference Regulatory Authorities	Roximycin tablet of (TGA approved)
	Me-too status	Maxolid tablet M/s Cherwel Pharmaceuticals
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
239.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sorelax 5mg Tablet

	Composition	Each film coated tablet contains: Solifenacin Succinate……..5mg
	Diary No. Date of R& I & fee	Dy.No.22891 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Treatment Of Urinary Incontinence
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications.
	Pack size & Demanded Price	10's, 20's,30's,40's 50's 60's,70's, 80's,; Rs.550/-tablet
	Approval status of product in Reference Regulatory Authorities	VESICARE 5 mg of MHRA approved.
	Me-too status	Solifen 5mg Tablet by M/s Getz Pharmaceuticals, Karachi
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved with change of brand name and innovator's specification.	
240.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Fexin Oral suspension 30mg/5ml
	Composition	Each 5ml contains: Fexofenadine HCL…30mg
	Diary No. Date of R& I & fee	Dy.No. 22887 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	10ml, 20ml, 30ml, 40ml, 60ml, 100ml, 120ml, 240ml RS:200/- per bottle
	Approval status of product in Reference Regulatory Authorities	USFDA apprpoved
	Me-too status	Aloc 30mg/5ml Susp M/s Bosch
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
241.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sefuspore 500mg Tablet
	Composition	Each film coated tablet contains: Cefuroxime as Axetil…500mg
	Diary No. Date of R& I & fee	Dy.No.22892 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's,30's,40's 50's 60's,70's, 80's, 90's, 100's ; RS:150/-tablet
	Approval status of product in Reference Regulatory Authorities	Cefuroxime as Axetil (film coate)of USFDA approved
	Me-too status	Furoxi 500mg Tablet of M/s Paramount Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	Cephalosporin tablet section available.
	Decision: Approved.	

242.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Ibu-Profen 600mg Tablet
	Composition	Each film coated tablet contains: Ibuprofen…600mg
	Diary No. Date of R& I & fee	Dy.No.22896 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	24's, 100's,250's,500's, 600's; RS:120/-tablet
	Approval status of product in Reference Regulatory Authorities	Brufen Tablets 600 mg of MHRA approved
	Me-too status	Fenbru 600mg Tablets M/s Platinum,
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved.	
243.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Domilis 100mg/5ml Syrup
	Composition	Each 5ml contains: Doxofylline…100mg
	Diary No. Date of R& I & fee	Dy.No. 22890 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Anti ashthamatic
	Type of Form	Form-5
	Finished product Specification	Manufacturers specification
	Pack size & Demanded Price	30ml, 60ml, 90ml, 100ml, 120ml & 450ml RS: 170/- per 30ml bottle RS: 180/- per 60ml bottle RS: 200/- per 90ml bottle RS: 220/- per 100ml bottle RS: 350/- per 120ml bottle RS: 500/- per 4500ml bottle
	Approval status of product in Reference Regulatory Authorities	Doxofillina Abc 200 Mg / 10 Ml Syrup Of Aifa Italy Approved
	Me-too status	Agolix Syrup Of M/S Hiranis
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
244.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Cetlis 10mg Tablet
	Composition	Each film coated tablet contains: Cetirizine 2HCL…….10mg
	Diary No. Date of R& I & fee	Dy.No. 22895 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Anti-histamine
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's,30's,40's 50's 60's,70's, 80's, 90's, 100's; RS:100/-tablet

	Approval status of product in Reference Regulatory Authorities	Zirtek tablet of (MHRA approved)
	Me-too status	Serzine 10mg Tablets of M/s Qintar Pharmaceuticals,
	GMP status	Last GMP inspection conducted on 24-04-2018 and report concludes that Overall the firm was working under satisfactory level of cGMP compliance "
	Remarks of the Evaluator	
	Decision: Approved.	
245.	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	IBU-P Tablet
	Composition	Each film coated tablet contains: Ibuprofen…200mg Pseudoephedrine HCL…30mg
	Diary No. Date of R& I & fee	Dy.No. 22931 dated 03-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Analgesics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10 x 10's ;RS: 270/-
	Approval status of product in Reference Regulatory Authorities	Lasynac 200mg/30mg Film Coated Tablets of MHRA approved
	Me-too status	Rovinac Tablets M/s Rock Pharmaceuticals
	GMP status	Last GMP inspection was conducted on 06-08-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator	
	Decision: Approved.	
246.	Name and address of manufacturer / Applicant	M/s English Pharmaceuticals Industries. Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Utifib 5mg Tablet
	Composition	Each Tablet Contains: Ulipristal Acetate…5mg
	Diary No. Date of R& I & fee	Dy.No. 22934 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	Selective Progesterone receptor modulator
	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	Ulipristal Acetate of MHRA approved
	Me-too status	Not found
	GMP status	Certificate of GMP Issued on 16-01-2018.
	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
	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 and confirmation of relevant section.	
247.	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-AH 5/12.5/160 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besilate…5mg Hydrochlorothiazide…12.5mg

		Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No. 24307 dated 12-07-2018 Rs.20,000/- 12-07-2018
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 28's, & 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Hct Of (USFDA Approved)
	Me-too status	Exforge Hct Of M/S Novartis Pharma
	GMP status	Last GMP inspection conducted on 16-02-2018 and report concludes that Overall the firm was considered at an satisfactory level of compliance with cGMP guidelines as of today
	Remarks of the Evaluator	
	Decision: Approved.	
248.	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-AH 5/25/160 mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine as Besilate…5mg Hydrochlorothiazide…25mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No. 24308 dated 12-07-2018 Rs.20,000/- 12-07-2018
	Pharmacological Group	Anti-hypertensive
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 28's, & 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Hct Of (USFDA Approved)
	Me-too status	Exforge Hct of M/S Novartis Pharma
	GMP status	Last GMP inspection conducted on 16-2-2018 and report concludes that overall firm was considered at an satisfactory level of compliance with cGMP guidelines as of today.
	Remarks of the Evaluator	
	Decision: Approved.	
249.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals. Plot No. 7-B, Value Addition City Faisalabad
	Brand Name +Dosage Form + Strength	Emflex 550mg Tablet
	Composition	Each Film Coated Tablet Contains: Naproxen Sodium……550mg
	Diary No. Date of R& I & fee	Dy.No. 22932 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	NSAIDs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Health Canada approved
	Me-too status	Fougera Tablet of M/s Hiranis
	GMP status	Last GMP inspection conducted on 07-12-2017and report concludes that was considered to be operating at good level of compliance with GMP.
	Remarks of the Evaluator	
	Decision: Approved.	

250.	Name and address of manufacturer / Applicant	M/s Reign Pharmaceuticals PCSIR-KLC Pvt Ltd. TBIC Building-1, PCSIR Laboratories Complex, Shahrahe Dr. Salim-us-Zaman Siddiqui, Off University Road,Karachi
	Brand Name +Dosage Form + Strength	Renflu 150mg Table
	Composition	Each Tablet Contains: Fluconazole…150mg
	Diary No. Date of R& I & fee	Dy.No.22884 dated 02-07-2018 Rs.20,000/- 02-07-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Diflucan 150mg Tablet of USFDA approved.
	Me-too status	Vzole 150mg Tablets of M/s Llyods Pharmaceutical
	GMP status	Last GMP inspection conducted on 8/11/2017and report concludes that All relevant activities in process areas, QC and ware house were found as good level of GMP compliance as per Drugs Act, 1976 and rules framed under. Based on the current inspection of M/s Reign Pharmaceuticals PCSIR-RLC Pvt. Ltd. all the observations/recommendations were discussed with management and an earlier compliance was assured from firm's management.."
	Remarks of the Evaluator	
	Decision: Approved.	
251.	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	Bolive 5mg Tablet
	Composition	Each tablet contains: Nebivolol HCL eq to Nebivolvol…5mg
	Diary No. Date of R& I & fee	Dy.No.22943 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	Beta-1 receptor blocker
	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	Bystolic Tablet Of (USFDA Approved)
	Me-too status	Nebilol 5mg Tablet M/s Genix Pharma
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes that firm has acceptable level of GMP.."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specfications.	
252.	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	Bolive 10mg Tablet
	Composition	Each tablet contains: Nebivolol HCL eq to Nebivolvol…10mg
	Diary No. Date of R& I & fee	Dy.No.22944 dated 03-07-2018 Rs.20,000/- 03-07-2018
	Pharmacological Group	Beta-1 receptor blocker
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Bystolic Of (USFDA Approved)

	Reference Regulatory Authorities	
	Me-too status	Nabilox 10mg Tablet M/s Nabiqasim
	GMP status	Last GMP inspection conducted on 15-09-2017and report concludes that firm has acceptable level of GMP.."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specfications.	
253.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt Limited. 9.5KM, Sheikhupura Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Gemgex 320mg tablets
	Composition	Each film coated contains: Gemifloxacin as mesylate……320mg
	Diary No. Date of R& I & fee	Dy.No.24303 dated 12-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Fluoroquinolone antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer,s specification
	Pack size & Demanded Price	7's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Factive tablet of USFDA approved
	Me-too status	Ifactiv 320mg Tablet M/s Hilton
	GMP status	Last GMP inspection conducted on 20-04-2016 and report concludes that firm has shown positive approach towards compliance of GMP advises given for further up gradation.
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.	
254.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt Limited. 9.5KM, Sheikhupura Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Topzol 40mg tablets
	Composition	Each enteric coated tablet contains: Pantoprazole as sodium Sesquehydrate…40mg
	Diary No. Date of R& I & fee	Dy.No.24301 dated 12-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's,30's, , ; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Pantoprazole 40 mg Tablet Of (MHRA Approved)
	Me-too status	Pantopraz 40mg Tablet M/s Klifton Pharma,
	GMP status	Last GMP inspection conducted on 20-04-2016 and report concludes that firm has shown positive approach towards compliance of GMP advises given for further up gradation.
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
255.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name +Dosage Form + Strength	Norflox 400mg tablets
	Composition	Each film coated tablet contains: Norfloxacin …..…400mg
	Diary No. Date of R& I & fee	Dy.No.24295 dated 12-07-2018 Rs.20,000/- 11-07-2018
	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	Noroxin of USFDA approved
	Me-too status	Bacnor Tablets 400mg of M/s Dyson Research Lab
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
256.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name +Dosage Form + Strength	Nimodip 30mg tablet
	Composition	Each film coated tablet contains: Nimodipine…30mg
	Diary No. Date of R& I & fee	Dy.No.24296 dated 12-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Calcium channel blocker
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Nimotop 30mg Tablets Of MHRA approved
	Me-too status	Nidopin Tablets of M/s Global Pharmaceuticals
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
257.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name +Dosage Form + Strength	Toldine 2mg tablet
	Composition	Each film coated tablet contains: Tolterodine tartrate…2mg
	Diary No. Date of R& I & fee	Dy.No.24294 dated 12-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	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	Detrusitol (film coated of MHRA approved
	Me-too status	Toltero Tablets of M/s CCL Pharmaceuticals
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifcations.	
258.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name +Dosage Form + Strength	Vigamark 500 tablet
	Composition	Each film coated contains: Vigabatrin…500mg
	Diary No. Date of R& I & fee	Dy.No.24293 dated 12-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Antiepileptic belongs to gamma amino acids and Derivatives.

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Sabril 500mg film coated tablet of MHRA approved
	Me-too status	Seizril 500mg Tablet of M/s Nabiqasim
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
259.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name +Dosage Form + Strength	Welrix SR 30mg Capsule
	Composition	Each Capsule contains: Cyclobenzaprine Hcl (Extended release pellets)…30mg
	Diary No. Date of R& I & fee	Dy.No.24291 dated 12-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	AMRIX of USFDA approved
	Me-too status	Skelebenz 30mg of M/s Nexus Pharma
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator	Source of Pellets: Vision Specifications of pellets: Inhouse
	Decision: Approved.	
260.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name +Dosage Form + Strength	Mucomark capsule 500mg
	Composition	Each Hard capsule contains: Carbocisteine…….375
	Diary No. Date of R& I & fee	Dy.No.24292 dated 12-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Mucolytic agent
	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	Mucodyne 375mg capsules of M/s Sanofi Aventis (MHRA Approved)
	Me-too status	Costa 375mg Capsule of M/s Macter Int
	GMP status	Firm has submitted copy of GMP inspection report conducted on 04-09-2018 & 26-09-2018, recommending renewal of DML
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification.	
261.	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	TINEA LOTION 10mg
	Diary No. Date of R& I & fee	Diary No: 23981 dated 11-07-2018 Rs.20,000/- 28-06-2018

	Composition	Each gram contains: Terbinafine HCl (BP)…….10 mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Manufacturing specifications
	Pack size & Demanded Price	20ml, 30ml, 60ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil Lotion 1% by M/s GSK Netherland
	Me-too status	Cutis of M/s Tabros Pharma (Reg # 067109)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name and innovator's specification.	
262.	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	Tinea Tablets 125mg
	Diary No. Date of R& I & fee	Dy.No: 3952 dated 11-07-2018 Rs.20,000/- 27-6-2018
	Composition	Each tablet contains Terbinafine as hydrochloride ……125mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Terbinafine 125mg Tablet Genus Pharmaceuticals Limited, MHRA Approved
	Me-too status	Lamisil Tablet by M/s Sandoz
	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.
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name.	
263.	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	Tinea Tablets 250mg
	Diary No. Date of R& I & fee	Diary No: 3953 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each tablet contains Terbinafine as hydrochloride……250mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Terbinafine 250mg Tablet Genus Pharmaceuticals Limited, MHRA Approved
	Me-too status	Lamisil Tablet by M/s Sandoz
	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.
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name.	
264.	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 250mg Tablet

	Diary No. Date of R& I & fee	Diary No: 23957 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each Film Coated Tablet Contains: Azithromycin Dihydrate Eq. to Azithromycin…250mg
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	6's and 10's/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Azithromycin tablet of (MHRA approved)
	Me-too status	Azic 250mg Tablet by M/s NabiQasim
	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.
	Remarks of the Evaluator.	Firm change formulation from uncoated to film coated With submission of RS: 5000/- fee Challan no:0778955 dated:06-08-2019
	Decision: Approved.	
265.	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 0.3% Otic Solution
	Diary No. Date of R& I & fee	Diary No: 23991 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each ml contains: Ciprofloxacin Hcl eq to Ciprofloxacin…3mg
	Pharmacological Group	Macrolides
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	5ml, AS per SRO
	Approval status of product in Reference Regulatory Authorities.	Ciloxan 3 mg/ml ear drops, solution, Ireland Approved
	Me-too status	Cipotic of M/s Barret Reg #032485
	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.
	Remarks of the Evaluator.	Section for otic preparation not available.
	Decision: Deferred for confirmation of approval of manufacturing facility / section from Licensing Division DRAP.	
266.	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	Corelex Injection 4mg/2ml
	Diary No. Date of R& I & fee	Diary No: 23910 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 2ml contains: Thiocolchicoside (BP)……4mg
	Pharmacological Group	Skeletal Muscle Relaxant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	6's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Coltramyl Injection by M/s Sanofi Aventis ANSM France
	Me-too status	Myovi 4mg/2ml Injection by Macter Int. (Reg.No. 058692)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specfications.	

267.	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	Aprecap Capsule 40mg
	Diary No. Date of R& I & fee	Diary No: 23995 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Composition	Each capsule contains: Aprepitant (USP)……40mg
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMEND Capsule of USFDA
	Me-too status	Apritus 40mg Capsule of M/s S.J&G
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
268.	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	Aprecap Capsule 80mg
	Diary No. Date of R& I & fee	Diary No: 23996 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Composition	Each capsule contains: Aprepitant (USP) ……80mg
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Emend capsule of USFDA
	Me-too status	Apritus 80mg Capsule of M/s S.J&G
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
269.	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	Aprecap Capsule 125mg
	Diary No. Date of R& I & fee	Diary No: 23997 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Composition	Each capsule contains: Aprepitant (USP)……125mg
	Pharmacological Group	Anti-emetic agent
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Emend Capsule of USFDA
	Me-too status	Apritus 125mg Capsule of M/s S.J&G
	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.

	Remarks of the Evaluator.	
	Decision: Approved.	
270.	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 Tablets 75mg/200mcg
	Diary No. Date of R& I & fee	Diary No: 23942 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each Compressed coated and enteric coated tablet contains: Diclofenac Sodium(USP)……..75mg Misoprostol(USP) 1% HPMC dispersion …….200mcg
	Pharmacological Group	NSAID along with mucoprotective
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arthrotec of USFDA Approved
	Me-too status	Rotec-50 Tablet by Searle Pakistan (Reg. No. 058523)
	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.
	Remarks of the Evaluator.	• The formulation contains misoprostol 1% HPMC dispersion and the formulation contains inner enteric coated layer of diclofenac sodium surrounded by misoprostol dispersion coating and the method of manufacturing submitted is inline with the innovator product. • Firm submitted Commercial Invoice for core covered rotary Tablet press machineZPW26, Operational Manuak for ZPW26 rotary tablet press.
	Decision: Deferred for submission of Installation Qualification & Performance Qualification Reports of required manufacturing equipment i.e. tablet biayered machine.	
271.	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	Atralex Injection 10mg/5ml
	Diary No. Date of R& I & fee	Diary No: 23908 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 5ml ampule contains: Atracurium Besylate (USP) …10mg
	Pharmacological Group	Non-depolarizing skeletal muscle relaxant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not found
	Me-too status	Atrac Injection by Schazoo Laboratories,
	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.
	Remarks of the Evaluator.	Evidence in reference agency 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.	
272.	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	FLUCA LOTION 0.05%
	Diary No. Date of R& I & fee	Diary No: 23978 dated 11-07-2018 Rs.20,000/- 28-06-2018

	Composition	Each gram contains: Fluticasone propionate (BP)…….0.5mg(0.05%)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml, 20ml, 30ml, 60ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cutivate lotion Fougera Pharma of USFDA
	Me-too status	Ticovate Lotion by Saffron Pharma (Reg. No. 067826)
	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.
	Remarks of the Evaluator.	Lotion General section available.
	Decision: Approved.	
273.	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	Amloval HCT Tablets 5/12.5/160mg
	Diary No. Date of R& I & fee	Diary No: 23926 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……5mg Hydrochlorothiazide(USP)……....12.5mg Valsartan(USP) ……...160mg
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT 5/160/12.5 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069548)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
274.	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	Amloval HCT Tablets 10/12.5/160mg
	Diary No. Date of R& I & fee	Diary No: 23928 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……10mg Hydrochlorothiazide(USP)……....12.5mg Valsartan(USP) ……...160mg
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT 10/160/12.5 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069548)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	

275.	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	Amloval HCT Tablets 5/25/160mg
	Diary No. Date of R& I & fee	Diary No: 23927 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……5mg Hydrochlorothiazide(USP)……....25mg Valsartan(USP) ……...160mg
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT 5/160/25 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069549)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
276.	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	Amloval HCT Tablets 10/25/160mg
	Diary No. Date of R& I & fee	Diary No: 23929 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……10mg Hydrochlorothiazide (USP)……....25mg Valsartan (USP) ……...160mg
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT 10/160/25 by Novartis (USFDA)
	Me-too status	Exforge HCT By Novartis (Reg. No. 069551)
	GMP status	04-10-2017 for Grant of new DML Panel recommends grant of new DML.
	Remarks of the Evaluator.	
	Decision: Approved.	
277.	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	Amloval HCT Tablets 10/25/320mg
	Diary No. Date of R& I & fee	Diary No: 23930 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Amlodipine as (Besylate) (USP)……10mg Hydrochlorothiazide (USP)……....25mg Valsartan (USP) ……...320mg
	Pharmacological Group	Anti-hypertension
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	7's, 10's. 14's, 28's, 30's / 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 29-05-2017, 30-05-2017 & 13-07-2017, 03-04-2017 and report concludes that panel recommends the grant of drug manufacturing license.
	Remarks of the Evaluator.	
	Decision: Approved.	
278.	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	Amloper Tablet 5mg/4mg
	Diary No. Date of R& I & fee	Diary No: 23922 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each tablet contains: Amlodipine as besylate (USP)……5mg Perindopril tert-butylamine (BP)……4mg
	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 30's, 50's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065962)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
279.	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	Amloper Tablet 5mg/8mg
	Diary No. Date of R& I & fee	Diary No: 23923 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each tablet contains: Amlodipine as besylate (USP)……5mg Perindopril tert-butylamine (BP)……8mg
	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 30's, 50's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065961)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
280.	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	Amloper Tablet 10/4mg
	Diary No. Date of R& I & fee	Diary No: 23924 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each tablet contains: Amlodipine as besylate (USP)……10mg Perindopril tert-butylamine (BP)……4mg

	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 30's, 50's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065959)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
281.	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	Amloper Tablet 10/8mg
	Diary No. Date of R& I & fee	Diary No: 23925 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each tablet contains: Amlodipine as besylate (USP)……10mg Perindopril tert-butylamine (BP)……8mg
	Pharmacological Group	Calcium Channel Blocker + ACE Inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's, 30's, 50's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Coversam Tablet by Servier Research Pharmaceuticals (Reg. No.065960)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
282.	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	Epian Tablets 250mg
	Diary No. Date of R& I & fee	Diary No: 23934 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Levetiracetam(USP)……...250mg
	Pharmacological Group	Anti-Epileptic
	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.	Keppra 250mg Tablets of UCB Inc. USA (USFDA)
	Me-too status	Levep 250mg Tablet by Hilton Pharma (Reg. No. 053348)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	

283.	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	Epian Tablets 500mg
	Diary No. Date of R& I & fee	Diary No: 23935 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Levetiracetam (USP)……...500mg
	Pharmacological Group	Anti-Epileptic
	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.	Keppra 500mg Tablets of UCB Inc. USA (USFDA)
	Me-too status	Levep 500mg Tablet by Hilton Pharma (Reg. No. 053349)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
284.	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	Epian Injection 500mg/5ml
	Diary No. Date of R& I & fee	Diary No: 23912 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 5ml contains: Levetiracetam (USP)……500mg
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Keppra 500mg/5ml Injection of M/s UCB Inc. USFDA
	Me-too status	Eplipsa 500mg/5ml Injection of M/s Helix (R.No. 075918)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
285.	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	Xeroclot Tablets 10mg
	Diary No. Date of R& I & fee	Diary No: 23954 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Rivaroxaban (MS)……...10mg
	Pharmacological Group	Anti-thrombic
	Type of Form	Form-5
	Finished Product Specification	Manufacturers specifications
	Pack size & Demanded Price	10's, 30's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xarelto 10 mg Tablet of (USFDA approved)
	Me-too status	Xerelto 10mg Tablet by Bayer Pakistan (Reg. No. 059057)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

286.	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	Xeroclot Tablets 15mg
	Diary No. Date of R& I & fee	Diary No: 23956 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Rivaroxaban (MS)……...15mg
	Pharmacological Group	Anti-thrombic
	Type of Form	Form-5
	Finished Product Specification	Manufacturers specifications
	Pack size & Demanded Price	7's, 10's,14's,/As per SRO
	Approval status of product in Reference Regulatory Authorities.	XARELTO 15mg Tablet of (USFDA approved)
	Me-too status	Xerelto 15mg Tablet by Bayer Pakistan (Reg. No. 072549)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
287.	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	Xeroclot Tablets 20mg
	Diary No. Date of R& I & fee	Diary No: 23955 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Rivaroxaban (MS)……..20mg
	Pharmacological Group	Anti-thrombic
	Type of Form	Form-5
	Finished Product Specification	Manufacturers specifications
	Pack size & Demanded Price	7's, 10's,14's,/As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xarelto 20mg Tablet of (USFDA approved)
	Me-too status	Xerelto 20mg Tablet by Bayer Pakistan (Reg. No. 072550)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
288.	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	Carsevel Tablets 800mg
	Diary No. Date of R& I & fee	Diary No: 23931 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Sevelamer Carbonate (MS)…….800mg
	Pharmacological Group	Phosphate binder
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	30's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Renvela by Sanofi (MHRA)
	Me-too status	Genovel Tablet by Genome Pharma (Reg. No. 085528)
	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.

	Remarks of the Evaluator.	Accelerated and Long term stability studies for 3 batches along with requisite documents.
	Decision: Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.	
289.	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	Cinitasol 1mg/5ml Solution
	Diary No. Date of R& I & fee	Diary No: 23961 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 5ml contains: Cinitapride hydrogen tartrate eq. to cinitapride…1mg
	Pharmacological Group	Gastrointestinal prokinetic
	Type of Form	Form-5
	Finished Product Specification	Manufacturers 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 (Spain Approved)
	Me-too status	Cidine of M/s Highnoon (Reg. No. 069457)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
290.	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	Faxid Tablet 60mg
	Diary No. Date of R& I & fee	Diary No: 23959 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film coated tablet contains: Fexofenadine HCl (BP)…….. 60mg
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fexofenadine hydrochloride Of (USFDA Approved)
	Me-too status	Epodin 60mg Tablet M/s Epoch Pharmaceutical,
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
291.	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	Faxid Tablet 180mg
	Diary No. Date of R& I & fee	Diary No: 23960 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film coated tablet contains: Fexofenadine HCl (BP)…….. 180mg
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fexofenadine hydrochloride Of (MHRA Approved)

	Me-too status	Epodin 180mg Tablet M/s Epoch Pharmaceutical,
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
292.	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	FAXID 30mg/5ml suspension
	Diary No. Date of R& I & fee	Diary No: 23965 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 5ml contains: Fexofenadine HCl (BP)…….. 30mg
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Fluzip by Winthrox Laboratories (Reg. No. 080533)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
293.	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	Minocil Tablets 100mg
	Diary No. Date of R& I & fee	Diary No: 23940 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Minocycline HCl(USP) eq. to Minocycline…….100mg
	Pharmacological Group	Broad Spectrum Tetracycline
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Minocycline HCl 100mg, of (MHRA approved)
	Me-too status	MINODERM Tablet by Martin Dow Pharma (Reg. No. 024308)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
294.	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	Proval Tablets 500mg
	Diary No. Date of R& I & fee	Diary No: 23945 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each enteric-coated tablet contains: Divalproex sodium is eq. to Valproic acid (USP)...500mg
	Pharmacological Group	Antiepileptic & Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's, 50's, 100's /As per SRO

	Approval status of product in Reference Regulatory Authorities.	Depakote tablet USFDA Approved
	Me-too status	Valrox Tab by Polyfine Chemical
	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.
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name.	
295.	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	Proval Injection 500mg/5ml
	Diary No. Date of R& I & fee	Diary No: 23919 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 5ml contains: Valproate Sodium (BP)……500mg
	Pharmacological Group	Anti-epileptic / Anti-convulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	5ml x 1's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Depacon Injection (USFDA)
	Me-too status	Valrate Injection 500mg of M/s AGP
	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.
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name.	
296.	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	Sebastine Tablets 20mg
	Diary No. Date of R& I & fee	Diary No: 23947 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Ebastine (BP)……...20mg
	Pharmacological Group	Non-sedating antihistamine
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Kestine tablet Approved by Netherland
	Me-too status	Kestine Flash 20mg (lyophillisate tablet)by HIGHNOON (Reg. No. 071143)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
297.	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	Solofer Injection 100mg/5ml
	Diary No. Date of R& I & fee	Diary No: 23920 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 5ml contains: Iron sucrose (BP) equivalent to elemental iron….100mg
	Pharmacological Group	HAEMATINIC
	Type of Form	Form-5

	Finished Product Specification	BP
	Pack size & Demanded Price	5's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Venofer Injection by Vifor (MHRA Approved)
	Me-too status	Venofer injection by Gastrocare ,
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
298.	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	Promiz Insta Capsule 20mg/1100mg
	Diary No. Date of R& I & fee	Diary No: 23999 dated 11.07.2018 Rs. 20,000/-10-07-2018
	Composition	Each Capsule contain Omeprazole (USP)……20mg Sodium bicarbonate (BP)……1100mg
	Pharmacological Group	Proton pump inhibitor + Antacid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer'sspecification
	Pack size & Demanded Price	5's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zegerid Capsule by Santarus(USFDA Approved)
	Me-too status	Zoltar Insta 20mg Capsule of M/s Pharmevo
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
299.	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	Promiz Insta Capsule 40mg/1100mg
	Diary No. Date of R& I & fee	Diary No: 24000 dated 11.07.2018 Rs. 20,000/- 10-7-2018
	Composition	Each Capsule contain Omeprazole (USP)……40mg Sodium bicarbonate (BP)……1100mg
	Pharmacological Group	Proton pump inhibitor + Antacid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	14's / As per SR
	Approval status of product in Reference Regulatory Authorities.	Zegerid Capsule 40/1100mg by Santarus Inc (USFDA Approved)
	Me-too status	Faast Plus Capsule by CCL Pharma (Reg# 060325)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
300.	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	Dobrid Capsule 500mg
	Diary No. Date of R& I & fee	Diary No: 23998 dated 11.07.2018 Rs. 20,000/- 10-7-2018
	Composition	Each capsule contains:

		Calcium Dobesilate Monohydrtate…500mg
	Pharmacological Group	Veno-tonic drug/Vaso-protective
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxium 500 of Swizmedics approved
	Me-too status	Caldob Capsules of M/s Genome Pharmaceuticals,
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
301.	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 0.3% w/v Opthalmic solution
	Diary No. Date of R& I & fee	Diary No: 23990 dated 11.07.2018 Rs. 20,000/-28-06-2018
	Composition	Each ml contains: Ofloxacin (USP) ……..…3mg
	Pharmacological Group	Fluroquinolone Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	5ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ocuflox of USFDA Approved)
	Me-too status	Ophix Sterile Ophthalmic Solution. of M/s Sami Pharmaceuticals
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
302.	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	SELPROFEN Sachet 600mg
	Diary No. Date of R& I & fee	Diary No: 23969 dated 11.07.2018 Rs. 20,000/-28-06-2018
	Composition	Each Sachet contains: Ibuprofen (USP)……600mg
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	20's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Brufen Granules 600mg by M/s BGP Products Ltd. MHRA approved
	Me-too status	Brufen by Abbot Labs. (Reg. No. 044414),
	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.
	Remarks of the Evaluator.	Sachet section available.
	Decision: Approved with innovator's specifications.	
303.	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	Frusol Solution 40mg/5ml

	Diary No. Date of R& I & fee	Diary No: 23966 dated 11.07.2018 Rs. 20,000 dated 28-06-2018
	Composition	Each 5ml contains: Furosemide (USP)……40mg
	Pharmacological Group	Diuretic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml,90ml, 120ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	FRUSOL 40mg/5ml MHRA Approved
	Me-too status	Fluromac oral solution of M/s Mac & Rains (Reg # 060629)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
304.	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	Nalbusol Injection 10mg/ml
	Diary No. Date of R& I & fee	Diary No: 23916 dated 11.07.2018 Rs. 20,000 dated 28-06-2018
	Composition	Each ml contains: Nalbuphine Hydrochloride (MS)…….10mg
	Pharmacological Group	Opioid Antagonist
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	1's, 2's, 5's and 10's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nubain Injection 10mg/ml of Health Canada approved
	Me-too status	Nalburax Injection by M/s Mediceena Pharma (R.#028830)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
305.	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	Nalbusol Injection 20mg/ml
	Diary No. Date of R& I & fee	Diary No: 23917 dated 11.07.2018 Rs. 20,000/-28-06-2018
	Composition	Each ml contains: Nalbuphine Hydrochloride (MS)…….20mg
	Pharmacological Group	Opioid Antagonist
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	5's and 10's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Nubain Injection 10mg/ml of Health Canada approved
	Me-too status	Nalbinor Injection by PHD Lab. (Reg. No. 025199)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	

306.	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	Calcid Injection 2mcg/ml
	Diary No. Date of R& I & fee	Diary No: 23909 dated 11.07.2018 Rs. 20,000/-28-06-2018
	Composition	Each ampule of ml contains: Alfacalcidol (BP)……2mcg
	Pharmacological Group	Vitamin D Analogue
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	10's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	One-Alpha of MHRA approved
	Me-too status	Actavit-D Injection 2mcg of M/s Ray
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
307.	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	SMECDRAL Sachet 3gm
	Diary No. Date of R& I & fee	Diary No: 23970 dated 11.07.2018 Rs. 20,000/-28-06-2018
	Composition	Each Sachet contains: Dioctahedral Smectite (MS)……3gm
	Pharmacological Group	Anti-diarrheal
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	30's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Smecta 3gm powder for oral suspension in sachet by M/s Ipsen Pharma, (ANSM approved)
	Me-too status	Smecta PDR by ATCOL (Reg. No. 010905)
	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.
	Remarks of the Evaluator.	Sachet General section available
	Decision: Approved with innovator's specifications.	
308.	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	MMS CREAM 0.1%
	Diary No. Date of R& I & fee	Diary No: 23974 dated 11.07.2018 Rs. 20,000/-28-06-2018
	Composition	Each gram contains: Mometasone Furoate (BP)…….0.1% (1mg)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	5gm, 15gm/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	ELOCON MSD (USFDA Approved)
	Me-too status	Momevate Cream by Pearl Pharma (Reg. No. 066606)
	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.
	Remarks of the Evaluator.	Steriod cream section available
	Decision: Approved.	

309.	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	MMS LOTION 0.1%
	Diary No. Date of R& I & fee	Diary No: 23979 dated 11.07.2018 Rs. 20,000/-28-6-2018
	Composition	Each gram contains: Mometasone Furoate (BP)… 1mg (0.1%)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	20ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	ELOCON MSD (USFDA Approved)
	Me-too status	Hivate Lotion by Saffron Pharma (Reg. No. 046430)
	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.
	Remarks of the Evaluator.	Lotion General section available
	Decision: Approved with innovator's specifications.	
310.	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	Acnefin 10mg Capsule
	Diary No. Date of R& I & fee	Diary No: 23993 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Composition	Each Capsule Contains: Acitretin(USP)…..…10mg
	Pharmacological Group	Antipsoriatics
	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.	Soriatane Approved by USFDA approved
	Me-too status	Acetin Capsules 10mg of M/s Genome Pharmaceuticals (Reg.# 064012)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
311.	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	Acnefin 25mg Capsule
	Diary No. Date of R& I & fee	Diary No: 23994 dated 11-07-2018 Rs.20,000/- 10-7-2018
	Composition	Each Capsule Contains: Acitretin (USP)……..…25mg
	Pharmacological Group	Second –Generation Retinoid
	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.	Soriatane Approved by USFDA approved
	Me-too status	Acetin Capsules 10mg of M/s Genome Pharmaceuticals (Reg.# 064012)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
312.	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	SILVA CREAM 1% w/w
	Diary No. Date of R& I & fee	Diary No: 23975 dated 11.07.2018 Rs. 20,000/- 28-6-2018
	Composition	Each gram contains: Silver sulfadiazine (USP)….1.0 % w/w
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	15gm, 30gm, 50gm, 250mg / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Silvadene Cream of USFDA approved
	Me-too status	Quench 1% Cream by Ferozsons (Reg. No. 013090)
	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.
	Remarks of the Evaluator.	General Cream section available
	Decision: Approved.	
313.	Name and address of manufacturer /Applicant	M/s Pharmasol (Pvt) Ltd. Plot No. 549, Sundar Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Inxamic Injection 500mg/5ml
	Diary No. Date of R& I & fee	Diary No: 23913 dated 11.07.2018 Rs. 20,000/- 28-6-2018
	Composition	Each 5ml contains: Tranexamic Acid (BP) …….500mg
	Pharmacological Group	Anti-Fibrinolytic Agent
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	CYKLOKAPRON 500mg Solution for Injection by M/s Pfizer Limited, MHRA
	Me-too status	Tremic -500 Injection of M/s M/s Fynk Pharmaceuticals,
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
314.	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	BEGENT CREAM 0.05% + 0.1%
	Diary No. Date of R& I & fee	Diary No: 23971 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each gram contains: Betamethasone Dipropinate(USP)……0.5mg Gentamicin Sulphate (USP)……1mg
	Pharmacological Group	Aminoglycoside/Glucocorticoid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10gm, 15gm /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diprogen cream of Health Canada
	Me-too status	Effigenta Cream by Mass Pharma (Reg. No. 024375)

	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.
	Remarks of the Evaluator.	General cream section available
	Decision: Approved.	
315.	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	BEGENT OINTMENT 0.05% + 0.1%
	Diary No. Date of R& I & fee	Diary No: 23976 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each gram contains: Betamethasone Dipropinate (USP) ……0.5mg Gentamicin Sulphate (USP)……1mg
	Pharmacological Group	Aminoglycoside/Glucocorticoid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10gm, 15gm /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diprogen Ointment of Health Canada
	Me-too status	Effigenta Ointment by Mass Pharma (Reg. No. 024376)
	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.
	Remarks of the Evaluator.	General Ointment section available
	Decision: Approved.	
316.	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	FUSID 2% w/w Cream
	Diary No. Date of R& I & fee	Diary No: 23972 dated 11.07.2018 Rs. 20,000/-28-6-2018
	Composition	Each gram contains Fusidic Acid (BP)…….20mg (2% w/w)
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	15gm, 30gm /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fucidin of MHRA Approved
	Me-too status	Ucid 2% Cream by Ciba Pharma (Reg. No. 081566)
	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.
	Remarks of the Evaluator.	General cream section available
	Decision: Approved.	
317.	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	Fudix 1% w/w Viscous Eye Drops
	Diary No. Date of R& I & fee	Diary No. 23984 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each gm Contains: Fusidic Acid (BP)……10mg (1% w/w)
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack size & Demanded Price	5ml /As per SRO
	Approval status of product in	Fucithalmic 1% w/w Viscous Eye Drops of MHRA

	Reference Regulatory Authorities.	Approved.5gm
	Me-too status	Sidic Eye Drops of M/s Epoch Pharmaceuticals
	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.
	Remarks of the Evaluator.	Eye Drops General section available
	Decision: Approved.	
318.	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	Lowsol Tablets 75/75mg
	Diary No. Date of R& I & fee	Diary No: 23936 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated bi-layered tablet contains: Clopidogrel bisulfate (BP) eq. to Clopidogrel…….75mg Aspirin (USP)……75mg
	Pharmacological Group	Antiplatelet drug
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specification
	Pack size & Demanded Price	10' s; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CoPlavix Tablet Of (TGA Approved)
	Me-too status	Clodril Plus Tablet M/s Macter International
	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.
	Remarks of the Evaluator.	Initally firm submitted Each film-coated bi-layered tablet contains; Clopidogrel bisulfate (BP) eq. to Clopidogrel…….75mg Aspirin (USP)……75mg Now firm informed it is mistakenly written and made correction as Each film coated (compressed coated tablet) contains: Clopidogrel bisulfate (BP) eq. to Clopidogrel…….75mg Each enteric coated tablet contains: Aspirin (USP)……75mg
	Decision: Deferred for confirmation of innovator's product (bi-layered or otherwise).	
319.	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	Ketasol Injection 500mg/10ml
	Diary No. Date of R& I & fee	Diary No: 23914 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 10ml contains: Ketamine HCl (USP) eq. to Ketamine ……500mg
	Pharmacological Group	General Anesthetic
	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.	Ketalar 50mg/ml Injection of MHRA approved
	Me-too status	Ketarol Injection by Global Pharma (Reg. No. 026630)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	

320.	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	Zedron Infusion 5mg/100ml
	Diary No. Date of R& I & fee	Diary No: 23921 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 100ml contains: Zoledronic acid (MS)……5mg
	Pharmacological Group	Osteoporosis
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	1's Vial / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Reclast USFDA Approved
	Me-too status	Aclasta by Novartis (Reg. No. 044831)
	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.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
321.	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	T-Prost 0.004% Ophthalmic Solution
	Diary No. Date of R& I & fee	Diary No: 23989 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each ml Contains: Travoprost……..0.04mg (0.004%)
	Pharmacological Group	Prostaglandin Analogue
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2.5ml LDPE container, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Travatan by Alcon (USFDA approved)
	Me-too status	Travopt by Barrett Hodgson
	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.
	Remarks of the Evaluator.	Eye Drops General section available
	Decision: Approved.	
322.	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	Mantin Tablets 10mg
	Diary No. Date of R& I & fee	Diary No: 23937 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each film-coated tablet contains: Memantine Hydrochloride (USP)…….10mg
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 56's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ymana 10 mg of MHRA Approved
	Me-too status	Memura Tablet by Pharmevo (Reg. No. 055485)
	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.

	Remarks of the Evaluator.	
	Decision: Approved.	
323.	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	Mantin Tablets 20mg
	Diary No. Date of R& I & fee	Diary No: 23938 dated 11-07-2018 Rs.20,000/- 27-6-2018
	Composition	Each film-coated tablet contains: Memantine Hydrochloride (USP)…….20mg
	Pharmacological Group	Anti-dementia drugs
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 56's / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ymana 20 mg of MHRA Approved
	Me-too status	Memura Tablet by Pharmevo (Reg. No. 055485)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
324.	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	K-Tin 0.025% Ophthalmic Solution
	Diary No. Date of R& I & fee	Diary No: 23985 dated 11-07-2018 Rs.20,000/- 28-6-2018
	Composition	Each ml Contains: Ketotifen Fumarate…0.25mg (0.025%)
	Pharmacological Group	Anti -Histamine
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	5ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zaditen 0.25 mg/ml, eye drops, solution of MHRA Approved
	Me-too status	Zaditor Eyes Drops of M/s Innvotek Pharmaceuticals
	GMP status	04-10-2017 for Grant of new DML Panel recommends grant of new DML.
	Remarks of the Evaluator.	Eye Drops General section available
	Decision: Approved with innovator's specifications.	
325.	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	Tanzoflex Tablets 2mg
	Diary No. Date of R& I & fee	Diary No: 23951 dated 11-07-2018 Rs.20,000/- 27-6-2018
	Composition	Each tablet contains: Tizanidine Hydrochloride(USP)……...2mg
	Pharmacological Group	Skeletal Muscle relaxant
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tizanidine of MHRA approved
	Me-too status	Mecost 10mg Tablet M/s Sigma
	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.

	Remarks of the Evaluator.	
	Decision: Approved.	
326.	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	SCAFIN LOTION 1% w/v
	Diary No. Date of R& I & fee	Diary No: 23980 dated 11-07-2018 Rs.20,000/- 28-6-2018
	Composition	Each ml contains: Lindane (USP)……10mg (1 % w/v)
	Pharmacological Group	Ecto-parasiticide and ovicide
	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.	Scabene Lotion (STIEFELS USA)USFDA approved
	Me-too status	Lice o nil of M/s Wilson Pharma
	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.
	Remarks of the Evaluator.	Lotion section available
	Decision: Approved.	
327.	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	Natasol 50mg/ml (5%) Ophthalmic Suspension
	Diary No. Date of R& I & fee	Diary No: 23988 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each ml Contains: Natamycin (USP)……50mg(5%)
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Natacyn 5% of USFDA Approved
	Me-too status	Natamin ophthalmic suspension by Alza Reg # 081628
	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.
	Remarks of the Evaluator.	Eye Drops General section available
	Decision: Approved.	
328.	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	Lonox 8mg/2ml Lyophilized Powder for Injection & Infusion
	Diary No. Date of R& I & fee	Diary No: 23915 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each 2ml vial contains Lornoxicam(MS)……8mg
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	1's Vial / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Xefo 8mg powder for solution for injection Of EMA approved
	Me-too status	Viltaz Injection 8mg/2ml by Wilshire (Reg. No. 077112)

	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.
	Remarks of the Evaluator.	
	Decision: Deferred for confirmation of manufacturing facility	
329.	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	Laxomove Sachet
	Diary No. Date of R& I & fee	Diary No: 23968 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each **13.8g** Sachet contains: **Macrogol** 3350 (BP)……..13.125gm Sodium bicarbonate (BP)……..350.7mg Potassium chloride (BP)……..46.6mg Sodium chloride (BP)……178.5mg
	Pharmacological Group	Osmotically active laxative
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's Sachet /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Movicol powder for oral solution by M/s Norgine Ltd. (MHRA approved)
	Me-too status	Atilief Oral of Getz Pharma (Reg. No. 076565),
	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.
	Remarks of the Evaluator.	Sachet section available
	Decision: Approved.	
330.	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	Lotifin-T 0.5%+3% Opthalmic suspension
	Diary No. Date of R& I & fee	Diary No: 23987 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each ml contains : Loteprednol Etabonate (MS)……5mg Tobramycin(USP) ……..3mg
	Pharmacological Group	Corticosteroid & Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	5ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zylet of (USFDA approved)
	Me-too status	Lotepred-T of M/s Elko
	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.
	Remarks of the Evaluator.	Eye Drops General section available
	Decision: Approved with innovator's specifications.	
331.	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	URSOLIC Oral Suspension 250mg/5ml
	Diary No. Date of R& I & fee	Diary No: 23967 dated 11-07-2018 Rs.20,000/- 28-6-2018
	Composition	Each 5 ml contains: Ursodeoxycholic acid (BP)……250mg
	Pharmacological Group	Bile-acid
	Type of Form	Form-5

	Finished Product Specification	BP
	Pack size & Demanded Price	30ml, 60ml, 90ml, 120ml /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ursofalk 250mg/5ml Suspension Of MHRA Approved
	Me-too status	Urso Suspension by AGP (Reg. No. 076152)
	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.
	Remarks of the Evaluator.	
	Decision: Approved.	
332.	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	Lotifin- 0.5% Opthalmic suspension
	Diary No. Date of R& I & fee	Diary No: 23986 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Composition	Each ml contains: Loteprednol Etabonate…5mg(0.5%)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	5ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lotemax 0.5% Eye Drops by MHRA approved
	Me-too status	Lotepred Forte of M/s Elko (REG NO: 067458)
	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.
	Remarks of the Evaluator.	Eye Drops General section available
	Decision: Approved with innovator's specifications.	
333.	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	Solocain 1% Injection
	Composition	Each ml Contains: Lidocaine HCl……10mg
	Diary No. Date of R& I & fee	Dy.No. 26451 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Local anaesthetic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Lidocaine Injection 1% w/v (MHRA approved)
	Me-too status	Lacain 1% Injection of M/s. Pulse Pharmaceuticals
	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.
	Remarks of the Evaluator	
	Decision: Approved.	
334.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Zibix 200mg Tablet
	Composition	Each film coated Tablet Contains: Celecoxib……200mg
	Diary No. Date of R& I & fee	Dy.No.16179 dated 02-05-2018 Rs.20,000/- 02-05-2018

	Pharmacological Group	Anti- inflammatory
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Not found
	Me-too status (with strength/dosage form)	Coxia 200 mg Tablets of M/s Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 28-09-2017 and the report concludes that firm was found at good level of GMP.
	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 the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Confirmation of DML status.**	
335.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Esofen 10mg Tablets
	Composition	Each Tablet Contains: Baclofen……..10mg
	Diary No. Date of R& I & fee	Dy.No. 16178 dated 02-05-2018 Rs.20,000/- 02-05-2018
	Pharmacological Group	Muscle Relaxant and antispastic
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10's, 20's, & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Baclofen of (MHRA approved)
	Me-too status (with strength/dosage form)	Baclin Tablets Of M/S Genome Pharmaceuticals
	GMP status	Last GMP inspection conducted on 28-09-2017 and the report concludes that firm was found at good level of GMP.
	Remarks of the Evaluator	Formulation change from coated tablet to uncoated tablet without submission of fee.
	Decision: Deferred for the following: • **Submission of fee for revision of formulation.** • **Confirmation of DML status.**	
336.	Name and address of manufacturer / Applicant	M/s Espoir Pharmaceuticals. PCSIR KLC TBIC-II PCSIR Laboratory Complex, Shahrah-e-Dr. Salim Uz Zaman Siddiqui Off University Road, Karachi
	Brand Name +Dosage Form + Strength	Glitapin 50mg Tablet
	Composition	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate Eq. to Sitagliptin…….50mg
	Diary No. Date of R& I & fee	Dy.No. 16177 dated 02-05-2018 Rs.20,000/- 02-05-2018
	Pharmacological Group	Antihyperglycemic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	10's, 20's, & 30's As per SRO
	Approval status of product in Reference Regulatory Authorities	Januvia tablets of (FDA approved)
	Me-too status (with strength/dosage form)	A-Glip Tablets of M/s Atco Labs
	GMP status	Last GMP inspection conducted on 28-09-2017 and the

		report concludes that firm was found at good level of GMP.
	Remarks of the Evaluator	Firm correct salt from Sitagliptin potassium monohydrate to Sitagliptin phosphate monohydrate without submission of fee.
	Decision: Deferred for the following: • **Submission of fee for revision of formulation.** • **Confirmation of DML status.**	
337.	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	Blukast 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Montelukast as Sodium…5mg
	Diary No. Date of R& I & fee	Dy.No. 17081 dated 09-05-2018 Rs.20,000/- 09-05-2018
	Pharmacological Group	Leukotriene receptor antagonist
	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	Singulair 5mg chewable of (USFDA approved)
	Me-too status	Lontuka 5mg Chewable Tablet M/s Linz Pharmaceuticals.
	GMP status	"Cetificate of Good manufacturing practices based on inspection conducted on 19-07-2019"
	Remarks of the Evaluator	The reference formulation is available as chewable tablet
	Decision: Deferred for revision of formulation to chewable tablet as per the reference product along with submission of fee for revision of formulation.	
338.	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	Blukast 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Montelukast as Sodium……..10mg
	Diary No. Date of R& I & fee	Dy.No. 17078 dated 09-05-2018 Rs.20,000/- 09-05-2018
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's' 14's' 30's ; 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	"Cetificate of Good manufacturing practices based on inspection conducted on 19-07-2019"
	Remarks of the Evaluator	
	Decision: Approved.	
339.	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	Blofar 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Warfarin Sodium…….5mg
	Diary No. Date of R& I & fee	Dy.No. 17079 dated 09-05-2018 Rs.20,000/- 09-05-2018
	Pharmacological Group	Thromboembolic conditions
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	10 x 10's :As per SRO
	Approval status of product in	COUMADIN of USFDA approved

	Reference Regulatory Authorities	
	Me-too status (with strength/dosage form)	Coagurin 5mg Tablets of M/S Atco Laboratories
	GMP status	"Cetificate of Good manufacturing practices based on inspection conducted on 19-07-2019"
	Remarks of the Evaluator	
	Decision: Approved.	
340.	Name and address of manufacturer / Applicant	M/S. Epharm Laboratpories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Azole 200mg Tablet
	Composition	Each film coated tablet contains: Albendazole…….200mg
	Diary No. Date of R& I & fee	Dy.No.16876; 03 -10-2017; Rs.20,000/- (03-10-2017)
	Pharmacological Group	Anthelmintic drug
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	2's, 6's, 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	ALBENZA of USFDA approved
	Me-too status (with strength/dosage form)	Acure Tablet 200mg Pharmix Labs Lahore (R#025875)
	GMP status	The last GMP inspection conducted on 01-03-2018 and report concludes that current level of compliance was noted as satisfactory.
	Remarks of the Evaluator	Firm change formulation from uncoated to film coating with submission of fee Rs: 5000/- dated: 29-07-2019 Challan No# 0588720
	Decision: Approved.	
341.	Name and address of manufacturer / Applicant	M/S. Epharm Laboratpories, A-40, Road No. 1, S.I.T.E, Super Highway Industrial Area, North Karachi
	Brand Name +Dosage Form + Strength	Hylupharm 1.8mg/ml ophthalmic Solution
	Composition	Each ml contains: Sodium Hyaluronate…….1.8mg
	Diary No. Date of R& I & fee	Dy.No.17991; 12 -10-2017; Rs.20,000/- (12-10-2017)
	Pharmacological Group	Lubricant
	Type of Form	Form 5
	Finished product Specifications	JP
	Pack size & Demanded Price	5ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by TGA
	Me-too status (with strength/dosage form)	Hylo Eye Drops of M/S Helix Pharma
	GMP status	The last GMP inspection conducted on 01-03-2018 and report concludes that current level of compliance was noted as satisfactory.
	Remarks of the Evaluator	Firm has ophthalmic Drop section. Firm has submitted revised form 5, composition and master formulation on 29-07-2019 as under: —Each ml contains: Sodium hyaluronate …. 2 mg With submission of fee RS: 5000/-challan no# 0588719 dated: 29-07-2019
	Decision: Deferred for submission of balance fee i.e. 15,000/- for the revision of formulation.	
342.	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Glyzia Met 50/850 mg Tablets

	Composition	Each film coated Tablet Contains: Sitagliptin (Phosphate Monohydrate)…50mg Metformin HCL …850mg
	Diary No. Date of R& I & fee	Dy.No. 26442 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Antihyperglycemic
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's, 14's, ; Rs: 448/ 10's, Rs: 627/14's
	Approval status of product in Reference Regulatory Authorities	Janumet tablets of (TGA approved)
	Me-too status	S-Gliptin Plus Tablets of M/s Barrett Hodgson
	GMP status	Last GMP inspection was conducted on 06-08-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
343.	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Vilzamet 50/1000 mg Tablet
	Composition	Each film coated Tablet Contains: Vildagliptin…50mg Metformin Hydrochloride…1000mg
	Diary No. Date of R& I & fee	Dy.No. 26445 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Antihyperglycemic agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's Rs: Rs: 1087.33
	Approval status of product in Reference Regulatory Authorities	GA Galvumet Tablet Of (TGA Approved)
	Me-too status	Vilget-M 50mg+1000mg Tablet M/s Getz
	GMP status	Last GMP inspection was conducted on 06-08-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator	shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.
	Decision: Approved with innovator's specifications and shelf life of 18 months with packaging material of PA/Al/PVC/Al -polyamide-aluminum foil-polyvinylchloride/aluminum foil or PCTFE/PVC/Alu or 2 years with PA/Alu/PVC/Alu.	
344.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	Sulpeol 25mg Tablet
	Composition	Each Uncoated Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy.No. 26423 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antipsychotic
	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	Levopraid 25 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 23-2-2018 & 26-2-2018

		and report concludes that firm has maintained a satisfactory level of GMP compliance."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
345.	Name and address of manufacturer / Applicant	M/s Demont Research Laboratories. 20km, Lahore-Sharikpur Road, Sheikhupura.
	Brand Name +Dosage Form + Strength	Sulpeol 50mg Tablet
	Composition	Each Uncoated Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy.No. 26424 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	LEVOPRAID 25 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	Last GMP inspection conducted on 23-2-2018 & 26-2-2018 and report concludes that firm has maintained a satisfactory level of GMP compliance."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
346.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Meskazole 100mg Tablets
	Composition	Each chewable tablet Contains: Mebendazole……100mg
	Diary No. Date of R& I & fee	Dy.No. 16683 dated 07-05-2018 Rs.20,000/- 07-05-2018
	Pharmacological Group	Anthelmintics (Benzimidazole derivatives)
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1's, 2's, 7's, 10's, 14's, 20's,28's, 30's, & 60's : As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Mebendazole 100 mg Chewable Tablets by M/s Johnson & Johnson (MHRA Approved)
	Me-too Status	Almeb Tablets 100mg of M/s Alsons Pharmaceuticals
	GMP status	"Last GMP inspection conducted on **09**-07-2019 and report concludes that Overall GMP of the firm is rated as Good, based on the area inspected, the people met and the documents reviewed.
	Remarks of the Evaluator	
	Decision: Approved.	
347.	Name and address of manufacturer / Applicant	M/s Atco Laboratories Limited. B-18, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Meskazole 500mg Tablets
	Composition	Each ChewableTablet Contains: Mebendazole……500mg
	Diary No. Date of R& I & fee	Dy.No. 16682 dated 07-05-2018 Rs.20,000/- 07-05-2018
	Pharmacological Group	Anti-infective/ Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	1's, 2's, 7's, 10's, 14's, 20's,28's, 30's, & 60's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Vermox 500mg chewable tablet of M/s Janssen Pharms (Discontinued in USFDA)

	Me-too status	Almeb Tablets 500mg of M/s Alsons Pharmaceuticals
	GMP status	"Last GMP inspection conducted on 09-07-2019 and report concludes that Overall GMP of the firm is rated as Good, based on the area inspected, the people met and the documents reviewed.
	Remarks of the Evaluator	Firm revise form 5 for chewable tablet without submission of fee.
	Decision: Deferred for following: • **Submission of fee for revision of formulation** • **Approval status in Reference regulatory authorities**	
348.	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	Terbimit 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine HCl eq. to Terbinafine…250mg
	Diary No. Date of R& I & fee	Dy.No. 26452 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1 x 10's, 3 x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Terbinafine 250mg Tablet MHRA Approved
	Me-too status	Lamisil Tablet by M/s Sandoz
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
349.	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	Coxwit 20mg/ml Injection
	Composition	Each ml Contains: Piroxicam……20mg
	Diary No. Date of R& I & fee	Dy.No. 26453 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	1ml x 5's & 1ml x 10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved by ANSM of France
	Me-too status	Salden 20mg Injection of M/s Danas Pharma (Reg#080373)
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
350.	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	Acmenoin 20mg Capsule
	Composition	Each Capsule Contains: Isotretinoin……20mg
	Diary No. Date of R& I & fee	Dy.No. 26454 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti. acne
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	4's ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Absorica 20mg capsules of (USFDA approved)
	Me-too status	Iret 20mg Capsule of M/s Baxter
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Deferred for confirmation whether applied as soft gel or otherwise and relevant manufacturing facility.	
351.	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	Fexmit 120mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…….120mg
	Diary No. Date of R& I & fee	Dy.No. 26465 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti histamines
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's,; As per SRO
	Approval status of product in Reference Regulatory Authorities	Fexofenadine hydrochloride 120mg film coated tablets by (MHRA Approved)
	Me-too status	Epodin 120mg Tablet M/s Epoch Pharmaceutical,
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
352.	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	Fexmit 180mg Tablet
	Composition	Each Film Coated Tablet Contains: Fexofenadine HCl…….180mg
	Diary No. Date of R& I & fee	Dy.No. 26466 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti histamines
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's, 3 x 10's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Fexofenadine hydrochloride 180 film coated tablets by (MHRA Approved)
	Me-too status	Fexamed 180mg Tablet M/s OBS Pharma
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
353.	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	Xaremit 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban…10mg
	Diary No. Date of R& I & fee	Dy.No. 26469 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti-thrombic
	Type of Form	Form-5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	10's, /As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 10 mg Tablet of (USFDA approved)
	Me-too status	Xerelto 10mg Tablet by Bayer Pakistan (Reg. No. 059057)
	GMP status	GMP Certificate issued on 10-12-2018.

	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
354.	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	Xaremit 15mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……15mg
	Diary No. Date of R& I & fee	Dy.No. 26470 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti-thrombic
	Type of Form	Form-5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	14's, /As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 15 mg Tablet of (USFDA approved)
	Me-too status	Xerelto 15mg Tablet by Bayer Pakistan (Reg. No. 059057)
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
355.	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	Xaremit 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Rivaroxaban……20mg
	Diary No. Date of R& I & fee	Dy.No. 26471 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti-thrombic
	Type of Form	Form-5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	14's /As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 20 mg Tablet of (USFDA approved)
	Me-too status	Xerelto 20mg Tablet by Bayer Pakistan (Reg. No. 059057)
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
356.	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	Diaxan 500mg Tablet
	Composition	Each Film Coated Tablet Contains: Nitazoxanide…….500mg
	Diary No. Date of R& I & fee	Dy.No. 26455 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Agents against amoebiasis and other protozoal diseases
	Type of Form	Form-5
	Finished product Specification	Manufacturers specifications
	Pack size & Demanded Price	2 x 10's, 3 x 10's /As per SRO
	Approval status of product in Reference Regulatory Authorities	Alinia Tablet of (USFDA approved)
	Me-too status	Nizonide 500mg Tablet of AGP
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
357.	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	Flucona 200mg Capsule

	Composition	Each Capsule Contains: Fluconazole…200mg
	Diary No. Date of R& I & fee	Dy.No. 26456 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	4's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	GA Azocan 200mg capsule Of (MHRA Approved)
	Me-too status	Fcozole 200mg Capsules M/s Medicraft pharmaceuticals
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
358.	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	Clomifen 50mg Tablet
	Composition	Each Tablet Contains: Clomiphene Citrate…50mg
	Diary No. Date of R& I & fee	Dy.No. 26457 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti-estrogen
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	1 x 10's , 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Clomid of (USFDA approved)
	Me-too status	Kins Tablets by Stanley Pharmaceuticals
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
359.	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	Wimdone SR 6mg Tablet
	Composition	Each Sustained Release Tablet Contains: Paliperidone……..6mg
	Diary No. Date of R& I & fee	Dy.No. 26458 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	14's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	INVEGA of USFDA approved.
	Me-too status	Avega 6mg Tablets of M/s Biogen Pharma
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Registration Board deferred the case for submission of manufacturing method of applied formulation in line with reference product which is prepared by OROS Push Pull tecnology.	
360.	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	Levopaid 25mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…25mg
	Diary No. Date of R& I & fee	Dy.No. 26461 dated 01-08-2018 Rs.20,000/- 01-08-2018

	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	LEVOPRAID 25 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
361.	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	Levopaid 50mg Tablet
	Composition	Each Tablet Contains: Levosulpiride…50mg
	Diary No. Date of R& I & fee	Dy.No. 26462 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	20's, 30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	LEVOPRAID 25 mg tablet of AIFA italy
	Me-too status	Scipride tablet M/s Getz Pharma
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
362.	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	Aripizole 10mg Tablet
	Composition	Each Tablet Contains: Aripiprazole…10mg
	Diary No. Date of R& I & fee	Dy.No. 26463 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Abilify of USFDA approved.
	Me-too status	Mactril Tablet 10mg of M/s Wilshire Laboratories
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	Firm change formulation from film coating to uncoated with out submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
363.	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	Aripizole 15mg Tablet
	Composition	Each Tablet Contains: Aripiprazole…15mg
	Diary No. Date of R& I & fee	Dy.No. 26464 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's ; As per SRO

	Approval status of product in Reference Regulatory Authorities	Abilify uncoated of USFDA approved.
	Me-too status	Mactril Tablet 10mg of M/s Wilshire Laboratories
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	Firm change formulation from film coating to uncoated with out submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
364.	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	Quwim 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate eq. to Quetiapine…25mg
	Diary No. Date of R& I & fee	Dy.No. 26459 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antipsychotic Drugs
	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	Seroquel of USFDA approved.
	Me-too status	Nubaquel 25mg Tablet of M/s Nabiqasim
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
365.	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	Quwim 100mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine Fumarate eq. to Quetiapine…100mg
	Diary No. Date of R& I & fee	Dy.No. 26460 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Antipsychotic Drugs
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Seroquel of USFDA approved.
	Me-too status	Nubaquel 25mg Tablet of M/s Nabiqasim
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
366.	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	Amsartan Plus 5mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine (as Besylate)…5mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No. 26468 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Of (USFDA Approved)
	Me-too status	Co-Valzaar 5mg/160mg Tablet by M/s Vision

		Pharmaceuticals
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
367.	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	Amsartan Forte 10mg/160mg Tablet
	Composition	Each Film Coated Tablet Contains: Amlodipine (as Besylate)….10mg Valsartan…160mg
	Diary No. Date of R& I & fee	Dy.No. 26467 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Calcium antagonist/Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Exforge Of (USFDA Approved)
	Me-too status	Co-Valzaar 10mg/160mg Tablet by M/s Vision Pharmaceuticals
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
368.	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	Olmifin 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…5mg
	Diary No. Date of R& I & fee	Dy.No. 26472 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Benicar Of (USFDA Approved)
	Me-too status	Basitec 5mg Tablet of M/s Barrett Hodgson
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
369.	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	Olmifin 10mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…10mg
	Diary No. Date of R& I & fee	Dy.No. 26473 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA approved
	Me-too status	Oscord 10mg Tablet of M/s Hilton Pharma
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	

	Decision: Approved.	
370.	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	Olmifin 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg
	Diary No. Date of R& I & fee	Dy.No. 26474 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Benicar Of (USFDA Approved)
	Me-too status	Basitec 20mg Tablet of M/s Barrett Hodgson
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
371.	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	Olmifin 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg
	Diary No. Date of R& I & fee	Dy.No. 26475 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Angiotensin II antagonist
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Benicar Of (USFDA Approved)
	Me-too status	Basitec 40mg Tablet of M/s Barrett Hodgson
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved.	
372.	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	Olmifin-A 20mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…20mg Amlodipine as Besylate…5mg
	Diary No. Date of R& I & fee	Dy.No. 26476 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti hypertension
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	20's,; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 20mg/5mg tablets Of (USFDA Approved)
	Me-too status	Baritec-A 20/5mg Of M/S Barret Hodgson
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	

373.	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	Olmifin-A 40mg Tablet
	Composition	Each Film Coated Tablet Contains: Olmesartan Medoxomil…40mg Amlodipine as Besylate…5mg
	Diary No. Date of R& I & fee	Dy.No. 26477 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anti hypertension
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	20's ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Azor 40mg/5mg tablets Of (USFDA Approved)
	Me-too status	Baritec-A 40mg/5mg Of M/S Barret Hodgson
	GMP status	GMP Certificate issued on 10-12-2018.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
374.	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	Nimsol Tablets 100mg
	Diary No. Date of R& I & fee	Diary No: 23943 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Composition	Each tablet contains: Nimesulide(BP) ……...100mg
	Pharmacological Group	NSAID Cox-2 Inhibitor
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specifications
	Pack size & Demanded Price	20's 30's /As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by EMA
	Me-too status	Nims Tablet by Sami Reg. No. 026657
	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.
	Remarks of the Evaluator.	Firm change formulation from "film coated tablet" to "uncoated tablet" with submission of fee Rs: 5000/- Challan No# 0778959 dated: 28-08-2019
	Decision: Approved with innovator's specifications.	
375.	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
	Diary No. Date of R& I & fee	Diary No: 23918 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Composition	Each 3ml contains: Thiamine Hydrochloride(USP)..…100mg Pyridoxine Hydrochloride(USP)…..100mg Cyanocobalamin (USP)……1000mcg
	Pharmacological Group	B-complex vitamin
	Type of Form	Form-5
	Finished Product Specification	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	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.
	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
	Decision: Deferred for submission of fee for revision of formulation.	

a. New DML

376.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals. Plot No. 220, Industrial Triangle, Kahuta Road, Islamabad, Pakistan
	Brand Name +Dosage Form + Strength	Rulex 250mg Capsule
	Composition	Each Capsule Contains: Cephalexin Monohydrate Eq to Cephalexin…250mg
	Diary No. Date of R& I & fee	Dy.No 3386 dated 24-01-2019 Rs.20,000/- 24-01-2019
	Pharmacological Group	Cephalosporins
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Cephalexin Capsules of USFDA approved
	Me-too status (with strength and dosage form)	Defmat 250mg Capsule by M/s Martin Dow
	GMP status	New license
	Remarks of the Evaluator	• New DML case • In 289th meeting of Registration board decision was not recorded.
	Decision: Approved.	

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a. New Cases

377.	Name and address of manufacturer / Applicant	M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi.
	Brand Name +Dosage Form + Strength	Nawazan DS suspension
	Composition	Each 100ml contains: levamisole Hcl…….3g Oxyclozanide…….6g
	Diary No. Date of R& I & fee	Dy.No.24002 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Anthelmintics
	Type of Form	Form 5
	Finished product Specification	Manufacturers specification
	Pack size & Demanded Price	100ml, 500ml, 1000ml, ; Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Leox D.S. Suspension Of Elko Organization
	GMP status	Last GMP inspection conducted on 30-04-2018 and report concludes that firm was found to be operating at a

		satisfactory level of GMP compliance."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
378.	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	Para-20 Powder
	Composition	Each 100gm Contains:- Paracetamol……..20.0gm. Vitamin C…….5.0gm. Potassium Carbonate..12.5gm. Sodium Bicarbonate..12.5gm. Vitamin E……12.5gm.
	Diary No. Date of R& I & fee	Dy.No. 23816 dated 10-07-2018 Rs.20,000/- 06-07-2018
	Pharmacological Group	Antioxodant, analgesic, antipyretic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	1gm, 200gm, 30gm, 50gm, 100gm, 250gm, 500gm, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg ; Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Para Ce Oral Powder. Of Biogen Pharma
	GMP status	Last GMP inspection conducted on 16-03-2017 and report concludes that firm was considerd to be operating at good level of GMP Compliance." Section evidence
	Remarks of the Evaluator	
	Decision: Registration Board referred the applied formulation to Expert Working Group on Veterinary Drugs for review.	
379.	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	Cina-F Suspension
	Composition	Each ml Contains: Trimethoprim…25mg Sulphamethazine…50mg Sulphamethoxypyradizine…75mg Enrofloxacin…75mg
	Diary No. Date of R& I & fee	Dy.No. 23817 dated 10-07-2018 Rs.20,000/- 06-07-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1 Liter, 2.5Liter, 5 Liter, 10Liter, 15Liter, 20 Liter, 25 Liter: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Cina T.S Oral Of M/S Vety-Care Pharmaceutical
	GMP status	Last GMP inspection conducted on 16-03-2017 and report concludes that firm was considerd to be operating at good level of GMP Compliance."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
380.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Spiral Powder

	Composition	Each gm Powder contains: Spiramycin adipate…75mg Lincomycin…25mg
	Diary No. Date of R& I & fee	Dy.No. 23243 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturers specification
	Pack size & Demanded Price	100gm, 200gm, 500gm, & 1000gm ; As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Specto Oral Powder Of M/S. Bio-Oxime Pharmaceuticals
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
381.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Prelinc Powder
	Composition	Each 1000g Powder contains: Lincomycin Hcl….4.4%(4.4gm)
	Diary No. Date of R& I & fee	Dy.No. 23244 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specification
	Pack size & Demanded Price	100GM, 500GM, 1KG, 2.5KG, 5KG, 10KG, 25KG ; As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Lincofas-44 Powder. Of M/S. Intervac
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
382.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Neocin 60mg Powder

	Composition	Each 100g Powder contains: Neomycin Sulphate…60mg
	Diary No. Date of R& I & fee	Dy.No. 23245 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Neocin-S Water Soluble Powder Of M/S Alina Combine
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
383.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Amprobate 200/20mg Powder
	Composition	Each gm Powder contains: Amprolium HCL…200mg Ethopabate…20mg
	Diary No. Date of R& I & fee	Dy.No. 23253 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Pharmacological Group	Antiprotozoal(Coccidiostat)
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Ethoprol Powder Of M/S Selmore Pharmaceuticals
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
384.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Biocolis Powder 500 MIU
	Composition	Each 100g Powder contains: Colistine Sulfate…500 Million IU
	Diary No. Date of R& I & fee	Dy.No. 23252 dated 05-07-2018 Rs.20,000/- 04-07-2018

	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100gm, 200gm, 500gm, 1000gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Colimark Powder Of M/S Westmont Pharmaceutical
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
385.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Biodox plus liquid
	Composition	Each ml liquid Contains: Doxycycline Hcl…200mg Tylosine tartrate…100mg Colistine Sulfate……500,000IU Bromhexine Hcl…10mg/ml
	Diary No. Date of R& I & fee	Dy.No. 23251 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Fagu Dox Oral liquid of M/s Farm Aid
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
386.	Name and address of manufacturer / Applicant	M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad
	Brand Name +Dosage Form + Strength	Trimet 250mg/ml Liquid
	Composition	Each 100ml contains: Tilmicosin as phosphate…250mg Liquid
	Diary No. Date of R& I & fee	Dy.No.23242 dated 05-07-2018 Rs.20,000/- 04-07-2018

	Pharmacological Group	Antibiotic/ Fluroquinolones
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml, 200ml, 500ml, 1000ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Biotil Liquid.Of M/S Bio-Labs
	GMP status	Last GMP inspection conducted on 12-12-2017 and report concludes that " No production activity have been observed during inspection. The mangment has informed they have not produced any batch since the grant of license I.e. Nov, 2016 and registeration i.e. Aug, 2017 Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection the management agreed to rectify the shortcomings pointed during inspection and will submit compliance report"
	Remarks of the Evaluator	
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
387.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Z-Trim 48 Oral Liquid 80mg/400mg
	Composition	Each ml Oral Liquid Contains: Trimethoprim…80mg Sulphadiazine…400mg
	Diary No. Date of R& I & fee	Dy.No. 26437 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Sulphonamides
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	50ml, 100ml, 500ml, 1000ml, 10liter, 25liter,:Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Sulphadi-Prim Oral Liquid Of M/S. Vantage Pharmaceutical,
	GMP status	Certificate of current Good manufacturing practice based on inspection conducted on 31-01-2018
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
388.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Z-Tylo 500 Water Soluble Powder
	Composition	Each 1000gm WSP Contains: Tylosin Tartrate…500g
	Diary No. Date of R& I & fee	Dy.No. 26438 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	25g, 50g, 100g, 500g, 1000g, 5Kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Pri-Macrocid Water Soluble Powder Of M/S Prix Pharmaceutica
	GMP status	Certificate of current Good manufacturing practice based on inspection conducted on 31-01-2018

	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
389.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Z-Oxy 95% Water Soluble Powder
	Composition	Each 100gm WSP Contains: Oxytetracycline HCl…95g
	Diary No. Date of R& I & fee	Dy.No. 26439 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Tetracycline
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	25g, 50g, 100g, 500g, 1000g, 5Kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Oxytrac 95% Water Soluble Powder Of M/S Prix Pharmaceutica
	GMP status	Certificate of current Good manufacturing practice based on inspection conducted on 31-01-2018
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
390.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Z-Brom Plus Water Soluble Powder
	Composition	Each 1g WSP Contains: Bromohexine HCl…20mg Menthol…4mg
	Diary No. Date of R& I & fee	Dy.No. 26441 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Expectorant, Decongestant
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	50g, 100g, 500g, 1000g, 5Kg, 10kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Tusnil 2% Powder Of M/S M/S. Univet Pharmaceuticals
	GMP status	Certificate of current Good manufacturing practice based on inspection conducted on 31-01-2018
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
391.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Z-Vit C Water Soluble Powder
	Composition	Each 100g WSP Contains: Vitamin C (Ascarbic Acid)…30g
	Diary No. Date of R& I & fee	Dy.No. 26434 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Vitamin
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	25g, 50g, 100g, 500g, 1000g, 5Kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Ceprix 300 Water Soluble Powder Of M/S Prix Pharmaceutica
	GMP status	Certificate of current Good manufacturing practice based on

		inspection conducted on 31-01-2018
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
392.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Sulfazoc Water Soluble Powder
	Composition	Each 100g WSP Contains: Sulfachlorpyrazine Sodium…30g
	Diary No. Date of R& I & fee	Dy.No. 26436 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	25g, 50g, 100g, 500g, 1000g, 5Kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Coxx 30 Water Soluble Powder Of Prix Pharmaceutica
	GMP status	Certificate of current Good manufacturing practice based on inspection conducted on 31-01-2018
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
393.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Z-Doxy 25% Water Soluble Powder
	Composition	Each 100g WSP Contains: Doxycycline Hyclate…25g
	Diary No. Date of R& I & fee	Dy.No. 26435 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Tetracycline
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	25g, 50g, 100g, 500g, 1000g, 5Kg, 25kg: Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Unidox Powder.Of M/S Nivet Pharmaceuticals,
	GMP status	Certificate of current Good manufacturing practice based on inspection conducted on 31-01-2018
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
394.	Name and address of manufacturer / Applicant	M/s Zoic International, Plot No. 573, S.I.E., Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Z-Pfloxin Oral Liquid
	Composition	Each 100ml Oral Liquid Contains: Pefloxacine Methanesulfonate…13.960g (Pefloxacine Base…10.000g)
	Diary No. Date of R& I & fee	Dy.No. 26440 dated 01-08-2018 Rs.20,000/- 31-07-2018
	Pharmacological Group	Synthesized quinolones carboxylic derivatives
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	50ml, 500ml, 1000ml, 2.5liter, 5liter: Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Peperoxin Solution of M/s Hassan Brothers Reg# 082807
	GMP status	Certificate of current Good manufacturing practice based on inspection conducted on 31-01-2018

	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
395.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Fospho-AV Injection 100ml
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin...0.05mg Taurine…37.3mg Nicotinamide…23.0mg DL-Methionine…18.7mg
	Diary No. Date of R& I & fee	Dy.No. 26448 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Phosphorus/Supplement/Vitamis/Aminoacids
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml,:Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Carasil Injection Of M/S Selmore Agencies Imported product from Korea
	GMP status	Last GMP inspection conducted on 02-01-2018, 16-01-2018 & 23-01-2018 and report concludes that firm was considered to be operating at a good level of GMP compliance."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
396.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Phosvit Injection 100ml
	Composition	Each ml Contains: Butaphosphan…100mg Cyanocobalamin…0.05mg
	Diary No. Date of R& I & fee	Dy.No. 26450 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Phosphorus/Supplement/Vitamis
	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	100ml,:Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Cynophos Injection Of M/S Elko Organization
	GMP status	Last GMP inspection conducted on 02-01-2018, 16-01-2018 & 23-01-2018 and report concludes that firm was considered to be operating at a good level of GMP compliance."
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications.	
397.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Vitamec Injection 10ml
	Composition	Each ml Contains: Ivermectin…10mg Vitamin A…40,000iu Sodium Selenite…500mcg Vitamin-E…10mg
	Diary No. Date of R& I & fee	Dy.No. 26446 dated 01-08-2018 Rs.20,000/- 01-08-2018
	Pharmacological Group	Anthelmintic/Vitamins/Dietary Supplements

	Type of Form	Form 5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	10ml,: As per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Armec Forte Injection Of M/S zakfas Pharmaceuticals
	GMP status	Last GMP inspection conducted on 02-01-2018, 16-01-2018 & 23-01-2018 and report concludes that firm was considered to be operating at a good level of GMP compliance."
	Remarks of the Evaluator	
	Decision: Registration Board referred the applied formulation to Expert Working Group on Veterinary Drugs for review.	

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

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

398.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Private Limited. Plot No. 44 A-B, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Bfolic 5mg Table
	Composition	Each Tablet Contains: Folic Acid…5mg
	Diary No. Date of R& I & fee	Dy.No. 41059 dated 06-12-2018 Rs.20,000/- 06-12-2018
	Pharmacological Group	Vitamin B9
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	28's, 100's: As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Zal 5mg Tablets of M/s Alsons Pharmaceuticals
	GMP status	Last GMP inspection conducted on 22-02-2018 and report concludes that was operating under satisfactory compliance of CGMP on the day of inspection.
	Remarks of the Evaluator	
	Decision: Approved.	
399.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Cincet 30mg Tablet
	Composition	Each Film Coated Tablet Contains: Cinacalcet as HCL…30mg
	Diary No. Date of R& I & fee	Dy.No. 3898 dated 26-12-2018 Rs.20,000/- 26-12-2018
	Pharmacological Group	Calcimimetic Agent
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's, 2 x 10's, 3 x 10's:As per SRO
	Approval status of product in Reference Regulatory Authorities	Sensipar Tablet 30mg of (USFDA approved)
	Me-too status	Mimcipar tablet 30mg by M/s Genome Pharma (Reg#082301)
	GMP status	Last GMP inspection conducted on 31-05-2018 & 01-06-2018 and report concludes that With reference to last inspection the firm has made improvements regarding previous GMP inspections and they

		have installed a new HPLC and double beam UV spectrophotometer. Firm has also improved their documentation regarding production, quality control and quality assurance. But it is further advised to keep compliance of all of the parameters as mentioned in schedule B-II GMP audit Performa."
	Remarks of the Evaluator	Submitt Accelerated and Long term stability studies for 3 batches
	Decision: Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.	
400.	Name and address of manufacturer / Applicant	M/s Pharmix Laboratories Pvt Ltd. 21 Km, Ferozepur Road, Lahore
	Brand Name +Dosage Form + Strength	Folac Tablet 5mg
	Composition	Each Tablet Contains: Folic Acid…5mg
	Diary No. Date of R& I & fee	Dy.No. 43896 dated 26-12-2018 Rs.20,000/- 26-12-2018
	Pharmacological Group	
	Type of Form	Vitamin B9
	Finished product Specification	Form 5
	Pack size & Demanded Price	USP
	Approval status of product in Reference Regulatory Authorities	10 x 10's: As per SRO
	Me-too status	MHRA Approved
	GMP status	Last GMP inspection conducted on 31-05-2018 & 01-06-2018 and report concludes that With reference to last inspection the firm has made improvements regarding previous GMP inspections and they have installed a new HPLC and double beam UV spectrophotometer. Firm has also improved their documentation regarding production, quality control and quality assurance. But it is further advised to keep compliance of all of the parameters as mentioned in schedule B-II GMP audit Performa."
	Remarks of the Evaluator	
	Decision: Approved.	
401.	Name and address of manufacturer / Applicant	M/s MKB Pharmaceuticals Pvt Ltd. 66-Hayatabad Industrial Estate, Peshawar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Tenovir-Alpha 25mg Tablets
	Composition	Each Film Coated Tablet Contains: Tenofovir Alafenamide Fumarate Eq. to Tenofovir Alafenamide…25mg
	Diary No. Date of R& I & fee	Dy.No. 44549 dated 31-12-2018 Rs.20,000/- 31-12-2018
	Pharmacological Group	Antiviral
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	30's :As per SRO
	Approval status of product in Reference Regulatory Authorities	VEMLIDY of (USFDA approved)
	Me-too status	
	GMP status	Last GMP inspection conducted on 01-02-2018 and report concludes that Overall the firm was working at satisfactory level of GMP compliance."
	Remarks of the Evaluator	Stability studies required.

	Decision: Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.	
402.	Name and address of manufacturer / Applicant	M/s MKB Pharmaceuticals Pvt Ltd. 66-Hayatabad Industrial Estate, Peshawar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Tenovir 300mg Tablet
	Composition	Each Film Coated Tablet Contains: Tenofovir Disoproxil Fumarate…300mg
	Diary No. Date of R& I & fee	Dy.No. 44548 dated 31-12-2018 Rs.20,000/- 31-12-2018
	Pharmacological Group	Anti-retroviral
	Type of Form	Form 5
	Finished product Specification	IP
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	VIREAD of (USFDA approved)
	Me-too status	Tenofo-B by Getz
	GMP status	Last GMP inspection conducted on 01-02-2018 and report concludes that Overall the firm was working at satisfactory level of GMP compliance."
	Remarks of the Evaluator	
	Decision: Approved.	
403.	Name and address of manufacturer / Applicant	M/s MKB Pharmaceuticals Pvt Ltd. 66-Hayatabad Industrial Estate, Peshawar, Kpk, Pakistan
	Brand Name +Dosage Form + Strength	Femar 2.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Letrozole…2.5mg
	Diary No. Date of R& I & fee	Dy.No. 44535 dated 31-12-2018 Rs.20,000/- 31-12-2018
	Pharmacological Group	Non-Steroidal aromatase inhibitor
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Femara of (USFDA approved)
	Me-too status	Femara 2.5mg Tablet by Novartis
	GMP status	Last GMP inspection conducted on 01-02-2018 and report concludes that Overall the firm was working at satisfactory level of GMP compliance."
	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.	

e. Export facilitation

Export Facilitation: Applications was received through letter No.F.1-6/2019-PR.I (EFD) "M/s Sami Pharmaceuticals (Pvt.) Limited have achieved benchmark OF USD 893,653.92 as defined in the Board's decision during fiscal year 2018-2019. In this regard, please find the following applications		
404.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Truva 20mg Tablet
	Composition	Each film coated tablet contains: Atorvastatin Calcium trihydrate USP equivalent to Atorvastatin…….20mg
	Diary No. Date of R& I & fee	Dy.No 6551 dated 14-02-2019 Rs. 20,000/- 09-08-2018
	Pharmacological Group	Hypolipidamic(Statin)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status (with strength/dosage form)	Lipitor of M/s parke-davis
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications.	
405.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Truva 40mg Tablet
	Composition	Each film coated tablet contains: Atorvastatin Calcium trihydrate USP equivalent to Atorvastatin…….40mg
	Diary No. Date of R& I & fee	Dy.No 6552 dated 14-02-2019 Rs. 20,000/- 09-08-2018
	Pharmacological Group	Hypolipidamic(Statin)
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status (with strength/dosage form)	Lipitor of M/s parke-davis
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications.	
406.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Ritban 2.5mg Tablet
	Composition	Each film coated tablet contains: Rivaroxaban MS…….2.5mg
	Diary No. Date of R& I & fee	Dy.No 11480 dated 05-03-2019 Rs. 20,000/- 05-03-2019
	Pharmacological Group	Antithrombotic
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Xarelto 2.5mg tablet Of (USFDA Approved)

	Me-too status (with strength/dosage form)	Xarelto 2.5mg Tablet Of M/S Bayer
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications.	
407.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Ibrad 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Ivabradine Hydrochloride Eq. to Ivabradine…5mg
	Diary No. Date of R& I & fee	Dy.No 11481 dated 05-03-2019 Rs. 20,000/- 05-03-2019
	Pharmacological Group	Antiangina
	Type of Form	Form 5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ivabradine tablet of (MHRA approved)
	Me-too status (with strength/dosage form)	Sivab tablets of M/s Getz
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications.	
408.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Ibrad 7.5mg Tablet
	Composition	Each Film Coated Tablet Contains: Ivabradine Hydrochloride Eq. to Ivabradine……..7.5mg
	Diary No. Date of R& I & fee	Dy.No 11479 dated 05-03-2019 Rs. 20,000/- 05-03-2019
	Pharmacological Group	Antiangina
	Type of Form	Form 5
	Finished product Specifications	Manufacture specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Ivabradine tablet of (MHRA approved)
	Me-too status (with strength/dosage form)	Sivab tablets of M/s Getz
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications.	
409.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Telarb-H 40mg/12.5mg Tablet
	Composition	Each Bilayered Tablet Contains: Telmisartan USP…….40mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy.No 11393 dated 05-03-2019 Rs. 20,000/- 04-03-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved) Of
	Me-too status (with strength/dosage form)	Cresar–H 40/12.5mg Tablet of M/S Tabros Pharma
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	Firm submitted Commercial Invoice for Double sided Rotary tablet Press Machine Model No CMB4-D27 Firm also submit Inspection report of 02-05-2013 in which bilayred machine mentioned by FID
	Decision: Approved.	
410.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Telarb-H 80mg/12.5mg Tablet
	Composition	Each Bilayered Tablet Contains: Telmisartan USP……80mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy.No 11393; dated 05-03-2019 Rs. 20,000/- 04-03-2019
	Pharmacological Group	Antihypertensive(Angiotensin II Receptor Antagonist, Thiazide Diuretic)
	Type of Form	Form 5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Micardis HCT of (USFDA Approved)
	Me-too status (with strength/dosage form)	Cresar–H 80/12.5mg Tablet of M/S Tabros Pharma
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	Firm submitted Commercial Invoice for Double sided Rotary tablet Press Machine Model No CMB4-D27 Firm also submit Inspection report of 02-05-2013 in which bilayred machine mentioned by FID
	Decision: Approved.	
411.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Brino 500mg Tablet
	Composition	Each film coated Tablet Contains: Tranexamic Acid ……500mg
	Diary No. Date of R& I & fee	Dy.No 32411; dated 28-09-2018 Rs. 20,000/- 28-09-2018
	Pharmacological Group	Antihaemorrhagic/ Antifibrinolytic
	Type of Form	Form- 5
	Finished product Specification	B.P
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tranexamic Acid 500mg film coated tablet of MHRA Approved
	Me-too status	Traumax of M/s Siza International (Reg. # 024787)
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved.	

412.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Onato-T 5mg/40mg Tablet
	Composition	Each Bilayer Tablet Contains: Amlodipine Besylate eq to Amlodipine….5mg Telmisartan USP…….40mg
	Diary No. Date of R& I & fee	Dy.No. 1685; dated 14-01-2019 Rs. 20,000/- Dated 14-01-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	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.	Twynsta of USFDA Approved
	Me-too status	Telam 40mg/5mg Tablet of M/s Macter
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	Firm submitted Commercial Invoice for Double sided Rotary tablet Press Machine Model No CMB4-D27 Firm also submit Inspection report of 02-05-2013 in which bilayred machine mentioned by FID
	Decision: Approved with innovator's specifications.	
413.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Onato-T 5mg/80mg Tablet
	Composition	Each Bilayer Tablet Contains: Amlodipine Besylate eq to Amlodipine….5mg Telmisartan USP…….80mg
	Diary No. Date of R& I & fee	Dy.No. 1687; dated 14-01-2019 Rs. 20,000/- Dated 14-01-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	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.	Twynsta of USFDA Approved
	Me-too status	Telam 80mg/5mg Tablet of M/s Macter
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	Firm submitted Commercial Invoice for Double sided Rotary tablet Press Machine Model No CMB4-D27 Firm also submit Inspection report of 02-05-2013 in which bilayred machine mentioned by FID
	Decision: Approved with innovator's specifications.	
414.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Onato-T 10mg/40mg Tablet
	Composition	Each Bilayer Tablet Contains: Amlodipine Besylate eq to Amlodipine….10mg Telmisartan USP…….40mg
	Diary No. Date of R& I & fee	Dy.No. 1686; dated 14-01-2019 Rs. 20,000/- Dated 14-01-2019

	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	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.	Twynsta of USFDA Approved
	Me-too status	Telam 40mg/10mg Tablet of M/s Macter
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	Firm submitted Commercial Invoice for Double sided Rotary tablet Press Machine Model No CMB4-D27 Firm also submit Inspection report of 02-05-2013 in which bilayred machine mentioned by FID
	Decision: Approved with innovator's specifications.	
415.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Onato-T 10mg/80mg Tablet
	Composition	Each Bilayer Tablet Contains: Amlodipine Besylate eq to Amlodipine….10mg Telmisartan USP……80mg
	Diary No. Date of R& I & fee	Dy.No. 1688; dated 14-01-2019 Rs. 20,000/- Dated 14-01-2019
	Pharmacological Group	Angiotensin-II Antagonist and Calcium Channel Blocker
	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.	Twynsta of USFDA Approved
	Me-too status	Telam 80mg/10mg Tablet of M/s Macter
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	Firm submitted Commercial Invoice for Double sided Rotary tablet Press Machine Model No CMB4-D27 Firm also submit Inspection report of 02-05-2013 in which bilayred machine mentioned by FID
	Decision: Approved with innovator's specifications.	
416.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95, S.I.T.E. Karachi.
	Brand Name +Dosage Form + Strength	Arcenate 30mg Injection
	Composition	Each vial contains: Sterile powder of Artesunate ph. Int…..30mg
	Diary No. Date of R& I & fee	Dy.No. 39864; dated 04-12-2018 Rs. 20,000/- Dated 04-12-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form- 5
	Finished product Specification	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Gen-M Injection of M/s Genix Pharma

	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved.	
417.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Arcenate 60mg Injection
	Composition	Each vial contains: Sterile powder of Artesunate ph. Int …..60mg
	Diary No. Date of R& I & fee	Dy.No. 39865; dated 04-12-2018 Rs. 20,000/- Dated 04-12-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form- 5
	Finished product Specification	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Misonate 60mg Injection by M/s Tabros Pharma (Reg#057719)
	GMP status	The last GMP inspection conducted on 07-2-2018 & 14-2-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved.	
418.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Arcenate 120mg Injection
	Composition	Each vial contains: Sterile powder of Artesunate ph. Int …..120mg
	Diary No. Date of R& I & fee	Dy.No. 40254; dated 05-12-2018 Rs. 20,000/- Dated 05-12-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form- 5
	Finished product Specification	IP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Gen-M Injection of M/s Genix Pharma
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP.
	Remarks of the Evaluator[4]	
	Decision: Approved.	
419.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% w/v (0.5ml)Injection
	Composition	Each 0.5ml Contains: Sodium Bicarbonate BP…….0.025gm
	Diary No. Date of R& I & fee	Dy.No. 39413; dated 30-11-2018 Rs. 20,000/- Dated 30-11-2018

	Pharmacological Group	Diluent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation diluent
	Me-too status	Sodium Bicarbonate 5% in 0.5ml Injection of M/s Genix Pharma
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications	
420.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% w/v (1ml) Injection
	Composition	Each ml Contains: Sodium Bicarbonate BP…….0.05gm
	Diary No. Date of R& I & fee	Dy.No. 39414; dated 30-11-2018 Rs. 20,000/- Dated 30-11-2018
	Pharmacological Group	Diluent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation diluent
	Me-too status	Sodium Bicarbonate 50mg/ml Injection of M/s Tabros Pharma
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications	
421.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Sodium Bicarbonate 5% w/v (2ml) Injection
	Composition	Each 2ml Contains: Sodium Bicarbonate BP…….0.1gm
	Diary No. Date of R& I & fee	Dy.No. 39415; dated 30-11-2018 Rs. 20,000/- Dated 30-11-2018
	Pharmacological Group	Diluent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation diluent
	Me-too status	Sodium Bicarbonate 5% w/v in 2ml Injection of M/s Genix Pharma
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to

		be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications	
422.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Sodium Chloride 0.9% w/v (2.5ml) Injection
	Composition	Each 2.5ml Contains: Sodium Chloride BP…….0.0225gm
	Diary No. Date of R& I & fee	Dy.No. 39412; dated 30-11-2018 Rs. 20,000/- Dated 30-11-2018
	Pharmacological Group	Diluent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation diluent
	Me-too status	Sodium Chloride Injection 0.9% w/v in 2.5ml Injection of M/s Genix Pharma
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications	
423.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Tacrim 0.1% Ointment
	Composition	Each 100g Contains: Tacrolimus monohydrate USP eq to Tacrolimus….0.1gm
	Diary No. Date of R& I & fee	Dy.No. 34705; dated 18-10-2018 Rs. 20,000/- Dated 18-10-2018
	Pharmacological Group	Agent for dermatitis, excluding corticosteroids
	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.	Protopic of USFDA approved
	Me-too status	Eczemus 0.1% Ointment of M/s Brookes Pharmaceuticals,
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications.	
424.	Name and address of manufacturer / Applicant	M/s Sami Pharmaceuticals (Pvt.) Limited. F-95 S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Tacrim 0.03% Ointment
	Composition	Each 100g Contains: Tacrolimus monohydrate USP eq to Tacrolimus….0.03gm
	Diary No. Date of R& I & fee	Dy.No. 34706; dated 18-10-2018 Rs. 20,000/- Dated 18-10-2018
	Pharmacological Group	Agent for dermatitis, excluding corticosteroids Immunosuppressive agent
	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.	Protopic of USFDA approved
	Me-too status	Eczemus 0.03% Ointment of M/s Brookes Pharmaceuticals,
	GMP status	The last GMP inspection conducted on 07-02-2018 & 14-02-2019 and report concludes that firm was considered to be operating at good compliance with GMP..
	Remarks of the Evaluator[4]	
	Decision: Approved with innovator's specifications.	

Case No. 05: Registration Applications of Import Cases.

a. Deferred cases

i. Human

425.	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	Deferred for evidence of free sale status. **(M-285)**
	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.: **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.
	Decision: Deferred for further deliberation.	
426.	Name and address of Applicant	M/s Al-Qasim Enterprises, Flat# 4, Minhas Plaza, Second floor, Munawar Colony, Adiala Road Rawalpindi, 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 12-4-2016 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	Deferred for evidence of free sale status.m(M-285)
	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**
	Decision: Deferred for further deliberation.	

Case no. 06 Registration applications of drugs for which stability study data is submitted

a. Deferred cases

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
427.	M/S Indus Pharma (Pvt) Ltd Plot No. 26, 27,63, 64, 65, 66 & 67, Sector-27, Korangi Industrial Area Karachi.	Exilant 60mg Capsule Each HPMC capsule contains: Dual Delayed Release dexlansoprazole pellets 23% eq to Dexlansoprazole…..60mg Proton Pump inhibitor (Manufacturers specifications)	Form 5 D 30-01-2018 Dy. No.3745 Rs.50,000/- 14's As per SRO	Dexilant Delayed Release Capsule 60mg of USFDA approved Last inspection was conducted on 16-08-2017 and report concludes that firm was considered to be operating at an acceptable level of GMP compliance	Differential fee of Rs: 50000 Deposit slip No: 0742299 dated 02-07-2018 submitted for pellets.

STABILITY STUDY DATA

Drug	Exilant 60mg Capsule		
Name of Manufacturer	M/S Indus Pharma (Pvt) Ltd Karachi		
Manufacturer of API	M/S Murli Krishan Pharma Pvt Ltd, India		
API Lot No.	MKPPLR-DEF-17001		
Description of Pack (Container closure system)	Alu/Alu		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0, ,3,6 (Month) Real Time: 0,3,6 (Month)		
Batch No.	P-1/DEX CAPS	P-2/DEX CAPS	P-3/DEX CAPS
Batch Size	2,500 capsules	2,500 capsules	2,500 capsules
Manufacturing Date	June– 2017	June – 2017	June – 2017

Date of Initiation	15-06-2017	15-06-2017	15-06-2017
No. of Batches	3		
Date of Submission	30-01-2018 (Dy. No3745)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status
1.	COA of API	Copy of COA from M/s Murli Krishan Pharma Pvt Ltd India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate No. New-WHO-GMP/CERT/PD/52224/2017/11/18462 issued by Food & Drug administration, M.S. Bandra-Kurla Complex, Maharashtra, India is submitted.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of ADC (Karachi) attested dated: 10-10-2017 Commercial Invoice No MKPPL/RG/011 Dated: 24-05-2017 issued by M/s Murli Krishan Pharama, India is submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- Commercial Invoice of API was attested by ADC Karachi on 10-10-2017 while all the 3 batches are produced in june 2017 and stability starts on 15-06-2017 .
- **Firm reply:**
- **"**Kindly note that the request for the issuance of form6/Clearnce certificate was submitted to DRAP-Karachi in letter dated 29th May 2017 along with required document.

We further investigated the concern from your office and were informed by the respective personnel of the concern department of Indus Pharma that during the evalution of our application by Drap- Karachi, we were informed by the Pakistan customs that our consignment of Dexlansoprazole DDR pellets 23% - 2.5 Kg for the testing and trial/Developmental Batches, had been released via the Green channel by the customs on 3rd June 2017, based on the submissionof soft copies of the essential documents on the computerized system weboc (web based one custom) of the Pakistan customs. We had the consignment cleared accordingly and was used for testing and development of trial batches in June 2017 and put on stability accordingly

As our application was al;ready filled in DRAP – Karachi, We received the Form-6 along with ADC/Ad attested commercial invoice on 10th October 2017**"**

- Certificate of analysis of API by manufacturer submitted is for different batch No than batch No mentioned on commercial invoice

Firm reply:

Kindly note that the batch No in certificate of analysis is a typographical error. The correct batch No is MKPPLR-DEF-17001 as mentioned in commercial invoice instead of MKPPLR-DLF-17001

Decision: The Registration Board decided to constitute the following panel for onsite investigation to confirm genuineness/ authenticity of stability data and associated

documents, import of API, quality, specification, test analysis, facilities etc.

Prof. Dr. Rafeeq Alam Khan, Member Registration Board.

- Dr. Saif ur Rehman Khattak, Director/FGA, CDL, Karachi.
- Mr. Sajjad Abbasi, FID, Karachi.

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Exilant 60mg (Dexlansoprazole) Capsules by M/s. Indus Pharma (Pvt.), Korangi Industrial Area, Karachi.

Reference No: F.13-11/2017-PEC (PT) dated 17th January, 2019.
Investigation Date and Time: 14th March, 2019 (Morning).
Investigation Site: Factory premises of M/s. Indus Pharma (Pvt.) Limited, Korangi Industrial Area, Karachi.

Background:
Chairman Registration Board considered the applications of M/s. Indus Pharma, Plots No. 26, 27, 63-67, Sector 27, Korangi Industrial Area, Karachi for registration of Exilant 60mg (Dexlansoprazole) Capsules and constituted a three-member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

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

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

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

Sr.No.	Question	Observation by panel
1.	Do you have documents confirming the import of Dexlansoprazole API including approval from DRAP?	The firm has imported 2.5kg Dexlansoprazole pellets from M/s Murli Krishna, India invoice number: MKPPL/RG/011 dated 24/05/2017.Approval from DRAP Office, Karachi was obtained on 10/10/2017 i.e. after a period of 4 months .
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implemented including Postal Audit checklist, Testing of the API and GMP approval by competent authority along with the DMF.
3.	Do you have documents confirming the import of Dexlansoprazole reference standard and impurity standard?	The firm has document confirming the imported Dexlansoprazole pellets (API), working standard of the API and 2 major impurities from the manufacturer of the API.
4.	Do you have certificate of Analysis of the API, reference standard of the API and impurity standard?	The firm has certificate of analysis for the API, working standard of the API and 2 major impurities standards.
5.	Do you have GMP certificate of API manufacturers issued by regulatory authorities of country of origin?	The firm has valid GMP certificate of the API manufacturer issued by the concerned provincial Regulatory Authority of the country of

		origin.
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing API.
7.	Do you have stability studies report on API?	The firm has stability studies reports on the API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified.
9.	Do you have method for quantifying the impurities in the API?	The firm has HPLC method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of the API, and working standard of API only.
11.	Have you used pharmaceutical grade excipients?	No excipients used, Only HMPC based capsule shells as used by the innovator.(Dexilant capsule manufactured by Takeda Pharma)
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipient.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipient used.
14.	Do you have written and authorized protocols for the development of Dexlansoprazole capsules?	The firm has written and authorized protocols for the development of Exilant Capsules 60mg (Dexlansoprazole).
15.	Have you performed Drug-excipient compatibility studies?	Same excipients were used as of innovator.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies on their capsules against the innovator product Dexilant Capsules 60mg batch no/lot no. A25777, Manufactured By: Takeda Pharma, USA). The firm's product has comparable dissolution profile with that of the innovator product.
17.	Do you have product development (R&D) section?	The firm does not have dedicated product development section. They have equipment's for manufacturing lab scale batches. Some of these equipment's are used while shifting them to the commercial manufacturing area, whereas, some equipment's of commercial scale manufacturing are being used for product development. Dedicated area for product development is under renovation. New small-scale equipment for R%D have arrived at the facility and will be commissioned after renovation work is completed.
18.	Do you have necessary equipment available in product development section for development of Dexlansoprazole capsules?	As above.
19.	Are the equipment in product development section qualified?	The available equipment for product development section are qualified. 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 with re- qualification program for the equipment used for product development.

21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has a team of 05 technical persons (04 Pharmacist & 1 MSC Chemistry) for product development. These personnel have proper knowledge and training in product development.
22.	Have you manufactured three stability batches for the stability studies of Dexlansoprazole capsules as required?	The firm has manufactured three stability batches of Exilant Capsules 60mg capsules having batch # P-1/DEX, P-2/DEX and P-3/ DEX each of 2500 capsules batch size. The capsules are packed in Alu Alu blisters of pack size 2x7s.
23.	Do you have any criteria for fixing the batch size of stability batches?	The criteria for fixing the batch size of stability batches is the quantity of capsules required per testing frequency and the number of testing frequencies.
24.	Do you have complete record of production of stability batches?	The firm has complete record of production of stability batches. All the Log Books are properly maintained.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The method is based upon the API method of API manufacturer. The firm has fully validated the method for testing of their finished product.
27.	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 performed complete validation studies.
28.	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Dexlansoprazole API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of the API and the finished drug.
29.	Do your method of analysis stability indicating?	The firm has performed forced degradation (FD) study on their product Exilant Capsules 60mg capsules for the conformance of stability indicating nature of their method for testing the finished product during stability studies.
30.	Do your HPLC software 21CFR Compliant?	1. Yes, HPLC software is 21 CFR Part 11 compliant where all user levels are properly defined. 2. No user or main user can delete, edit or manipulate data from software. 3. All actions are recorded in audit trails. 4. Created strict policies on windows and disable options like "Delete, Copy, Paste and rename" of any file from user level. Furthermore, the following improvements are being made in order to strengthen it further. 1. A new HPLC of "Agilent Infinity series" has been installed in Quality Control Laboratory & two more are under procurement and will be commissioned by the mid of 2019. 2. Chromatography Data System (CDS) Software is also being procured for Compliance and Data Security. With the ever-evolving emphasis on data security, data integrity, and compliance, it is of vital importance that the software provides comprehensive preventive and detection technical controls. This will enable us to meet

		the latest regulatory requirements and ensure the highest levels of data quality.
31.	Can you show Audit trail reports on Dexlansoprazole testing?	Audit trail on the testing reports is available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches only.
33.	Do you have stability batches kept on stability testing?	The firm has three stability batches kept on real time stability testing.18 months studies have been completed on these batches with satisfactory results.
34.	Do you have valid calibration status for equipment's used in Dexlansoprazole capsules production and analysis?	The firm has valid calibration status for the equipment used in Exilant Capsules 60mg production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Adequate monitoring and control are available for stability chambers including data loggers and centralized controlling software.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are in compliance.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Exilant 60mg (Dexlansoprazole) Capsules is verifiable to satisfactory level .
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited For the manufacturing of Exilant 60mg (Dexlansoprazole) Capsules.

Recommendations:

1. Since Exilant 60mg Capsules are modified release (delayed release) capsules therefore, post registration Bioequivalence studies should be conducted on the product before marketing.
2. Firm must developed specific identification test for dexlansoprazole in the pallets and the finished product .
3. The firm may kindly be granted necessary registration of Exilant 60mg (Dexlansoprazole) Capsules.

Note: The firm has submitted written undertaking for post registration bioequivalence studies on the capsules.

Previous Decision (M-289):

Deffered for following reason:

- Commercial Invoice of API was attested by ADC Karachi on 10-10-2017 while all the 3 batches are produced in june 2017 and stability starts on 15-06-2017 .
- Recommendation by panel that "Firm must developed specific identification test for dexlansoprazole in the pallets and the finished product"

Evaluation by PEC: Firm submitted reply as:

1	Commercial Invoice of API was attested by ADC Karachi on 10-10-2017 while all the 3 batches are produced in june 2017 and stability starts on 15-06-2017	Kindly note that the request for the issuance of form6/Clearnce certificate was submitted to DRAP-Karachi in letter dated 29th May 2017 along with required document. We further investigated the concern from your office and were informed by the respective personnel of the concern department of Indus Pharma that during the evalution of our application by Drap- Karachi, we were informed by the Pakistan customs that our consignment of Dexlansoprazole DDR pellets 23% - 2.5 Kg for the testing and trial/Developmental Batches, had been released via the Green channel by the customs on 3rd June 2017, based on the submissionof soft copies of the essential documents on the computerized system weboc (web based one custom) of the Pakistan customs. We had the consignment cleared accordingly and was used for testing and development of

		trial batches in June 2017 and put on stability accordingly As our application was al;ready filled in DRAP – Karachi, We received the Form-6 along with ADC/Ad attested commercial invoice on 10th October 2017"
2	Recommendation by panel that "Firm must developed specific identification test for dexlansoprazole in the pallets and the finished product"	Firm submitted Identification testing for pellets and capsule by Running pellets and capsule of dexlansoprazole on HPLC against the Lansoprazole standard and Dexlansoprazole standard.

Decision: Deferred for scientific justification of not performing the identification test for dexlansoprazole during the performance of stability studies.

Case no. 08 Miscellaneous cases

428.	Name and address of manufacturer / Applicant	M/S Cibex (Pvt) Ltd. F-405, S.I.T.E., Karachi
	Brand Name +Dosage Form + Strength	Famcon 500mg+ 267mg/10ml Suspension
	Composition	Each 10ml contains: Sodium Alginate……500mg Sodium Bicarbonate……..267mg
	Diary No. Date of R& I & fee	Dy.No.18919; 24 -10-2017; Rs.20,000/- (23-10-2017)
	Pharmacological Group	Antacid
	Type of Form	Form 5
	Finished product Specifications	Manufacturer specification
	Pack size & Demanded Price	120ml, ; As per SRO
	Approval status of product in Reference Regulatory Authorities	Gaviscon Original Aniseed Relief Of MHRA Approved
	Me-too status (with strength and dosage form)	N-Tasid 500mg/267mg Of M/S Getz
	GMP status	Last GMP Inspection of Cibex Pvt. Ltd conducted on 29-8-17 with conclusive remarks of satisfactory level of cGMP compliance
	Remarks of the Evaluator[4]	
	Previous Decision	Approved with innovator's specification.(M-284)
	Remarks of the Evaluator[4]	**Case no: 227 DRB 284th meeting** "Gaviscon Original Aniseed Relief contains 250mg sodium alginate, 133.5mg sodium bicarbonate and 80mg calcium carbonate per 5ml" firm added calcium carbonate 160mg as excipient while in reference calcium carbonate is used as active.
	Decision: Registration Board noted the correction in the decision and decided to defer the case for evidence of approval of applied formulation in reference regulatory authorities which were adapted by the Board in its 275th meeting.	
429.	Name and address of manufacturer / Applicant	M/s Invictus Pharmaceuticals. Plot No. 21,26, Street No.NS-2, National Industrial Zone, Rawat, Rawalpindi
	Brand Name +Dosage Form + Strength	Itopic 150mg Tablets
	Composition	Each film coated Tablet Contains: Itopride as HCL…150mg
	Diary No. Date of R& I & fee	Dy.No 1720 dated 14-01-2019 Rs.20,000/- Dated 14-

		01-2019
	Pharmacological Group	Prokinetics
	Type of Form	Form 5
	Finished product Specifications	Manufacturer's specification
	Pack size & Demanded Price	1 x 10's , 1 x 20's, 1 x 30's & 1 x 50's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Ganaton of M/s Abbott Laboratories (PMDA) Japan Approved
	Me-too status (with strength and dosage form)	Dysrid-150mg Tablets by M/s Onyx Pharmaceuticals
	GMP status	Last inspection conducted on 13-11-2018 and panel recommend grant of DML
	Remarks of the Evaluator[4]	
	Previous Decision	Approved with innovator's specification.(M-288)
	Remarks of the Evaluator[4]	**Case no: 723 DRB 288th meeting** Not available in any reference agency
	Decision: Decision: Registration Board noted the correction in the decision and decided to defer the case for evidence of approval of applied formulation in reference regulatory authorities which were adapted by the Board in its 275th meeting.	

Evaluator PEC-V

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

a. New cases

430.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt. Ltd. Fine Chemicals & Pharmaceuticals Manufacturers, 9.5 m, Sheikupura Road, Lahore **Contract manufacturing by** M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi
	Diary No. Date of R& I & fee	Diary No:3182, 24/01/2018, Rs: 50,000/- Dated 23/01/2018
	Brand Name +Dosage Form + Strength	Xpertec DS Suspension 200/5ml
	Composition	Each 5ml contains: Cefixime Trihydrate eq. to cefixime…200mg
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml bottle
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	073248; Stlicef Dry Suspension 200mg Treat Pharma A-37, Industrial Estate Kohat Road,Bnnu (contract manufacturing will be conducted by M/s. Shawan Pharmaceuticals, Rawat)"
	GMP status	31-07-2018, Good
	Remarks of the Evaluator.	• Copy of agreement has been submitted. • Number of sections of applicant approved by Licensing Board. Firm has submitted 8 approved section. • Number of products already registered/approved on contract manufacturing in the name of applicant.Nil.
	Decision: Approved	

431.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt. Ltd. Fine Chemicals and Pharmaceuticals Manufacturers, 234-325, Ravi Park, Lahore **Contract manufacturing by** M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi
	Diary No. Date of R& I & fee	Diary No:3181, 24/01/2018, Rs: 50,000/- Dated 23/01/2018
	Brand Name +Dosage Form + Strength	Xpertec Suspension 100/5ml
	Composition	Each 5ml contains: Cefixime Trihydrate eq. to cefixime…100mg
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml bottle
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	073247; Stlicef Dry Suspension 100mg Treat Pharma A-37, Industrial Estate Kohat Road,Bnnu (contract manufacturing will be conducted by M/s. Shawan Pharmaceuticals, Rawat)"
	GMP status	31-07-2018; Good
	Remarks of the Evaluator.	• Copy of agreement has been submitted. • Number of sections of applicant approved by Licensing Board. Firm has submitted 8 approved section. • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil.
	Decision: Approved	
432.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt. Ltd. Fine Chemicals and Pharmaceuticals Manufacturers, 234-325, Ravi Park, Lahore Contract manufacturing by M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi
	Diary No. Date of R& I & fee	Diary No:3190, 24/01/2018, Rs: 50,000/- Dated 28/12/2017
	Brand Name +Dosage Form + Strength	Phyxone Injection 500mg IV
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone…500mg
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Glass II vials, 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	062328 "Cefaben 500 mg IV Injection " Imco Pharmaceuticals Laboratories, 73/A.S Industrial Estate, Jamrud Road, Peshawar. (contract manufacturing conducted by M/s. Caraway Pharmaceuticals, Rawat, Islamabad)"
	GMP status	31-07-2018 Good
	Remarks of the Evaluator.	• Copy of agreement has been submitted. • Number of sections of applicant approved by Licensing

		Board. Firm has submitted 8 approved section. • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil.
	Decision: Approved.	
433.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt. Ltd. Fine Chemicals and Pharmaceuticals Manufacturers, 234-325, Ravi Park, Lahore **Contract manufacturing by** M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi
	Diary No. Date of R& I & fee	Diary No:3190, 24/01/2018, Rs: 50,000/- Dated 28/12/2017
	Brand Name +Dosage Form + Strength	Phyxone Injection 1000mg IV
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone…1000mg
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Glass II vials, 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	070663 ; Martixon 1gm I.V Dry powder Injection by Alkemy Hyderabad
	GMP status	31-07-2018; Good
	Remarks of the Evaluator.	• Copy of agreement has been submitted. • Number of sections of applicant approved by Licensing Board. Firm has submitted 8 approved section. • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil.
	Decision: Approved.	
434.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt. Ltd. Fine Chemicals and Pharmaceuticals Manufacturers, 234-325, Ravi Park, Lahore **Contract manufacturing by** M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi
	Diary No. Date of R& I & fee	Diary No:3193, 24/01/2018, Rs: 50,000/- Dated 28/12/2017
	Brand Name +Dosage Form + Strength	Phyxone Injection 1000mg IM
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone…1000mg
	Pharmacological Group	Third-generation cephalosporin
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Glass II vials, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Rocephin IM 1 g powder and solvent for solution for injection by M/s Roche Products Ltd (MHRA Approved)
	Me-too status	079446; Accucef Injection 1 gm IM Injection Powder WelWink Pharmaceuticals, G.T Road, Industrial Estate Gujranwala Cantt.
	GMP status	31-07-2018; Good

	Remarks of the Evaluator.	• Copy of agreement has been submitted. • Number of sections of applicant approved by Licensing Board. Firm has submitted 8 approved section. • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil.
	Decision: Approved.	
435.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt. Ltd. Fine Chemicals and Pharmaceuticals Manufacturers, 234-325, Ravi Park, Lahore **Contract manufacturing by** M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi
	Diary No. Date of R& I & fee	Diary No:3183, 24/01/2018, Rs: 50,000/- Dated 28/12/2017
	Brand Name +Dosage Form + Strength	Bactum Plus Injection 1g
	Composition	Each vial contains: Cefoperazone Sodium….0.5g Salbactum Sodium…0.5g
	Pharmacological Group	Third-generation cephalosporin, β-lactamase inhibitor
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	vials, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Sulperazon Injection by Pfizer Inc. (PMDA Approved)
	Me-too status	078771 "Perbactum 1gm Dry Injection M/s Vega Pharmaceuticals (Pvt) Ltd, Plot # 4, Pharma City, 30 KM, Multan Road, Lahore
	GMP status	31-07-2018; Good
	Remarks of the Evaluator.	• Copy of agreement has been submitted. • Number of sections of applicant approved by Licensing Board. Firm has submitted 8 approved section. • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil.
	Decision: Approved.	
436.	Name and address of manufacturer / Applicant	M/s Unexolabs Pvt. Ltd. Fine Chemicals and Pharmaceuticals Manufacturers, 234-325, Ravi Park, Lahore **Contract manufacturing by** M/s Safe Pharmaceutical Private Limited, C-I-20, Sector 6-B, North Karachi, Industrial Area, Karachi
	Diary No. Date of R& I & fee	Diary No:3184, 24/01/2018, Rs: 50,000/- Dated 28/12/2017
	Brand Name +Dosage Form + Strength	Bactum Plus Injection 2g
	Composition	Each vial contains: Cefoperazone Sodium….1g Salbactum Sodium…1g
	Pharmacological Group	Third-generation cephalosporin, β-lactamase inhibitor
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	vials, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by 3 European countries: **Czech**: http://www.sukl.eu/modules/medication/detail.php?code=0015273&tab=info

		Slovakia: https://www.sukl.sk/hlavna-stranka/english-version/Specificationialpages/medical-product-detail?page_id=842&lie_id=6343A **Poland:** http://pub.rejestrymedyczne.csioz.gov.pl/?AspxAutoDetectCookieSupport=1#results Links are assessed on 1st Oct 2018
	Me-too status	073853 Woncef 2gm Injection PharmEvo Karachi .
	GMP status	31-07-2018 Good
	Remarks of the Evaluator.	• Copy of agreement has been submitted. • Number of sections of applicant approved by Licensing Board. Firm has submitted 8 approved section. • Number of products already registered/approved on contract manufacturing in the name of applicant. Nil.
	Decision: Approved.	
437.	**Name and address of manufacturer / Applicant**	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar"
	Diary No. Date of R& I & fee	Dy.No 21499 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Midopine HCT 5/160/25 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besylate…5mg Valsartan…160mg Hydrochlorothiazide…25mg"
	Pharmacological Group	Angiotensin II Receptor Blockers (ARBS), Combinations
	Type of Form	Form-5
	Finished product Specification	USP.
	Pack size & Demanded Price	As per SRO, Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT USFDA Approved.
	Me-too status	081148; Aldric-H 5/160/25mg Martin Dow Ltd. Karachi . .
	GMP status	04-09-2018 & 26-09-2018. Conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	Approved in USFDA with box warning.
	Decision: Approved.	
438.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar"
	Diary No. Date of R& I & fee	Dy.No 21498 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Pitavas 4mg Tablet
	Composition	Each Film Coated Tablet Contains: Pitavastatin as Calcium…4mg
	Pharmacological Group	Lipid Modifying Agents, Plain C10AA08
	Type of Form	Form-5

	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, Alu-Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	Livalo USFDA Approved Each film-coated tablet of LIVALO contains 1.045 mg, 2.09 mg, or 4.18 mg of pitavastatin calcium, which is equivalent to 1 mg,2 mg, or 4 mg
	Me-too status	073687; Pitalo 4mg Tablet by Genix Pharma Karachi .
	GMP status	04-09-2018 & 26-09-2018. Conclusion:As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	
	Decision: Approved.	
439.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar"
	Diary No. Date of R& I & fee	Dy.No 21497 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Pitavas 2mg Tablet
	Composition	Each Film Coated Tablet Contains: Pitavastatin as Calcium…2mg
	Pharmacological Group	Lipid Modifying Agents, Plain C10AA08
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO, ALu Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	Livalo USFDA Approved Each film-coated tablet of LIVALO contains 1.045 mg, 2.09 mg, or 4.18 mg of pitavastatin calcium, which is equivalent to 1 mg,2 mg, or 4 mg
	Me-too status	070656; Pitalip Tablets 2mg By Hilton Karachi
	GMP status	04-09-2018 & 26-09-2018. Conclusion:As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	
	Decision: Approved.	
440.	**Name and address of manufacturer / Applicant**	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar"
	Diary No. Date of R& I & fee	Dy.No 21501 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Simze 10/40 mg Tablet
	Composition	Each Tablet Contains: Simvastatin…10mg Ezetimibe…40mg
	Pharmacological Group	Lipid Modifying Agents, Combinations C10BA02

	Type of Form	Form-5
	Finished product Specification	In-house Specification.
	Pack size & Demanded Price	As per SRO.Alu-Alu Blister pack.
	Approval status of product in Reference Regulatory Authorities.	Vytorin USFDA Approved.
	Me-too status	059303; Neutrachol Plus Tablets By Wilson's Pharmaceuticals, 387-388, I-9, Sector, Industrial Area, Islamabad.
	GMP status	04-09-2018 & 26-09-2018. Conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	The chemistry review Vytorin of USFDA states that in solid state,oxidation of simvastatin can occur, especially at elevated temperature, therefore,butylated hydroxyanisole is added to the drug substance. Butylated hydroxyanisole NF, citric acid monohydrate USP, and propyl gallate NF are three antioxidants used in applied formulation. **Stability of drug product** The stability studies are based on 3 stability batches per strength, and stability data are available at 40°C/75% RH (6 months), 30°C/65% RH (12 months) and 25°C/60% RH (18 months). After 18 months. Long-term conditions, a decrease of simvastatin is observed in all strengths. After 12 months intermediate conditions in general moderate simvastatin decreases are observed. The MAH attributes the simvastatin assay losses to thermal degradation of simvastatin in the presence of oxygen. The product is photostable. Based on the available stability data the shelf-life accepted is 18 months if stored in aluminum-aluminum blisters not above 25°C. **Manufacturing process** The manufacture comprises steps of sifting of the main excipients, preparation of the drug dispersion, top spray granulation and drying, spraying of the antioxidants solution on the granules, dry screening, blending and lubrication, and compression. **Quality control of drug product** The finished product Specifications are adequate to control the relevant parameters for the dosage form. The Specification includes tests for description, identification of ezetimibe and simvastatin, identification of antioxidant, identification of propyl gallate, identification of citric acid monohydrate, uniformity of dosage units, loss on drying, dissolution, microbial enumeration test and microbial test for Specificationified organisms, content of antioxidant, content of propyl gallate, content of citric acid monohydrate, assay, related substances and residual solvents. **Reference:** ✓ Ezetimibe/Simvastatine SUN Pharma 10 mg/10 mg, 10 mg/20 mg and 10 mg/40 mg tablets from Sun

		Pharmaceutical Industries Europe B.V. ✓ Chemistry review Vytorin of USFDA. **Conclusion of Evaluation:** Hence, based on the information extracted from Public assessment report it is concluded that simvastatin losses to thermal degradation in the presence of oxygen antioxidants shall be added in the formulation. These antioxidants shall also be quantified by suitable test method. The manufacturing of the applied formulation should also be as per innovator that involves the following steps: a) sifting of the main excipients b) preparation of the drug dispersion c) top spray granulation and drying d) spraying of the antioxidants solution on the granules, e) dry screening, f) blending and lubrication g) compression. Moreover, the shelf life accepted is 18 months if stored in aluminum-aluminum blisters not above 25°C. As Zone IV A is more severe condition the shelf life will be more stringent.
	Decision: Deferred for revision of formulation as per the reference product.	
441.	Name and address of manufacturer / Applicant	"M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate, Hattar"
	Diary No. Date of R& I & fee	Dy.No 21502 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Simze 10/80 mg Tablet
	Composition	Each Tablet Contains: Simvastatin…10mg Ezetimibe…80mg
	Pharmacological Group	Lipid Modifying Agents, Combinations C10BA02
	Type of Form	Form-5
	Finished product Specification	Inhouse Specification.
	Pack size & Demanded Price	As per SRO.Alu-Alu Blister pack.
	Approval status of product in Reference Regulatory Authorities.	Vytorin USFDA Approved.
	Me-too status	059304; Neutrachol Plus Tablets By Wilson's Pharmaceuticals, Industrial Area, Islamabad.
	GMP status	04-09-2018 & 26-09-2018. Conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	The chemistry review Vytorin of USFDA states that in solid state,oxidation of simvastatin can occur, especially at elevated temperature, therefore,butylated hydroxyanisole is added to the drug substance. Butylated hydroxyanisole NF, citric acid monohydrate USP, and propyl gallate NF. **Stability of drug product** The stability studies are based on 3 stability batches per strength, and stability data are available at

		40°C/75% RH (6 months), 30°C/65% RH (12 months) and 25°C/60% RH (18 months). After 18 months Long-term conditions, a decrease of simvastatin is observed in all strengths. After 12 months intermediate conditions in general moderate simvastatin decreases are observed. The MAH attributes the simvastatin assay losses to thermal degradation of simvastatin in the presence of oxygen. The product is photostable. Based on the available stability data the shelf-life accepted is 18 months if stored in aluminum-aluminum blisters not above 25°C. **Manufacturing process** The manufacture comprises steps of sifting of the main excipients, preparation of the drug dispersion, top spray granulation and drying, spraying of the antioxidants solution on the granules, dry screening, blending and lubrication, and compression. It is considered a non-standard process in view of the relatively low ezetimibe content in the 10 mg/ It is noted that the percentage content of ezetimibe in the 10 mg/80 mg tablet strength is 1.25%, i.e. this tablet strength is a unit dose product containing drug in low content (≤2% of composition), which implies that this tablet strength is in fact a non-standard dosage form in accordance with EU "Annex II to note for guidance on process validation CHMP/QWP/848/99 and EMEA/CVMP/598/99 non standard processes". It is considered a non-standard process in view of the relatively low ezetimibe content in the 10 mg/80 mg strength. The manufacturing process has to be validated according to relevant European/ICH guidelines. Process validation data on the product should be presented for 3 batches per strength in accordance with the relevant European guidelines. **Conclusion of Evaluation:** Hence, based on the information extracted from Public assessment report it is concluded that simvastatin losses to thermal degradation in the presence of oxygen antioxidants shall be added in the formulation. These antioxidants shall also be quantified by suitable test method. The manufacturing of the applied formulation should also be as per innovator that involves the following steps: a) sifting of the main excipients b) preparation of the drug dispersion c) top spray granulation and drying d) spraying of the antioxidants solution on the granules, e) dry screening, f) blending and lubrication g) compression. Moreover, the shelf life accepted is 18 months if stored in aluminum-aluminum blisters not above 25°C. As Zone IV A is more severe condition the shelf life will be more stringent. It is considered a non-standard process in view of the relatively low ezetimibe content in the 10 mg/80 mg strength. The manufacturing process has to be validated according to relevant European/ICH guidelines.
	Decision: Deferred for revision of formulation as per the reference product.	

442.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21510 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	J-Linz 600mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linezolid…600mg"
	Pharmacological Group	Antibacterial for systemic use. J01XX08
	Type of Form	Form-5
	Finished product Specification	Inhouse Specification.
	Pack size & Demanded Price	5's, 10's, 12's, Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets USFDA Approved.
	Me-too status	055773; Leckzolid 600mg Tablet Medimarker's Pharmaceutical, Hyderabad
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	LINEZOLID SANDOZ 600 MG Pharmaceutical development The substance exhibits at least three polymorphic forms, and one chiral center. Linezolid has the S-configuration. the polymorph manufactured is Form-III. Linezolid can exist in different polymorphic forms. While in the innovator product polymorphic form II is present, the applied product uses drug substance with polymorphic form III. Since the bioequivalence of the applied product Linezolid 600 mg film-coated tablets (polymorphic form III) versus the reference product (polymorphic form II) has been demonstrated, it can be assumed that polymorphic forms does not affect in-vivo performance. Reference: Linezolid Sandoz 600 mg, film-coated tablets (linezolid) NL/H/2965/001/DC (Date: 8 January 2015) https://mri.cts-mrp.eu/Human/Downloads/NL_H_2965_001_PAR.pdf Shortcoming 1. Provide the polymorphic form of linezolid used in the applied formulation. Firms Response Firm has provided COA of SYMED LABS LIMITED which does not mention the polymorphic form.
	Decision: Approved with innovators' Specification.	
443.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21509 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	J-Linz 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Linezolid…400mg"
	Pharmacological Group	Antibacterial for systemic use. J01XX08
	Type of Form	Form-5
	Finished product Specification	Inhouse Specification.

	Pack size & Demanded Price	5's, 10's, 12's, Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	ZYVOX Tablets 400MG **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons* Discontinued USFDA Approved.
	Me-too status	055434; Lyzon 400mg Tablet Getz Pharma Karachi
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	1. Provide the polymorphic form of linezolid used in the applied formulation. Firm has provided COA of SYMED LABS LIMITED which does not mention the polymorphic form.
	Decision: Approved with innovators' Specification.	
444.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21503 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Jupram 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Escitalopram as Oxalate Eq. to Escitalopram…10mg"
	Pharmacological Group	Antidepressants Selective serotonin reuptake inhibitors N06AB10
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,20's,28's,30's, Alu-Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	054911; Citowel 10mg Tablets Wellborne Pharmachem and Biologicals, Plot#51/1 Phase I&II Industrial Estate,Hattar.
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	1. Provide which enantiomer will be used for the manufacture of drug substance. **Firm's Response** Citalopram is a racemic mixture of S-citalopram and R-citalopram. The clinical activity of citalopram is believed +to reside in the S-enantiomer of citalopram whereas, the R-enantiomer is inactive. Escitalopram is the single isomer of the racemic citalopram. **Reference:** https://mri.cts-mrp.eu/Human/Downloads/DE_H_0672_002_PAR.pdf
	Decision: Approved.	
445.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21505 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	J-Rosta 10mg Tablets

	Composition	"Each Film Coated Tablet Contains: Rosuvastatin as Calcium…10mg"
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	10's, 20's , Alu/Alu/PVC Blisters
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	054788; Pasage Tablets 10mg Werrick Pharmaceuticals, Industrial Area, Islamabad.
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	
	Decision: Approved with USP.	
446.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21506 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	J-Rosta 20mg Tablets
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin as Calcium…20mg"
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	10's, 20's , Alu/Alu/PVC Blisters
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	054789; Pasage Tablets 20mg Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications.	
447.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21511 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	J-Dine 60mg Tablet
	Composition	"Each Film Coated Tablet Contains: Fexofenadine Hydrochloride…60mg"
	Pharmacological Group	Antihistamine for systemic use. R06AX26
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, As per SRO.

	Approval status of product in Reference Regulatory Authorities.	ALLEGRA ALLERGY ® USFDA Approved.
	Me-too status	052779; Fanoxin Tablets 60mg "M/s Jawa Pharmaceutical (Pvt) Ltd, Industrial Area Kot Lakhpat,Lahore
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
448.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21512 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	J-Dine 120mg Tablet
	Composition	"Each Film Coated Tablet Contains: Fexofenadine Hydrochloride…120mg"
	Pharmacological Group	Antihistamine for systemic use. R06AX26
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	10's, 20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ALLEGRA® USFDA Approved.
	Me-too status	052778; Fanoxin Tablets 120mg "M/s Jawa Pharmaceutical (Pvt) Ltd, Kot Lakhpat,Lahore
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	The active substance is slightly soluble in water. The active substance exists in different polymorphic forms. The active substance manufacturers produce polymorphic form I. Fexofenadine has one asymmetric carbon atom. It is used as racemic mixture. **Reference** Fexofenadine Sandoz 120 mg and 180 mg film-coated tablets (fexofenadinehydrochloride) NL/H/3619/001-002/DC
	Decision: Approved.	
449.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21507 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Jufin 125mg Tablet
	Composition	Each Tablet Contains: Terbinafine as Hydrochloride…125mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's Alu/PVC Blister
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.

	Me-too status	070118 "; Terbizine Tablet By Candid Pharmaceuticals,Opposite Pasrur Sugar Mills,Sialkot Road, Pasrur"
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
450.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21508 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Jufin 250mg Tablet
	Composition	Each Tablet Contains: Terbinafine as Hydrochloride…250mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,20's Alu/PVC Blister
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.
	Me-too status	080847; Logirid Tablet 250mg "Lowitt Pharmaceutical (Pvt) Ltd, Industrial Estate,Peshawar.
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	
451.	Name and address of manufacturer / Applicant	"M/s Jupiter Pharma. Plot No. 25, Street # S-6, National Industrial Zone, Rawat, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 21513 dated 14-06-2018 Rs.20,000/- 14-06-2018
	Brand Name +Dosage Form + Strength	Judep Plus 25/3 mg Capsule
	Composition	"Each Capsule Contains: Fluoxetine as Hydrochloride…25mg Olanzapine…3mg"
	Pharmacological Group	Antidepressant
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x7's, Alu-Alu/PVC Blister
	Approval status of product in Reference Regulatory Authorities.	Symbyax USFDA Approved
	Me-too status	73777; Lenzif 3mg/25mg Capsule Martin Dow Karachi .
	GMP status	31-01-2018 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	
	Decision: Approved.	

452.	Name and address of manufacturer / Applicant	"M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 21762 dated 21-06-2018 Rs.20,000/- 21-06-2018 Rs. 5000/- for change of formulation
	Brand Name +Dosage Form + Strength	Micolin Oral Gel 2.0% Dakrin, Micono.
	Composition	"Each gram of Gel Contains: Miconazole Nitrate eq. to miconazole…20mg"
	Pharmacological Group	Antifungals For Topical Use D01AC02
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO, Alu tubes of 15g and 30g
	Approval status of product in Reference Regulatory Authorities.	Daktarin (Miconazole nitrate 2% w/w). MHRA Approved
	Me-too status	070057 "Mycon Oral Gel Each gm contains: Miconazole as Nitrate …. 2 % w/w BP . "ValorPharmaceuticals,124/A,KahutaRoad,Islamabad
	GMP status	12-06-2018, GMP Compliant.
	Remarks of the Evaluator.	The reference formulation contains miconazole without nitrate salt
	Decision: Deferred for revision of formulation as per the reference product along with submission of fee for revision of formulation.	
453.	Name and address of manufacturer / Applicant	"M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 21763 dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name +Dosage Form + Strength	Rozin 10mg Tablet Rozix, Statol, Sterol
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. to Rosuvastatin…10mg"
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO.Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	054788; Pasage Tablets 10mg Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	12-06-2018, GMP Compliant.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications 41 (First supplement).	
454.	Name and address of manufacturer / Applicant	"M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 21764 dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name +Dosage Form + Strength	Rozin 20mg Tablet Rozix, Statol, Sterol
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin Calcium Eq. to Rosuvastatin…20mg"
	Pharmacological Group	HMG CoA reductase inhibitors

		C10AA07
	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO. Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	081460; Rosan 20mg Tablet Sante Karachi . .
	GMP status	12-06-2018, GMP Compliant.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specifications 41 (First supplement).	
455.	Name and address of manufacturer / Applicant	"M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 21765 dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name +Dosage Form + Strength	Arti-M 20/120 mg Tablet
	Composition	"Each Tablet Contains: Artemether…20mg Lumefantrine…120mg"
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	Inhouse.
	Pack size & Demanded Price	1x8's, 2x8's, Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	Coartem (artemether/lumefantrine) Tablets USFDA Approved
	Me-too status	47214 A-Fantrine Tablets M/s Atco Labs, Karachi
	GMP status	12-06-2018, GMP Compliant.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specifications.	
456.	Name and address of manufacturer / Applicant	"M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 21766, dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name +Dosage Form + Strength	Arti-M 40/240 mg Tablet Artix,Artin
	Composition	"Each Tablet Contains: Artemether…40mg Lumefantrine…240mg"
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x8's, 2x8's, Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified drug
	Me-too status	053368; A-Fantrine DS Tablet Atco Laboratories Limited, Karachi
	GMP status	12-06-2018, GMP Compliant.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specifications.	
457.	Name and address of manufacturer / Applicant	"M/s Linta Pharmaceuticals Pvt Ltd. Plot No. 03, Street No S-5, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 21767, dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name +Dosage Form + Strength	Arti-M 80/480 mg Tablet

		Artix,Artin
	Composition	"Each Tablet Contains: Artemether…80mg Lumefantrine…480mg"
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	As per SRO, Alu-Alu Blister
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified drug
	Me-too status	081928; Marlin DS Tablet M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad
	GMP status	12-06-2018, GMP Compliant.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specifications.	
458.	Name and address of manufacturer / Applicant	"M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24309 dated 12-07-2018 Rs.20,000/- 12-07-2018
	Brand Name +Dosage Form + Strength	Exval-AH 10/12.5/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besilate…10mg Hydrochlorothiazide…12.5mg Valsartan…160mg"
	Pharmacological Group	Angiotensin II Receptor Blockers (ARBS), Combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's,14's,28's,30's, As per PRC,Alu-Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT USFDA Approved with box warning.
	Me-too status	Aldric-H 10/160/12.5mg Tablet Martin Dow Ltd. Karachi . .
	GMP status	10-04-2019 Conclusion: Based upon the areas inspected, the people met and the documents reviewed and considering the findings of the insoection, including the observation listed in the Inspection Report, M/s Genix Pharma is operating at a acceptable level of Cgmp compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
459.	Name and address of manufacturer / Applicant	"M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24310 dated 12-07-2018 Rs.20,000/- 12-07-2018
	Brand Name +Dosage Form + Strength	Exval-AH 10/25/160 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besilate…10mg Hydrochlorothiazide…25mg Valsartan…160mg"
	Pharmacological Group	Angiotensin II Receptor Blockers (ARBS), Combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 28's,30's, As per PRC,Alu-Alu Blister.

	Approval status of product in Reference Regulatory Authorities.	Exforge HCT USFDA Approved with box warning.
	Me-too status	Aldric-H 10/160/25mg Tablet Martin Dow Ltd. Karachi . .
	GMP status	10-04-2019 Conclusion: Based upon the areas inspected, the people met and the documents reviewed and considering the findings of the insoection, including the observation listed in the Inspection Report, M/s Genix Pharma is operating at a acceptable level of Cgmp compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
460.	Name and address of manufacturer / Applicant	"M/s Genix Pharma Pvt Ltd.44,45-B, Korangi Creek Road, Karachi, 75190, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24311 dated 12-07-2018 Rs.20,000/- 12-07-2018
	Brand Name +Dosage Form + Strength	Exval-AH 10/25/320 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Amlodipine as Besilate…10mg Hydrochlorothiazide…25mg Valsartan…320mg"
	Pharmacological Group	Angiotensin II Receptor Blockers (ARBS), Combinations
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 28's,30's, As per PRC,Alu-Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	Exforge HCT USFDA Approved with box warning.
	Me-too status	Aldric-H 10/320/25mg Tablet Martin Dow Ltd. Karachi . .
	GMP status	10-04-2019 Conclusion: Based upon the areas inspected, the people met and the documents reviewed and considering the findings of the inspection, including the observation listed in the Inspection Report, M/s Genix Pharma is operating at acceptable level of Cgmp compliance.
	Remarks of the Evaluator.	
	Decision: Approved.	
461.	Name and address of manufacturer / Applicant	"M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24445 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Calcit Chewable Tablets
	Composition	Each Tablet contains: Calcium Carbonate…1250mg Eq. to 500mg of elemental Calcium Colecalciferol 400 IU Eq. to 10 mcg Vitamin D3
	Pharmacological Group	Vitamin D Calcium supplement
	Type of Form	Form 5
	Finished product Specification	-
	Pack size & Demanded Price	10,15,30,60,100 tablets in polypropylene tube with stopper containing silica gel desiccant.
	Approval status of product in Reference Regulatory Authorities.	IDEOS 500 mg / 400 IU ANSM Approved
	Me-too status	

	GMP status	M/s Pharmedic Laboratories, Lahore 24-06-2019 Decision of the 270th Meeting of CLB: The board after detailed discussion on the investigation report of FID dated 13-05-2019, in the compliance to 267th meeting of CLB, decided to issue show cause notice to the following accused persons and give them opportunity of personal hearing n the next meeting of CLB on the matter of unauthorized manufacturing in the Liquid Injection Section (General). I- M/s Pharmedic Laboratories Pvt Ltd, Lahore through its CEO. II- Management of M/s Pharmedic Laboratories Lahore as per Form-29 of SECP i- Mr Waqar A Sheikh CNIC No 35202-9152354-3 ii- Mr Adeel A Sheikh CNIC No 35202-9143709-3 III- Mr Muhammad Nouman Ahmed, Quality Control Incharge S/O Muhammad Anwar ul Haq, CNIC No. 35202-2745122-9 IV- Mr Jamshaid Ghani, Production Incharge S/O Abdul Ghani, CNIC No 54400-0548981-5
	Remarks of the Evaluator.	Vitamin D IU = 0.025 mcg • Evidence of Me too formulation. • Provide reference for Specification for chewable tablets.
	Decision: Registration Board deferred 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 and referred the case to QA & LT Division for updated GMP status of the firm.	
462.	Name and address of manufacturer / Applicant	"M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24444 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Flostin Tablets
	Composition	Each film coated tablet contains: Fluoxetine as HCl….10mg
	Pharmacological Group	Selective serotonin reuptake inhibitors N06AB03
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2,10,20,30 PVC Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	044602; "Futine 10 mg Tab. "M/s Wilshire Laboratories, 124/A, Kotlakhpat, Indus. Area, Township Scheme, Lahore.
	GMP status	24-06-2019 Decision of the 270th Meeting of CLB: The board after detailed discussion on the investigation report of FID dated 13-05-2019, in the compliance to 267th meeting of CLB, decided to issue show cause notice to the following accused persons and give them opportunity of personal hearing n the next meeting of CLB on the matter of unauthorized manufacturing in the Liquid Injection Section (General). I- M/s Pharmedic Laboratories Pvt Ltd, Lahore through its CEO. II- Management of M/s Pharmedic Laboratories Lahore as

		per Form-29 of SECP i- Mr Waqar A Sheikh CNIC No 35202-9152354-3 ii- Mr Adeel A Sheikh CNIC No 35202-9143709-3 III- Mr Muhammad Nouman Ahmed, Quality Control Incharge S/O Muhammad Anwar ul Haq, CNIC No. 35202-2745122-9 IV- Mr Jamshaid Ghani, Production Incharge S/O Abdul Ghani, CNIC No 54400-0548981-5
	Remarks of the Evaluator.	Justification for 3% overage.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
463.	Name and address of manufacturer / Applicant	"M/s Pharmedic Laboratories Pvt Ltd. 16-km, Multan Road Lahore, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24443 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Biofol Dry Suspension
	Composition	Each 5ml contains: Iron as Iron III hydroxide polymaltose complex… 50mg Folic Acid…0.43mg
	Pharmacological Group	Antianemic
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	60 ml amber color, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	042952; Hemoplex-F Syrup M/s Synchro Pharmaceuticals, Kot Lakhpat, Lahore
	GMP status	24-06-2019: Decision of the 270th Meeting of CLB: The board after detailed discussion on the investigation report of FID dated 13-05-2019, in the compliance to 267th meeting of CLB, decided to issue show cause notice to the following accused persons and give them opportunity of personal hearing in the next meeting of CLB on the matter of unauthorized manufacturing in the Liquid Injection Section (General). I- M/s Pharmedic Laboratories Pvt Ltd, Lahore through its CEO. II- Management of M/s Pharmedic Laboratories Lahore as per Form-29 of SECP i- Mr Waqar A Sheikh CNIC No 35202-9152354-3 ii- Mr Adeel A Sheikh CNIC No 35202-9143709-3 III- Mr Muhammad Nouman Ahmed, Quality Control Incharge S/O Muhammad Anwar ul Haq, CNIC No. 35202-2745122-9 IV- Mr Jamshaid Ghani, Production Incharge S/O Abdul Ghani, CNIC No 54400-0548981-5
	Remarks of the Evaluator.	Evidence of international availability. Section approval certificate
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
464.	Name and address of manufacturer / Applicant	"M/s Scilife Pharma Pvt Ltd. Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi"
	Diary No. Date of R& I & fee	Dy.No 24482 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Aspy 81mg Tablet

	Composition	Each Enteric Coated Tablet Contains: Acetylsalicylic Acid (Aspirin)…81mg"
	Pharmacological Group	Other Analgesics And Antipyretics N02BA01
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's Alu Alu Blister.
	Approval status of product in Reference Regulatory Authorities.	02237726; Aspirin 81mg (Enteric-Coated) Health Canada
	Me-too status	076199; Aslow-81 OF Helix Pharma Karachi .
	GMP status	24-04-2019 Conclusion: Based upon the areas inspected, the people met and the documents reviewed during the inspection of M/s Scilife Pharma. Pvt. Ltd., Karachi, it was concluded that M/s Scilife Pharma. Pvt. Ltd., Karachi is operating at a accpetable level of good compliance with GMP guidelines.
	Remarks of the Evaluator.	.
	Decision: Approved.	
465.	Name and address of manufacturer / Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24435 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Trascot Plus 37.5/325 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tramadol Hydrochloride…37.5mg Paracetamol…325mg"
	Pharmacological Group	Opioids in combination with non-opioid analgesics. N02AJ13
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO, 2x5's, 10's
	Approval status of product in Reference Regulatory Authorities.	Tramacet Manufacturer/ sponsor: Janssen Ortho Inc. Health Canada Approved
	Me-too status	081956; Radol-P Tablet 325/37.5 mg M/s Regal Pharmaceuticals, Plot # 2-A, Street # S-5, National industrial zone Rawat.Islamabad
	GMP status	10-10-2018 & 17-10-2018 Recommendations: Firm has been adhering to GMP guidelines and showing good compliance with quality policy completely implemented. Guidelines, SOP's and written instructions for each and every step in manufacturing testing, and storage ensuring quality products are intact and implemented. Keeping in view the above, the panel unanimously recommends for grant of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved.	
466.	Name and address of manufacturer / Applicant	"M/s Kanel Pharma.Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24687 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Kanset 8mg tablets
	Composition	"Each film coated contains: Ondansetron as Hydrochloride dihydrate…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, 3x10'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 ,Genix Pharma Karachi . .
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved.	
467.	**Name and address of manufacturer / Applicant**	"M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24688 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Berox 8mg tablets
	Composition	"Each tablet contains: Betahistine dihydrochloride…8mg"
	Pharmacological Group	Antivertigo preparations N07CA01
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO.2x10's, alu Alu blister
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	081874; Betalin Tablet 8mg M/s Linear Parma, Plot # 18, Street S-4, National Industrial Zone, Rawat.Islamabad
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved.	
468.	Name and address of manufacturer / Applicant	"M/s Kanel Pharma. Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24689 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Berox 16mg tablets
	Composition	"Each tablet contains: Betahistine dihydrochloride…16mg"
	Pharmacological Group	Antivertigo preparations N07CA01
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO.2x10's, alu Alu blister
	Approval status of product in Reference	MHRA Approved.

	Regulatory Authorities.	
	Me-too status	073883; Kert 16mg Tablet High-Q Pharmaceuticals, Karachi
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved.	
469.	Name and address of manufacturer / Applicant	"M/s Kanel Pharma.Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24692 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Telide 400mg Tablets
	Composition	"Each film coated contains: Telithromycin…400mg"
	Pharmacological Group	Macrolides J01FA15
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's, Alu Alu Blister
	Approval status of product in Reference Regulatory Authorities.	Ketek tablet 400mg of Sanofi Aventis, Austria
	Me-too status	072443 "Tel-mycin 400 mg Tablets "Winilton Pharmaceuticals P No 45, Street, S-5, National Industrial Zone,Rawat"
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specification.	
470.	**Name and address of manufacturer / Applicant**	"M/s Kanel Pharma.Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24694 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Kenderm 100mg tablet
	Composition	"Each film coated contains: Minocycline as HCl…100mg"
	Pharmacological Group	Tetracyclines J01AA08
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	070523 Cycloxin 100mg Tablet Medisure, Karachi .
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during

		inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved.	
471.	Name and address of manufacturer / Applicant	"M/s Kanel Pharma.Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24695 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Fuken 250mg tablet
	Composition	"Each film coated tablet contains: Sodium fusidate…250mg
	Pharmacological Group	Anti-infective
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	2x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	081426 Pandate 250mg Tablets M/s Panacea Pharmaceuticals, Islamabad
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specification.	
472.	Name and address of manufacturer / Applicant	"M/s Kanel Pharma.Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad
	Diary No. Date of R& I & fee	Dy.No 24691 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Kexidol 20mg tablets
	Composition	"Each tablet contains: Piroxicam as betacyclodextrin…20mg"
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	2x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ANSM and ITALY Approved.
	Me-too status	079264 "Fedracam-BCD Tablets 20mg "Fedro Pharmaceutical, 149, Industrial Estate, Jamrud Road,Peshawar
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of

		improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specification.	
473.	Name and address of manufacturer / Applicant	"M/s Kanel Pharma.Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad
	Diary No. Date of R& I & fee	Dy.No 24690 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Kbandro 150mg tablets
	Composition	"Each film coated contains: Ibandronate monosodium monohydrate equivalent to Ibandronate…150mg"
	Pharmacological Group	Drugs Affecting Bone Structure And Mineralization M05BA06 Bisphosphonates
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1's, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Boniva USFDA Approved.
	Me-too status	075912 Ibanate tablet Helix Karachi .
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the representatives of the firm.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specification.	
474.	Name and address of manufacturer / Applicant	"M/s Kanel Pharma.Plot # 6, St # SS-3, National Industrial Zone, Rawat, Islamabad
	Diary No. Date of R& I & fee	Dy.No 24693 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Kendrate-D Tablets
	Composition	"Each uncoated contains: Ibandronate sodium trihydrate equivalent to Ibandronate…70mg Colecalciferol….70µg(2800IU)"
	Pharmacological Group	Drugs Affecting Bone Structure And Mineralization M05BA06 Bisphosphonates
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	1x10's, 3x10's, Alu-Alu Blister as per SRO.
	Approval status of product in Reference Regulatory Authorities.	ALENDRONATE PLUS D3 70 mg/70 ug APOTEX alendronate (as sodium) 70 mg and colecalciferol 70 Microgram Uncoated Tablets TGA Approved.
	Me-too status	069420; "Alendo-Tab D. "M/s Himont Pharma, Lahore
	GMP status	06-03-2019 Recommendations: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Kanel Pharma Rawat is operating in compliance to GMP guidelines as of today. However the points of improvements have been discussed and agreed by the

		representatives of the firm.
	Remarks of the Evaluator.	✓ The firm has revised their formulation from film coated tablet to uncoated tablet with fee of Rs. 5000/- dated 27-08-2019. **PEC Query:** The reference product shelf life is 18 months whereas, you have applied for 24months. Justify or submit evidence for 24 months shelf life. **<u>References</u>** **Shelf Life Status in TGA** Alendronate Plus D3 70 mg/70 microgram Shelf Life: Blister Pack PA/Al/PVC/Al -polyamide-aluminium foil-polyvinylchloride/aluminium foil 18 Months Store below 25 degrees Celsius **Shelf Life Status in MHRA** FOSAVANCE® 70 mg/2,800 IU tablets Aluminium/aluminium blisters, Shelf life 18 months. **Firms' Response** The firm has submitted that they are unable to justify or submit data regarding the enhance shelf life of 24 months, so kindly consider 18 months shelf life.
	Decision: Approved with shelf life of 18 months.	
475.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24454 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Ziocin 250mg Tablet
	Composition	"Each film coated tablet Contains: Azithromycin dihydrate equivalent to 250 mg of azithromycin…250mg"
	Pharmacological Group	Macrolide J01FA10
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	6's,10's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX USFDA Approved
	Me-too status	074869; Genthro 250mg M/s Genix Pharma Karachi . .
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator.	Firm has revised their formulation from uncoated tablet to film coated tablet with submission of Rs. 5000/- dated 28-08-2018.
	Decision: Approved.	
476.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24455 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Ziocin 500mg Tablet
	Composition	"Each film coated Tablet Contains:

		Azithromycin as dihydrate…500mg"
	Pharmacological Group	Macrolide J01FA10
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	6's, 10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX USFDA Approved.
	Me-too status	074870; Genthro 500mg Tablet M/s Genix Pharma Karachi
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator.	✓ Firm has revised their formulation from uncoated tablet to film coated tablet with submission of Rs. 5000/- dated 28-08-2018.
	Decision: Approved.	
477.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24456 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Ziocin 200mg/5ml Suspension
	Composition	"Each 5ml Contains: Azithromycin dihydrate eq. to azithromycin…200mg"
	Pharmacological Group	Macrolide J01FA10
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	15,30,60ml,Amber glass bottle, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	ZITHROMAX USFDA Approved.
	Me-too status	081946; J-Mac Dry Powder for Suspension M/s Jupiter PharmaPlot # 25, St# S6 RCCI, Rawat Islamabad
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator.	Oral Liquid Syrup section is present.
	Decision: Approved.	
478.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24447 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Siphage 50/1000 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCL…1000mg"
	Pharmacological Group	Drugs Used In Diabetes A10BD07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's,30's Rs 102.00 per Tablet.
	Approval status of product in Reference Regulatory Authorities.	Janumet Approved in USFDA with box warning.

	Me-too status	076400 Silmax-M 50mg/1000mg Tablet M/s High-Q Pharmaceuticals, Karachi . .
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator.	
	Decision: Approved.	
479.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24446 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Siphage 50/500 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sitagliptin as phosphate monohydrate…50mg Metformin HCL…500mg"
	Pharmacological Group	Drugs Used In Diabetes A10BD07
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's,30's Rs 101.00 per Tablet.
	Approval status of product in Reference Regulatory Authorities.	Janumet Approved in USFDA with box warning.
	Me-too status	076399 Silmax-M 50mg/500mg Tablet M/s High-Q Pharmaceuticals, Karachi . .
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator.	Not present in USP.
	Decision: Approved.	
480.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24449 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Vildaphage 50/1000 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Vildagliptin…50mg Metformin Hydrochloride…1000mg"
	Pharmacological Group	Drugs Used In Diabetes A10BD08
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's:Rs 850.63 per unit pack 30's: Rs 2551.80 per unit pack.
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.
	Me-too status	081907; Galmet 50mg/1000mg Tablet M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing,

		relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specifications with a shelf life of 18 months.	
481.	Name and address of manufacturer / Applicant	"M/s Martin Dow Marker Limited. 7, Jail Road, Quetta, Pakistan"
	Diary No. Date of R& I & fee	Dy.No 24448 dated 13-07-2018 Rs.20,000/- 13-07-2018
	Brand Name +Dosage Form + Strength	Vildaphage 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	Inhouse
	Pack size & Demanded Price	10's:Rs 773.30 per unit pack 30's:Rs 2319.90 per unit pack.
	Approval status of product in Reference Regulatory Authorities.	GALVUMET\ TGA Approved
	Me-too status	081906; Galmet 50mg/850mg Tablet M/s Vision Pharmaceuticals, Plot No. 22 & 23, Industrial Triangle Kahuta Road, Islamabad.
	GMP status	29-01-2018 Conclusion: "After reviewing their QA System, QC & Manufacturing, relevant documents, utilities and personal capacity the current GMP are rated as GOOD."
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specifications with a shelf life of 18 months.	
482.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab.28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22071 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Medipine 30mg Tablet
	Composition	"Each Film Coated Tablet Contains: Nimodipine…30mg
	Pharmacological Group	Selective Calcium Channel Blockers With Mainly Vascular Effects C08CA06 Dihydropyridine derivatives
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	3x10's, Alu-Alu blister.As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Nimotop MHRA Approved
	Me-too status	046975 "Nimopro Tablets 30mg. "M/s. Pulse Pharmaceutical,Mozay Badoke, Raiwind Road,Lahore.
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair

		compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	
	Decision: Approved.	
483.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22072 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Doxy 400mg Tablet
	Composition	"Each Uncoated Tablet Contains: Doxofylline…400mg"
	Pharmacological Group	Other Systemic Drugs For Obstructive Airway Diseases R03DA11 Xanthines
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	10 tablet in Alu- Alu, As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Ansimar Italy Approved.
	Me-too status	073744 Profylline Tablet M/s Kaizen Karachi.
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	
	Decision: Approved with innovators' Specification.	
484.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"Medipine 30mg Tablet
	Diary No. Date of R& I & fee	Dy.No 22074 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Tarbo 125mg Tablet
	Composition	"Each Tablet Contains: Terbinafine as HCL…125mg"
	Pharmacological Group	Antifungals for systemic use D01BA02
	Type of Form	Form 5
	Finished product Specification	USP/BP
	Pack size & Demanded Price	10 tab Alu-Alu blister, As per SRO,
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 125mg (uncoated tablets) TGA Approved.
	Me-too status	070118; "Terbizine Tablet M/s Candid Pharma, Pasrur"
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair

		compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	• Firm has revised their formulation from film coated to uncoated tablet with submission of Rs. 5000/- dated 30-08-2019.Evidence as film coated tablet. **Shortcoming:** The master formulation mentions Qty. of API per tablet is 150 mg.Justify. **Firms' Response** The firm has mentioned in master formulation that Qty. of terbinafine as hydrochloride per tablet is 140.64mg. **PEC Evaluation** • The provided master formulation is erroneous as the label claim of applied formulation is "Terbinafine as HCL…125mg".
	Decision: The Registration Board deferred the applied formulation as the label claim of applied formulation is "Terbinafine as HCL…125mg" whereas, the master formulation mentions "Terbinafine as HCL…140.64mg".Therefore, the Board directed to revise the master formulation as per the label claim along with the submission of requisite fee.	
485.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22075 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Tarbo 250mg Tablet
	Composition	"Each uncoated 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	10 tablet Alu- Alu blister, 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	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	✓ Firm has revised their formulation from film coated to uncoated tablet with submission of Rs. 5000/- dated 28-08-2019.Evidence as film coated tablet. **Shortcoming:** The master formulation mentions Qty. of API per tablet is 300mg. Justify. **Firms' Response** The firm has mentioned in master formulation that Qty. of terbinafine as hydrochloride per tablet is 281.28mg. **PEC Evaluation** The provided master formulation is erroneous as the label

		claim of applied formulation is "Terbinafine as HCL…250mg".
	Decision: The Registration Board deferred the applied formulation as the label claim of applied formulation is "Terbinafine as HCL…250mg" whereas, the master formulation mentions "Terbinafine as HCL…281.28mg".Therefore, the Board directed to revise the master formulation as per the label claim along with the submission of requisite fee.	
486.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab.,28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22076 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Pantomed 20mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Pantoprazole as Sodium Sesquihydrate…20mg"
	Pharmacological Group	Proton pump inhibitors A02BC02
	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	14's,Alu-Alu blister, As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Protonix USFDA Approved.
	Me-too status	081050 Panzet 20mg Tablet M/s Noa hemis Karachi . .
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	**Shortcoming:** The master formulation mentions Qty. of API per tablet is 24.50mg.Justify. **Firms' Response** The firm has mentioned in master formulation that pantoprazole. per tablet is 22.54 mg. **PEC Evaluation** The provided master formulation is erroneous as the label claim of applied formulation is "Pantoprazole as Sodium Sesquihydrate…20mg ".
	Decision: The Registration Board deferred the applied formulation as the label claim of applied formulation is "Pantoprazole as Sodium Sesquihydrate…20mg " whereas, the master formulation mentions "Pantoprazole as Sodium Sesquihydrate…22.54mg ".Therefore, the Board directed to revise the master formulation as per the label claim along with the submission of requisite fee.	
487.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22077 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Pantomed 40mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Pantoprazole as Sodium Sesquihydrate…40mg"
	Pharmacological Group	Proton pump inhibitors A02BC02

	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Protonix USFDA Approved.
	Me-too status	079782; "Pantberg Tablet M/s Iceberg Pharmaceuticals (Pvt) Ltd, Risalpur, KPK
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	
	Decision: Approved.	
488.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22078 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Esomed 20mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate…20mg"
	Pharmacological Group	Proton pump inhibitors A02BC05
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Nexium 24hr USFDA Approved.
	Me-too status	078496; "Navix 20 mg Tablets WnsFeild Pharmaceuticals,Plot.No.122, Block-A, Phase-V,Industrial Estate,Hattar.
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator Specifications.	
489.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22079 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Esomed 40mg Tablet
	Composition	"Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate…40mg"
	Pharmacological Group	Proton pump inhibitors A02BC05
	Type of Form	Form 5

	Finished product Specification	Innovator
	Pack size & Demanded Price	14's, Alu-Alu blister, As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole 40 mg gastro-resistant tablets MHRA Approved
	Me-too status	048444; Althia 40mg Tablets M/s Tabros Pharma, Karachi
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	
	Decision: Approved with Innovator Specifications.	
490.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22073 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Dekmed 50mg Capsule
	Composition	"Each Hard Gelatin Capsule Contains Diacerin…50mg"
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	30's, Alu-Alu, As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Approved by Austria.
	Me-too status	071639; "Dibro 50mg Capsules " Winbrain Research Laboratories, Industrial Estate,Hattar
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	
	Decision: Registration Board approved the formulation for the following clinical indication only."Treatment of symptoms of osteoarthritis of the hip or knee joint."	
491.	Name and address of manufacturer / Applicant	"M/s Medpharm Research Lab. 28 km, Ferozepur Road, Lahore"
	Diary No. Date of R& I & fee	Dy.No 22070 dated 25-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Medpectam 2000mg Injection "
	Composition	"Each Vial Contains: Cefoperazone as Sodium…1000mg Sulbactam as Sodium…1000mg"
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished product Specification	JP

	Pack size & Demanded Price	As per SRO, Type 1 glass vial.
	Approval status of product in Reference Regulatory Authorities.	Approved in Europe (Poland, Slovakia, Czech Republic)by EMA
	Me-too status	060124 "Sebactum 2gm Injection " Swat Pharmaceuticals, Saidu Sharif, Road Amankot, Swat.(contract manufacturing will be conducted by M/s. Biorex Pharmaceuticals, Islamabad)"
	GMP status	12-04-2019 Recommendations: Panel has thoroughly inspected the unit. Panel has evaluated various documents in regards with production, quality control, quality assurance. On the basis of evaluation of documents and inspection of manufacturing facility, the panel concluded that on the day of inspection the firm has fair compliance of GMP, however some advises were also given in report to the firm for up gradation. Copy of report is handed over to the firm.
	Remarks of the Evaluator.	
	Decision: Approved.	
492.	Name and address of manufacturer / Applicant	"M/s Titlis Pharma.,528-A, Sundar Industrial Estate, Raiwind Road, Lahore
	Diary No. Date of R& I & fee	Dy.No 21701 dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name +Dosage Form + Strength	Azilis 500mg Tablet
	Composition	"Each film coated tablet Contains: Azithromycin as Dihydrate…500mg"
	Pharmacological Group	Macrolide J01FA10
	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 USFDA Approved.
	Me-too status	074870; Genthro 500mg Tablet M/s Genix Pharma Karachi.
	GMP status	11-07-2018. GMP Certificate issued dated 27-07-2018.
	Remarks of the Evaluator.	Justification for 5.2% overage along with supporting data. **Firms' response:** Firm has provided following justification. "4.8 % inactive moiety and moisture".
	Decision: The Registration Board deferred the applied formulation for justification on scientific basis for addition of 4.8% overage in master formulation.	
493.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24575 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Lovast 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin as calcium…10mg"
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO, Alu foil and PVC blister.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.

	Me-too status	054788; Pasage Tablets 10mg Werrick Pharmaceuticals, I-10/3, Industrial Area, Islamabad.
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specification.	
494.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24575 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Lovast 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin as calcium…5mg"
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO, Alu foil and PVC blister.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.
	Me-too status	056102; Pasage Tablets mg Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved with USP Specification.	
495.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24574 Dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Lovast 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Rosuvastatin as calcium…20mg"
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	As per SRO, Alu foil and PVC blister.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved.

	Me-too status	054789 ; Pasage Tablets 20mg M/s Werrick Pharmaceuticals, 216-217, I-10/3, Industrial Area, Islamabad.
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.official strains of microbes for media testing."
	Remarks of the Evaluator.	
	Decision: Approved with USP Specification.	
496.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24569 Dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Donozil 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Donepezil HCL…5mg"
	Pharmacological Group	Anti-Dementia Drugs N06DA02 Anticholinesterases
	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Aricept 5 mg and 10 mg film-coated tablet USFDA Approved.
	Me-too status	045401 Remembrin Tablets 5mg PharmEvo, Karachi
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
497.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24570 Dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Donozil 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Donepezil HCL…10mg"
	Pharmacological Group	Anti-Dementia Drugs N06DA02 Anticholinesterases
	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	As per SRO.

	Approval status of product in Reference Regulatory Authorities.	Aricept 5 mg and 10 mg film-coated tablet USFDA Approved.
	Me-too status	045402 Remembrin Tablets 10mg PharmEvo, Karachi
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
498.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24567 Dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Prolidine 5mg Tablet
	Composition	Each Uncoated Tablet Contains: Procyclidine HCL …5mg
	Pharmacological Group	Anticholinergic Agents N04AA04 Tertiary amines
	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Discontinued in USFDA. KEMADRIN procyclidine hydrochloride 5mg tablet TGA Approved.
	Me-too status	041018; "Proclidine Tablets " Shaheen Pharmaceuticals,3Km Murghzar Road Saidu Sharif,Swat."
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
499.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24571 Dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	L-Itrat 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Levocetirizine dihydrochloride …5mg"
	Pharmacological Group	Antihistamines for Systemic Use R06AE09 Piperazine derivatives

	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	074588 ; "LevoTiczine Tablets " Lowitt Pharmaceutical (Pvt) Ltd, Peshawar."
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
500.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24577 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	C.C.Don Forte Tablet
	Composition	"Each Film Coated Tablet Contains: Ibuprofen…400mg Pseudoephedrine HCL…60mg"
	Pharmacological Group	Antiinflammatory And Antirheumatic Products, Non-Steroids
	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lasynac Tablets MHRA Approved.
	Me-too status	039129; Feecop DS Tablets Roomi Enterprises, Karachi
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on area inspected, people met & document reviewed and considering findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 & rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
501.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24568 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Prolidine 5mg/ml Injection
	Composition	"Each 2ml Ampoule contains: Procyclidine HCL …10mg
	Pharmacological Group	Anticholinergic Agents N04AA04 Tertiary amines

	Type of Form	Form 5
	Finished product Specification	Present in BP.
	Pack size & Demanded Price	2ml glass ampoules.As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	009572 Kemadrin Injection WELLCOME UK WELLCOME KARACHI
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	Firm has injectable liquid section and infusion small volume.
	Decision: Approved.	
502.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24566 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Phrenno-F 3/25 mg Capsule
	Composition	"Each Capsule Contains: Olanzapine…3mg Fluoxetine as HCL…25mg
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Symbyax USFDA Approved with boxwarning.
	Me-too status	73777; Lenzif 3mg/25mg Capsule Martin Dow Karachi .
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
503.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24579 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Phrenno-F 6/25 mg Capsule
	Composition	"Each Capsule Contains: Olanzapine…6mg Fluoxetine as HCL…25mg
	Pharmacological Group	Antipsychotics

	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Symbyax USFDA Approved with box warning.
	Me-too status	081974 ; Olanzo – F 6/25 Capsule M/s Regal Pharmaceuticals, Rawat.Islamabad
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
504.	Name and address of manufacturer / Applicant	"M/s Saydon Pharmaceutical Industries Pvt Ltd. 77-A, Hayatabad Industrial Estate, Peshawar"
	Diary No. Date of R& I & fee	Dy.No 24578 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Phrenno-F 12/25 mg Capsule
	Composition	"Each Capsule Contains: Olanzapine…12mg Fluoxetine as HCL…25mg
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Symbyax USFDA Approved with box warning.
	Me-too status	081975; Olanzo – F 12/25mg Capsule M/s Regal Pharmaceuticals, Rawat.Islamabad
	GMP status	22-10-2018 and 22-11-2018 Conclusion: Overall the firm was in good working condition and following the GMP guidelines as per Drugs, Act, 1976 and rules framed there under. Based on the area inspected the people met and document reviewed and considering the findings of inspection of M/s Saydon Peshawar is considered to be operated at acceptable level of compliance with GMP guideline as per Drugs, Act, 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
505.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24736 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Flexilor 4mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lornoxicam…4mg"
	Pharmacological Group	NSAID, M01AC05
	Type of Form	Form 5

	Finished product Specification	Innovator
	Pack size & Demanded Price	5's,10's,20's, PVC-ALU blister.
	Approval status of product in Reference Regulatory Authorities.	Xefo 4mg Tablet Swissmedic Approved
	Me-too status	074896 ; Orno 4mg Tablet Sami Karachi . .
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
506.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24733 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Flexilor 8mg Tablet
	Composition	"Each Film Coated Tablet Contains: Lornoxicam…8mg"
	Pharmacological Group	NSAID, M01AC05
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	5's,10's, 20's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	NOXON AIFA Approved
	Me-too status	075824; Xoni-Fast 8mg Tablet M/s Macter International, F-216, Karachi .
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
507.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24724 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Tramadan 100mg/2ml Injection
	Composition	"Each Ampoule (2ml) Contains: Tramadol Hydrochloride…100mg"
	Pharmacological Group	Analgesics N02AX02 Opioids
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	1's, 5's, 10's, 20's, 30's, 50's, 2ml Type 1 clear glass ampoule in Alu-PVC Blister.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved.
	Me-too status	053224; Tonoflex Injection Sami Pharmaceuticals, Karachi

	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
508.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24723 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Myorexil 4mg Capsule
	Composition	"Each Capsule Contains: Thiocolchicoside…4mg"
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents M03BX05
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	10's, 20's, Alu-PVC Blister.
	Approval status of product in Reference Regulatory Authorities.	MuscoRil 4 mg capsule rigide MuscoRil 8 mg capsule rigide AIFA Approved
	Me-too status	081968 ; Muscodid 4mg Capsule M/s Regal Pharmaceuticals, Rawat.Islamabad
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	• European Medicines Agency recommends restricting use of thiocolchicoside by mouth or injection. • Medicine only to be used at low doses for additional short-term relief of painful muscle contractures. For more details Reference: https://www.ema.europa.eu/en/medicines/human/referrals/thiocolchicoside-containing-medicines
	Decision: Approved.	
509.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24725 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Myorexil 4mg/2ml IM Injection
	Composition	"Each Ampoule (2ml) Contains: Thiocolchicoside…4mg"
	Pharmacological Group	Muscle Relaxants, Centrally Acting Agents M03BX05
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	1mlx1's, 1mlx5's, 1mlx6's, Type 1 clear glass ampoule
	Approval status of product in Reference Regulatory Authorities.	Miorel ANSM approved.

	Me-too status	Could not be confirmed.
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	Me too couldnot be confirmed. • European Medicines Agency recommends restricting use of thiocolchicoside by mouth or injection. • Medicine only to be used at low doses for additional short-term relief of painful muscle contractures. For more details Reference: https://www.ema.europa.eu/en/medicines/human/referrals/thiocolchicoside-containing-medicines
	Decision: The Registration Board deferred the applied formulation for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm.	
510.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24740 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Lincodan 600 mg/2ml Injection
	Composition	Each ampoule contains: Lincomycin as HCL…600mg"
	Pharmacological Group	Antibacterials For Systemic Use
	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	2mlx1's, 2mlx5's, 2mlx10's, Type 1 glass ampoule.
	Approval status of product in Reference Regulatory Authorities.	Lincocin 600 mg solution for injection "- 1 ampoule of 2 ml - AIC No. 02060103 AIFA Approved.
	Me-too status	016990 ; Lincomycin Hcl Injection WENZHOU Pharma, China.Ghazali Brothers Karachi / Swiss Pharma (Pvt) Ltd Karachi
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
511.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24740 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Lincodan 500 mg Capsules
	Composition	Each capsule contains: Lincomycin as Hydrochloride …500mg"
	Pharmacological Group	Antibacterials For Systemic Use Macrolides, Lincosamides And Streptogramins J01FF02 Lincosamides

	Type of Form	Form 5
	Finished product Specification	Present in USP.
	Pack size & Demanded Price	12's, Alu-PVC Blister, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Lincocin hard capsules Each capsule contains: lincomycin hydrochloride 544.81 mg (equivalent to 500 mg lincomycin base).
	Me-too status	080450; F-Linco Capsule 500mg M/s Fresh Pharmaceuticals, Islamabad
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	
	Decision: Approved.	
512.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24726 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Nalfon 20mg/ml Injection
	Composition	"Each Ampoule (1ml) Contains: Nalbuphine Hydrochloride…20mg"
	Pharmacological Group	Analgesics Opioid Morphinan Derivatives N02AF02
	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	1mlx1's, 1mlx 5's, 1mlx10's, Type 1 glass ampoule, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	080235 "Qenz Injection 20mg "Saydon Pharmaceuticals Industries Ltd. 77/A, Hayatabad, Industrial Estate, Peshawar.
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	Not in USP and BP.
	Decision: Approved.	
513.	Name and address of manufacturer / Applicant	"M/s Danas Pharmaceuticals Pvt Ltd 312, Industrial Triangle, Kahuta Road, Islamabad"
	Diary No. Date of R& I & fee	Dy.No 24726 dated 17-07-2018 Rs.20,000/- 17-07-2018
	Brand Name +Dosage Form + Strength	Injectafer 500mg/10ml Injection
	Composition	"Each Ampoule (10ml) Contains: Iron (as Ferric Carboxymaltose)…500mg"
	Pharmacological Group	Pharmacotherapeutic group: Iron trivalent, parenteral preparation, ATC code: B03AC

	Type of Form	Form 5
	Finished product Specification	Innovator
	Pack size & Demanded Price	10ml x1's, Type 1 clear glasss ampoule in Alu-PVC Blister.
	Approval status of product in Reference Regulatory Authorities.	Ferinject 50 mg iron/mL solution for injection/infusion. MHRA Approved. TGA Approved.
	Me-too status	072548 "Ferinject Injectable (VIAL M/s. RG Pharmaceutica (Pvt.) Ltd.,Suit # 703, Progressive Square,P.E.C.H.S., Block-6, Shahrah-e-Faisal,Karachi."
	GMP status	03-10-2017 Recommendations/Desired Actions: Based on the areas inspected, the people met and documents reviewed, after considering the findings of the inspection M/s Danas Pharmaceuticals, Islamabad having DML 000569 was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs, Act 1976 and rules framed there under.
	Remarks of the Evaluator.	**EMA Referral** • New recommendations to manage risk of allergic reactions with intravenous iron-containing medicines
	Decision: Approved.	
514.	Name and address of manufacturer / Applicant	"M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi"
	Diary No. Date of R& I & fee	Dy.No 24559 dated 22-06-2018 Rs.20,000/- 07-06-2018
	Brand Name +Dosage Form + Strength	Ryxon 250mg IV Injection
	Composition	"Each Vial Contains: Ceftriaxone (as Ceftriaxone Sodium)…250mg"
	Pharmacological Group	Third-generation cephalosporins J01DD04
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	250mg Vial, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Rocephin 250 mg Powder for solution for injection. MHRA Approved.
	Me-too status	075935; Breezon Injection 250mg M/s Pliva Balochistan
	GMP status	15-07-2019 Conclusion: Based on the above observations the panel unanimously recommends the firm for the grant of GMP Certificate for export purpose.
	Remarks of the Evaluator.	
	Decision: Approved.	
515.	**Name and address of manufacturer / Applicant**	"M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi"
	Diary No. Date of R& I & fee	Dy.No 21796 dated 22-06-2018 Rs.20,000/- 07-06-2018
	Brand Name +Dosage Form + Strength	Lamadol 50mg Tablet
	Composition	"Each Film Coated Tablet Contains: Tramadol Hydrochloride…50mg"
	Pharmacological Group	Analgesic N02AX02
	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.	USFDA Approved.
	Me-too status	073707 Damor 50mg Tablet Opal Lab. Karachi .
	GMP status	15-07-2019 Conclusion: Based on the above observations the panel unanimously recommends the firm for the grant of GMP Certificate for export purpose.
	Remarks of the Evaluator.	
	Decision: Approved.	
516.	Name and address of manufacturer / Applicant	"M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Diary No. Date of R& I & fee	Dy.No 24561 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Aprep 125mg Capsule
	Composition	"Each capsule contains: Aprepitant…125mg"
	Pharmacological Group	Anti-emetics and Anti-nauseants A04AD12
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2's, 4's, 6's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	EMEND®(aprepitant) USFDA Approved.
	Me-too status	074887 Apritus 125mg M/s S.J&G Karachi . .
	GMP status	07-02-2019, Issuance of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved.	
517.	Name and address of manufacturer / Applicant	"M/s Pharmevo Private Limited. Plot # A-29, North Western Industrial Zone, Port Qasim, Karachi"
	Diary No. Date of R& I & fee	Dy.No 24564 dated 16-07-2018 Rs.20,000/- 16-07-2018
	Brand Name +Dosage Form + Strength	Aprep 80mg Capsule
	Composition	"Each capsule contains: Aprepitant…80mg"
	Pharmacological Group	Anti-emetics and Anti-nauseants A04AD12
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	2's, 4's, 6's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	EMEND®(aprepitant) USFDA Approved.
	Me-too status	074886 Apritus 80mg M/s S.J&G Karachi . .
	GMP status	07-02-2019, Issuance of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved.	

518.	Name and address of manufacturer / Applicant	"M/s Wnsfeild Pharmaceuticals. Plot # 122, Block A, Phase V, Hattar Industrial Estate, Hattar"
	Diary No. Date of R& I & fee	Dy.No 21046 dated 21-06-2018 Rs.20,000/- 11-06-2018
	Brand Name +Dosage Form + Strength	Artidoxin 100/25/500 mg Tablet
	Composition	"Each Combokit Contains: **Sulfadoxine+Pyremethamine Tablets:** Each Uncoated Tablet Contains: Sulfadoxine…500mg Pyremethamine…25mg **Artesunate Tablets** Each Uncoated Tablet Contains: Artesunate…100mg"
	Pharmacological Group	Antimalarial.
	Type of Form	Form 5
	Finished product Specification	Sulfadoxine+Pyremethamine (USP), Artesunate (IP)
	Pack size & Demanded Price	1x9's, (3+6). As per SRO.
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified Drug. Manufacturer of Prequalified Product: Guilin Pharmaceutical Co. Ltd.Oral Solid Dosage workshop (OSD-1),No. 43 Qilidian Road, Guilin, Guangxi, China, 541004
	Me-too status	045098 Artesul Tablets for Adults M/s Zafa Pharmaceutical, Karachi
	GMP status	18-01-2018. Conclusion: "As per observations made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall CGMP compliance status of the firm, the panel unanimously recommend the renewal of DML no. 000610 by way of formulation granted to M/s Wnsfield Pharma Hattar."
	Remarks of the Evaluator.	
	Decision: The Registration Board deferred for submission of evidence of availability of co-blister machine.	
519.	Name and address of manufacturer / Applicant	"M/s The Searle Company Limited.F-319 SITE, Karachi,Pakistan
	Diary No. Date of R& I & fee	Dy.No 21757 dated 21-06-2018 Rs.20,000/- 21-06-2018
	Brand Name +Dosage Form + Strength	Ketrolac 30mg/ml *I*njection
	Composition	Each ml Contains: Ketorolac Tromethamine…30mg"
	Pharmacological Group	Anti-inflammatory And Anti-rheumatic Products, Non-Steroids M01AB15
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1ml ampoule, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Tora-Dol 30 mg/ml AIFA Approved.
	Me-too status	080560 "Orkit Injection IV Aulton Pharmaceuticals, Industrial Estate, Hattar.
	GMP status	30-01-2019 Conclusion: Based on the areas visited, commitment of the firm for continous improvement and people met, it is concluded that the firm is operating at a Good level of GMP compliance.

	Remarks of the Evaluator.	
	Decision: Approved.	
520.	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 22196 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name +Dosage Form + Strength	Thyromax Tablet 5mg
	Composition	"Each tablet contains: Carbimazole…5mg"
	Pharmacological Group	Anti-thyroid Preparations H03BB01 Sulfur-containing imidazole derivatives
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per PRC.
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved(EMC)\
	Me-too status	038674; "Carbil Tablet 5 mg "Danas Pharmaceutical (Pvt) Ltd, Kahuta Road, 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.	
	Decision: Approved.	
521.	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 22193 dated 26-06-2018 Rs.20,000/- 26-06-2018
	Brand Name +Dosage Form + Strength	Piro 2% Ointment w/w USP Mumax Netmax Genmax
	Composition	Each gm of ointment contains: 21.5mg Mupirocin calcium eq to 20.0mg mupirocin"
	Pharmacological Group	Antibiotics For Topical Use D06AX09
	Type of Form	Form 5
	Finished product Specification	USP and BP
	Pack size & Demanded Price	5g, 15g, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	ACTROBAN MUPIROCIN 2% **Federal Register determination that product was not discontinued or withdrawn for safety or efficacy reasons** USFDA Approved.
	Me-too status	079996 Mucin 20mg Ointment M/s Alza Pharmaceuticals, (Formerly M/s Alshife Trust Eye Hospital), Rawalpindi
	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.	
522.	Name and address of manufacturer / Applicant	"M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrial Area, Superhighway, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22177 dated 26-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Acido-20 20/1680mg Sachet
	Composition	"Each sachet contains: Omeprazole…20mg Sodium bicarbonate…1680mg"
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, 30's, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zegerid USFDA Approved
	Me-too status	060289 Omezonate Sachet 20mg Global Pharmaceuticals, Plot No 204-205, Kahuta Triangle, Industrial Area, Islamabad.
	GMP status	Last GMP Inspection of Conducted on 31-May-18, GMP certificate was provided.
	Remarks of the Evaluator.	✓ Firm has sachet section. Zegerid Powder for Oral Suspension is an immediate-release formulation that contains sodium bicarbonate to protect omeprazole from acid degradation.
	Decision: Approved.	
523.	Name and address of manufacturer / Applicant	"M/s Ciba pharmaceuticals (pvt) Ltd. Plot NO. A-371, Noorabad Site Industrial Area, Superhighway, Karachi"
	Diary No. Date of R& I & fee	Dy.No 22172 dated 26-06-2018 Rs.20,000/- 25-06-2018
	Brand Name +Dosage Form + Strength	Acido-40 40/1680mg Sachet
	Composition	"Each sachet contains: Omeprazole…40mg Sodium bicarbonate…1680mg"
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's, 30's, as per SRO.
	Approval status of product in Reference Regulatory Authorities.	Zegerid USFDA Approved
	Me-too status	060290; Omezonate Sachet 40mg Global Pharmaceuticals, Plot No 204-205, Kahuta Triangle, Industrial Area, Islamabad.
	GMP status	Last GMP Inspection of Conducted on 31-May-18, GMP certificate was provided.
	Remarks of the Evaluator.	✓ Firm has sachet section. Zegerid Powder for Oral Suspension is an immediate-release formulation that contains sodium bicarbonate to protect omeprazole from acid degradation.
	Decision: Approved.	

524.	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	Livazo Tablets 1mg
	Composition	Each film coated tablet contains: Pitavastatin as Calcium……..1mg
	Diary No. Date of R& I & fee	Dy.No 6385 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	JP Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Livalo 1mg Tablet, Kowa Co. Ltd., USA (USFDA Approved)
	Me-too status	081095 Pitastin 1mg Tablet M/s Atco Lab. 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.	
525.	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	Livazo Tablets 2mg
	Composition	Each film coated tablet contains: Pitavastatin as Calcium ……..2mg
	Diary No. Date of R& I & fee	Dy.No 6386 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	JP Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Livalo 2mg Tablet, Kowa Co. Ltd., USA (USFDA Approved)
	Me-too status	081094 Pitastin 2mg Tablet M/s Atco Lab. 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.	
526.	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	Livazo Tablets 4mg

	Composition	Each film coated tablet contains: Pitavastatin as Calcium……..4mg
	Diary No. Date of R& I & fee	Dy.No 6387 dated 21-02-2018 Rs. 20,000/- Dated 19-02-2018 ,Fee Rs, 5000/- dated 15-04-2019 ,for revision of formulation.
	Pharmacological Group	Statin / HMG-CoA Reductase Inhibitor
	Type of Form	Form-5
	Finished product Specification	JP Specifications
	Pack size & Demanded Price	10's, 20's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Livalo 4mg Tablet, Kowa Co. Ltd., USA (USFDA Approved)
	Me-too status	081093; Pitastin 4mg Tablet M/s Atco Lab. 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.	
527.	Name and address of manufacturer / Applicant	"M/s Honig Pharmaceuticals Laboratories. 14 km-Adyala Road, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 6483 dated 21-02-2018 Rs. 20,000/- 21-02-2018
	Brand Name +Dosage Form + Strength	Isoning 20mg Capsule
	Composition	"Each hard gelatin Capsule Contains: Isotretinoin…20mg"
	Pharmacological Group	Vitamin A derivative
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's, 2x10's, 3x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Hard Gelatin Capsule: Absorica™
	Me-too status	073629; Iret 20mg Capsule M/s Baxter Karachi .
	GMP status	14-12-2017, Grant of DML and additional sections.
	Remarks of the Evaluator.	✓ •Capsule section is present. •Provide the details as per Registration Board decision of M-250; I. Applicants shall revise their formulation as per innovator (new registration application with complete fee) if manufacturing facility is approved by CLB. II. Scientifically rationale lab scale stability data shall also be submitted.Isotretinoin degrades when exposed to light or atmospheric oxygen. Batches of drug substance are stored under argon and protected from light. Therefore, a powder filled hard gelatin capsule or tablet dosage form may not be stable. Hard Gelatin Capsule: Absorica™ (isotretinoin), a retinoid, is available in 10 mg, 20 mg, 30 mg and 40 mg hard gelatin capsules for oral administration.
	Decision: Deferred for submission of stability studies data as per format decided in 278th DRB meeting.	

528.	Name and address of manufacturer / Applicant	"M/s Honig Pharmaceuticals Laboratories. 14 km-Adyala Road, Rawalpindi"
	Diary No. Date of R& I & fee	Dy.No 6482 dated 21-02-2018 Rs. 20,000/- 21-02-2018
	Brand Name +Dosage Form + Strength	Sacip 250mg/5m Dry Suspension
	Composition	"Each 5ml after reconstitution Contains: Ciprofloxacin pellets…250mg"
	Pharmacological Group	Fluoroquinolones
	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.	Cipro USFDA Approved.
	Me-too status	075808 ; Axcin 250mg/5ml Dry Suspension M/s Novartis Pharma, Jamshoro
	GMP status	14-12-2017, Grant of DML and additional sections.
	Remarks of the Evaluator.	✓ Approved in USFDA with box warning. ✓ Oral dry powder suspension section is present. ✓ Source of granules :Vision Pharma. Vision has used Ciprofloxacin as Hydrochloride. It is composed of ciprofloxacin microcapsules and diluent which are mixed prior to dispensing .The components of the suspension have the following compositions: □ Microcapsules–ciprofloxacin, povidone, methacrylic acid copolymer, hypromellose, magnesium stearate, and Polysorbate 20. □ Diluent–medium-chain triglycerides, sucrose, lecithin, water, and strawberry flavor. □ Five (5) mL of 5% suspension contains approximately 1.4 g of sucrose and 5 mL of 10% suspension contains approximately 1.3 g of sucrose.
	Decision: The Registration Board deferred the case for revision of formulation, as the innovators' formulation contains Ciprofloxacin granules for oral suspension containing ciprofloxacin base whereas, the applied formulation is composed of Ciprofloxacin as Hydrochloride.	
529.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories Pvt. Limited 20 Km , Lahore, Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Funge Tablet 125 mg
	Diary No. Date of R& I & fee	Diary No:25683, 22/12/2017, Rs: 20,000/- Dated 22/12/2017
	Composition	Each tablet contains: Terbinafine Hydrochloride eq. to Terbinafine ..125mg
	Pharmacological Group	Antifungals for systemic use (D01BA02)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 125mg (as hydrochloride) TGA Approved uncoated.
	Me-too status	081045 Mycoderm 125mg Tablet M/s Nabiqasim Karachi
	GMP status	23-02-2018 & 26-02-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded

		that the firm M/s Demont Research Lab Sheikhupura has maintained a satisfactory level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	✓ Firm has revised their formulation from film coated to uncoated tablet with fee of Rs. 5000/- dated: 18-06-2019.
	Decision: Approved.	
530.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories Pvt. Limited 20 Km , Lahore, Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Funge Tablet 250 mg
	Diary No. Date of R& I & fee	Diary No:25682, 22/12/2017, Rs: 20,000/- Dated 22/12/2017
	Composition	Each tablet contains: Terbinafine Hydrochloride eq. to Terbinafine ..250mg
	Pharmacological Group	Antifungals for systemic use (D01BA02)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	LAMISIL terbinafine 250mg (as hydrochloride) TGA Approved uncoated.
	Me-too status	081184; Cutis 250mg Tablet M/s Tabros Pharma Karachi . .
	GMP status	23-02-2018 & 26-02-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satisfactory level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	Firm has revised their formulation from film coated to uncoated tablet with fee of Rs. 5000/- dated: 18-06-2019.
	Decision: Approved.	
531.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories Pvt. Limited 20 Km , Lahore, Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Gemiflox Tablet 320mg
	Diary No. Date of R& I & fee	Diary No:25684, 22/12/2017, Rs: 20,000/- Dated 21/12/2017
	Composition	Each film coated tablet contains: Gemifloxacin as mesylate….320mg
	Pharmacological Group	Fluoroquinolones (J01MA15)
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1x7's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	FACTIVE® film coated tablets USFDA Approved
	Me-too status	081167; Gemlox 320mg M/s Reign Pharma, Karachi. .
	GMP status	23-02-2018 & 26-02-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satisfactory level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	✓ Firm has revised formulation from uncoated tablet to film coated tablet with fee of Rs. 5000/- 19-06-2019.
	Decision: Approved.	

532.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories Pvt. Limited 20 Km , Lahore, Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Aezit Tablets 250mg
	Diary No. Date of R& I & fee	Diary No:25681, 22/12/2017, Rs: 20,000/- Dated 21/12/2017
	Composition	Each film coated tablet contains: Azithromycin as dihydrate….250mg
	Pharmacological Group	Macrolide (J01FA10)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved Film coated
	Me-too status	076686; Zetamax 250mg Tablet M/s Pfizer Pak. Karachi .
	GMP status	23-02-2018 & 26-02-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satisfactory level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	
	Decision: Approved.	
533.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories Pvt. Limited 20 Km , Lahore, Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Aezit Tablets 500mg
	Diary No. Date of R& I & fee	Diary No:25680, 22/12/2017, Rs: 20,000/- Dated 21/12/2017
	Composition	Each film coated tablet contains: Azithromycin as dihydrate….500mg
	Pharmacological Group	Macrolide (J01FA10)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x10's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved Film coated
	Me-too status	076685; Zetamax 500mg Tablet M/s Pfizer Pak. Karachi.
	GMP status	23-02-2018 & 26-02-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satisfactory level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	.
	Decision: Approved.	
534.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories Pvt. Limited 20 Km , Lahore, Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Clocit Tablet 50mg
	Diary No. Date of R& I & fee	Diary No:25679, 22/12/2017, Rs: 20,000/- Dated 21/12/2017
	Composition	Each tablet contains: Clomiphene Citrate…50mg
	Pharmacological Group	Nonsteroidal, ovulatory stimulant

	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x30's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	GENRX CLOMIPHENE clomifene citrate 50mg uncoated TGA Approved. USFDA Discontinued
	Me-too status	075806; Florid 50mg Tablet M/s Opal Labs, Karachi
	GMP status	23-02-2018 & 26-02-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satisfactory level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator.	✓ Revision of formulation from film coated tablet to uncoated tablet with submission of fee Rs. 5000/- dated 19-06-2019.. Registration Board in its 277th meeting approved registration of the above applied product in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.
	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.	

b. Deferred Cases.

535.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories Pvt. Limited 20 Km , Lahore, Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	Deslo Tablet 5 mg
	Diary No. Date of R& I & fee	Diary No:25678, 22/12/2017, Rs: 20,000/- 22/12/2017
	Composition	Each film coated tablet contains: Desloratadine…5mg
	Pharmacological Group	Antihistamine (R06AX27)
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1x30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CLARINEX® (desloratadine) Tablets USFDA Approved
	Me-too status	052562; Desolar Tablets. M/s Bryon Pharma (Pvt.) Ltd., Peshawar.
	GMP status	23-02-2018 & 26-02-2018 Recommendations: Based on the physical inspection of the unit, the technical personal met and documents evaluated, the panel concluded that the firm M/s Demont Research Lab Sheikhupura has maintained a satisfactory level of GMP compliance as per Schedule B-II of the Drugs Lic, Advt, Reg Rules 1976.
	Remarks of the Evaluator. Evidence of Monograph of BP. of finished product.	
	Previous Decision (287) : Deferred for justification of submitted finished product Specifications, since firm has claimed BP Specifications whereas BP monograph is not available for applied formulation.	
	Evaluation by PEC: Firm has now claimed innovator Specifications.	
	Decision: Approved with Innovators' Specfication.	
536.	Name and address of manufacturer / Applicant	M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value Addition City, Faisalabad
	Brand Name+Dosage Form + Strength	Trirosu 5mg Tablets
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium Salt…5mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 36225 dated 31-10-2018 Rs.20,000/- 31-10-2018
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished Product Specification	USP (not in Usp)
	Pack size & Demanded Price	1x10,1x20,1x30, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved
	Me-too status	081964; Rostin Tablet M/s Regal Pharmaceuticals,.Islamabad
	GMP status	Grant of DML
	Remarks of Evaluator	• The Master formulation mentions the quantity of API as 10.40mg. However, the label claim is 5mg. • Methylene chloride are discontinued/banned excipients. • Provide evidence of availability of finished product in USP. • Justify the use of three binders in master formulation.

	Previous Decision (287th): Deferred for following: • Revision of master formulation as per reference product along with submission of requisite fee for change of formulation. • Justification for submitted finished product Specifications, since firm has referred to USP monograph, whereas USP monograph is not available for applied formulation. • Justification for the use of three binders in master formulation.	
	Evaluation by PEC: 1) Revision of master formulation as per reference product along with submission of requisite fee for change of formulation. Firms' Response: Firm has revised their master formulation as per reference product without the submission of requisite fee. 2) Justification for submitted finished product Specifications, since firm has referred to USP monograph, whereas USP monograph is not available for applied formulation. Firms' Response: USP 41 monograph has been provided by the firm 3) Justification for the use of three binders in master formulation. **Firms' Response:** Firm has revised their formulation.	
	Decision: The Registration Board deferred the formulation for submission of Rs 20,000/- as the firm has revised their master formulation as per reference product.	
537.	Name and address of manufacturer / Applicant	M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value Addition City, Faisalabad
	Brand Name +Dosage Form + Strength	Trirosu 10mg Tablets
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium Salt…10mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 36226 dated 31-10-2018 Rs.20,000/- Dated 31-10-2018
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished Product Specification	USP 41(not in Usp)
	Pack size & Demanded Price	1x10,1 x 20,1 x 30, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved
	Me-too status	081965; Rostin Tablet M/s Regal Pharmaceuticals,.Islamabad
	GMP status	Grant of DML
	Remarks of Evaluator	• The Master formulation mentions the quantity of API as 20.80mg. However, the label claim is 10mg. • Methylene chloride are discontinued/banned excipients.For this reason, you have to revise the formulation and re-submit the same. • Provide evidence of availability of finished product in USP. • Justify the use of three binders in master formulation.
	Previous Decision (287th): Deferred for following: • Revision of master formulation as per reference product along with submission of requisite fee for change of formulation. • Justification for submitted finished product Specifications, since firm has referred to USP monograph, whereas USP monograph is not available for applied formulation. • Justification for the use of three binders in master formulation.	
	Evaluation by PEC: 1) Revision of master formulation as per reference product along with submission of requisite	

	fee for change of formulation. Firms' Response: Firm has revised their master formulation as per reference product without the submission of requisite fee. 2) Justification for submitted finished product Specifications, since firm has referred to USP monograph, whereas USP monograph is not available for applied formulation. Firms' Response: USP 41 monograph has been provided by the firm 3) Justification for the use of three binders in master formulation. Firms' Response: Firm has revised their formulation.	
	Decision: The Registration Board deferred the formulation for submission of Rs 20,000/- as the firm has revised their master formulation as per reference product.	
538.	Name and address of manufacturer / Applicant	M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value Addition City, Faisalabad
	Brand Name +Dosage Form + Strength	Trirosu 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Rosuvastatin as Calcium Salt…20mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 36227 dated 31-10-2018 Rs.20,000/- Dated 31-10-2018
	Pharmacological Group	HMG CoA reductase inhibitors C10AA07
	Type of Form	Form 5
	Finished Product Specification	USP 41(not in Usp)
	Pack size & Demanded Price	1x10's, 1x20's,1x30's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	CRESTOR Tablets USFDA Approved
	Me-too status	081460 Rosan 20mg M/s Sante Karachi . .
	GMP status	Grant of DML
	Remarks of Evaluator	• The Master formulation mentions the quantity of API as 41.6 mg. However, the label claim is 20mg. • Methylene chloride are discontinued/banned excipients. For this reason, you have to revise the formulation and re-submit the same. • Provide evidence of availability of finished product in USP. • Justify the use of three binders in master formulation.
	Previous Decision (287th): Deferred for following: • Revision of master formulation as per reference product along with submission of requisite fee for change of formulation. • Justification for submitted finished product Specifications, since firm has referred to USP monograph, whereas USP monograph is not available for applied formulation. • Justification for the use of three binders in master formulation.	
	Evaluation by PEC: 1) Revision of master formulation as per reference product along with submission of requisite fee for change of formulation. Firms' Response: Firm has revised their master formulation as per reference product without the submission of requisite fee. 2) Justification for submitted finished product Specifications, since firm has referred to USP monograph, whereas USP monograph is not available for applied formulation. Firms' Response:	

	USP 41 monograph has been provided by the firm 3) Justification for the use of three binders in master formulation. Firms' Response: Firm has revised their formulation.	
	Decision: The Registration Board deferred the formulation for submission of Rs 20,000/- as the firm has revised their master formulation as per innovator.	
539.	Name and address of manufacturer / Applicant	M/s Trillium Pharmaceuticals Pvt Ltd. Plot No. C-3 & C-4, Value Addition City, Faisalabad
	Brand Name +Dosage Form + Strength	Triflox 750mg Tablet
	Composition	Each Film Coated Tablet Contains: Levofloxacin Hemihydrate Eq. to levofloxacin…750mg"
	Diary No. Date of R& I & fee	Form-5 Dy.No 36215 dated 31-10-2018 Rs.20,000/- Dated 31-10-2018
	Pharmacological Group	Fluoroquinolones J01MA12
	Type of Form	Form 5
	Finished Product Specification	USP 41
	Pack size & Demanded Price	1x10's, 1x30's,1x60's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Evoxil Film-Coated Tablets USFDA Approved
	Me-too status	079617 Fuvelox 750 mg M/s Martin Dow Ltd. Karachi . .
	GMP status	Grant of DML
	Remarks of Evaluator	• Justify the quantity of Levofloxacin Hemihydrate as 750mg.
	Previous Decision (287th): Deferred for revision of master formulation as per reference product.	
	Evaluation by PEC: 1) Revision of master formulation as per reference product. Firms' Response: Firm has revised their master formulation as per reference product without the submission of requisite fee.	
	Decision: The Registration Board deferred the formulation for submission of requisite fee as the firm has revised their master formulation as per reference product.	
540.	Name and address of Manufacturer / Applicant	"M/s Briell Pharmaceutical (Pvt) Ltd. 538C Sundar Industrial Estate Multan Road, Lahore."
	Diary No. Date of R&I & fee	Dy.No 27077 dated 07-08-2018 Rs.20,000/- 07-08-2018
	Brand Name+Dosage Form+Strength	Famera 2.5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Letrozole…2.5mg"
	Pharmacological Group	Hormone antagonists and related agents, Aromatase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	3x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities	Femara USFDA Approved.
	Me-too status	075805 Letzole 2.5mg Tablet M/s Opal Labs, Karachi.
	GMP status	Last inspection report dated 25-04-2017, the panel recommended the grant of New DML.
	Remarks of Evaluator	Form 5 not signed by applicant and undertaking also not signed.

	Previous Decision (288): Deferred for clarification as Form 5 and undertaking were not signed by applicant.	
	Evaluation by PEC: Firm has submitted duly signed Form 5 and undertaking.	
	Decision: Approved.	
541.	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
	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 (288): 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 GMP status 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.	
542.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals. Plot No.249/A, Industrial, Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Medarone 200mg tablet
	Composition	Each film coated tablet contains: Amiodarone HCl……200mg
	Diary No. Date of R& I & fee	Dy.No 1166 dated 30-10-2017 Rs. 20,000/- 25-10-2017
	Pharmacological Group	Antiarrythmatic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	3 x 10's As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved as uncoated tablet
	Me-too status	Amid Tablets 20mg by CCL 045972
	GMP status	23-11-2017 firm was considered to be operating at fair compliancewith GMP guidelines.
	Remarks of the Evaluator.	Me-too status could not be confirmed in the available database.
	Previous Decision:	M-287: Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation.

	Evaluation by PEC:	Firm has deposited Rs. 5,000/- Deposit Slip No. (1921545) and requested (on covering letter) to change our product from film coated tablet to uncoated tablet. The firm has not submitted revised master formulation.
	Previous Decision (288): Deferred for submission of documents and master formulation for uncoated tablet.	
	Evaluation by PEC: Firm has submitted revised master formulation.	
	Decision: Approved.	
543.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd, Plot 2, Street 4, National Industrial Zone, Rawat
	Brand Name +Dosage Form + Strength	Terbinafine Tablet 250 mg Terbimed, Finomed, Binomed
	Diary No. Date of R& I & fee	Duplicate dossier
	Composition	Each film coated tablet contains: Terbinafine Hydrochloride eq. to Terbinafine ..250mg
	Pharmacological Group	Antifungals for systemic use (D01BA02)
	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	10's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lamisil terbinafine 250mg (as hydrochloride) TGA Approved uncoated.
	Me-too status	081184; Cutis 250mg Tablet M/s Tabros Pharma Karachi.
	GMP status	06-02-2018 Conclusion: Keeping in view of the above facts, overall GMP compliance is found Good as of today.
	Remarks of the Evaluator.	□ Evidence of international availability and me-too as film coated tablet is required. □ Firm has provided evidence of film coated tablets which could not be confirmed. □ Present in USP
	Previous Decision(288): Deferred for following: □ Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm □ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting □ Confirmation from R&I section for date of submission of original dossier along with details of submitted fee.	
	Evaluation by PEC: Firm has revised their formulation from film coated to uncoated tablet with submission of Rs. 5000/- dated 26-06-2019. Firm has not provided evidence for confirmation from R&I section for date of submission of original dossier along with details of submitted fee.	
	Decision: The Regitration Board deferred the applied formulation for evidence for confirmation from R&I section for date of submission of original dossier along with details of submitted fee.	
544.	Name and address of manufacturer / Applicant	M/s Medera Pharmaceuticals Pvt. Ltd Plot 2, Street 4, National Industrial Zone, Rawat
	Brand Name +Dosage Form + Strength	Orlimed Capsules 120 mg Statomed, Obestat Capsule
	Diary No. Date of R& I & fee	Duplicate dossier
	Composition	Each Capsule Contains: Orlistat…120mg
	Pharmacological Group	Peripherally acting anti-obesity products (A08AB01)

	Type of Form	Form-5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	30's Alu Alu Blister, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Beacita 120mg Capsules, hard MHRA Approved
	Me-too status	055576; Orlisat 120mg Capsules M/s Sharp & Dhome, Karachi
	GMP status	06-02-2018 Conclusion: Keeping in view of the above facts, overall GMP compliance is found Good as of today.
	Remarks of the Evaluator.	Present in USP. Provide source of pellets.
	Previous Decision(288): Deferred for source of pellets, along with stability studies data, GMP certificate of Supplier and differential fee in case of import of pellets	
	Evaluation by PEC: Firm has submitted that their source of pellets is Vision Pharmaceuticals.	
	Decision: The Registration Board deferred for further deliberation upon stability data requirement for orlistat pellets and submission of evidence for confirmation from R&I section for date of submission of original dossier along with details of submitted fee.	
545.	Name and address of manufacturer / Applicant	M/s Bloom Pharmaceuticals Pvt. Ltd. Plot No. 30, Phase I and II, Industrial Estate, Hattar
	Diary No. Date of R& I & fee	Diary No:3046, 23/01/2018, Rs: 20,000/- 23/01/2018
	Brand Name +Dosage Form + Strength	Blomine Tablet 500mcg
	Composition	Each sugar coated tablet contains: Mecobalamin….500mcg
	Pharmacological Group	Vitamin B12.
	Type of Form	Form 5
	Finished product Specification	JP
	Pack size & Demanded Price	2x10's, 3x10's, 10x10's, As per SRO.
	Approval status of product in Reference Regulatory Authorities.	PMDA Approved sugar coated
	Me-too status	081876; Heam 500 mcg Tablet M/s Linear Parma.
	\GMP status	07-04-2018. Conclusion: Overall the firm was operating under good level of cGMP.
	Remarks of the Evaluator.	Firm has revised their formulation from film coated to sugar coated tablet without the submission of requisite fee.
	Previous Decision (288): Deferred for submission of fee for revision of formulation	
	Evaluation by Pec: Firm has revised their formulation with submission of requisite fee (challan copy).	
	Decision: Approved. Fee shall be verified as per procedure adopted in 285th meeting.	

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

a. New Cases

550.	Name and address of Manufacturer / Applicant	"M/s Biorific Pharma.Plot No.143, Industrial Triangle, Kahuta road, Islamabad"
	Diary No. Date of R&I & fee	Dy.No 23250 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Brand Name+Dosage Form+Strength	Broxim 10mg/ml Liquid
	Composition	Each ml liquid Contains: Bromhexine HCL…10mg
	Pharmacological Group	Expectorant R05CB02
	Type of Form	Form 5
	Finished Product Specification	Innovator
	Pack Size & Demanded Price	100ml,200ml,500ml,1000ml,Plastic container, As per SRO.
	Approval status of product in Reference Regulatory Authorities	N/a
	Me-too status	Brofarm Liquid 088625
	GMP status	12-12-2017, No production activities have been observed during inspection. The management has informed they have not produced any batch since the grant of license i.e. Nov 2016 and registrations i.e. Aug 2017. Based on the areas in Specificationted, the people met and the documents reviewed and considering the findings of the inspection the management agreed to rectify the shortcomings pointed out during inspection and will submit compliance report.
	Remarks of Evaluator	Firm has dry powder and liquid syrup section.
	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. Morover, the Registration Board referred the case to QA & LT to update GMP status of the firm on priority.	
551.	Name and address of Manufacturer / Applicant	"M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad"
	Diary No. Date of R&I & fee	Dy.No 23249 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Brand Name+Dosage Form+Strength	Chlormulin 45% Powder
	Composition	"Each 1000gm powder Contains: Tiamulin hydrogen fumarate…45%
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator
	Pack Size & Demanded Price	100g,200g,500g, 1000g
	Approval status of product in Reference Regulatory Authorities	N/a
	Me-too status	006846 ; Tiamutin 45% Hilton Karachi
	GMP status	12-12-2017, No production activities have been observed during inspection. The management has informed they have not produced any batch since the grant of license i.e. Nov 2016 and registrations i.e. Aug 2017. Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection the management agreed to rectify the shortcomings

		pointed out during inspection and will submit compliance report.
	Remarks of Evaluator	
	Decision: The Registration Board referred the case to QA & LT to update GMP status of the firm on priority.	
552.	Name and address of Manufacturer / Applicant	"M/s Biorific Pharma.Plot No.143, Industrial Triangle, Kahuta road, Islamabad"
	Diary No. Date of R&I & fee	Dy.No 23248 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Brand Name+Dosage Form+Strength	Enrofic-C Oral Solution
	Composition	"Each 1000ml contains: Enrofloxacin…20% Colistin Sulphate…3%"
	Pharmacological Group	Antibiotic, Flouroquinolone
	Type of Form	Form 5
	Finished Product Specification	Innovator
	Pack Size & Demanded Price	100ml, 500ml, 1000ml, Plastic Container, As per SRO.
	Approval status of product in Reference Regulatory Authorities	N/a
	Me-too status	Enrosir-20 Oral Liquid "Each 100ml Contains:- Enrofloxacin .....20%.. Colistin Sulphate…3.0% "Attabak Pharmaceutical Islamabad."
	GMP status	12-12-2017, No production activities have been observed during inspection. The management has informed they have not produced any batch since the grant of license i.e. Nov 2016 and registrations i.e. Aug 2017. Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection the management agreed to rectify the shortcomings pointed out during inspection and will submit compliance report.
	Remarks of Evaluator	The applied formulation is "Each 1000ml contains: Enrofloxacin…20% Colistin Sulphate…3%" Whereas, the locally approved drug is: Each 100ml Contains:- Enrofloxacin .....20%. Colistin Sulphate…3.0% "Attabak Pharmaceutical Islamabad."
	Decision: The Registration Board 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 and referred the case to QA & LT to update GMP status of the firm on priority.	
553.	Name and address of Manufacturer / Applicant	"M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad"
	Diary No. Date of R&I & fee	Dy.No 23247 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Brand Name+Dosage Form+Strength	Flocol liquid
	Composition	"Each 100ml contains: Florofenicol…23gm Colistin Sulphate…50MIU"
	Pharmacological Group	Antibiotic
	Type of Form	Form 5

	Finished Product Specification	In-house
	Pack Size & Demanded Price	100ml, 230ml, 500ml, 1000ml, Plastic container.
	Approval status of product in Reference Regulatory Authorities	N/a
	Me-too status	072680; FLOTIN Liquid "D-Maarson Pharmaceuticals, Plot # 17, Street SS-2, National Industrial Zone, Rawat, Islamabad.
	GMP status	12-12-2017, No production activities have been observed during inspection. The management has informed they have not produced any batch since the grant of license i.e. Nov 2016 and registrations i.e. Aug 2017. Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection the management agreed to rectify the shortcomings pointed out during inspection and will submit compliance report.
	Remarks of Evaluator	
	Decision: The Registration Board referred the case to QA & LT to update GMP status of the firm on priority.	
554.	Name and address of Manufacturer / Applicant	"M/s Biorific Pharma. Plot No.143, Industrial Triangle, Kahuta road, Islamabad"
	Diary No. Date of R&I & fee	Dy.No 23246 dated 05-07-2018 Rs.20,000/- 04-07-2018
	Brand Name+Dosage Form+Strength	Lincof powder
	Composition	"Each 100g powder contains: Lincomycin as Hcl…10gm Colistin Sulphate…80,000,000IU
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Innovator
	Pack Size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities	N/a
	Me-too status	079863; LC-100 Oral Powder M/s Ras Pharmaceuticals (Pvt) Ltd., Multan."
	GMP status	12-12-2017, No production activities have been observed during inspection. The management has informed they have not produced any batch since the grant of license i.e. Nov 2016 and registrations i.e. Aug 2017. Based on the areas inspected, the people met and the documents reviewed and considering the findings of the inspection the management agreed to rectify the shortcomings pointed out during inspection and will submit compliance report.
	Remarks of Evaluator	
	Decision: The Registration Board referred the case to QA & LT to update GMP status of the firm on priority.	

Case no. 03 Registration applications of categories to be considered on priority

f. 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.		
555.	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 21795 dated 22-06-2018 Rs.20,000/- 22-06-2018
	Brand Name +Dosage Form + Strength	Cortinide Rotacap 200mg/6mcg Capsule
	Composition	"Each Rotacap Contains: Budesonide…200mcg Formoterol Fumarate Dihydrate…6mcg"
	Pharmacological Group	Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics R03AK07
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	30's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	081177; Venticort rotacaps 200mcg+6mcg M/s Macter Intr. F-216, Karachi . .
	GMP status	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.	Capsule Section approval.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting and submission of evidence of steroidal capsule section for DPIs wit relevant manufacturing and quality control equipment.	
556.	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 21794 dated 22-06-2018 Rs.20,000/- 22-06-2018
	Brand Name +Dosage Form + Strength	Cortinide Rotacap 100mg/6mcg Capsule
	Composition	"Each Rotacap Contains: Budesonide…100mcg Formoterol Fumarate Dihydrate…6mcg"
	Pharmacological Group	Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics R03AK07
	Type of Form	Form 5
	Finished product Specification	Inhouse
	Pack size & Demanded Price	30's, As per PRC.
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	081176; Venticort Rotacaps 100mcg+6mcg Capsule M/s Macter Intr. F-216, Karachi .

	GMP status	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.	
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting and submission of evidence of steroidal capsule section section for DPIs wit relevant manufacturing and quality control equipment.	
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.		
557.	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 22190 dated 26-06-2018 Rs.20,000/- Dated 26-06-2018 Duplicate
	Brand Name +Dosage Form + Strength	Terbison Tablets 250mg
	Composition	"Each Tablet Contains: Terbinafine HCL…250mg"
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs. 1121 packof 10 Tab.
	Approval status of product in Reference Regulatory Authorities.	TGA Approved.
	Me-too status	080847; Logirid Tablet 250mg Lowitt Pharmaceutical (Pvt) Ltd, Industrial estate,Peshawar
	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.	3 % overage has been added without justification.
	Decision: Deferred for revision of formulation as per innovator i.e. "Terbinafine as HCL…250mg", whereas, the applied formulation is "Terbinafine HCL…250mg" and justification of 3% overage on the basis of scientific data.	
Export Facilitation: Applications was received through letter No.F.-1-6/2019-PR.1 (EFD) " M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar. ", Pakistan" have achieved benchmark of USD 131,844 as defined in the Board's decision during fiscal year 2017-2018. In this regard, please find the following applications submitted by the firm.		
558.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Winspat 50mg Tablet
	Composition	Each Film Coated Tablet Contains Lacosamide ……50mg
	Diary No. Date of R& I & fee	Dy.No 36056 dated 31-10-2018 Rs.20,000/- 30-10-2018
	Pharmacological Group	Antiepileptics N03AX18
	Type of Form	Form 5
	Finished product Specifications	Innovator's Specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat MHRA Approved.
	Me-too status	075947; Atcomid 50mg Tablet Atco Lab. Karachi . .
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018 and The report concludes renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
559.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Winspat DS 100mg Tablet
	Composition	Each Film Coated Tablet Contains Lacosamide ……100mg
	Diary No. Date of R& I & fee	Dy.No 34360 dated 16-10-2018 Rs.20,000/- 09-10-2018
	Pharmacological Group	Antiepileptics N03AX18
	Type of Form	Form 5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat MHRA Approved.
	Me-too status	075948; Atcomid 100mg Tablet Atco Lab. Karachi . .
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018 and The report concludes renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
560.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Winspat 200mg Injection
	Composition	Each Vial (20mL) Contains: Lacosamide ….200 mg
	Diary No. Date of R& I & fee	Dy.No 36056 dated 31-10-2018 Rs.20,000/- 30-10-2018
	Pharmacological Group	Antiepileptics N03AX18
	Type of Form	Form 5
	Finished product Specifications	Innovator's Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Vimpat Injection 10mg/ml MHRA Approved
	Me-too status	076431; Lalap Injection M/s Genix Pharma Karachi . .
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-01-2018 and The report concludes renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
561.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Moxtrex 400mg Tablet
	Composition	Each Film Coated Tablet Contains Moxifloxacin as Hcl……400mg
	Diary No. Date of R& I & fee	Dy.No 34364 dated 16-10-2018 Rs.20,000/- 09-10-2018
	Pharmacological Group	Fluoroquinolones J01MA14

	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	Moxifloxacin 400mg Tablet by Bayer Health Care USFDA Approved
	Me-too status	074931; Moxpin 400 mg Tablet M/s Winthrox Karachi . .
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-1-2018 and The report concludes renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
562.	Name and address of manufacturer / Applicant	M/s Wnsfeild Pharmaceuticals. Plot no. 122, Phase V, Block A, Industrial Estate Hattar.
	Brand Name +Dosage Form + Strength	Moxtrex 400mg Infusion
	Composition	Each Vial (250 mL) Contains: Moxifloxacin (As Hydrochloride)…….400 mg
	Diary No. Date of R& I & fee	Dy.No 34363 dated 16-10-2018 Rs.20,000/- 09-10-2018
	Pharmacological Group	Fluoroquinolones J01MA14
	Type of Form	Form 5
	Finished product Specifications	Inhouse
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Avelox MHRA Approved
	Me-too status	080973 ; "Moxisaf 400mg Injection Saaaf Pharmaceuticals, Industrial Estate, (SIZ) Risaipur,Nowshera.
	GMP status	Last GMP inspection of Wnsfeild conducted on 18-1-2018 and The report concludes renewal of DML
	Remarks of the Evaluator	Section approval certificate is required.
	Decision: Approved.	

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

i. Human

563.	Name and address of Applicant	M/s Premier Agencies, 1 A/15, Sector 15, Korangi Industrial Area Karachi-74900, Pakistan
	Detail of Drug Sale License	**Address**: M/s Premier Agencies **Validity:** Plot no. D-3, D-4 & D-5 Sector 6-F, Mehran Town **Status:** By way of Wholesale **Validity:**14-05-2020
	Name and address of manufacturer	M/s GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo, Norway Site: Nycoveien 1, NO-0485 Oslo, Norway
	Name and address of marketing authorization holder	M/s GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo, Norway
	Name of exporting country	Norway
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 3305 Dated 25/1/2018
	Fee including differential fee	Rs. 100,000/- Dated 24/1/2018
	Brand Name +Dosage Form + Strength	Clariscan 0.5mmol/ml Solution for injection
	Composition	1 ml solution for injection contains: Gadoteric Acid …279.3mg Active corresponding to Gadolinium oxide….90.62mg Tetraxetan…202.46mg Other Constituent Tetraxetan… 0.25mg Meglumine….97.6mg Water for injection…ad vol.
	Finished Product Specification	Inhouse
	Pharmacological Group	Paramagnetic contrast media for magnetic resonance imaging ATC Code: V08 CA 02
	Shelf life	2 years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	20ml glass vial
	International availability	Sweden
	Me-too status	---
	Detail of certificates attached	<u>Original legalized CoPP</u> Certificate No: Certifying Authority: Norwegian Medicines Agency Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 13-Dec-2018 <u>Agreement</u> M/s GE Healthcare AS, Nycoveien 1-2, P.O. Box 4220 Nydalen, NO-0401 Oslo, Norway authorize M/s Premier Agencies, 1 A/15, Sector 15, Korangi Industrial Area Karachi-74900, Pakistan to register , distribute and sale all strength of Clariscan 0.5mmol/mL Solution for injection in Pakistan.
	Remarks of the Evaluator.	• In the finished product label the Urdu version of dosage is missing. • Certificate number on COPP is missing.

	Decision: Approved as per policy for inspection of manufacturer abroad with innovator's specifications.	
564.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	**Address**: B-23 Site Karachi. **Validity:** 05-02-2019 **Status:** By Way Of Wholesale
	Name and address of manufacturer	M/s Fisons Limited London Road, Holmes Chapel, Crewe, CW4 8BE UK (as per Form 5 A)
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW, UK
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 11716 Dated 30/03/2018
	Fee including differential fee	Rs. 50,000/- Dated 30/03/2018
	Brand Name +Dosage Form + Strength	Flutiform 125µg/5µg per actuation pressurized Inhalation Suspension
	Composition	Each metered dose ex-valve contains: Fluticasone propionate….125µg Formoterol fumarate dihydrate…5µg
	Finished Product Specification	Inhouse
	Pharmacological Group	Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics
	Shelf life	2 Years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	120 actuations per inhaler Multipack of 3x1 inhaler 120 actuations
	International availability	MHRA Approved
	Me-too status	
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10152239 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 26, October 2017 Copy GMP certificate Certificate No: UK MIA 113 Insp GMP/IMP 113/15353-0025 Certifying Authority: MHRA Validity: 20-07-2018 Letter of Authorization Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration. Dated : 19-01-2018
	Stability Studies	**Storage condition** Do not store above 30°C or indirect sunlight. Do not freeze. Real time : 30C/75%RH: 24 months

	Remarks of the Evaluator.	PEC Query **1.** In relationship letter between different entities you have mentioned Fisons Limited (also known as Sanofi Aventis) is involved in manufacturing , packaging, and batch release QC testing. This information is not in line with status provided on COPP that mentions different sites for manufacturing, packaging and batch release. Clarification is required. Firm's Response The applicant has provided clarification letter for COPP of NAPP Pharmaceuticals Limited: *Catalant UK packaging limited and Mundipharma GmbH* were listed in the original EU MAA as an alternative site for foil pouching but has never been used since. *Bard Pharmaceuticals* is the batch release site for UK. We confirm that manufacturer to be approved in Pakistan is as the below: Fison Limited /UK is the Bulk manufacturer, packager for Flutiform. Napp Pharmaceuticals Limited is the Marketing Authorization Holder. **2.** The description of the dosage form mentions Fluticasone Propionate content per actuation is 0.125mg and contents per canister is 20.0mg, where the total number of actuations are 120. Clarification is required how the Fluticasone Propionate contents per actuation i.,e. 0.125mg equivalent to contents per canister i.e. 20.0mg with number of actuations 120mg. The applicant has submitted that stated number of 120 actuations is minimum number of actuations available for inhalation actual number may be more than that. Please note that first four actuations go into the air and some quantity of the contents is not extractable. **3.** In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. The label mentions manufacturer Recipharm HC limited and Logo Mundipharm. **4.** Stability studies data sheets of the following batches AA11023A, AA11026A, AA11027A is required as per stability protocol, whereas the submitted data is of different batches. **5.** The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi.
	Decision: The Registration Board deferred the applied formulation for the following reasons: • **Submission of latest COPP as per current manufacturing site details in line with Form 5 A.** • **Submission of label mentioning correct manufacturing site.** • **Submission of real time stability studies as per Zone IVA condition as the provided stability is not according to Zone IVA condition.**	

565.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s Fisons Limited London Road, Holmes Chapel, Crewe, CW4 8BE UK (as per Form 5 A)
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW, UK
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 11715 Dated 30/03/2018
	Fee including differential fee	Rs. 50,000/- Dated 30/03/2018
	Brand Name +Dosage Form + Strength	Flutiform 50µg/5µg per actuation pressurized Inhalation Suspension
	Composition	Each metered dose ex-valve contains: Fluticasone propionate….50µg Formoterol fumarate dihydrate…5µg
	Finished Product Specification	Inhouse
	Pharmacological Group	Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics
	Shelf life	2 Years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	120 actuations per inhaler Multipack of 3x1 inhaler 120 actuations
	International availability	MHRA Approved
	Me-too status	
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10152238 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 26, October 2017 Copy GMP certificate Certificate No: UK MIA 113 Insp GMP/IMP 113/15353-0025 Certifying Authority: MHRA Validity: 20-07-2018 Letter of Authorization Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration. Dated : 19-01-2018
	Stability Studies	Storage condition Do not store above 30°C or indirect sunlight. Do not freeze. Real time : 30C/75%RH: 24 months

	Remarks of the Evaluator.	**1.** In relationship letter between different entities you have mentioned Fisons Limited (also known as Sanofi Aventis) is involved in manufacturing , packaging, and batch release QC testing. This information is not in line with status provided on COPP that mentions different sites for manufacturing, packaging and batch release. Clarification is required. The applicant has provided clarification letter for COPP of NAPP Pharmaceuticals Limited: *Catalant UK packaging limited and Mundipharma GmbH* were listed in the original EU MAA as an alternative site for foil pouching but has never been used since. *Bard Pharmaceuticals* is the batch release site for UK. We confirm that manufacturer to be approved in Pakistan is as the below: Fison Limited /UK is the Bulk manufacturer, packager for Flutiform. Napp Pharmaceuticals Limited is the Marketing Authorization Holder. **2.** The description of the dosage form mentions Fluticasone Propionate content per actuation is 0.050 mg and contents per canister is 8.01mg, where the total number of actuations are 120. Clarification is required how the Fluticasone Propionate contents per actuation i.,e. 0.050 mg equivalent to contents per canister i.e. 8.01 mg with number of actuations 120mg. The applicant has submitted that stated number of 120 actuations is minimum number of actuations available for inhalation actual number may be more than that. Please note that first four actuations go into the air and some quantity of the contents is not extractable. **3.** In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. The label mentions manufacturer Recipharm HC limited and Logo Mundipharm. **4.** Stability studies data sheets of the following batches AA11031A, AA11038A, AA11039A is required as per stability protocol, whereas the submitted data is of different batches. **5.** The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi.
	Decision: The Registration Board deferred the applied formulation for the following reasons: • **Submission of latest COPP as per current manufacturing site details in line with Form 5 A.** • **Submission of label mentioning correct manufacturing site.** • **Submission of real time stability studies as per Zone IVA condition as the provided stability is not according to Zone IVA condition.**	
566.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi.

		Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s Fisons Limited London Road, Holmes Chapel, Crewe, CW4 8BE UK (as per Form 5 A)
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW, UK
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 11717 Dated 30/03/2018
	Fee including differential fee	Rs. 50,000/- Dated 30/03/2018
	Brand Name +Dosage Form + Strength	Flutiform 250µg/10µg per actuation pressurized Inhalation Suspension
	Composition	Each metered dose ex-valve contains: Fluticasone propionate….250µg Formoterol fumarate dihydrate…10µg
	Finished Product Specification	Inhouse
	Pharmacological Group	Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics
	Shelf life	2 Years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	120 actuations per inhaler Multipack of 3x1 inhaler 120 actuations
	International availability	MHRA Approved
	Me-too status	
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10152240 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 26, October 2017 Copy GMP certificate Certificate No: UK MIA 113 Insp GMP/IMP 113/15353-0025 Certifying Authority: MHRA Validity: 20-07-2018 Letter of Authorization Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration. Dated : 19-01-2018
	Stability Studies	Storage condition Do not store above 30°C or indirect sunlight. Do not freeze. Real time : 30C/75%RH: 24 months
	Remarks of the Evaluator	**1.** In relationship letter between different entities you have mentioned Fisons Limited (also known as Sanofi Aventis) is involved in manufacturing , packaging, and batch release QC testing. This information is not in line with status provided on COPP that mentions different sites for manufacturing, packaging and batch

		release. Clarification is required. The applicant has provided clarification letter for COPP of NAPP Pharmaceuticals Limited: *Catalant UK packaging limited and Mundipharma GmbH* were listed in the original EU MAA as an alternative site for foil pouching but has never been used since. *Bard Pharmaceuticals* is the batch release site for UK. We confirm that manufacturer to be approved in Pakistan is as the below: Fison Limited /UK is the Bulk manufacturer, packager for Flutiform. Napp Pharmaceuticals Limited is the Marketing Authorization Holder. **2.** The description of the dosage form mentions Fluticasone Propionate content per actuation is 0.250 mg and contents per canister is 40 mg, where the total number of actuations are 120. Clarification is required how the Fluticasone Propionate contents per actuation i.,e. 0.250mg equivalent to contents per canister i.e. 40.0mg with number of actuations 120mg. The applicant has submitted that stated number of 120 actuations is minimum number of actuations available for inhalation actual number may be more than that. Please note that first four actuations go into the air and some quantity of the contents is not extractable. **3.** In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. The label mentions manufacturer Recipharm HC limited and Logo Mundipharm. **4.** Stability studies data sheets of the following batches 2H006F, 2H009F and 2H010F is required as per stability protocol, whereas the submitted data is of different batches. **5.** The drug sale license mentions the following information: • Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi.
	Decision: The Registration Board deferred the applied formulation for the following reasons: • **Submission of latest COPP as per current manufacturing site details in line with Form 5 A.** • **Submission of label mentioning correct manufacturing site.** • **Submission of real time stability studies as per Zone IVA condition as the provided stability is not according to Zone IVA condition.**	
567.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	Helsinn Birex Pharmaceuticals Ltd. Damastown, Mulhuddart, Dublin 15, Ireland
	Name and address of marketing authorization holder	Helsinn Birex Pharmaceuticals Ltd. Damastown, Mulhuddart, Dublin 15, Ireland

	Name of exporting country	Ireland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 23423 Dated 07/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 07/12/2017
	Brand Name +Dosage Form + Strength	Akynzeo Capsule 300mg/0.5mg
	Composition	Each capsule contains : Netupitant ….300 mg Palonosetron hydrochloride equivalent to 0.5 mg of palonosetron
	Finished Product Specification	Innovator
	Pharmacological Group	Antiemetics and antinauseants, serotonin (5-HT3) antagonists; ATC code:A04AA55
	Shelf life	36 Months
	Demanded Price	To be communicated at the time of pricing.
	Pack size	Alu-Alu blister of 1 capsule
	International availability	MHRA Approved
	Me-too status	N/A
	Detail of certificates attached	Original legalized CoPP Certificate No: 12/17/111204 Certifying Authority: Europeon Medicines Agency Free Sale: Confirms the free sale of the product in exporting country. The facilities and operations conform to WHO-GMP. Issue Date: 26-07- 2017 GMP certificate Certificate No: 15413/M294 Certifying Authority: Health Product Regulatory Authority HPRA Issue Date : 20-01-2017 Validity : 3 Years
	Remarks of the Evaluator.	**1.** In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. The label mentions Logo of Mundipharm and the composition mentions incorrect spelling of Netupitant. Clarify. In the finished product label the Urdu version of dosage is missing. **2.** Submit stability profile for shelf life of 48 months as provided data is of 42 months. Firm has submitted to approve shelf life of 36 months. **3.** The signatures of technical person on stability data is missing. The product is not to be manufactured locally. It is an EMA approved product and will be imported in finished form, the signatures of technical person on stability documents are not mandatory.
	Decision: Approved with shelf life of 36 months and as per Policy for inspection of Manufacturer abroad.The firm will import product with label as per Drugs (Labelling and Packing) rules 1986.	
568.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi.

		Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	B Braun Melsungan AG, Mistelweg 2 Berlin D-12357 Germany
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW United Kingdom
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 11171 Dated 27/03/2018
	Fee including differential fee	Rs. 50,000/- Dated 19/03/2018
	Brand Name +Dosage Form + Strength	OxyNorm Injection 10mg/ml (SC or IV Solution for Injection/ Infusion)
	Composition	Each ml contains: Oxycodone Hydrochloride….10mg
	Finished Product Specification	BP
	Pharmacological Group	Natural Opium Alkaloid ATC Code: N02AA05
	Shelf life	5 years
	Demanded Price	At the time of price fixation.
	Pack size	Ampoule 1ml
	International availability	MHRA Approved
	Me-too status	-
	Detail of certificates attached	<u>Original legalized CoPP</u> Certificate No: PP10144090 Certifying Authority: The Medicine and Health Care Products Regulatory Agency, UK Free Sale: Confirms the free sale of the product in exporting country. The facilities and operations conform to WHO-GMP. Issue Date: 13, June 2016 Applicant for Certificate: MundiPharma Medical Company Limited Cambridge Science Park Milton Road Cambridge CB4 0AB United Kingdom <u>Legalized GMP certificate</u> Certificate No: DE_BE_01_GMP_2016_0027 Certifying Authority: Landesamt Fur Gesundheit und Soziales Berlin Validity: 10-03-2019 <u>Letter of Authorization</u> Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration. Dated : 08-04-2019
	Remarks of the Evaluator.	• Approved in USFDA with box warning. 1. The stability storage site for applied formulation is Bard Pharmaceuticals Limited, Cambridge Science Park , Milton

		Road, Cambridge, UK. Clarification is required as manufacturing site of the applied formulation is different than stability conduction site. Napp Pharmaceuticals Ltd authorize Bard Pharmaceuticals Ltd. Cambridge Science Park, Milton Road, Cambridge CB4 0GW to perform stability studies on OxyNorm Injection on behalf of the manufacturer B Braun Melsungan AG, Mistelweg 2, Berlin, D-12357, Germany. 2. Specify the fill volume whether 1 ml or 2 ml as only one will be granted. The firm has requested to grant 1 ml ampoule. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing.
	Decision: The Registration Board deferred the applied formulation for the following reasons: **i. Submission of justification for not conducting stability studies at the manufacturing site i.e. B Braun Melsungan AG, Mistelweg 2, Berlin, D-12357, Germany.** **ii. Submission of the finished product label mentioning Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction.**	
569.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s Bard Pharmaceuticals Limited Cambridge Science Park, Milton Road, Cambridge, CB4 0AB, UK
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 23426 Dated 07/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 07/12/2017
	Brand Name +Dosage Form + Strength	OxyNorm Capsule 5mg
	Composition	Each hard gelatin capsule contains: Oxycodone Hydrochloride….. 5mg (Eq. to oxycodone base……4.5mg)
	Finished Product Specification	….
	Pharmacological Group	Natural Opium Alkaloid ATC Code: N02AA05
	Shelf life	4 years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	28’s, 56’s, 112 PVdC Coated PVC Blister packs with aluminium Backing foil
	International availability	MHRA Approved
	Me-too status	N/A
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10143836 Certifying Authority: The Medicine and Health Care Products Regulatory Agency

		Free Sale: Confirms the free sale of the product in exporting country. The facilities and operations conform to WHO-GMP. Issue Date: 13, June 2016 GMP certificate Certificate No: UK MIA 1811 Insp GMP/IMP 1811/21989-0031 Certifying Authority: MHRA Validity: 08-11-2019 Letter of Authorization Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration. Dated : 09-10-2017
	Remarks of the Evaluator.	• Approved in USFDA with box warning. • The finished product is available in BP .However, provided Specifications and stability data is not according to British Pharmacopoeia monograph. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage is missing. • There are typographical errors in Label. • The marketing authorization holder mentioned on Label is M/s Ali Gohar and Company (Private Limited).
	Decision: The Registration Board approved the applied formulation with BP specifications. The firm will import product with label as per Drugs (Labelling and Packing) rules 1986.	
570.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s Bard Pharmaceuticals Limited Cambridge Science Park, Milton Road, Cambridge, CB4 0AB, UK
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 23424 Dated 07/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 07/12/2017
	Brand Name +Dosage Form + Strength	OxyNorm Capsule 10mg
	Composition	Each hard gelatin capsule contains: Oxycodone Hydrochloride….. 10mg (Eq. to oxycodone base……9mg)
	Finished Product Specification	….
	Pharmacological Group	Natural Opium Alkaloid ATC Code: N02AA05
	Shelf life	4 years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	28's, 56's, 112 PVdC Coated PVC Blister packs with aluminium Backing foil
	International availability	MHRA Approved

	Me-too status	N/A
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10143832 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. The facilities and operations conform to WHO-GMP. Issue Date: 13, June 2016 GMP certificate Certificate No: UK MIA 1811 Insp GMP/IMP 1811/21989-0031 Certifying Authority: MHRA Validity: 08-11-2019 Letter of Authorization Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration. Dated : 09-10-2017
	Remarks of the Evaluator.	• Approved in USFDA with box warning. • The finished product is available in BP .However provided Specifications and stability data according to British Pharmacopoeia monograph. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage is missing. • There are typographical errors in Label. • The marketing authorization holder mentioned on Label is M/s Ali Gohar and Company (Private Limited).
	Decision: The Registration Board approved the applied formulation with BP specifications. The firm will import product with label as per Drugs (Labelling and Packing) rules 1986.	
571.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s Bard Pharmaceuticals Limited Cambridge Science Park, Milton Road, Cambridge, CB4 0AB, UK
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 23424 Dated 07/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 07/12/2017
	Brand Name +Dosage Form + Strength	OxyNorm Capsule 20mg
	Composition	Each hard gelatin capsule contains: Oxycodone Hydrochloride….. 20mg (Eq. to oxycodone base……18mg)
	Finished Product Specification	….
	Pharmacological Group	Natural Opium Alkaloid ATC Code: N02AA05

	Shelf life	4 years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	28's, 56's, 112 PVdC Coated PVC Blister packs with aluminium Backing foil
	International availability	MHRA Approved
	Me-too status	N/A
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10143833 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. The facilities and operations conform to WHO-GMP. Issue Date: 13, June 2016 GMP certificate Certificate No: UK MIA 1811 Insp GMP/IMP 1811/21989-0031 Certifying Authority: MHRA Validity: 08-11-2019 Letter of Authorization Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration. Dated : 09-10-2017
	Remarks of the Evaluator.	• Approved in USFDA with box warning. • The finished product is available in BP .However provided Specifications and stability data according to British Pharmacopoeia monograph. • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage is missing. • There are typographical errors in Label. • The marketing authorization holder mentioned on Label is M/s Ali Gohar and Company (Private Limited).
	Decision: The Registration Board approved the applied formulation with BP specifications. The firm will import product with label as per Drugs (Labelling and Packing) rules 1986.	
572.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	**Address**: B-23 Site Karachi. **Validity:** 05-02-2019 **Status:** By Way Of Wholesale
	Name and address of manufacturer	M/s Bard Pharmaceuticals Limited Unit 191, Cambridge Science Park, Milton Road, Cambridge, CB4 0AB, UK
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 25297 Dated 20/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 15/12/2017
	Brand Name +Dosage Form Strength	TARGINACT Prolonged Release Tablet 10mg/5mg

	Composition	Each prolonged release tablet contains: Oxycodone hydrochloride….10mg Naloxone hydrochloride….5mg
	Finished Product Specification	Provide reference
	Pharmacological Group	Analgesic ; Opioid ; Natural Opium Alkaloids ATC Code: N02AA55
	Shelf life	3 Years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	56 tab, PVC Alu- Blister
	International availability	USFDA Approved
	Me-too status	---
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10149852 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 14, June 2017 GMP certificate Certificate No: UK MIA 1811 Insp GMP/IMP 1811/21989-0031 Certifying Authority: MHRA Validity: 08-11-2019 Agreement Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration.
	Stability Studies	Storage condition Do not store above 30°C. Real time : 30C/65%RH: 36 months
	Remarks of the Evaluator.	• Approved in USFDA with box warning.(not marketed) 1. Valid drug sale license is missing. The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi. 2. Agreement between applicant for COPP i.e. MundiPharm Medical Company Limited and Napp Pharmaceuticals Ltd is missing. Relationship letter between Mundipharma group of companies and Napp Pharmaceuticals Limited. Firm has submitted that Mundipharma has network of independent associated companies in Europe, USA,Asia, Alatin, America and now in Middle East and Africa. Napp Pharmaceuticals Limited is an independent Associate Company within the Mundi Pharm Network of independent associated companies. 3. Provide reference for Finished Product Specification. Firm has claimed EU Specifications. But the product is not present in EU. 4. The brand name mentioned on Label is UPPERCASE i.e. TARGINACT while the brand name mentioned in COPP and Form 5 only mentions T and A in Capital

		letters . TarginAct will appear in upper case on the artwork i.e. 1.i.e. "TarginAct" TARGINACT. 5. In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. 6. The date of manufacturing of batch is 06/2006 and stability has been initiated on 01/2007. Justify the delay in stability commencement on scientific basis. Stability study can be initiated at any time after manufacturing. Delay in initiation can only have a positive effect on the outcome.
	Decision: The Registration Board approved the applied formulation as per policy of inspection of manufacturer abroad. The firm will import product with label as per Drugs (Labelling and Packing) rules 1986.	
573.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	**Address**: B-23 Site Karachi. **Validity:** 05-02-2019 **Status:** By Way Of Wholesale
	Name and address of manufacturer	M/s Bard Pharmaceuticals Limited Unit 191, Cambridge Science Park, Milton Road, Cambridge, CB4 0AB, UK
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 25298 Dated 20/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 15/12/2017
	Brand Name +Dosage Form + Strength	TarginAct Prolonged Release Tablet 20mg/10mg
	Composition	Each prolonged release tablet contains: Oxycodone hydrochloride….20mg Naloxone hydrochloride….10mg
	Finished Product Specification	Provide reference
	Pharmacological Group	Analgesic ; Opioid ; Natural Opium Alkaloids ATC Code: N02AA55
	Shelf life	3 Years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	56 tabs, PVC Alu- Blister
	International availability	USFDA Approved
	Me-too status	---
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10150115 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 27, June 2017 GMP certificate

		Certificate No: UK MIA 1811 Insp GMP/IMP 1811/21989-0031 Certifying Authority: MHRA Validity: 08-11-2019 <u>Agreement</u> Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration.
	Remarks of the Evaluator.	• Approved in USFDA with box warning.(not marketed) 1. Valid drug sale license is missing. The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi. 2. Agreement between applicant for COPP i.e. MundiPharm Medical Company Limited and Napp Pharmaceuticals Ltd is missing. Relationship letter between Mundipharma group of companies and Napp Pharmaceuticals Limited. Firm has submitted that Mundipharma has network of independent associated companies in Europe, USA,Asia, Alatin, America and now in Middle East and Africa. Napp Pharmaceuticals Limited is an independent Associate Company within the Mundi Pharm Network of independent associated companies. 3. Provide reference for Finished Product Specification. Firm has claimed EU Specifications. But the product is not present in EU. 4. The brand name mentioned on Label is UPPERCASE i.e. TARGINACT while the brand name mentioned in COPP and Form 5 only mentions T and A in Capital letters . TarginAct will appear in upper case on the artwork i.e. 1.i.e. "TarginAct" TARGINACT. 5. In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. 6. The date of manufacturing of batch is 06/2006 and stability has been initiated on 01/2007. Justify the delay in stability commencement on scientific basis. • Stability study can be initiated at any time after manufacturing. Delay in initiation can only have a positive effect on the outcome.
	Decision: The Registration Board approved the applied formulation as per policy of inspection of manufacturer abroad. The firm will import product with label as per Drugs (Labelling and Packing) rules 1986.	
574.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	**Address**: B-23 Site Karachi. **Validity:** 05-02-2019 **Status:** By Way Of Wholesale
	Name and address of manufacturer	M/s Bard Pharmaceuticals Limited Unit 191, Cambridge Science Park, Milton Road, Cambridge, CB4 0AB, UK
	Name and address of marketing	Napp Pharmaceuticals Ltd

	authorization holder	Cambridge Science Park Milton Road Cambridge CB4 0GW
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 25299 Dated 20/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 15/12/2017
	Brand Name +Dosage Form + Strength	TarginAct Prolonged Release Tablet 40mg/20mg
	Composition	Each prolonged release tablet contains: Oxycodone hydrochloride….40mg Naloxone hydrochloride….20mg
	Finished Product Specification	Provide reference
	Pharmacological Group	Analgesic ; Opioid ; Natural Opium Alkaloids ATC Code: N02AA55
	Shelf life	3 Years
	Demanded Price	To be communicated at the time of pricing.
	Pack size	56 tabs, PVC Alu- Blister
	International availability	USFDA Approved
	Me-too status	---
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10149854 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to WHO-GMP. Issue Date: 14, June 2017 GMP certificate Certificate No: UK MIA 1811 Insp GMP/IMP 1811/21989-0031 Certifying Authority: MHRA Validity: 08-11-2019 Agreement Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration.
	Remarks of the Evaluator.	• Approved in USFDA with box warning.(not marketed). 1. Valid drug sale license is missing. The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi. 2. Agreement between applicant for COPP i.e. MundiPharm Medical Company Limited and Napp Pharmaceuticals Ltd is missing. Relationship letter between Mundipharma group of companies and Napp Pharmaceuticals Limited. Firm has submitted that Mundipharma has network of independent associated companies in Europe, USA,Asia, Alatin, America and now in Middle East and Africa. Napp Pharmaceuticals Limited is an independent Associate Company within the Mundi Pharm Network of independent

		associated companies. 3. Provide reference for Finished Product Specification. Firm has claimed EU Specifications. But the product is not present in EU. 4. The brand name mentioned on Label is UPPERCASE i.e. TARGINACT while the brand name mentioned in COPP and Form 5 only mentions T and A in Capital letters . TarginAct will appear in upper case on the artwork i.e. 1.i.e. "TarginAct" TARGINACT. 5. In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing. 6. The date of manufacturing of batch 149829 is 04/2009 and stability has been initiated on 08/2009. Justify the delay in stability commencement on scientific basis. Similarly this has been observed for other batches. Clarify. Stability study can be initiated at any time after manufacturing. Delay in initiation can only have a positive effect on the outcome.
	Decision: The Registration Board approved the applied formulation as per policy of inspection of manufacturer abroad. The firm will import product with label as per Drugs (Labelling and Packing) rules 1986.	
575.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s LTS Lohmann Therapie-Systeme AG Lohmannstraβe 2 D-56626 Andernach Germany
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW, UK Applicant for Certificate MundiPharm Medical Company Limited Cambridge Science Park Milton Road Cambridge CB4 0AB, UK
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 25300 Dated 20/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 15/12/2017
	Brand Name +Dosage Form + Strength	BuTrans Transdermal Patch 5µg/hr
	Composition	5µg/hr Transdermal Patch contains: Buprenorphine….5mg Area containing active substance: 6.25 cm^2 Nominal release rate : 5 µg of buprenorphine per hour (over a period of 7 days)
	Finished Product Specification	BP

	Pharmacological Group	Opioid analgesic ATC Code: N02AE01
	Shelf life	2 years
	Demanded Price	To be communicated at the time of price fixation
	Pack size	1, 2, 3, 4, 5, 8 ,10, 12 transdermal patches Not all pack sizes may be marketed.
	International availability	USFDA Approved
	Me-too status	--
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10143834 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. Issue Date: 13, June 2016 GMP certificate Certificate No: DE_RP_01_GMP_2016_0024 Certifying Authority: German Health Authority Date of inspection: 12-11-2015 Validity: 3 years Agreement Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration.
	Stability Studies	70011 A3 DOM: 03-05-2001 Stability Initiation Date: 04-10-2001 Initial Testing: 07-08-2001
	Remarks of the Evaluator.	• Approved in USFDA with box warning. The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi. • Agreement between applicant for COPP i.e. MundiPharm Medical Company Limited and Napp Pharmaceuticals Ltd is missing. Relationship letter between Mundipharma group of companies and Napp Pharmaceuticals Limited. Firm has submitted that Mundipharma has network of independent associated companies in Europe, USA,Asia, Alatin, America and now in Middle East and Africa. Napp Pharmaceuticals Limited is an independent Associate Company within the Mundi Pharm Network of independent associated companies. • The finished product is available in BP .However you have not provided Specifications and stability data according to British Pharmacopoeia monograph. Clarify. The firm has submitted that their Specifications are as per EU requirement. However, this is not the case. The BP Specifications are more stringent then provided Specifications.
	Decision: The Registration Board deferred the applied formulation for the following reasons: **i. Revision of specification of finished product as per BP as the BP Specifications are more stringent then provided Specifications.**	

	ii. Justification is required for yellowish discoloration of the matrix. iii. **Justification for not performing test for release rate of drug over a period of 7 days as per label claim as aforesaid test has been performed upto 24 hrs.**	
576.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s LTS Lohmann Therapie-Systeme AG Lohmannstraβe 2 D-56626 Andernach Germany
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW, UK Applicant for Certificate MundiPharm Medical Company Limited Cambridge Science Park Milton Road Cambridge CB4 0AB, UK
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 25301 Dated 20/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 15/12/2017
	Brand Name +Dosage Form + Strength	BuTrans Transdermal Patch 10µg/hr
	Composition	10µg/hr Transdermal Patch contains: Buprenorphine….10mg Area containing active substance: 12.5 cm^2 Nominal release rate : 10 µg of buprenorphine per hour (over a period of 7 days)
	Finished Product Specification	BP
	Pharmacological Group	Opioid analgesic ATC Code: N02AE01
	Shelf life	2 years
	Demanded Price	To be communicated at the time of price fixation
	Pack size	1, 2, 3, 4, 5, 8 ,10, 12 transdermal patches Not all pack sizes may be marketed.
	International availability	USFDA Approved
	Me-too status	--
	Detail of certificates attached	Original legalized CoPP Certificate No: PP10143831 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. Issue Date: 13, June 2016 GMP certificate Certificate No: DE_RP_01_GMP_2016_0024 Certifying Authority: German Health Authority Date of inspection: 12-11-2015 Validity: 3 years

		Agreement Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration.
	Remarks of the Evaluator.	• Approved in USFDA with box warning. • Valid drug sale license is missing. The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi. • Agreement between applicant for COPP i.e. MundiPharm Medical Company Limited and Napp Pharmaceuticals Ltd is missing. Relationship letter between Mundipharma group of companies and Napp Pharmaceuticals Limited. Firm has submitted that Mundipharma has network of independent associated companies in Europe, USA,Asia, Alatin, America and now in Middle East and Africa. Napp Pharmaceuticals Limited is an independent Associate Company within the Mundi Pharm Network of independent associated companies. • The finished product is available in BP .However you have not provided Specifications and stability data according to British Pharmacopoeia monograph. Clarify. The firm has submitted that their Specifications are as per EU requirement. However, this is not the case. The Eu Specifications are more stringent then provided Specifications. • Stability protocol missing. • The stability data submitted by you is confusing Kindly arrange the data and submit for review duly signed by technical staff.
	Decision: The Registration Board deferred the applied formulation for the following reasons: **i. Revision of specification of finished product as per BP as the BP Specifications are more stringent then provided Specifications.** **ii. Justification is required for yellowish discoloration of the matrix.** **iii. Justification for not performing test for release rate of drug over a period of 7 days as per label claim as aforesaid test has been performed upto 24 hrs.**	
577.	Name and address of Applicant	M/s Ali Gohar and Company (Private Limited) State life Building ,1B, I.I, Chundrigar Road, Karachi
	Detail of Drug Sale License	Address: B-23 Site Karachi. Validity: 05-02-2019 Status: By Way Of Wholesale
	Name and address of manufacturer	M/s LTS Lohmann Therapie-Systeme AG Lohmannstraβe 2 D-56626 Andernach Germany
	Name and address of marketing authorization holder	Napp Pharmaceuticals Ltd Cambridge Science Park Milton Road Cambridge CB4 0GW, UK Applicant for Certificate MundiPharm Medical Company Limited Cambridge Science Park

		Milton Road Cambridge CB4 0AB, UK
	Name of exporting country	United Kingdom
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 25302 Dated 20/12/2017
	Fee including differential fee	Rs. 50,000/- Dated 15/12/2017
	Brand Name +Dosage Form + Strength	BuTrans Transdermal Patch 20µg/hr
	Composition	20µg/hr Transdermal Patch contains: Buprenorphine….20mg Area containing active substance: 25 cm^2 Nominal release rate : 20 µg of buprenorphine per hour (over a period of 7 days)
	Finished Product Specification	BP
	Pharmacological Group	Opioid analgesic ATC Code: N02AE01
	Shelf life	2 years
	Demanded Price	To be communicated at the time of price fixation
	Pack size	1, 2, 3, 4, 5, 8 ,10, 12 transdermal patches Not all pack sizes may be marketed.
	International availability	USFDA Approved
	Me-too status	--
	Detail of certificates attached	<u>Original legalized CoPP</u> Certificate No: PP10143835 Certifying Authority: The Medicine and Health Care Products Regulatory Agency Free Sale: Confirms the free sale of the product in exporting country. Issue Date: 13, June 2016 <u>GMP certificate</u> Certificate No: DE_RP_01_GMP_2016_0024 Certifying Authority: German Health Authority Date of inspection: 12-11-2015 Validity: 3 years <u>Agreement</u> Napp Pharmaceuticals Ltd an independent associated company of Mundipharm is the marketing authorization holder and authorizes Ali Gohar & Company to apply for the registration.
	Remarks of the Evaluator.	• Approved in USFDA with box warning. • Valid drug sale license is missing. The drug sale license mentions the following information: Ali Gohar Company Ltd. being authorized agent of M/s Alcon Pharmaceuticals Limited is hereby licensed to sell stock and exhibit for sale and distribute drugs by way of wholesale on the premises situated at B-23 Site Karachi. • Agreement between applicant for COPP i.e. MundiPharm Medical Company Limited and Napp Pharmaceuticals Ltd is missing. Relationship letter between Mundipharma group of companies and Napp Pharmaceuticals Limited. Firm has submitted that Mundipharma has network of independent associated companies in Europe, USA,Asia, Alatin, America and now in Middle East and Africa.

		Napp Pharmaceuticals Limited is an independent Associate Company within the Mundi Pharm Network of independent associated companies. • The finished product is available in BP .However you have not provided Specifications and stability data according to British Pharmacopoeia monograph. Clarify. The firm has submitted that their Specifications are as per EU requirement. However, this is not the case. The Eu Specifications are more stringent then provided Specifications. • Stability protocol missing. • The stability data submitted by you is confusing Kindly arrange the data and submit for review duly signed by technical staff.
	Decision: The Registration Board deferred the applied formulation for the following reasons: **i. Revision of specification of finished product as per BP as the BP Specifications are more stringent then provided Specifications.** **ii. Justification is required for yellowish discoloration of the matrix.** **iii. Justification for not performing test for release rate of drug over a period of 7 days as per label claim as aforesaid test has been performed upto 24 hrs.**	

ii. Veterinary

578.	Name and address of Applicant	M/s ICI Pakistan Ltd, ICI House , 5 West Wharf, Karachi
	Detail of Drug Sale License	**Address:** 5 West Wharf, Karachi **Validity:** 19-02-2020 **Status:** Drug License by way of Wholesale.
	Name and address of manufacturer	M/s Intervet Productions SA Rue De Lyons, 27460 Igoville, France
	Name and address of marketing authorization holder	M/s Intervet International BV Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No Dated 26/05/2017
	Fee including differential fee	Rs. 100,000/- Dated 23/02/2018
	Brand Name +Dosage Form + Strength	Exzolt Solution 10mg/ml for use in Drinking Water
	Composition	Each ml contains: Fluralaner…10mg
	Target Specificationie	Chickens (pullets, breeders, layer hen)
	Finished Product Specification	Inhouse
	Pharmacological Group	Ectoparasitcides
	Shelf life	3 years
	Demanded Price	As per SRO
	Pack size	Bottle of 1 L, 4 L
	International availability	Approved in ANSM
	Me-too status	--
	Detail of certificates attached	**Original Legalized COPP** Certificate No. 06/17/113733 Certified by: EMA Free sale: Yes GMP : GMP Complaint

		Issue Date: 12-10-2017 **Letter of Authorization** M/s Intervet International BV Wim de Korverstraat 35, 5831 AN Boxmeer, The Netherlands & M/s ICI Pakistan LTD ICI House , 5 West Wharf, Karachi Dated: Nov, 2017
	Remarks of the Evaluator.	Withdrawal Period Meat and Offal: 14 days Eggs: Zero days • In the finished product label the Urdu version of the following namely; (i) Name of drug (ii) dosage; and (iii) Instruction is missing.
	Decision: Deferred for further deliberation regarding use of applied formulation in chickens.	

Case No. 04: Registration Applications of Import Cases.

a. New Cases (Veterinary)

579.	Name and address of Applicant	M/s Atzan pharmaceuticals, Commercial Area, Aziz Bhatti Town, Sargodha.
	Detail of Drug Sale License	Address: 13-E, Commercial Area, Aziz Bhatti Road, District Sargodha Validity: 14-04-2020 Status: License to sell drugs as a Distributor
	Name and address of manufacturer	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company. Lot D1–D4 Dong Tho Industrial Complex, Yen Phong District Bac Ninh Province, Vietnam.
	Name and address of marketing authorization holder	M/s Vietnam Sakan Technology Development & Investment Joint Stock Company. Lot D1–D4 Dong Tho Industrial Complex, Yen Phong District Bac Ninh Province, Vietnam.
	Name of exporting country	The Socialist Republic of Vietnam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.16450 Dated 28/09/2017
	Fee including differential fee	Rs. 100,000/- Dated 25/09/2017
	Brand Name +Dosage Form + Strength	Doxy 50% Gold Oral Water Soluble Powder
	Composition	Each 100g contains: Doxycycline HCl….50g Bromhexine HCl…..250mg
	Target Specificationies	Chicken, Ducks, Geese, Quail, Cattle
	Finished Product Specification	-
	Pharmacological Group	Antibiotic
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	20g, 50g, 100g
	International availability	-
	Me-too status	-
	Detail of certificates attached	Copy legalized Free sale certificate Certificate No. 491/2017/QLT-CFS Certified by: Ministry of Agriculture and Rural Development Department of Animal Health Issued on: 26/06/2017 Copy of GMP certificate Scanned Authorization Letter M/s Atzan pharmaceuticals, Commercial Area, Aziz Bhatti Town, Sargodha. & M/s Vietnam Sakan Technology Development & Investment Joint Stock Company. Lot D1–D4 Dong Tho Industrial Complex, Yen Phong District Bac Ninh Province, Vietnam. Dated: 01,June,2017
	Remarks of the Evaluator.	• Withdrawal Period Meat-7 days • In case of finished product label, the Urdu version of, dosage as per requirement of (Drugs labeling and prescribing rules) 1986 is missing.. • Reference for international availability.

		Firms' Response: Firm has submitted the following reply; Regarding the formulation of Doxy 50% Gold powder, its active ingredient is doxycycline hyclate 500g/kg. The other ingredient are used as excipients and also not include in label claim. Moreover, the firm provided the following role of Bromhexine in Doxy 50 % Gold Powder. • Bromhexine in a non-antimicrobial agent and it has a synergic effect for better absorption and penetration of antibiotics (e.g. Doxycycline, amoxicillin, oxytetracycline etc.) when use in small concentration. Bromhexine modifies the distribution of antibiotics in the organism and increases their concentration in the serum and the nasal secretions. • Generally, Bromhexine shows its therapeutic effect in concentrations of 1%, 2%, 4%, 5%, 10% etc. • It is mostly used in 1% to 5% concentration for its therapeutic effect in combination with Doxycycline, tylosine for treatment of respiratory diseases in poultry. A number of Doxycycline and Bromhexine powder combination have been registered in Pakistan for their effective usage in veterinary diseases. • Doxycycline powder with 50% concentration is also widely registered in Pakistan and Europe. • In our applied formulation doxy 50% Gold powder, Bromhexine has been used in 0.2% concentration. In this concentration, it only has a synergic effect for better absorption and penetration of Doxycycline and it is not directly inducing any therapeutic effect to cure respiratory disease of poultry. • It is also not included in the label claim of the product. • New Free sale certificate Now the firm has provided new free sale certificate and changed the composition from "Each 100g contains: Doxycycline HCl….50g+Bromhexine HCl…..250mg" to Doxycycline HCl….50g. <u>Details of Free sale certificate</u> • Copy legalized Free sale certificate Certificate No. 300/2019/QLT-CFS Certified by: Ministry of Agriculture and Rural Development Department of Animal Health Issued on: 22/04/2019 • Revised Form 5 A certificate Firm has also revised their form 5 A and changed the composition from "Each 100g contains: Doxycycline HCl….50g +Bromhexine HCl…..250mg" to Doxycycline HCl….50g. and submitted Rs. 5000/- 18-07-2019. The address of manufacturing site address mentioned on Form 5A is different then COPP. Manufacturing Site Add. On Form 5 A: No. 33,Alley 70, Street 8/3, Quynh Mai Ward, Hai Ba Trung District , Ha Noi City, Vietnam Manufacturing Site Add. On COPP: Lot D1–D4 Dong Tho Industrial Complex, Yen Phong District Bac Ninh Province, Vietnam. Conclusion of Evaluation: Initially, the firm has applied for Doxycycline

		HCl….50g,Bromhexine HCl…..250mg but due to unavailability of applied formulation internationally and locally, the firm has revised their formulation from fixed dose combination to single ingredient formulation with submission of only Rs. 5000/-. With label claim "Each 100g contains:Doxycycline HCl….50g". Moreover,at the same time firm has also tried to justify that bromhexine is not directly inducing any therapeutic effect to cure respiratory disease of poultry and it is also not included in the label claim of the product.
	Decision: The Registration Board after through deliberation deferred the applied formulation and decided as follow: • **Submission of complete application per percribed form along with submission of Rs, 100000/- for revision of formulation.** • **Justification for difference in manufacturing site mentioned on COPP and Form 5A.**	

c. Deferred Cases.

i. Human

580.	Name and address of Applicant	M/s Global Pharmaceutical (Pvt.) Ltd., plot No. 22-23, Kahuta Industrial Triangle, Islamabad.
	Detail of DSL	**Address: Plot No**. 22-23, Kahuta Industrial Triangle, Islamabad. **Validity:** 16 March 2019 **Status:** License to sell drugs in a wholesale distributor
	Name and address of manufacturer	M/s AY Pharmaceuticals Co., Ltd., Saitama Plant 6-8, Haichiman, Khawajima-machi, Hiki-gun, Saitama, Japan
	Name and address of Marketing authorization holder	M/s Ajinomoto Pharmaceuticals Co., Ltd., 1-1, Irifune 2-chrome, Chuo ku, Tokyo, Japan
	Exporting country	Japan
	Brand Name+Dosage Form + Strength	PN-TWIN NO.1 Intravenous Infusion
	Composition	Each bag of 1000ml Contains: Solution I Glucose….. 120g Sodium Chloride…… 2.920g Potassium Acetate…...2.160g Monobasic Potassium Phosphate…..1.088g Magnesium Sulfate….0.7400g Calcium Gluconate….1.792g Zinc Sulfate Hydrate….5.752mg Citric Acid Hydrate…..Optimum Dose Water for Injection…...Optimum Dose Solution II L-Isoleucine……..1.120g L-Leucine……...2.500g L-Lycine Acetate...2.480g L-Methionine…….0.700g L-Phenylalanine….1.870g L-Threonine……...1.300g L-Tryptophan…….0.260g L-Valine…….0.900g L-Alanine……...1.240g L-Arginine…….1.580g L-Aspartic Acid….0.760g L-Cysteine…….0.200g L-Glutamic Acid…1.300g

		L-Histidine…….1.200g L-Proline…….0.660g L-Serine……..0.440g L-Tyrosine……..0.070g Glycine……...2.140g Sodium Bisulfate..0.030g Water for Injection….Optimum Dose
	Pharmacological Group	Supplement of water, Electrolyte, Amino Acid and Calories for patients (TPN)
	Finished product Specification	In House
	Shelf life	3 years
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 744 Dated 26/12/2014
	Fee including differential fee	Rs. 50,000/- Dated 26/12/2014
	Pack size	Double chamber Kit Preparation that consists of Solution I (glucose and Electrolyte) and Solution II (Amino Acid) divided with a partition in a plastic container.
	Demanded Price	As per SRO
	International Availability	Available in Japan as per CoPP
	Me-too status	N/A
	Detail of certificates attached	**Original legalized CoPP** **Certificate No.** 1189 **Issued by**: Ministry of Health, Labour and Welfare, Government of Japan on11/06/2014 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 for In House manufacturing Specifications while the product is not present in USP/BP. • The name of manufacturer mentioned in form 5-A and distribution agreement is different from the name written on CoPP. • The CoPP shows the marketing authorization holder and manufacturer of the product is Ay Pharmaceuticals Co.Ltd.).While according to form 5-A and distribution agreement the marketing authorization holder is "M/s Ajinomoto Pharmaceuticals Co., Ltd."
	Previous Decision (M-283) : Deferred for clarification since the CoPP mentions the marketing authorization holder and manufacturer of the product as "Ay Pharmaceuticals Co., Ltd".Whereas, Form 5-A and distribution agreement between importer and exporter mentions marketing authorization holder as "M/s Ajinomoto Pharmaceuticals Co., Ltd".	
	Evaluation by PEC: **1) <u>Explanation Letter Change of Company name from M/s Ajinomoto Pharmaceuticals to M/s EA Pharma.</u>** Letter of Explanation: Contents of Explanation: EA Pharma Co Ltd are located at Address: 1-1, Irifune 2-chome, Chou-ku, Tokyo, Japan Hereby, we confirmed that the relationship between EA Pharma Co Ltd and AY Pharma Co Ltd as below history. 1- AJINOMOTO Pharmaceuticals CO Ltd was established on 1st April, 2010. 2- AY Pharmaceuticals Co Ltd, who is manufactured of PN-Twin No.1, was spinned off from AJINOMOTO Pharmaceuticals CO Ltd on 1st July, 2013. Hence, the marketing authorization holder of PN-Twin No.1 was transferred from AJINOMOTO Pharmaceuticals CO Ltd to AY Pharmaceuticals Co Ltd in Japan AJINOMOTO Pharmaceuticals CO Ltd had been sorely exporter of PN-Twin No 1 to	

	Pakistan. 3- Global Pharmaceuticals pvt Ltd and AJINOMOTO Pharmaceuticals CO Ltd has been contracted the exclusive distributorship agreement of PN-Twin No.1 in Pakistan on 27th March, 2014. 4- The company name of AJINOMOTO Pharmaceuticals CO Ltd has been changed to EA Pharma Co Ltd since 1st April, 2016. 5- Now, EA Pharma Co Ltd is sorely exporter of PN-Twin No.1 and AY Pharmaceuticals Co Ltd. **2) <u>Authorization letter for Exportation</u>** The firm has submitted authorization letter which mentions AY Pharmaceuticals Co. Ltd. Hereby appoint EA Pharma to authorize for exportation of PN-Twin No. 1 EA Pharma will be exporter of this product and will be responsible with Ministry of Health for exportation of product to Pakistan. **Conclusion of Evaluation** • The letter of explanation has not been signed by authorized personnel. • The indentor or agent mentioned on Form 5 A is EA Pharma Co. Ltd. Address:1-1,Irifune 2-chome, Chuo-ku, Tokyo, Japan whereas, the applicant/agent in Pakistan is Global Pharmaceuticals Pvt. Ltd. • The agreement dated April 1, 2016 is between Global Pharmaceuticals and EA Pharma (Exporter) .However, this agreement mentions AJINOMOTO Pharmaceuticals(former name of EA Pharma Co Ltd) and the agreement has not been signed by Global Pharmaceuticals.	
	Decision:The Registration Board deferred the applied formulation due to the following reasons: • **Submission of letter of explanation signed by authorized personnel.** • **Submission of revised application form mentioning the indentor or agent as M/s Global Pharmaceuticals Pvt. Ltd instead of EA Pharma Co. Ltd. Address:1-1,Irifune 2-chome, Chuo-ku, Tokyo, Japan, as the applicant in Pakistan is M/s Global Pharmaceuticals Pvt. Ltd.** • **Submission of signed agreement between marketing authorization holder i.e. EA Pharma Co Ltd and M/s Global Pharmaceuticals Pvt. Ltd.**	
581.	Name and address of Applicant	M/s Iqbal & Company,1st floor, Al-Falah Manzil, Opp. National Police Foundation, St.No. 26, Sector E-11/4, Islamabad.
	Detail of Drug Sale License	Address: 1st floor, Al-Falah Manzil, St. No. 26, Sector E-11/4, Islamabad. Validity: 04/02/2018 Status: drug to sell drugs in a wholesale distributor
	Name and address of manufacturer	M/s Bieffe Medital S.P.A Via Stelvio 94, 230 35 Sondalo (SO), I-23035, Italy
	Name and address of marketing authorization holder	M/s Gambro Lundia AB Box ,Magistratsvagen 16, Lund, SE-22643, Sweden
	Name of exporting country	Italy
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. Dated 01/08/2016(Duplicate)
	Fee including differential fee	Rs. 50,000/- Dated 01/08/2016(Duplicate)
	Brand Name +Dosage Form + Strength	HEMOSOL B0 Solution for Haemodialysis/Haemofiltration
	Composition	Each ml of 2 compartment bag contains: Medimar Electrolyte solution (Small Compartment A-250ml) lactic acid ……. 5.4mg Calcium chloride dehydrate …… 5.145mg Magnesium chloride hexahydrate……. 2.033mg Buffer Solution (Large Compartment B-4750 ml) Sodium Chloride…… 6.450mg Sodium hydrogen carbonate…….. 3.090mg After Reconstitution

		Calcium (Ca+2)…….. 1.75 mmol/L Magnesium (Mg+2)……..... 0.5 mmol/L Sodium (Na+)……..…… 140 mmol/L Chloride (Cl-)……..…….. 109.5 mmol/L Lactate……..... 3 mmol/L Hydrogen carbonate (HCO3-)…….. 32mmol/L
	Finished Product Specification	BP
	harmacological Group	Hemofiltrates
	Shelf life	18 months (Polyolefin bag)
	Demanded Price	Not proposed
	Pack size	(2 x 5000ml) polyolefin bags, in a box
	International availability	Sweden Approved
	Me-too status	N/A
	Detail of certificates attached	Valid and Legalized CoPP Certificate No: 5.8.1-2018/007) Certified by: Medical Product Agency, Sweden Issued on: 23/01/2018: GMP certificate issued by AIFA, Italy dated 28/10/2016 (validity 3 years)
	Remarks of the Evaluator.	
	Previous Decision (M-279)	Deferred for following: • Submission of valid DSL of the applicant. • Evidence of free sale of applied formulation in country of origin. • Submission of valid legalized agreement between Market Authorization Holder and applicant for CoPP.
	Fresh Evaluation: Firm has submitted 1. **Valid DSL**. Address: Al-Falah Manzil, St. No. 26, Sector E-11/4, Islamabad. Validity: 04/01/2020 Status: Sell drugs in a wholesale distributor 2. **Original Legalized COPP** Certificate No: PP10156320 Issued by : MHRA Issued on: 20, July 2018 Free sale: Yes GMP as Recommended by: WHO: N/A 3. **Scanned Letter of Authorization** This shall confirm that Baxter AG ("Baxter"), a company established and existing under the laws of Switzerland, do hereby declare that we are the manufacturer of the following products. We do hereby appoint Iqbal & Company at 1st Floor Alfalah Manzil, Street # 26, Opposite National Police Foundation, Sector E-11/4, Islamabad, as our distributor for Pakistan. This agreement letter will remain valid up to the 5th March 2019. In September, 2013 – Baxter International Inc. ("Baxter") Announced that the company has successfully completed the acquisition of Gambro AB ("Gambro"), a privately held global medical technology company and leader in dialysis products based in Lund, Sweden. 4. **Relationship between MAH and Batch releaser** Both companies are wholly owned by Baxter International, thus fall under the same legal entity.	
	Previous Decision 285th : Registration Board referred the case to Medical Device Division for the opinion whether the applied formulation falls under the category of Medical Device or otherwise.	

	Fresh Evaluation: Medical Device Division with reference to letter no. F. No. 16-4/2018-MD has submitted that: Upon evaluation of the dossier, the above mentioned products shall be dealt as DRUGS due to following reasons. I. The firm have provided CoPP (Certificate of Pharmaceutical Products) of the above mentioned product from Sweden which is issued only for the Pharmaceutical products and not for medical devices. II. The above mentioned product has been registered as drug in different countries live UK, Sweden,Netherlands, Germany, Belgium, Australia etc. and their Market Authorization numbers are available. III. Above mentioned product is categorized as Pharmacotherapeutic group: Hemofiltrates, ATC code: B05ZB as mentioned in SPC (Summary of Product Characteristics). The Anatomical Therapeutic Chemical (ATC) Classification System is used for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, Pharmacological and chemical properties. IV. The formulation of the above mentioned product is also available in European Pharmacopoeia. V. The product is administered directly into the bloodstream (Intravenously). GMDN code is available for Haemodialysis concentrate and dialysate solution but no GMDN code is found for solution to be administered intravenously to correct chemical imbalance of the blood caused by kidney failure.
	Previous Decision 288th : Registration Board deferred the case for further deliberation
	Firm's Response Considering the reply from Medical Devices Division in 288th Meeting of Registration Board approved the products of Fresenius Medical Care Pakistan and our case of Hemosol B0 was deferred for further deliberation. Therefore, firm requested to consider the reply of Medical Devices and dealing it as a drug and also approve registration of Hemosol B0. **PEC Evaluation:** <u>Approved Products of Fresenius Medical Care Pakistan</u> • multiBic potassium free solution for haemodialysis/haemofiltration. • multiBic 3 mmol/l potassium solution for haemodialysis/haemofiltration • multiBic 4 mmol/l potassium solution for haemodialysis/haemofiltration • multiBic 2 mmol/l potassium solution for haemodialysis/haemofiltration.
	Decision: Approved as per policy of inspection of manufacturer abroad.

ii. Veterinary

582.	Name and address of Applicant	M/s Fair International Trading Co. 11 A-Syed Arcade, 2nd floor, Block 5, Gulshan e Iqbal, Karachi
	Detail of Drug Sale License	**Address:** D-94, Block 7, Gulshane Iqbal, Karachi **Validity:** 04-07-2020 **Status:** Way of Wholesale
	Name and address of manufacturer	M/s Cenavisa, S.L. 43205-RUES/Spain Cami Pedra Estela, s/n
	Name and address of marketing authorization holder	M/s Cenavisa, S.L. 43205-RUES/Spain Cami Pedra Estela, s/n
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 550 Dated 17/11/2016
	Fee including differential fee	Rs. 100,000/- Dated 17/11/2016
	Brand Name +Dosage Form + Strength	CENAMICINA FORTE 100mg Solution for use in drinking water
	Composition	Each ml contains: Enrofloxacin…….. 100mg
	Target Specificationies	Chicken (broilers)
	Finished Product Specification	In House

	Pharmacological Group	Anti-microbial
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml bottle, 1 litre bottle, 5 litre barrel HDPE bottles
	International availability	Baytril 10% Oral Solution by M/s Baeyer PLC UK Approved
	Me-too status	Enflox 10% solution by M/s Alina combine Pakistan (R#035157)
	Detail of certificates attached	• **Original Legalized CoPP** Certificate No. 752/2018 Certifying Authority: Agencia Espanola de medicaomentos Y productos sanitarios Date of Issue: 30-10-2018 Dated: 05-011-2018 Validity: 3 years
	Stability data	Batch no. 07201/13 (DOM:01-2013), 07202/13 (DOM: 02-2013), 07205/13 (DOM:03-2013),
	Remarks of the Evaluator.	• The firm has claimed In House Specifications and the product is not present in BP/USP. • Clarification for change in address mentioned on drug sale license and Form 5 A. Firm has submitted that address mentioned on DSL is their warehouse and on Form 5A is office address. • Submit valid GMP certificate as provided one is not valid. CENAVISA S.L. stablished in Cami Pedra Estela s/n in Reus/Spain, certifies that GPM certificate submitted with Application form for the registration procedure of CENAMICINA FORTE on the year 2016, was valid until 01/07/2018. During this current year 2018, CENAVISA S,L. have been updating its facilities (Injectable line), for this reason, Spanish Authorities gave us an extension for this Certificate until 01/01/2019. Next year, form that data, our authorities will conduct a new inspection to our factory and CENAVISA S.L. expect to be authorized and renew once again the GMP certification. **Shortcomings** • Long term stability studies conducted under the conditions of zone IV-A of 03 batches till shelf life along with the supporting document, chromatograms, raw data sheets etc as the provided data at condition IVA mentions the same batches as submitted initially at condition II. Clarification is also required in this regard. Firm has submitted long term stability data as per Zone IVA but the supporting documents i.e. chromatograms does not support the datasheets. There are following observations in the submitted data. 1. The sample injection of all time points seems to be run on same day. 2. The firm has not submitted standard chromatograms, the peaks are not symmetrical, retention time vary at different time points. 3. The submitted sample chromatograms are at following time points 0,12,24,36M. 4. Firm has not submitted raw data sheets. 5. Firm has not submitted clarification.

	Previous Decision 288th : Deferred for the following: • Submission of valid GMP certificate. • Clarification regarding submitted Long term stability studies conducted under the conditions of zone IV-A of 03 batches till shelf life as the provided data at condition IVA mentions the same batches as submitted initially at condition I	
	Evaluation by PEC: **1. Submision of valid GMP certificate.** **Firm' Reponse:** **Original Legalized GMP certificate** **Certificate No.:** ES/029HV/19 **Certifying Authority:** Spanish medicine agency **Validity:** 05-12-2020. 1. Clarification regarding submitted Long term stability studies conducted under the conditions of zone IV-A of 03 batches till shelf life as the provided data at condition IVA mentions the same batches as submitted initially at condition I **Firms' Response:** The stability studies submitted at first are carried out according to the guideline: EMEA/CVMP/846/99-Final. These stability studies were carried out with six industrial batches; batch size: 2300 L each one with batch numbers: 07201,07202, 07203, 07204, 07205 and 07206 manufactured at 2013 of Veterinary Medicinal Product, CENAMICINA FORTE, oral solution, packaged in the different commercial sizes: 1L, 5L and 100ml. These stability studies were submitted according to European requirements, (guideline; EMEA/CVMP/846/99 – Final). These conditions are for Climatic Zone II. As a European company, Cenavisa S.L. adheres to European practice by default. Hence, Cenavisa S.L. carried the stability studies in conditions of Climatic Zone II but samples of each product from each batch are also stored in different climatic conditions in order to fulfill the requirements of each exporting country. In the case of the current stability report, since Pakistan (like other countries we export too) is classified as Zone IV Climatic (Hot and humidity), Cenavisa S.L. submitted stability studies of three batches (each one representative of different packages: 100ml, 1L and 5L) stored in Climatic Zone IV conditions during 36 months (0,3,6,9,12,18,24 and 36 months). Firm has submitted long term stability data as per Zone IVA but the supporting documents i.e. chromatograms does not support the datasheets. There are following observations in the submitted data. 1. The sample injection of all time points seems to be run on same day. 2. The firm has not submitted standard chromatograms, the peaks are not symmetrical, retention time varies at different time points. 3. The submitted sample chromatograms are at following time points 0,12,24,36 M. 4. Firm has not submitted raw data sheets.	
	Decision: The Registration Board deferred the applied formulation due to the following reasons: **i. Submission of chromatograms of standard solution of all time points of all batches.** **ii. Submission of chromatograms of sample solution of all time points (0,3,6,9,12,18,24 and 36 months) as submitted data is only at 0,12,24,36M.** **iii. Clarifications/ justification for asymmetrical peaks in sample chromatograms.** **iv. Justification for difference in retention time at different time points.** **v. Submission of raw data sheets of all time points.**	
583.	Name and address of Applicant	**M/s Mustafa Brothers,**186-D, Peoples Colony No.1, Faisalabad.
	Detail of Drug Sale License	**Address:** Mustafa Brothers, P-186-D, Peoples Colony No.1Faisalabad. **Validity:** 21/06/2020 **Status:** License to sell drugs as a Distributor
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical Co. Ltd, No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City,

		Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical CO. LTD, No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 14754 Dated 12/09/2017
	Fee including differential fee	Rs. 100,000/- Dated 12/09/2017
	Brand Name +Dosage Form + Strength	Marbofloxacin 25 Solution for Injection
	Composition	Each 1 ml contains: Marbofloxacin…25mg
	Target Specificationies	Cattle, Poultry
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial for systemic use, Flouroquinolones
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100 ml Glass bottle
	International availability	International availability could not be confirmed.
	Me-too status	N/A
	Detail of certificates attached	**Original Legalized Free sale Certificate** **Certificate no.** 260/2017/QLT-CFS **Certifying Authority:** Ministry of Agriculture and Rural Development, Department of Animal Health **Validity:** 30-03-2019 **Original Legalized GMP certificate** Certifying Authority: Ministry of Agriculture and Rural Development, Validity: Aug 2022. **Copy of Distribution Agreement** M/s Mustafa Brothers 186-D, Peoples Colony No.1, Faisalabad. & M/s Asia Animal Pharmaceutical CO. LTD No. 130, 1A Highway , Ba Lang Ward, Cai Rang District,Can Tho City, Vietnam **Validity:** 24, Aug, 2021
	Stability Studies	• Zone IV A. 36 months data.
	Remarks of the Evaluator.	• Step of terminal sterilization has not been mentioned in manufacturing outline. Justify and clarify the same. • Firm has used filtration process through micro filter (1 mm-0.2mm) filter. • Agreement does not mention the list of product to be imported.
	Previous Decision(288): Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting. • Clarification regarding step of terminal sterilization is needed.	
	1. Evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting. **Firms` Response**	

International availability	Me too
Marbocyl SA Injection	Marboflox of M/s Selemore Pharmaceuticals

	Vetoquinol UK	Reg. No. 088088 Marbostar of M/s Komipharma Korea Reg. No. 074054

PEC Evaluation

The international availability and Me too provided by the firm have different composition. Therefore, both are incorrect.

2. **Clarification regarding step of terminal sterilization is needed.**

Firms` Response

Firm has applied filtration process by filtering through micro filter (0.2µm).

PEC Evaluation

Firm has not provided clarification regarding the step of terminal sterilization.

Decision: The Registration Board deferred the applied formulation due to the following reasons:

i. **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**
ii. **Clarification regarding not performing the step of terminal sterilization.**

584.		
	Name and address of Applicant	M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad.
	Detail of Drug Sale License	**Address:** Mustafa Brothers, P-186-D, Peoples Colony No.1 Faisalabad. **Validity:** 21/06/2020 **Status:** License to sell drugs as a Distributor
	Name and address of manufacturer	M/s Asia Animal Pharmaceutical CO. LTD No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name and address of marketing authorization holder	M/s Asia Animal Pharmaceutical CO. LTD No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam
	Name of exporting country	Vietnam
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 14756 Dated 12/09/2017
	Fee including differential fee	Rs. 100,000/- Dated 12/09/2017
	Brand Name +Dosage Form+Strength	Thiamsone Injectable Solution
	Composition	Each 1 ml contains: Thiamphenicol …100mg Oxytetracycline…50mg Dexamethasone…. 1mg
	Target Specificationies	Cattle, Poultry
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial for systemic use
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100 ml Glass bottle
	International availability	International availability could not be confirmed.
	Me-too status	N/A
	Detail of certificates attached	**Original Legalized Free sale Certificate** **Certificate no.** 262/2017/QLT-CFS **Certifying Authority:** Ministry of Agriculture and Rural Development, Department of Animal Health **Validity:** 30-03-2019 **Original Legalized GMP certificate** Certifying Authority: Ministry of Agriculture and Rural Development,

		Validity: Aug 2022. **Agreement** M/s Mustafa Brothers, 186-D, Peoples Colony No.1, Faisalabad. & M/s Asia Animal Pharmaceutical CO. LTD No. 130, 1A Highway , Ba Lang Ward, Cai Rang District, Can Tho City, Vietnam **Validity:** 24, Aug, 2021
	Stability Studies	• Zone IV A. 36 months data.
	Remarks of the Evaluator.	• Step of terminal sterilization has not been mentioned in manufacturing outline. Justify and clarify the same. Firm has used filtration process through micro filter (1 mm-0.2mm) filter. • Agreement does not mention the list of product to be imported.
	Decision: Deferred for following: • Evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting • Clarification regarding step of terminal sterilization is needed.	
	1. Evidence of approval of applied formulation in reference regulatory authorities/agencies as adopted by Registration Board in its 275th meeting **Firms` Response:** Firm has not provided the international availability. **2. Clarification regarding step of terminal sterilization is needed.** **Firms` Response** Firm has applied filtration process by filtering through micro filter (0.2µm). **PEC Evaluation** Firm has not provided clarification regarding the step of terminal sterilization.	
	Decision: The Registration Board deferred the applied formulation due to the following reasons: **i. Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting or evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** **ii. Clarification regarding not performing the step of terminal sterilization.**	
585.	Name and address of Applicant	M/s. Saadat International, 117-Habitat Apartments, Shadman-II, Jail Road, Lahore
	Detail of Drug Sale License	Address: 117 Habitat Flat Shadman II Jail Road Lahore Validity: 19-06-2018 Status: License to sell drugs as a Distributor
	Name and address of manufacturer	Merial, 4 Chemin du Calquet, 31000 Toulouse, France
	Name and address of Product License Holder	Merial, 29 avenue Tony Garnier, 69007 Lyon, France
	Exporting Country	France
	Brand Name +Dosage Form + Strength	Broadline Spot on Solution Spot-on-Solution for cats < 2.5 Kg Spot-on-Solution for cats 2.5 – 7.5 Kg
	Diary No. Date of R& I & fee	Dy No. 137, 19-08-2014 Rs.100,000/-, 13-08-2014
	Composition	**For Cats <2.5 Kg** Each unit dose (0.3ml) applicator delivers Fipronil……24.9mg S)-methoprene…….... 30mg

		Eprinomectin…….. 1.2mg, Praziquantel…… 24.9mg **For Cats 2.5 – 7.5 Kg** Each unit dose (0.9ml) applicator delivers Fipronil…….... 74.7mg, (S)-methoprene……... 90mg, Eprinomectin…….. 3.6mg, Praziquantel……...…… 74.7mg; 1,3,4 or 6 applicator/s
	Pharmacological Group	Antiparasitic products, eprinomectin in combinations ATC VET Code: QP54AA54
	Target Specificationie	Cats
	Shelf Life	2 years
	Type of Form	Form 5-A
	Finished Product Specification	Firm has claimed In-house Specifications
	Pack size & Demanded Price	0.3ml: 1,3 or 4 applicator's 0.9 ml: 1, 3, 4 or 6 applicator's DECONTROLLED
	Approval status of product in	● Product is available and approved by ANSES France ● Approved by EMA
	Me-too status	Could not be confirmed
	CoPP/GMP/ Free sale Certificate	● **Original Legalized CoPP** **Certificate No.** 04/18/118603 **Certified by**: EMA **Issued on** 20-03-2018 **Free sale of the product in exporting country: Yes** The facilities and operations conform to GMP as recommended by WHO as per CoPP. Legalized copy of GMP certificate issued by ANSES also confirms GMP. ● **Copy Letter of authorization** Between Merial, registered office at P.O. Box 327, SandringhamHouse, Sandringham Avenue, Harlow Business Park, Harlow ,England and domesticated in Delaware , USA as Merial LLC and M/s Saadat International**,** 117 Habitat Flat Shadman II Jail Road Lahore. Saadat International has been appointed as the exclusive distributorof all the products of **Merial and its affiliates** in Pakistan from 1January 2002.
	Remarks of the Evaluator	**Proposed Shelf Life:** 24 Months (Supported by stability study data) ● In COPP the postal code of manufacturer is 31300 Toulouse,France. (Firm has submitted that there postal code has been updated from 31300to 31000). ● Shelf life in SMPC of provided formulation mentions 2 years however you have applied for 3 years. ● Excipients mentioned in composition in Form 5-A are different from that mentioned in CoPP. (Disodium edetate not mentioned on Form 5A). ● Product is also exported to Austria, Belgium, Denmark, France, Germany.

Previous Decision (282nd): Deferred for the following reasons:

● Submission of separate application on Form 5A for each of 0.3ml and 0.9ml applicator and also inform which strength to be considered for this application.

● Submission of documentary evidence showing relationship between Marketing Authorization Holder "M/s Merial, 29 avenue Tony Garnier, 69007 Lyon, France" and "M/s Merial, Sandringham House, UK" and submit authorization letter from marketing Authorization Holder.

● Submission of correct composition on Form5A as excipients mentioned on Form 5-A are different from CoPP. Disodium Edetate is not mentioned on Form 5A.

● Justify that shelf life in SMPC of provided formulation mentions 2 years however, you have applied for 3 years.

Evaluation by PEC:

1. **Submission of separate application on Form 5A for each of 0.3ml and 0.9ml applicator and also inform which strength to be considered for this application.**

Firms' Response

Please note that the application form is represent the same product, with the same concentration and the same formulation with different pack sizes.

The Broadline in centrally registered in Europe in all European state member, the different pack sizes are approved under the same registration number, we would appreciate if we could proceed with the same application for the two pack sizes.

2. Submission of documentary evidence showing relationship between Marketing Authorization Holder "M/s Merial, 29 avenue Tony Garnier, 69007 Lyon, France" and "M/s Merial, Sandringham House, UK" and submit authorization letter from marketing Authorization Holder.

Firms' Response

Authorization Letter

We, Merial S.A.S., located 29 Avenue Tony Garnier, 69007 Lyon France, represent the marketing authorization holder of the product Broadline Spot-on Solution in all state members of the European Union.

We are also the authorized entity to request all official documents related to said product, in behalf of Merial Animal Health Limited, located Sandringham House, Harlow, Essex-UK, which has contractual relationship with M/s Saadat International, our distributor in Pakistan.

Hence the only Merial legal entity to issue an authorization letter, for use in Pakistan, is Merial Animal Health Limited- UK.

3. Submission of correct composition on Form5A as excipients mentioned on Form 5-A are different from CoPP. Disodium Edetate is not mentioned on Form 5A.

Firms' Response

The formulation in both versions of the CoPP is the same and both are not conflict with the formulation in the Form 5-A, please see formulation as both formulas do not have Disodium Edetate in the excipients,

The list of excipients mentioned in the point 6.1 from the SMPC attached to the CoPP are Including below,

Glycerol formal (-Disodium Edetate, -Propyl gallate, -Thiodipropionic acid)

- Dimethyl isosorbide
- Butylhydroxytoluene

As per the submitted dossier part 2a: Qualitative and quantative particulars, section 3.2.3 Excipients, please see enclosed in the attachment 4, the stabilized glycerol formal is a slightly viscous colorless liquid and is used as a co-solvent to keep praziquantel in solution. The solvent contains thiodipropionic acid, a non-propyl gallate and disodium EDTA to prevent its oxidation).

4. Justify that shelf life in SMPC of provided formulation mentions 2 years however, you have applied for 3 years.

Firms' Response

Please note that as per the updated CoPP form the EMEA issued in 2018 we will submit for 2 years shelf life, as per the updated CoPP.

	PEC Evaluation: The following justification could not be verified. "The stabilized glycerol formal is a slightly viscous colorless liquid and is used as a co-solvent to keep praziquantel in solution. The solvent contains thiodipropionic acid, a non-propyl gallate and disodium EDTA to prevent its oxidation."
	Decision: The Registration Board after thorough deliberation approved the formulation of only 0.3ml applicator. **For Cats <2.5 Kg** **Each unit dose (0.3ml) applicator delivers** **Fipronil……24.9mg** **S)-methoprene……... 30mg** **Eprinomectin…….. 1.2mg,** **Praziquantel…… 24.9mg** **The Board further decided that firm may submit new application for 0.9ml applicator.**

Case No. 05 Registration applications of drugs for which stability study data is submitted

a. Verification of stability study data

586.	Name and address of manufacturer / Applicant	M/s Ferozsons Laboratories Limited, Amangarh Nowshera, KPK
	Brand Name+Dosage Form + Strength	Hexigard Gel 4%
	Composition	Each g contains: Chlorhexidine …40mg Chlorhexidine gluconate 7.1% eq. to chlorhexidine 4%
	Diary No. Date of R& I & fee	Dy. No. 26247; 31-07-2018; Rs. 50,000/-, 30-07-2018
	Pharmacological Group	Antiseptic and disinfectant
	Type of Form	Form-5D
	Finished product Specifications	BP Specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Umbipro WHO approved formulation
	Me-too status (with strength and dosage form)	N/A
	GMP status	10-01-2018 Recommends issuance of GMP.

STABILITY STUDY DATA			
Drug	Hexigard Gel 4%		
Name of Manufacturer	M/s Ferozsons Laboratories Limited		
Manufacturer of API	M/s Smaart Pharmaceuticals, India		
API Lot No.	SMAART/CHG/2017/063		
Description of Pack (Container closure system)	10g gel filled in Al tube, crimped and sealed.		
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	Real Time: 0,3,6 Months(on going) Accelerated: 0,1,2,3,4,6 Months		
Batch No.	CHGel-001	CHGel-002	CHGel-003
Batch Size	6.5 kg	6.5 kg	6.5 kg
Manufacturing Date	Dec 2017	Dec 2017	Dec 2017

Date of Initiation	Jan 2018	Jan 2018	Jan 2018
No. of Batches	03		
Date of Submission	Dy. No. 26247; 31-07-2018		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes Lot number: SMAART/CHG/2017/063
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Certificate No. 6079163 Valid up to 25-12-2018 Issued by FDA, Maharashtra State
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested reSpecificationtive documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Yes Invoice No: E-020 Not attested by ADC Attested Quantity: 50 Kg Form 6 ADC attested dated: 01-06-2017 and batch no. not mentioned.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR		
Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their product "Quench Plus Cream", which was conducted on 02nd May, 2018 and was presented in 283rd meeting of Registration Board held on 27-29th June, 2018. Following two observations were reported in the report: i. The HPLC software is 21CFR Compliant. ii. Firm has shown all Audit trail reports. iii. Adequate monitoring and control are available for stability chambers. Data Loggers are also placed in stability chambers for monitoring

<table>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>• Copy of Form 6 (License to Import drug for clinical trial examination, test or analysis) issued by ADC (Karachi) dated 01-06-2017, for the import of Chlorhexidine gluconate 20% solution BP, quantity of drug 50.00kg has been submitted.
• Copy of Commercial Invoice (invoice no. E-020) not attested by ADC has been submitted.
Batch No SMAART/CHG/2017/063.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>Firm has submitted DHL of Chlorhexidine Acetate but receiver is Neon Chemicals.
Firm has submitted that:
Neon Chemicals is authorized distributor of Smart Pharmaceuticals in Pakistan.</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>Certificate No. 6079163
Valid up to 25-12-2018
Issued by FDA, Maharashtra State</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for the induction of new vendor of raw material and packaging material in order to ensure that the selected supplier will meet the supply and quality requirements.
I. Material Management department will provide samples of API in three different lots with new vendor assessment form to quality control department.
II. The samples will be analyzed in Lab against the currant Specifications and report will be provided to material management Department. In case of non-compliance, MQC will return the form to MM Department with remarks.
III. After approval of samples by the QC department the material Management Department will arrange adequate quantity of API along with stability studies and DMF where possible to conduct a trial batch of the Finished Product. The performance of the material supplied will be judged by the results of QC analysis of the stability samples.
IV. On the basis of the stability results successful trials and vendor sample assessment, the supplier will be accepted and rejected.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copies of COAs of API have been submitted, detailed as under:
<table><tr><th>API</th><th>Batch. #</th><th>Quantity</th></tr><tr><td>Chlorhexidine Gluconate 20 % Solution</td><td>SMAART/CHG/2017/063.</td><td>50 Kg</td></tr><tr><td>Chlorhexidine Acetate Working standard</td><td>SMAART/QC/CH A/WS/2017/002</td><td>0.5g</td></tr></table></td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted commercial invoices from relevant manufacturers.
<table><tr><td>Excipient</td><td>Manufacturer</td><td>Batch No.</td></tr><tr><td>Benzalkonium Chloride</td><td>Sigma</td><td>020M6884 500ml</td></tr><tr><td>Guar Gum Super Gel 200 2Kg</td><td>Pakistan Gum and Chemical</td><td>037105 2 kg</td></tr></table></td></tr>
</table>

<table>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff along with their training record involved in product development.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted SOP of Product development and protocol for stability studies.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and BPR of the following 03 Batches.
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Yield</th></tr>
<tr><td>001</td><td>6.5Kg</td><td>6.2 Kg</td></tr>
<tr><td>002</td><td>6.5 Kg</td><td>6.250 Kg</td></tr>
<tr><td>003</td><td></td><td>6.3 Kg</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Batch No.</th><th>Batch Produced</th><th>Stability Samples</th></tr>
<tr><td>001</td><td>479</td><td>85</td></tr>
<tr><td>002</td><td>495</td><td>85</td></tr>
<tr><td>003</td><td>480</td><td>856</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 30-08-2018 to 31-08-2018 that shows excursions (54.6%RH) .
Firm has submitted as follows:
When the doors of the climatic chamber are opened for loading or unloading of the samples, there can be a momentarily change in temperature and humidity. However when the doors are shut, the set values are recovered quickly.
Data logger values on 31/08/2018 at 08:53 am & 12:53 pm due to open of door at that moment. This momentarily change has no influence on the stability studies.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has claimed BP method for analysis of API but has not performed analysis accordingly.
Chlorhexidine Gluconate 20%
<table>
<tr><th>BP</th><th>Firm Specifications.</th></tr>
<tr><td>Appearance
Almost colourless or pale-yellowish liquid</td><td>Almost white liquid</td></tr>
<tr><td>First identification A, B.
Second identification B, C, D</td><td>A,C D</td></tr>
<tr><td>pH (2.2.3)
5.5 to 7.0.</td><td>5.5-5.7</td></tr>
<tr><td>Impurity P (chloroaniline)</td><td>Not performed</td></tr>
<tr><td>Related substances</td><td>Not performed</td></tr>
</table></td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has claimed BP method for analysis of FP but has not performed analysis accordingly.
Firm has submitted complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td></tr>
</table>

<table>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted copies of reports of 06 Months Accelerated and 48 Months Real Time Stability Study (30ºC±2 ºC, 65±5%) Data of 03 Batches of API.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copies of its own Analytical reports for all excipients used in product development.
<table>
<tr><th>Tests</th><th>BP</th><th>Firm</th></tr>
<tr><td>Identification</td><td>Ist :B,E
2nd :A,C,D,E</td><td>A, E</td></tr>
<tr><td>Appearance of solution</td><td>✓</td><td>X</td></tr>
<tr><td>Average relative molecular mass and ratio of alkyl components</td><td>✓</td><td>X</td></tr>
<tr><td>Impurities A, B and C</td><td>✓</td><td>X</td></tr>
<tr><td>Amines and amine salts</td><td>✓</td><td>X</td></tr>
<tr><td>Assay</td><td>✓</td><td>X</td></tr>
</table></td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>Not performed.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Not performed.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted audit trail reports for stability studies analysis of three batches.</td></tr>
</table>

Evaluation by PEC:

Sr. No	Deficiencies/Shortcomings	Reply
1.	Commercial invoice is not ADC attested.	Invoice No: E-020 Not attested by ADC Attested Quantity: 50 Kg Form 6 ADC attested dated: 01-06-2017 and batch no. not mentioned.
2.	Provide reference for assay calculation formula i.e. Assay=average sample area /average standard areax100.	For the quantitation formula, in chromatographic method, normally USP & BP recommends the peak areas, if the sample and reference concentrations are the same. Please see the attached pharmacopeia reference. *"In the linear range, peak areas and peak heights are usually proportional to the quantity of compound eluting. The peak areas and peak heights are commonly measured by electronic integrators but may be determined by more classical approaches. Peak areas are generally used but may be less accurate if peak interference occurs. The components measured are separated from any interfering components. Peak tailing and fronting is minimized, and the measurement of peaks on tails of other peaks are avoided when possible."* Evaluation The following justification is insufficient to justify the provided formula. Moreover, raw data sheets does not confirm that concentration is same.
3.	Viscosity to be established after completion of stability studies. Clarify.	Viscosity is a measure of a formulation's resistance to flow and is an assessment of a rheological property of a semi solid dosage form. As viscosity limits are not identified in the BP Specificationific drug product

		monograph, so we perform extra testing and study the viscosity of our Hexigard Gel, during the stability studies for six months. The viscosity limits are as follows; Viscosity: 44500 – 43500 cp.
4.	Injection volume in BP is 100ul whereas, you have used 20ul.Justify.	British Pharmacopeia (BP) recommends 100µl injection volume, however the General Monograph allows for Adjustment of Chromatographic Conditions accordingly. Please refer to BP 2018 general monograph (attached). In our analysis development, the injection volume of 100 µl gave a very high peak response which goes to infinity (injection volume 100 µl chromatogram attached for your reference). Therefore, it was determined that injection volume 20 µl is sufficient to give a high resolution peak and the same was used for our method development.
5.	Variation in retention time of API and internal standard at different time points and same time points between standard and sample e.g. 9.2 min of standard and 7.8 min of sample of initial time point for batch no CHGel-001. Justify and clarify the variations.	The chromatographic conditions are not constant due to seasonal changes in ambient temperature. Therefore, seasonal temperature change results in variation of the retention time. However this has no effect on the testing procedure or on the accuracy of the test.
6.	Batch no 001, accelerated condition, at 4 month time point, the peak of internal standard and API are very close to each other and this trend vary from other time points i.e. the resolution is very poor. Justify and clarify the variations.	Due to extensive and detailed study of analytical method validation, HPLC column get overloaded and it need a long time to wash the column. While performing 4th month stability studies, this problem was observed and then we recover the column through very long term washing procedure so that it can maintain its actual position. The regeneration and washing of column behavior reflects in our 6th month stability data chromatograms which had been already submitted to you. Whereas low resolution is concerned, the minimum requirement of resolution in the chromatographic analysis is more than 1.50 (please see the attached highlighted references). In the 4th month stability studies, chromatograms shows two components of the sample are well separated and the resolution value of all the chromatograms is more than 1.60 (please see the attached 4th month study chromatograms with highlighted resolution).
7.	Firm has not submitted COAs of impurity standards.	Firm has submitted COA of impurity standard but has not performed impurities.
8.	The digital printouts of graphical chart for Accelerated Conditions starting from 30-08-2018 to 31-08-2018 shows excursions (as low as 54.6%RH). Provide justification.	When the doors of the climatic chamber are opened for loading or unloading of the samples, there can be a momentarily change in temperature and humidity. However when the doors are shut, the set values are recovered quickly. Data logger values on 31/08/2018 at 08:53 am & 12:53 pm due to open of door at that moment. This momentarily change has no influence on the stability studies.

<table>
<tr><td>9.</td><td>Explanation is required regarding path case study, as mentioned in Drug-excipients compatibility studies?</td><td>Path case study is a working paper prepared for the UN Commission on Life saving commodities for women and children for appropriate Technology in Health through USAID program.</td></tr>
<tr><td>10.</td><td>Submit and justify the formula for potency adjustment for API.</td><td>Molecular Weight of Chlorhexidine Gluconate (CHXG)= 897.762
Molecular Weight of Chlorhexidine (CHX)= 505.452
Factor= 897.762/505.452 =1.777
We, Have 20% CHXG Solution
For 1ml of 7.1% CHXG Solution, we require= 7.1/20= 0.355ml (of 20% CHXG Solution)
7.1% CHXG= 4% CHX
Assay/Potency API=100.85%
So, for Batch Size 6.5Kg = (0.355*6.5*100)= 2.308 Kg CHXG
Remarks: Adjustment of potency not required since potency is more than 100%.</td></tr>
<tr><td>11.</td><td>No preservative is used in innovator formulation i.e. Umbipro whereas, you have used preservative i.e. Benzalkonium Chloride. Justify.</td><td>We followed the formulation available in working paper, prepared for the UN commission on Life-saving commodities for women and children, attached.
In Ferozson’s formulation, Benzalkonium Chloride is used which is most frequently used as preservative.
The manufacturer of Umbipro also used the antimicrobial preservative (Sodium Acetate trihydrate), which may be for any reasons suiting the manufacturer.
Umbipro Formulation:<table><tr><td colspan="2">Umbipro Formulation:</td></tr><tr><td>Ingredients</td><td>Role</td></tr><tr><td>Chlorhexidine Gluconate</td><td>API</td></tr><tr><td>Guar Gum</td><td>Gelling Agent</td></tr><tr><td>Sodium Acetate Trihydrate</td><td>Antimicrobial Preservative</td></tr><tr><td>Purified Water</td><td>Solvent</td></tr></table>Whereas SMPC mentions as follows:
Sodium acetate trihydrate was shown to result in the lowest level of drug-related impurities and was selected as the pH stabiliser.
Moreover, the case study data provided by firm mentions the following statement regarding the safe use of benzalkonium chloride.
“Some manufacturers have chosen to add small amounts of 50 % benzalkonium chloride(0.10%) to CHX products as a preservative but stability tests conducted by PATH have shown that this may not be a crucial addition.</td></tr>
<tr><td>12.</td><td>The reference for API Specifications. is BP but testing is not performed as per BP.
Chlorhexidine Gluconate<table><tr><td>BP</td><td>Firm Specifications.</td></tr></table></td><td><u>Identification test clarification</u>
BP has recommended 4 qualitative identification test A, B, C, D. We have performed 3 out of 4 qualitative tests which confirm the identity of the material. Test B was not performed due to non-availability of reference standard of Calcium gluconate by B.P.
<u>Impurity P (chloroaniline)</u></td></tr>
</table>

	Appearance Almost colourless or pale-yellowish liquid: Almost white liquid First identification A, B. Second identification B, C, D: A,C D pH (2.2.3) 5.5 to 7.0.: 5.5-5.7 Impurity P (chloroaniline): Not performed Related substances: Not performed	British Pharmacopeia (BP) provides the impurity testing on Specificationialized Gas Chromatograph equipped with detector ECD (Electron Capturing). Since the Electron capturing Detector (ECD) cell contains a Radioactive Isotope 63Ni and it is a Radioactive source, therefore the import of this detector is prohibited by Pakistan Nuclear Regulatory Authority (PNRA) for commercial use (please see the highlighted information for your record). We have the facility of Gas Chromatograph equipped with FID (Flame Ionization detector), which is most commonly used in pharmaceutical API/Excipients and product testing.
13.	**Benzalkonium Chloride** **Tests** / **BP** / **Firm** Identification: 1st :B,E 2nd:A,C,D,E / A, E Appearance of solution: ✓ / X Average relative molecular mass and ratio of alkyl components: ✓ / X Impurities A, B and C: ✓ / X Amines and amine salts: ✓ / X Assay: ✓ / X	**B**P has recommended 5 qualitative identification test A, B, C, D, E. Previously, we have performed 2 out of 5 qualitative tests which confirm the identity of the material. Test C and D performed dated: 07-02-2019, See attached revised COA. Test B could not performed due to non-availability of Benzalkonium chloride for system suitability CRS standard by B.P. **Appearance of solution** Test performed dated: 07-02-2019. **Average relative molecular mass and ratio of alkyl components** Test was not performed due to non-availability of Benzalkonium chloride for system suitability CRS standard **Impurities A, B and** Impurities not performed due to non-availability of impuirty standard A, impuirty standard B and impuirty standard C by B.P. **Amines and amine salts** Test performed dated: 07-02-2019. **Assay** Average relative molecular mass value used in the calculation of assay, whereas Average relative molecular mass test was not performed due to non-availability of Benzalkonium chloride for system suitability CRS standard
14.	The BP mentions appearance as almost colorless or pale-yellowish liquid while you have mentioned almost white liquid. Clarify	<u>Appearance clarification</u> It is to clarify that our analyst mistakenly wrote description "Almost white liquid" instead of clear colorless liquid" COA of API from Smaart Pharmaceuticals is attached bearing appearance as "clear colorless liquid" and sample of API is also provided herewith our clarification for your visual inspection. Copy of corrected analysis report with initials of that analyst for API.
15.	The COA of API and COA of benzalkonium chloride mentions that these raw materials are provisionally approved. Clarify and Justify the same.	New API and excipients are provisionally approved based on QC testing and Finally approved for commercial use after completing trials and stability studies to make sure product is stable during stability

16.	The SMPC of Umbipro mentions that sodium acetatae trihydrate was selected as the pH stabilizer. While you have mentioned it as an antimicrobial agent. Clarify.	Sodium acetate trihydrate has dual action i.e. As pH stabilizer as well as Preservative.

Previous Decision (288th): Registration Board decided to constitute panel for onsite investigation to confirm genuineness / authenticity of stability data and associated documents, import of API, quality, Specification, test analysis, facilities etc., along with observations presented in table above.

Verification of Authenticity of Stability Data submitted for Registration of Hexigard Gel (Chlorhexidine Gluconate) by M/s Ferozesons Laboratories Ltd, Nowshera

Inspection date: 26th July 2019
Inspection site: Factory Premises of M/s Ferozsons Laboratories Nowshera.

The constituted Panel for the verification of authenticity of stability data was comprised of the following members,

1. Dr. Jamshed Ali Khan, Member Central Licensing Board.
2. Director DTL, Peshawar.
3. Syed Adnan Ali Shah, Assistant Director PE & R, Islamabad.

The constituted panel conducted detailed inspection of M/s Ferozsons Laboratories Ltd, Nowshera, Khyber Pakhtunkhwa as per following details:

(S.No)	**Question**	**Observation by panel**
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	Firm has documents confirming the import of 50kg of Chlorhexidine gluconate 20% solution.
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	The firm has informed that they have selected the said manufacturer being GMP compliant and has provided stability data of the said API.
Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	Firm has documents confirming the import of reference standards and impurity standards.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	Firm has certificate of analysis of API and reference standards.
Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has copy of GMP certificate of API manufacturer issued by regulatory authority of country of origin.
Q.No.6	Do you use API manufacturer method of testing for testing API?	The firm has used manufacturer method of testing for testing of API.
Q.No.7	Do you have stability studies reports on API?	The firm has real time and accelerated stability study data sheets provided by the API manufacturer.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability studies have been performed as per SIM method.
Q.No.9	Do you have method for quantifying the impurities in the API?	Not Applicable

Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has record of remaining quantities of API, its reference standard and impurities standard.
Q.No.11	Have you used pharmaceutical grade excipients?	All excipients used in the formulation were of pharmaceutical grade.
Q.No.12	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the purchase of excipients used in the formulation from local supplier. COAs were available.
Q.No.13	Do you have test reports and other records on the excipients used?	The firm has complete testing records for the excipients used in the formulation.
Q.No.14	Do you have written and authorized protocols for the development of applied product?	The firm has written and authorized protocols for the development of applied product.
Q.No.15	Have you performed Drug-excipients compatibility studies?	The firm has not performed Drug-excipients compatibility studies.
Q.No.16	Have you performed comparative dissolution studies?	Not Applicable
Q.No.17	Do you have product development (R&D) section	The firm has dedicated product development (R&D) section.
Q.No.18	Do you have necessary equipments available in product development section for development of applied product?	The firm has necessary equipment in product development section.
Q.No.19	Are the equipments in product development section qualified?	The equipment used in the product development section were qualified.
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance and calibration for the equipment used in product development.
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	Firm has qualified staff with proper knowledge and training in product development.
Q.No.22	Have you manufactured three stability batches for the stability studies of applied product as required?	The firm has manufactured three stability batches for the stability studies.
Q.No.23	Do you have any criteria for fixing the batch size of stability batches?	Firm has informed that a criterion for fixing batch size was based on their minimum requirements for stability samples used in stability studies.
Q.No.24	Do you have complete record of production of stability batches?	The firm has complete batch manufacturing record of all the stability batches.
Q.No.25	Do you have protocols for stability testing of stability batches?	Firm has protocols for stability testing of the stability batches.
Q.No.26	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated the method for the testing of stability batches.

Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Not Applicable
Q.No.28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Firm has all relevant documents confirming the qualification of equipments/instruments used in the test and analysis of API and the finished drug.
Q.No.29	Is your method of analysis stability indicating?	The method of analysis used for analysis of stability batches was stability indicating.
Q.No.30	Is your HPLC software is 21CFR compliant?	The HPLC software is 21CFR compliant.
Q.No.31	Can you show Audit Trail reports on stability studies testing?	Firm has demonstrated audit trail reports of testing.
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	The firm has some remaining quantities of stability batches/ degradation products.
Q.No.33	Do you have stability batches kept on stability testing?	The firm has remaining quantities of stability batches kept on stability testing.
Q.No.34	Do you have valid calibration status for the equipments used in production and analysis?	The firm has valid calibration status of the equipment used in production and analysis.
Q.NO.35	Do proper and continuous monitoring and control are available for stability chamber?	The firm has stability chambers for carrying out accelerated and real time stability studies provided with uninterrupted power supply and data loggers.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Related manufacturing area, equipment, personnel and utilities are as per GMP compliance.

The observations highlighted by evaluator discussed and details are provided as follow;

S.#	**Points Highlighted**	**Response**
1.	Commercial invoice is not ADC attested.	Form 6 is attested by ADC having details of invoice. Firm informed that commercial invoice needs no attestation, as informed by ADC.
2.	Provide reference for assay calculation formula i.e. Assay=average sample area /average standard area x 100.	Firm informed that the assay calculation formula is in accordance with USP general monograph <621> (Chromatography).
3.	Viscosity to be established after completion of stability studies. Clarify.	Firm informed that B.P general monograph for gel dosage form does not viscosity limits, therefore, after ascertaining viscosity limits after six months stability studies (i.e 44500-43500cp) the same is performed at other time points of stability studies.
4.	Injection volume in BP is 100ul whereas, you have used 20ul. Justify.	Firm informed that the adjustment made in injection volume is in accordance with B.P system suitability studies. Furthermore, injection volume of 100ul provided a very high peak upto infinity.
5.	Variation in retention time of API and internal standard at different time points and same time points between standard and sample e.g. 9.2 min of standard and 7.8 min of sample of	Firm informed that seasonal temperature change results in variation of the retention time due to use of columns (to be stored at ambient temperature). However this has no effect on the testing procedure or on the accuracy of the test.

<table>
<tr><td></td><td>initial time point for batch no CHGel-001. Justify and clarify the variations</td><td></td></tr>
<tr><td>6.</td><td>Batch no 001, accelerated condition, at 4 month time point, the peak of internal standard and API are very close to each other and this trend vary from other time points i.e. the resolution is very poor. Justify and clarify the variations.</td><td>Firm informed that the resolution is well within limit i.e not less than 1.5
Furthermore, column regeneration and washing of columns has been done for other time points to get proper resolution which is evident from chromatograms.</td></tr>
<tr><td>7.</td><td>The digital printouts of graphical chart for Accelerated Conditions starting from 30-08-2018 to 31-08-2018 shows excursions (as low as 54.6%RH). Provide justification.</td><td>This momentarily change is due to opening of doors of the climatic chamber for loading or unloading of the samples and it has got no influence on the stability studies.</td></tr>
<tr><td>8.</td><td>Explanation is required regarding path case study, as mentioned in Drug-excipients compatibility studies?</td><td>Firm informed that Path case study is a working paper prepared for the UN Commission on Life saving commodities for women and children for appropriate Technology in Health through USAID program.</td></tr>
<tr><td>9.</td><td>No preservative is used in innovator formulation i.e. Umbipro whereas, you have used preservative i.e. Benzalkonium Chloride. Justify</td><td>The manufacturer of Umbipro used antimicrobial preservative (Sodium Acetate trihydrate) whereas M/s. Ferozsons Laboratories has followed the formulation available in working paper, prepared for the UN commission on Life-saving commodities for women and children.</td></tr>
<tr><td>10.</td><td>The reference for API Specs. is BP but testing is not performed as per BP.
Chlorhexidine Gluconate
<table>
<tr><th>BP</th><th>Firm specs.</th></tr>
<tr><td>Appearance
Almost colorless or pale-yellowish liquid</td><td>Almost white liquid</td></tr>
<tr><td>First identification A, B.
Second identification B, C, D</td><td>A,C D</td></tr>
<tr><td>pH (2.2.3)
5.5 to 7.0.</td><td>5.5-5.7</td></tr>
<tr><td>Impurity P (chloroaniline)</td><td>Not performed</td></tr>
<tr><td>Related substances</td><td>Not performed</td></tr>
</table></td><td>
<table>
<tr><th>BP</th><th>Firm specs.</th><th>Response</th></tr>
<tr><td>Appearance
Almost colorless or pale-yellowish liquid</td><td>Almost white liquid</td><td>Correction made and reported by firm.</td></tr>
<tr><td>First identification A, B.
Second identification B, C, D</td><td>A,C D</td><td>B qualitative test not performed due to non-availability. Now performed for other time points after availability of ref standard.</td></tr>
<tr><td>pH (2.2.3)
5.5 to 7.0.</td><td>5.5-5.7</td><td>pH limit is 5.5-7.0</td></tr>
<tr><td>Impurity P (chloroaniline)</td><td>Not performed</td><td>Not performed due to prohibition of radioactive isotope, used in testing.</td></tr>
<tr><td>Related substances</td><td>Not performed</td><td>-do-</td></tr>
</table></td></tr>
<tr><td>11.</td><td>
<table>
<tr><th>Tests</th><th>BP</th><th>Firm</th></tr>
<tr><td>Identification</td><td>Ist :B,E
2nd:A,C,D ,E</td><td>A, E</td></tr>
<tr><td>Appearance of solution</td><td>✓</td><td>X</td></tr>
</table></td><td>Firm informed that B test for qualitative identification is not performed due to non availability of ref standard. Now, after availability of the said impurity, the same will be performed by them. However, firm performed sufficient tests including spectral range, melting point etc for qualitative and quantitative testing of Benzalkonium Chloride.</td></tr>
</table>

	Average relative molecular mass and ratio of alkyl components	✓	X
	Impurities A, B and C	✓	X
	Amines and amine salts	✓	X
	Assay	✓	X
12.	The BP mentions appearance as almost colorless or pale-yellowish liquid while you have mentioned almost white liquid. Clarify	It was a typo error and correction has been made accordingly.	
13.	The COA of API and COA of benzalkonium chloride mentions that these raw materials are provisionally approved. Clarify and Justify the same	"Provisionally approved" term internally used by the firm for New API and excipients, after testing has been performed. Firm has revised their SOP to avoid confusion in future.	
14.	The SMPC of Umbipro mentions that sodium acetatae trihydrate was selected as the pH stabilizer. While you have mentioned it as an antimicrobial agent. Clarify.	Firm informed that Sodium acetate trihydrate has dual action i.e. As pH stabilizer as well as Preservative.	
15.	Firm has not submitted COAs of impurity standards.	Firm has submitted COA of impurity standard.	
16.	Submit and justify the formula for potency adjustment for API.	Firm informed that potency of the API was not adjusted as the increase in potency is very slight and has got no significant effect.	

Conclusion:
On risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Hexigard Gel (Chlorhexidine Gluconate) **i**s verifiable to satisfactory level.

Evaluation by PEC:
The firm has applied for exemption but due to various observations in stability data the Registration Board constituted a panel to verify the confirm genuineness / authenticity of stability data and associated documents, import of API, quality, Specification, test analysis, facilities etc., along with observations but inspection report does not Specificationifically mentions regarding the observations for which panel was constituted.

Decision: Registration Board decided to approve registration of "Hexigard Gel 4%" with BP specifications by M/s Ferozesons Laboratories. **Manufacturer will place first three production batches of product on long term stability studies throughout proposed shelf life and on accelerated studies for six months.**

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

a. Deferred cases

587.	Name and address of manufacturer / Applicant	M/s Relizon Pharmaceuticals, Raiwind road, Lahore
	Brand Name +Dosage Form + Strength	Reltane 25mg tablet
	Composition	Dy. No.8065; 16-5-2018; Rs.20,000/- (16-5-2018)
	Diary No. Date of R& I & fee	Each film coated tablet contains: Exemestane……25mg
	Pharmacological Group	aromatase Inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	15's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Aromasin 25 mg coated tablets by M/s Pfizer Limited (MHRA Approved)
	Me-too status	Ph&T Exemestane 25mg Coated Tablets by M/s Mehran International (Reg#078122)
	GMP status	DML issue date 21-2-2018
	Remarks of the Evaluator.	
	Previous Decision and replies:	**Decision of 284th** Deferreed for further deliberation on the applied product.
	Evaluation by PEC:	
	Decision: Deferred for clarification regarding manufacturing facility whether steroidal or non-steroidal hormone section.	

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

b. New/Additional section(s)

Central Licensing Board in its 270th meeting held on 23rd MAY, 2019 has considered and approved the following 4 additional section of firm M/s Arreta Pharmaceuticals Pvt Ltd.
Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi as under:-

Sr. No	Section
01	Sterile Dry powder for Injection(Cephalosporin)
02	Dry powder for suspension (Cephalosporin)
03	Capsule Section Cephalosporin
04	Ware house Cephalosporin

Sterile Dry Powder for Injection (Cephalosporin)
4 Molecules/ 11 Products

588.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	C-Tri 2g IV Injection
	Diary No. Date of R& I & fee	Dy.No 13384 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…2000mg
	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	MHRA Approved
	Me-too Status	Titan 2gm IV Inj by M/s Macter Pharma (R.No.075825)
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	

589.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	C-Tri 1g IV Injection
	Diary No. Date of R& I & fee	Dy.No 13383 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…1000mg
	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	USFDA Approved
	Me-too Status	Martixon 1gm (Ceftriaxone sodium) I.V Dry powder Injection by Alkemy Pharma. Reg. No. 70663
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
590.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	C-Tri 500mg IV Injection
	Diary No. Date of R& I & fee	Dy.No 13382 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	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	USFDA Approved
	Me-too Status	Wincef 500 mg (Ceftriaxone sodium) IV by Wel Wink Pharmaceuticals. Reg. No. 78097
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
591.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd.Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	C-Tri 250mg IV Injection
	Diary No. Date of R& I & fee	Dy.No 13381 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	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	USFDA Approved
	Me-too Status	Ceftirains 250mg (ceftriaxone Sodium) I.V Injection by Sunrise Pharma (Pvt) Ltd. Reg. No. 78655
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
592.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi.
	Brand Name +Dosage Form + Strength	C-Tri 250mg IM Injection

	Diary No. Date of R& I & fee	Dy.No 13415 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	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	MHRA Approved
	Me-too Status	Traxon Injection 250mg by GSK
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
593.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	C-Tri 500mg IM Injection
	Diary No. Date of R& I & fee	Dy.No 13416 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	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	USFDA Approved
	Me-too Status	Wincef 500 mg (Ceftriaxone sodium) IM injection by Wnsfeild Pharmaceuticals. Reg. No. 68371
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
594.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd.Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Alzone 1g/1g Injection
	Diary No. Date of R& I & fee	Dy.No 13416 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	1's /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too Status	Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027
	GMP Status	
	Remarks of the Evaluator.	
	Decision: **Approved.**	
595.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Afurox 750mg Injection
	Diary No. Date of R& I & fee	Dy.No 13418 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains:

		Cefuroxime (as Sodium)…..750mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	1's /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	ZINACEF 750MG INJ by M/s GSK Pakistan (Reg#006222)
	GMP Status	
	Remarks of the Evaluator.	
	Decision: **Approved.**	
596.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Arretaz 500mg Injection
	Diary No. Date of R& I & fee	Dy.No 13405 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Ceftazidime Pentahydrate with L-Arginine Eq. to Ceftazidime…500mg
	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	MHRA Approved
	Me-too Status	Ceftaz by Pharmedic
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
597.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Afurox 1.5g Injection
	Diary No. Date of R& I & fee	Dy.No 13396 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Vial Contains: Cefuroxime (as Sodium)…1.5g
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	1's /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Zecef Injection 1.5gm by M/s Bosch Pharmaceuticals (Pvt) Ltd, (Reg#026898)
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
Dry powder for suspension (Cephalosporin) 3-Molecules/ 3 Products		
598.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Arrelexin 250mg/5ml Suspension
	Diary No. Date of R& I & fee	Dy.No 13400 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each 5ml suspension After Reconstitution Contains: Cephalexin as Monohydrate…250mg

	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	60ml /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Vegzin 250mg Dry Powder Suspension of M/s Vega Pharmaceuticals
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
599.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Arredoxime 40mg/5ml Dry Suspension
	Diary No. Date of R& I & fee	Dy.No 13407 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each 5ml After Reconstitution Contains: Cefpodoxime Proxetil Eq. to Cefpodoxime…40mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	50ml /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Podomax Dry Suspension of M/s Hicon Pharmaceuticals
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
600.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Afurox 125mg/5ml Dry Suspension
	Diary No. Date of R& I & fee	Dy.No 13394 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each 5ml After Reconstitution Contains: Cefuroxime as Axetil…125mg
	Pharmacological Group	Cephalosporin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	50ml /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Optik DS Dry Suspension of M/s Wilshire Laboratories (Pvt) Ltd (Reg.# 053644)
	GMP Status	
	Remarks of the Evaluator.	
	Decision: Approved.	
Capsule Section Cephalosporin 1-Molecule/ 1Product		
601.	Name and address of manufacturer / Applicant	M/s Arreta Pharmaceuticals Pvt Ltd. Plot No. 13, Street N-5, RCCI, Industrial Estate, Rawalpindi
	Brand Name +Dosage Form + Strength	Arofixime 400mg Capsule
	Diary No. Date of R& I & fee	Dy.No 13391 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Capsule Contains: Cefixime Trihydrate Eq. to Cefixime…400mg
	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	USFDA Approved
	Me-too Status	CEFIGET Capsule 400 mg by Getz Pharma
	GMP Status	
	Remarks of the Evaluator.	
	Decision: **Approved.**	

Central Licensing Board in its 270th meeting held on 23rd MAY, 2019 has considered and approved the following 2 additional section of firm M/s Jinnah Pharmaceuticals Pvt Ltd.
13 km, Lahore Road, Multan as under:-

Sr. No	Section
01	Tablet Section (Psychotropic/Narcotic)
02	Oral Liquid/Suspension General Section

Tablet Section (Psychotropic/Narcotic)
5-Molecules/ 6 Products

602.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Jolip 10mg Tablet
	Diary No. Date of R& I & fee	Dy.No 16246 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Composition	Each Tablet Contains: Zolpidem as tartrate…10mg
	Pharmacological Group	Sedative agents
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1 x 14'S /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Olida 10mg Tablets of M/s Glitz Pharmaceuticals, Islamabad (Reg.# 081418)
	GMP Status	New Section
	Remarks of the Evaluator.	RRA product is film coated tablet
	Decision: Deferred for consideration on its turn with respect to the queue.	
603.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Jampro 5mg Tablets
	Diary No. Date of R& I & fee	Dy.No 16245 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Composition	Each Tablet Contains: Procyclidine as Hcl…5mg
	Pharmacological Group	Anti cholinergic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10 x 10's /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Kemadrin (uncoated) Tablets 5mg by Aspen Pharma (MHRA Approved)
	Me-too Status	Kemadrin Tablet by GSK (Reg# 000363)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Deferred for consideration on its turn with respect to the queue.	
604.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	Jadol-P 325/37.5 mg Tablet
	Diary No. Date of R& I & fee	Dy.No 16244 dated 06-03-2019 Rs. 20,000/- 07-03-2019

	Composition	Each Tablet Contains: Paracetamol…325mg Tramadol as Hcl…37.5mg
	Pharmacological Group	Analgesic
	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	ULTRACET by Janssen Pharmaceuticals, Inc. MHRA Approved
	Me-too Status	Misadol Plus tablet of M/s Mission pharma
	GMP Status	New Section
	Remarks of the Evaluator.	Salt factor is not correct
	Decision: Deferred for consideration on its turn with respect to the queue.	
605.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	J-Zolam 0.25mg Tablet
	Diary No. Date of R& I & fee	Dy.No 16241 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Composition	Each Tablet Contains: Alprazolam…0.25mg
	Pharmacological Group	Benzodiazepines
	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	MHRA Approved
	Me-too Status	Alprazolam 0.25mg Tablets by M/s Heal Pharmaceuticals (Reg#079390)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: **Approved.**	
606.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	J-Zolam 0.5mg Tablet
	Diary No. Date of R& I & fee	Dy.No 16242 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Composition	Each Tablet Contains: Alprazolam…0.5mg
	Pharmacological Group	Benzodiazepines
	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	MHRA Approved
	Me-too Status	Alprazolam 0.5mg Tablets by M/s Heal Pharmaceuticals
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
607.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals Pvt Ltd. 13 km, Lahore Road, Multan
	Brand Name +Dosage Form + Strength	J-Brom 3mg Tablet
	Diary No. Date of R& I & fee	Dy.No 16243 dated 06-03-2019 Rs. 20,000/- 07-03-2019
	Composition	Each Tablet Contains: Bromazepam…3mg
	Pharmacological Group	Benzodiazepines

	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	3 x 10's /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	TGA Approved
	Me-too Status	079327; "Normeez 6mg Tablets By Navegal Lab.
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: **Approved.**	

Central Licensing Board in its 266th meeting held on 24th Oct 2018 has approved the 15 additional section of M/s Rotex Pharma Pvt Ltd, Plot No. 206,207, Industrial Triangle, Khuta road, Islamabad.

Sr. No	Section	No. of products	No. of molecules
01	Eye/Ear/Nasal Drops (Steroid Section)	11	10
	Eye/Ear/Nasal Section 11-Products/ 10-Moleules		

608.	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	Ronec Opthalmic Suspension eye drops
	Diary No. Date of R& I & fee	Dy.No 14252 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml contains: Nepafenac…0.1%
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specification
	Pack Size & Demanded Price	5ml, As per Sro
	Approval Status of Product in Reference Regulatory Authorities	USFDA Approved
	Me-too Status	Pafnac by Medicaids (Pak) Ltd (R. No. 076374)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
609.	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	Rotamox Eye Drops
	Diary No. Date of R& I & fee	Dy.No 16788 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Composition	Each ml contains: Moxifloxacin…0.5%
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specification
	Pack Size & Demanded Price	3ml, 5ml, As per Sro
	Approval Status of Product in Reference Regulatory Authorities	VIGAMOX by Novartis (USFDA Approved)
	Me-too Status	Oxcin by Atco
	GMP Status	New Section
	Remarks of the Evaluator.	Salt factor is not written. Firm has not mentioned whether it is solution or suspension.
	Decision: Deferred for the following: **□ Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee.** **□ Clarify the dosage form.**	
610.	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	Dexatobin Opthelmic Suspension Drops

	Diary No. Date of R& I & fee	Dy.No 16793 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Composition	Each ml contains: Tobramycin…3mg Dexamethasone…1mg
	Pharmacological Group	Aminoglycoside/Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5ml, As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Tobradex eye drops of Novartis
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
611.	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	Rolopat Opthelmic Solutions
	Diary No. Date of R& I & fee	Dy.No 14270 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Composition	Each ml contains: Olopatadine…0.2%
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5ml, As per SRO
	Approval Status of Product in Reference Regulatory Authorities	USFDA Approved
	Me-too Status	Aptadine eye drops of Barrett Hodgson
	GMP Status	New Section
	Remarks of the Evaluator.	Salt factor (HCL) is not mentioned.
	Decision: Deferred for the following: **□ Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee..**	
612.	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	Rolopat Opthelmic Solutions
	Diary No. Date of R& I & fee	Dy.No 17478 dated 07-03-2019 Rs.20,000/- 07-03-2019
	Composition	Each ml contains: Olopatadine…0.1%
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5ml, As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Patanol by Alcon (USFDA)
	Me-too Status	Patlerg by Medicaids (Pak) Ltd (R. No. 061089)
	GMP Status	New Section
	Remarks of the Evaluator.	Salt factor (HCL) is not mentioned.
	Decision: Deferred for the following: **□ Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee..**	
613.	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	Zortim Opthelmic Solution 20mg/5mg
	Diary No. Date of R& I & fee	Dy.No 14257 dated 07-03-2019 Rs. 20,000/- 07-02-2019

	Composition	Each ml contains: Dorazolamide as Hcl…20mg Timolol as Maleate…5mg
	Pharmacological Group	Beta-blocker
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	5ml, As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Cosopt eye drops of OBS
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
614.	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	Rolene Eye Drops 0.4%/0.3%
	Diary No. Date of R& I & fee	Dy.No 14272 dated 07-03-2019 Rs. 20,000/- 07-02-2019
	Composition	Each ml contains: Polyethylene glycol…0.4% Propylene Glycol…0.3%
	Pharmacological Group	Lubricant
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specification
	Pack Size & Demanded Price	10ml, 15ml, 30ml, As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Systane of Alcon, UK, OTC product (Daily Med)
	Me-too Status	Eyecane by Innvotek Pharma
	GMP Status	New Section
	Remarks of the Evaluator.	Firm has not mentioned whether it is solution or suspension
	Decision: Deferred for clarification of dosage form.	
615.	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	Roprost Eye Drops
	Diary No. Date of R& I & fee	Dy.No 16802 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each 2.5ml Contains Travoprost…0.0041%
	Pharmacological Group	Prostaglandin
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specification
	Pack Size & Demanded Price	2.5ml As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Travoprost 40 micrograms/ml eye drops, solution by Teva UK Limited, (MHRA Approved)
	Me-too Status	Travop ophthalmic solution 0.004% by Alza Reg. # 081621
	GMP Status	New Section
	Remarks of the Evaluator.	Firm has not mentioned whether it is solution or suspension
	Decision: Deferred for clarification of dosage form.	
616.	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	Anrost Eye Drops Solution
	Diary No. Date of R& I & fee	Dy.No 16791 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml Contains: Latanoprost…50mcg
	Pharmacological Group	Prostaglandin
	Type of Form	Form-5

	Finished Product Specification	Manufacturer's specification
	Pack Size & Demanded Price	2.5ml As per SRO
	Approval Status of Product in Reference Regulatory Authorities	XALATAN by Pharmacia (USFDA Approved)
	Me-too Status	XALATAN by Pfizer
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
617.	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	Biprost 0.03% Eye Drops 3ml
	Diary No. Date of R& I & fee	Dy.No 16804 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml Contains: Bimatoprost…0.3mg
	Pharmacological Group	Prostaglandin
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's specification
	Pack Size & Demanded Price	3ml As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Bimatoprost of Apotex Inc (**USFDA**)
	Me-too Status	Lumigan eye drops of Barret Hodgson (Reg # 033177)
	GMP Status	New Section
	Remarks of the Evaluator.	Firm has not mentioned whether it is solution or suspension
	Decision: Deferred for clarification of dosage form.	
618.	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	Brimon Eye Drops
	Diary No. Date of R& I & fee	Dy.No 16798 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each 5ml Contains: Brimonidine…0.2%
	Pharmacological Group	Alpha 2 agonist
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	5ml As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too Status	Brimonidine Tartrate Ophthalmic Solution 0.2%. of M/s Ali Gohar & Company (Pvt.) ltd., Karachi (Reg.# 044835)
	GMP Status	New Section
	Remarks of the Evaluator.	Salt factor is not mentioned
	Decision: Deferred for the following: **□ Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee..** **□ Clarify the dosage form.**	

Central Licensing Board in its 253rd meeting held on 15 and 16th May 2017 has approved the following 3 additional section of M/s Legacy Pharmaceuticals pvt Ltd, 111-A, Industrial Estate Hayatabad Peshawar

Sr. No	Section	No. of products	No. of molecules
01	Tablet Psychotropic Section in Place of Tablet Secion Quinolone		
03	Dry powder Suspension Section (Pencillin)		
04	Tablet Section Hormone		

Dry powder Suspension Section (Pencillin)
3-Molecule/ 5-Product

619.	Name and address of manufacturer / Applicant	M/s Legacy Pharmaceuticals pvt Ltd 111-A, Industrial Estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Legomentin 156.25mg/5ml Dry Suspension
	Diary No. Date of R& I & fee	Dy.No 6515 dated 14-02-2019 Rs.20,000/- 14-02-2019
	Composition	Each 5ml contains: Amoxicillin as Amoxicillin Trihydrate…125mg Clavulanic Acid as Potassium salt…31.25mg
	Pharmacological Group	Broad Spectrum penicillin
	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	MHRA Approved
	Me-too Status	Augmiclav by Lisko Pharma Reg # 027240
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name.	
620.	Name and address of manufacturer / Applicant	M/s Legacy Pharmaceuticals pvt Ltd 111-A, Industrial Estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Lemoxil 125mg/1.25ml Suspension
	Diary No. Date of R& I & fee	Dy.No 6414 dated 14-02-2019 Rs.20,000/- 14-02-2019
	Composition	Each 1.25ml contains: Amoxicillin as trihydrate…125mg
	Pharmacological Group	Broad Spectrum penicillin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20ml /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Could not be confirmed
	Me-too Status	Could not be confirmed
	GMP Status	New Section
	Remarks of the Evaluator.	RRA and me-too status could not be confirmed
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
621.	Name and address of manufacturer / Applicant	M/s Legacy Pharmaceuticals pvt Ltd 111-A, Industrial Estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Lemoxil 125mg/5ml Suspension
	Diary No. Date of R& I & fee	Dy.No 6512 dated 14-02-2019 Rs.20,000/- 14-02-2019
	Composition	Each 5ml contains: Amoxicillin as trihydrate…125mg
	Pharmacological Group	Broad Spectrum penicillin

	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amoxicilin 125 mg / 5ml USFDA Approved
	Me-too Status	Adamox 125mg suspension by Adamji
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name.	
622.	Name and address of manufacturer / Applicant	M/s Legacy Pharmaceuticals pvt Ltd 111-A, Industrial Estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Lemoxil 250mg/5ml Dry Suspension
	Diary No. Date of R& I & fee	Dy.No 6513 dated 14-02-2019 Rs.20,000/- 14-02-2019
	Composition	Each 5ml contains: Amoxicillin as trihydrate…250mg
	Pharmacological Group	Broad Spectrum penicillin
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Amoxicilin 250 mg / 5ml USFDA Approved
	Me-too Status	Amoxicap by DonValley.
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved with change of brand name.	
623.	Name and address of manufacturer / Applicant	M/s Legacy Pharmaceuticals pvt Ltd 111-A, Industrial Estate Hayatabad Peshawar
	Brand Name +Dosage Form + Strength	Xactum 500mg/60ml Dry Suspension
	Diary No. Date of R& I & fee	Dy.No 12222 dated 06-03-2019 Rs. 20,000/- 06-03-2019
	Composition	Each 5ml contains: Amoxicillin as trihydrate…250mg Sulbactum as Sodium…250mg
	Pharmacological Group	Broad Spectrum penicillin
	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	Could not be confirmed
	GMP Status	New Section
	Remarks of the Evaluator.	RRA and me-too status could not be confirmed
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	

Central Licensing Board in its 266th meeting held on 24th October 2018 has considered and approved the 2 Additional sections of firm M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad.
as under:-

Sr. No	Section	No. of products	No. of molecules
01	Capsule General Section		
02	Topical Lotion	12	10

624.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Fari-Derm 0.05% Lotion
	Diary No. Date of R& I & fee	Dy.No 17060 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Gram Contains: Clobetasol Proptionate…0.5mg
	Pharmacological Group	Glucocorticoid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved (Aluminim tube)
	Me-too Status	Clobeta of Saffron pharmaceuticals.
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
625.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Minoxifr 5% Lotion
	Diary No. Date of R& I & fee	Dy.No 17056 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Gram Contains: Minoxidil…50mg
	Pharmacological Group	Topical hair growth promoter
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Regaine for Men Extra Strength Scalp Solution 5% w/v Cutaneous Solution by M/s McNeil Products Limited (MHRA Approved)
	Me-too Status	Minoxin Plus Solution5% by M/s Brooks Pharmaceuticals (Reg#034492)
	GMP Status	New Section
	Remarks of the Evaluator.	RRA product is in mg/ml
	Decision: Deferred for revision of formulation along with applicable fee.	
626.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Minoxifr 2% Lotion
	Diary No. Date of R& I & fee	Dy.No 17062 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Gram Contains: Minoxidil…20mg
	Pharmacological Group	Topical hair growth promoter
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	APO-GAIN LIQ 20MG/ML By M/s APOTEX INC (Health Canada Approved)

	Me-too Status	Hair max 2% by M/s Sante pharma (Reg # 020254)
	GMP Status	New Section
	Remarks of the Evaluator.	RRA product is in mg/ml
	Decision: Deferred for revision of formulation along with applicable fee.	
627.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Wart Nill Lotion
	Diary No. Date of R& I & fee	Dy.No 17061 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Gram Cream Contains: Salicylic Acid…167mg Lactic Acid…167mg
	Pharmacological Group	Topical 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	Salactol Collodion by M/s Diomed Developments Limited (MHRA Approved)
	Me-too Status	Duofilm by Stiefel (Reg#005032)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
628.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Skannar 0.01% Oil (Topical Liquid)
	Diary No. Date of R& I & fee	Dy.No 17066 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml Contains: Fluocinolone Acetonide…0.1mg
	Pharmacological Group	Topical 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	Fluocinolone Acetonide of Bausch And Lomb (USFDA)
	Me-too Status	Derma-Smooth topical oil of M/s Valor Pharma (068638)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
629.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals. Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Scabon 10% Lotion
	Diary No. Date of R& I & fee	Dy.No 17064 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each 100gm Contains: Crotamiton…10gm Sulfur…2gm
	Pharmacological Group	Scabicide
	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	Not confirmed
	Me-too Status	SEBION 2GM LOTION by M/s Atco (Reg#012229)
	GMP Status	New Section
	Remarks of the Evaluator.	Approval Status of Product in Reference Regulatory Authorities not confirmed.

	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
630.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals.Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Scabon Forte Lotion
	Diary No. Date of R& I & fee	Dy.No 17058 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml Contains: Crotamiton…100mg Sulfur…50mg
	Pharmacological Group	Scabicide
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Not confirmed
	Me-too Status	Not confirmed
	GMP Status	New Section
	Remarks of the Evaluator.	Approval Status of Product in Reference Regulatory Authorities and me-too status not confirmed.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
631.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals.Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ketozol 2% Lotion
	Diary No. Date of R& I & fee	Dy.No 17063 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml Contains: Ketoconazole…20mg
	Pharmacological Group	Antifungal
	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	Nizora Anti-Dandruff Shampoo 2%w/w by M/s McNeil Products Limited (MHRA Approved)
	Me-too Status	Ketonaz Lotion by M/s Sante (Reg#073453)
	GMP Status	New Section
	Remarks of the Evaluator.	RRA product is in w/w whereas firm has submitted in w/v
	Decision: Deferred for revision of formulation along with applicable fee.	
632.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals.Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ciclop-S Lotion
	Diary No. Date of R& I & fee	Dy.No 17065 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml Contains: Ciclopirox Olamine……1.5% Salicylic Acid……3%
	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	Not confirmed.
	Me-too Status	Stieproxal by Stiefel (Reg.# 048074)

	GMP Status	New Section
	Remarks of the Evaluator.	RRA product is not confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
633.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals.Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Ciclop Topical Liquid 1.5% w/w
	Diary No. Date of R& I & fee	Dy.No 17071 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Gram Contains: Ciclopirox Olamine…15mg
	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	Stieprox 15mg/g Shampoo by M/s GlaxoSmithKline (Ireland) Limited (HPRA Ireland Approved
	Me-too Status	Stieprox Topical Liquid by M/s GSK (Reg#026392)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
634.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals.Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Clinda T 1% Lotion
	Diary No. Date of R& I & fee	Dy.No 17072 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each ml Contains: Clindamycin as phosphate…10mg
	Pharmacological Group	Antiinfective
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Dalacin T Topical Lotion 1%w/v by M/s Pfizer Limited (MHRA Approved)
	Me-too Status	Dalacin-T lotion by M/s Pfizer Pakistan (Reg#013582)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved.	
635.	Name and address of manufacturer / Applicant	M/s Fresh Pharmaceuticals.Plot No. 7, Street No. S-6, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Mite-Cid 5% Lotion
	Diary No. Date of R& I & fee	Dy.No 17057 dated 07-03-2019 Rs20,000/- 07-03-2019
	Composition	Each Gram Contains: Permethrin…50mg
	Pharmacological Group	Scabicides
	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	Permethrin lotion 5% w/w by M/s GSK Consumer Healthcare (UK) Trading Ltd (MHRA Approved)
	Me-too Status	Plaveo Lotion by M/s Hiranis (Reg#076508)
	GMP Status	New Section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	

CLB in its 270th meeting held on 23rd May 2019, has considered and approved the following five additional sections of the firm M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore.

Sr. No.	Section
1	Dry Powder Suspension (General)
2	Cream/Ointment/Gel (General)
3	Tablet General
4	Capsule General Section
5	Sachet General Section

Cream/ointment/gel section
11 Products/ 10 Molecules

636.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Lorix cream
	Diary No. Date of R& I & fee	Dy.No. 4129 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Permethrin …….50mg (5% w/w)
	Pharmacological Group	Scabicide
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	30gm,50gm /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Bioscab Cream (Reg#.074773)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
637.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Musidic cream
	Diary No. Date of R& I & fee	Dy.No. 4122 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Fusidic acid…… 20mg
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	15gm,30gm,50gm /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Fucidin cream of M/s LEO Laboratories Limited, approved by MHRA of UK
	Me-too Status	Mirazym Cream of M/s Hiranis Karachi (Reg.# 076516)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
638.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Voral gel
	Diary No. Date of R& I & fee	Dy.No. 4128 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Diclofenac diethylamonium …. 23.2mg eq to diclofenac sodium…20mg
	Pharmacological Group	NSAIDS
	Type of Form	Form-5
	Finished Product Specification	BP
	Pack Size & Demanded Price	20gm,30gm,50gm/As per SRO

	Approval Status of Product in Reference Regulatory Authorities	Voltarol 2.32% Gel GlaxoSmithKline Consumer Healthcare (UK) Trading Limited,
	Me-too Status	Voltral gel by Novartis
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved.	
639.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Hyzole cream 1%w/w
	Diary No. Date of R& I & fee	Dy.No. 4110 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Clotrimazole ……10mg (1% w/w) Hydrocortisone ……10mg (1% w/w)
	Pharmacological Group	Corticosteroid , Anti-fungal
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	20gm,30gm,50gm /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Canesten Hydrocortisone Athlete's Foot 1%, 1% w/w Cream (MHRA Approved)
	Me-too Status	Hydrozole cream by M/s GSK (Reg#029329)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
640.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Dermacare cream
	Diary No. Date of R& I & fee	Dy.No. 4139 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Silver sulfadiazine……..10mg
	Pharmacological Group	Topical antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20gm,25gm,30gm,50gm/As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Silvadene 1% cream of M/s King Pharms LLC approved USFDA
	Me-too Status	030940: Flamoff 1% Cream Contains:- M/s Valor Pharmaceuticals, 124/A, Kahuta Road, Islamabad
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved.	
641.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Glovate cream 0.05% w/w
	Diary No. Date of R& I & fee	Dy.No. 4109 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Clobetasol propionate…0.5mg (0.05%w/w)
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20gm,30gm,50gm/As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ClobaDerm 500 micrograms/g Cream by Auden Mckenzie (Pharma Division) Ltd. MHRA approved
	Me-too Status	Clobevate cream by Stiefel Laboratories
	GMP Status	New section

	Remarks of the Evaluator.	
	Decision: Approved.	
642.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Megent-g cream
	Diary No. Date of R& I & fee	Dy.No. 4119 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Betamethasone(as dipropionate)……. 0.5mg Gentamicin (as sulphate)…… 1.0mg
	Pharmacological Group	Topical corticosteroid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	10gm, 15gm & 30gm /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diprogenta cream by MSD (Germany Approved)
	Me-too Status	Effigenta by mass Pharma
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
643.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Megent-g ointment
	Diary No. Date of R& I & fee	Dy.No. 4118 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Betamethasone(as dipropionate)……. 0.5mg Gentamicin (as sulphate)…… 1.0mg
	Pharmacological Group	Topical corticosteroid
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	10gm, 15gm & 30gm /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Diprogenta ointment by MSD (Germany Approved)
	Me-too Status	Effigenta ointment by mass Pharma
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
644.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Cosmo gel
	Diary No. Date of R& I & fee	Dy.No. 4071 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Isotretinoin….. 0.5mg
	Pharmacological Group	Vitamin A derivative, Retinoid
	Type of Form	Form-5
	Finished Product Specification	BP spec.
	Pack Size & Demanded Price	5gm,10gm,15gm /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ISOTREX 0.05% w/w GEL by M/s Stiefel Laboratories, Inc. (MHRA Approved)
	Me-too Status	Isotrex Gel 0.05% by M/s GSK (Reg#015717)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved.	

645.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Dermin gel
	Diary No. Date of R& I & fee	Dy.No. 4401 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Clindamycin Phosphate….. 12mg (1.2%w/w) Tretinoin …….. 0.25mg (0.025%w/w)
	Pharmacological Group	Antibiotic , Retinoids
	Type of Form	Form-5
	Finished Product Specification	Masfa specs
	Pack Size & Demanded Price	10gm,15gm,20,gm,30gm/As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Clindamycin phosphate and tretinoin gel by Actavis (USFDA Approved)
	Me-too Status	Acnicot Gel by M/s Nabiqasim (Reg#080660)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	
646.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form + Strength	Terbina cream
	Diary No. Date of R& I & fee	Dy.No. 4112 dated: 05-03-2019 Rs.20,000/
	Composition	Each gm contains: Terbinafine Hcl ….10mg (1%w/w)
	Pharmacological Group	Anti-fungal
	Type of Form	Form-5
	Finished Product Specification	JP
	Pack Size & Demanded Price	10gm,20gm,30gm /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	LAMISIL® 1% CREAM (terbinafine hydrochloride) Mhra approved
	Me-too Status	Terbiaim cream by Aims Pharmaceuticals
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved.	
SACHET SECTION 06 Products/ 05 Molecules		
647.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form +Strength	Lyte sachet
	Diary No. Date of R& I & fee	Dy.No. 4117 dated: 05-03-2019 Rs.20,000/
	Composition	Each sachet contains Rice powder masfa ……6gm Sodium Chloride …… 0.35gm Potassium Chloride …..0.3gm Sodium Citrate ……. 0.58gm
	Pharmacological Group	Electrolyte solution
	Type of Form	Form-5
	Finished Product Specification	Masfa specs
	Pack Size & Demanded Price	1*10 & 1*20 /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	MHRA Approved
	Me-too Status	Hilyte-R Sachet by M/s Hilton. (Reg.# 073733)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification.	

648.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form +Strength	Mecta 3gm sachet
	Diary No. Date of R& I & fee	Dy.No. 4075 dated: 05-03-2019 Rs.20,000/
	Composition	Each sachet contains: Dioctahedral smectite…….3gm
	Pharmacological Group	Antidiarrhoeal
	Type of Form	Form-5
	Finished Product Specification	Masfa specs
	Pack Size & Demanded Price	1*30's /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	Smecta 3 g powder for oral suspension in sachet by M/s Ipsen Pharma (ANSM approved)
	Me-too Status	Diosecta 3g sachet by M/s Woodwards Pharma (R#061111)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: **Approved with innovator's specification.**	
649.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form +Strength	Newsol sachet
	Diary No. Date of R& I & fee	Dy.No. 4074 dated: 05-03-2019 Rs.20,000/
	Composition	Each Sachet contains Anhydrous Glucose…….13.5g Tri sodium citrate Dihydrate……..2.9g Sodium Chloride……2.6g Potassium Chloride……..1.5g
	Pharmacological Group	Oral rehydration solution
	Type of Form	Form-5
	Finished Product Specification	IP
	Pack Size & Demanded Price	1*10 & 1*20 /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	WHO Approved formulation
	Me-too Status	Orsol Sachet by M/s Kaizan (Reg#073897)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: **Approved.**	
650.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form +Strength	Monkast sachet
	Diary No. Date of R& I & fee	Dy.No. 4111 dated: 05-03-2019 Rs.20,000/
	Composition	Each sachet powder contain Montelukast sodium eq.to montelukast acid 4mg
	Pharmacological Group	Mucolytic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1*14 & 1*28 /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	a) MHRA Approved
	Me-too Status	Singulair 4mg Oral Granules by Merck (Reg# 031377)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: **Approved.**	

651.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form +Strength	Mezole insta 20 sachet
	Diary No. Date of R& I & fee	Dy.No. 4116 dated: 05-03-2019 Rs.20,000/
	Composition	Each sachet contain Omeprazole…….20mg sod.bicarbonate……..1680mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1*10 & 1*20 /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ZEGERID Powder for Oral Suspension by M/s Santarus, Inc. (USFDA Approved)
	Me-too Status	Ruling+ 20mg/1680mg powders by M/s High-Q. (Reg#070634)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: **Approved.**	
652.	Name and address of manufacturer / Applicant	M/s Masfa Industries (Pvt) Ltd. 17km Sheikhupura road, Lahore
	Brand Name +Dosage Form +Strength	Mezole insta 40 sachet
	Diary No. Date of R& I & fee	Dy.No. 4073 dated: 05-03-2019 Rs.20,000/
	Composition	Each sachet contain Omeprazole……40mg sod.bicarbonate……1680mg
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1*10 & 1*20 /As per SRO
	Approval Status of Product in Reference Regulatory Authorities	ZEGERID Powder for Oral Suspension by M/s Santarus, Inc. (USFDA Approved)
	Me-too Status	RULING+ 40mg/1680mg powders by M/s High-Q. (Reg#070633)
	GMP Status	New section
	Remarks of the Evaluator.	
	Decision: **Approved.**	

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.

Injectable Section (Cephalosporin)
05 Molecules 10 Products

653.	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	Cefmark 250mg I.V Dry Powder Injection
	Composition	Each Vial Contains Ceftriaxone Sodium eq to Ceftriaxone ……..250mg
	Diary No. Date of R&I &fee	Dy. No. 8439 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Ceftriaxone 250mg (IV). US-FDA approved
	Me-too status	Palzon 250mg I.V Injection Palpex Pharmaceuticals (Pvt) Ltd, Karachi
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 047030) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
654.	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	Cefmark 1gm I.V Dry Powder Injection
	Composition	Each Vial Contains Ceftriaxone Sodium eq to Ceftriaxone ……..1gm
	Diary No. Date of R&I &fee	Dy. No. 8451 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Rocephin Injection by Roche (**MHRA** Approved)
	Me-too status	Palzon 1gm I.V Injection Palpex Pharmaceuticals (Pvt) Ltd, Karachi
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved .The earlier registration (Reg. 047032) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
655.	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	Markxim 250mg Dry Powder Injection
	Composition	Each Vial Contains Cefotaxime Sodium eq to Cefotaxime……250mg
	Diary No. Date of R&I &fee	Dy. No. 8446 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Claforan 250mg Injection by Sanofi Aventis (**Netherland** Approved)
	Me-too status	Palfotax 250mg Injection Palpex Pharmaceuticals (Pvt) Ltd, Karachi
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 047033) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
656.	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	Markxim 1gm Dry Powder Injection
	Composition	Each Vial Contains Cefotaxime Sodium eq to Cefotaxime……1gm
	Diary No. Date of R&I &fee	Dy. No. 8447 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Cefotaxime Injection (**MHRA** Approved)
	Me-too status	Palfotax 1gm Injection Palpex Pharmaceuticals (Pvt) Ltd, Karachi
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 047035) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
657.	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	Rifodime 250mg Dry Powder Injection
	Composition	Each Vial Contains Ceftazidime pentahydrate eq to Ceftazidime……250mg
	Diary No. Date of R&I &fee	Dy. No. 8455 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Fortum 250 mg Dry Powder Injection M/s GlaxoSmithKline UK (MHRA Approved)
	Me-too status	Panacef Injection 250mg M/s CCL Laboratories
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 047036) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
658.	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	Rifodime 1gm Dry Powder Injection
	Composition	Each Vial Contains Ceftazidime pentahydrate eq to Ceftazidime……1gm
	Diary No. Date of R&I &fee	Dy. No. 8454 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Fortum 1gm Dry Powder Injection M/s GlaxoSmithKline UK (MHRA Approved)
	Me-too status	Astedime injection 1gm M/s Astellas Pharmaceuticals,
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 047038) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
659.	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	Markpime 500mg Dry Powder Injection
	Composition	Each Vial Contains Cefepime Hydrochloride eq to Cefepime……500mg
	Diary No. Date of R&I &fee	Dy. No. 8452 21/02/2019, PKR 20,000/=
	Pharmacological Group	4th Generation Cephalosporin Antibiotics
	Type of Form	Form – 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Cefipime hydrochloride 500mg Injection M/s Hospira, Inc. (USFDA approved)
	Me-too status	Uspime 500mg Injection Usawa Pharmaceuicals
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved .The earlier registration (Reg. 047039) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
660.	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	Markpime 1gm Dry Powder Injection
	Composition	Each Vial Contains Cefepime Hydrochloride eq to Cefepime……1gm
	Diary No. Date of R&I &fee	Dy. No. 8453 21/02/2019, PKR 20,000/=
	Pharmacological Group	4th Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Cefipime hydrochloride 1gm Injection M/s Hospira, Inc. (USFDA approved)
	Me-too status	Uspime 1gm Injection Usawa Pharmaceuicals
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 047040) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
661.	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	Cefbisul 2gm Dry Powder Injection
	Composition	Each Vial Contains Cefoperazone Sodium ….1000mg Sulbactam Sodium ……1000mg
	Diary No. Date of R&I &fee	Dy. No. 8443 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporins Antibiotics with Beta-lactamase inhibitors
	Type of Form	Form – 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Sulperazon Injection Pfizer Inc. PMDA Approved
	Me-too status	2SUM Injection 2gm Sami Pharmaceuticals (Pvt) Ltd.
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 058531) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
662.	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	Cefbisul 1gm Dry Powder Injection
	Composition	Each Vial Contains Cefoperazone Sodium ….500mg Sulbactam Sodium ……..500mg

	Diary No. Date of R&I &fee	Dy. No. 8444 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporins Antibiotics with Beta-lactamase inhibitors
	Type of Form	Form – 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Sulperazon Injection Pfizer Inc. PMDA Approved
	Me-too status	Ectafin Injection 1gm Hi-Medic Pharmaceuticals (Pvt) Ltd.
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
Dry Syrup Section (Cephalosporin) 05 Molecules 10 Products		
663.	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	C – Mark 100mg Dry Powder for Suspension
	Composition	Each 5ml Contains: Cefixime Trihydrate eq. to Cefixime……100mg
	Diary No. Date of R&I &fee	Dy. No. 8448 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	SUPRAX 100mg/5ml Dry Powder Suspension Lupin Ltd. (FDA) Approved. USA
	Me-too status	Cefspan 100mg/5ml Dry Powder Suspension Barrett Hodgson Pharma (Pvt) Ltd
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved. The earlier registration (Reg. 047041) of firm's product shall stand cancelled due to none extension of contract manufacturing.**	
664.	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	C – Mark 200mg Dry Powder for Suspension
	Composition	Each 5ml Contains: Cefixime Trihydrate eq. to Cefixime……200mg
	Diary No. Date of R&I &fee	Dy. No. 8449 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	SUPRAX 200mg/5ml Dry Powder Suspension Lupin Ltd. (FDA) Approved. USA
	Me-too status	PALXIME DS 200mg /5ml Dry Powder Suspension Palpex Pharmaceuticals (Pvt) Ltd, Karachi
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
665.	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	C – Clor 125mg Dry Powder for Suspension

	Composition	Each 5ml Contains: Cefaclor Monohydrate eq: to Cefaclor ……125mg
	Diary No. Date of R&I &fee	Dy. No. 8459 21/02/2019, PKR 20,000/=
	Pharmacological Group	2nd Generation Cephalosporin
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Cefaclor 125mg/5ml Suspension M/s Strides Pharma UK Ltd (MHRA approved)
	Me-too status	Sac-Lor 125mg/5ml Dry Suspension M/s Semos Pharma
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
666.	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	C – Clor 250mg Dry Powder for Suspension
	Composition	Each 5ml Contains: Cefaclor Monohydrate eq: to Cefaclor ……250mg
	Diary No. Date of R&I &fee	Dy. No. 8458 21/02/2019, PKR 20,000/=
	Pharmacological Group	2nd Generation Cephalosporin
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Cefaclor 250mg/5ml Suspension M/s Strides Pharma UK Ltd (MHRA approved)
	Me-too status	Sac-Lor 250mg/5ml Dry Suspension M/s Semos Pharma
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
667.	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	C – Clor 50mg Dry Powder for Oral Drops
	Composition	Each ml Contains: Cefaclor Monohydrate eq: to Cefaclor ……50mg
	Diary No. Date of R&I &fee	Dy. No. 8457 21/02/2019, PKR 20,000/=
	Pharmacological Group	2nd Generation Cephalosporin
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Cefaclor for Oral Suspension 50mg/5ml Yung Shin Pharmaceutical Ind. Co., Ltd. Taiwan (FDA Approved)
	Me-too status	Ceclor Drops 50mg/1ml Eli Lilly Pakistan
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
668.	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	M – UROX 250mg/5ml Dry Powder Suspension
	Composition	Each 5ml Contains Cefuroxime Axetil eq to Cefuroxime ……250mg
	Diary No. Date of R&I &fee	Dy. No. 8465 21/02/2019, PKR 20,000/=

	Pharmacological Group	2nd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	ZINNAT 250 mg /5ml Dry Powder Suspension Glaxo Wellcome Stockley Park West Uxbridge, Middlesex UB 11, 1BT UK Limited
	Me-too status	ZINNAT 250 mg /5ml Dry Powder Suspension M/s GSK Pakistan
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
669.	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	Mednir 125mg Dry Powder For Suspension
	Composition	Each 5 ml Contains: Cefdinir ……..125 mg
	Diary No. Date of R&I &fee	Dy. No. 8464 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Cefdinir 125mg/5ml powder for Suspension M/s Lupin LTD (USFDA approved)
	Me-too status	Zefnir 125mg/5ml dry Suspension M/s Genome Pharmaceuticals
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
670.	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	Mednir 50mg Dry Powder for Oral Drops
	Composition	Each ml Contains: Cefdinir ……50mg
	Diary No. Date of R&I &fee	Dy. No. 8473 21/02/2019, PKR 20,000/=
	Pharmacological Group	3rd Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	CEFDINIR 50 mg / 5ml Dry Powder Suspension SANDOZ EMC Approved EUROPE
	Me-too status	DINACOR 50 mg Dry Powder Suspension HILTON Pharmaceuticals (Pvt) Ltd Karachi Pakistan
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
671.	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	Medroxi 125mg Dry Powder For Suspension
	Composition	Each 5 ml Contains: Cefadroxil Monohydrate eq: to Cefadroxil ….125 mg
	Diary No. Date of R&I &fee	Dy. No. 8475 21/02/2019, PKR 20,000/=
	Pharmacological Group	1st Generation Cephalosporin Antibiotics
	Type of Form	Form – 5

	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	ORACEFAL 125 mg / 5 ml powder for oral suspension M/sBristol - Myers Squibb (ANSM Approved)
	Me-too status	Evacef Suspension 125mg/5ml M/s Highnoon Laboratories, Lahore
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	
672.	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	Medroxi 250mg Dry Powder For Suspension
	Composition	Each 5 ml Contains: Cefadroxil Monohydrate eq: to Cefadroxil ….250 mg
	Diary No. Date of R&I &fee	Dy. No. 8466 21/02/2019, PKR 20,000/=
	Pharmacological Group	1st Generation Cephalosporin Antibiotics
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	ORACEFAL 250 mg / 5 ml powder for oral suspension M/sBristol - Myers Squibb (ANSM Approved)
	Me-too status	Evacef Suspension 250mg/5ml M/s Highnoon Laboratories, Lahore
	GMP status	
	Remarks of the Evaluator	
	Decision: **Approved.**	

The firm has been granted with NEW Section (dry powder injection, Ceph) vide letter no.F.2-8/93-Lic (Vol-III) dated 25th June, 2019.
The firm has applied for:
Number of products: 30
Number of molecule/formulations: 10

673.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Time 250mg Injection (IV)
	Composition	Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone..... 250mg
	Diary No. Date of R& I & fee	Dy.No.8722 dated 27/02/2019Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Rocephin by M/s Hoffman LA Roche, USFDA approved
	Me-too status	Cefxone 250mg Injection Reg: No. 017656 of M/s BOSCH PHARMACEUTICAL, Karachi
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
674.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Time 500mg Injection (IV)
	Composition	Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone.....500mg

	Diary No. Date of R& I & fee	Dy.No.8723 dated 27/2/2019 Rs.20,000/- 26.2.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Rocephin by M/s Hoffman LA Roche, USFDA approved
	Me-too status	Cefxone 500mg Injection Reg: No. 017657 of M/s BOSCH PHARMACEUTICAL, Karachi
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
675.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Time 1g Injection (IV)
	Composition	Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone.....1g
	Diary No. Date of R& I & fee	Dy. No. 8724 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: priceas per SRO
	Approval status of product in Reference Regulatory Authority	Rocephin by M/s Hoffman LA Roche, USFDA approved
	Me-too status	Cefxone 1g Injection Reg: No. 017739 of M/s BOSCH PHARMACEUTICAL, Karachi
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
676.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Time 2g Injection (IV)
	Composition	Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone.....2g
	Diary No. Date of R& I & fee	Dy. No. 8725 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Rocephin by M/s Hoffman LA Roche, USFDA approved
	Me-too status	Cefxone 2g Injection Reg: No. 055913 of M/s BOSCH PHARMACEUTICAL, Karachi
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	

677.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cefron 250mg Injection
	Composition	Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime.....250mg
	Diary No. Date of R& I & fee	Dy. No. 8728 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	CEFOTAXIMA NORMON 250 mg POWDER AND SOLVENT FOR SOLUTION INJECTABLE IV EFG. CIMA approved
	Me-too status	Claforan 250mg Injection Reg: No. 006056 of M/s Sanofi Aventis
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
678.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cefron 500mg Injection
	Composition	Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime.....500mg
	Diary No. Date of R& I & fee	Dy. No. 8726 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's:
	Approval status of product in Reference Regulatory Authority	Cefotaxime by M/s Fresenius Kabi USA, USFDA Approved
	Me-too status	Claforan 500mg Injection Reg: No. 006057 of M/s Sanofi Aventis
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
679.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cefron 1g Injection
	Composition	Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime.....1g
	Diary No. Date of R& I & fee	Dy. No. 8729 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefotaxime by M/s Fresenius Kabi USA, USFDA Approved
	Me-too status	Claforan 1g Injection Reg: No. 006058 Sanofi Aventis

	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
680.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cefron 2g Injection
	Composition	Each Vial Contains: Cefotaxime Sodium eq. to Cefotaxime.....2g
	Diary No. Date of R& I & fee	Dy. No. 8727 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefotaxime by M/s Fresenius Kabi USA, USFDA Approved
	Me-too status	Claforan 2g Injection Reg: No. 076156 Sanofi Aventis
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
681.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Fort-M 250mg Injection
	Composition	Each Vial Contains: Ceftazidime Pentahydrate eq. to Ceftazidime.....250mg
	Diary No. Date of R& I & fee	Dy. No. 8719 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	MHRA approved
	Me-too status	Cefcom 250mg Injection R# 025965 Barrett Hodgson
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
682.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Fort-M 500mg Injection
	Composition	Each Vial Contains: Ceftazidime Pentahydrate eq. to Ceftazidime.....500mg
	Diary No. Date of R& I & fee	Dy. No. 8720 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Tezicef by Ms/ Hospira, USFDA Approved

	Me-too status	Cefcom 500mg Injection Reg: No. 025966 Barrett Hodgson
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
683.	Name and address of manufacturer / Applicant	"Amros Pharmaceuticals" A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Fort-M 1g Injection
	Composition	Each Vial Contains: Ceftazidime Pentahydrate eq. to Ceftazidime.....1g
	Diary No. Date of R& I & fee	Dy. No. 8721 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Tezicef by Ms/ Hospira, USFDA Approved
	Me-too status	Cefcom 1g Injection Reg: No. 025967 Barrett Hodgson
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
684.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Magnes 500mg Injection
	Composition	Each vial contains: Cefoperazone sodium eq.to Cefoperazone..... 250mg Sulbactum Sodium eq. Sulbactum …….....250 mg
	Diary No. Date of R& I & fee	Dy. No 8703 dated 27/02/2019 Rs.20,000/- 26-02-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	1's as per policy
	Approval status of product in Reference Regulatory Authority	
	Me-too status	
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	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**	
685.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Magnes 1g Injection
	Composition	Each vial contains: Cefoperazone sodium eq.to Cefoperazone..... 500 mg Sulbactum Sodium eq.to Sulbactum .....500 mg

	Diary No. Date of R& I & fee	Dy. No. 8701 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	1's:
	Approval status of product in Reference Regulatory Authority	PMDA Japan Approved
	Me-too status	Cebac Injection 1gm by M/s Bosch (Reg#037630)
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
686.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Magnes 2g Injection
	Composition	Each vial contains: Cefoperazone sodium eq.to Cefoperazone..... 1000 mg Sulbactum Sodium eq.to Sulbactum .....1000 mg
	Diary No. Date of R& I & fee	Dy. No. 8700 dated 27/02/2019 Rs.20,000/- 26-2-2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	1's: Price as per policy
	Approval status of product in Reference Regulatory Authority	Approved in Europe (Poland, Slovakia, Czech Republic) by EMA
	Me-too status	Cebac Injection 2gm by M/s Bosch (Reg#037631)
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
687.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Magnes 3g Injection
	Composition	Each vial contains: Cefoperazone sodium eq.to Cefoperazone..... 2000 mg Sulbactum Sodium eq.to Sulbactum .....1000 mg
	Diary No. Date of R& I & fee	Dy.# 8702 dated 27/2/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	JP
	Pack size & Demanded Price	1's:
	Approval status of product in Reference Regulatory Authority	Cannot be confirmed
	Me-too status	Not Available
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	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**	

688.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cpime 500mg Injection
	Composition	Each vial contains: Cefepime HCl eq. to Cefepime (with L-Arginine).....500mg
	Diary No. Date of R& I & fee	Dy. No. 8717 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Maxipime by M/s Hospria INC, USFDA Approved
	Me-too status	Maxipime 500mg Injection Reg: No. 025548 of M/s GSK
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
689.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cpime 1g Injection
	Composition	Each vial contains: Cefepime HCl eq. to Cefepime (with L-Arginine).....1g
	Diary No. Date of R& I & fee	Dy. No. 8718 dated 27/07/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Maxipime by M/s Hospria INC, USFDA Approved
	Me-too status	Maxipime 1g Injection Reg: No. 025549 Bristol by M/s GSK
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
690.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Volvocef 250mg Injection
	Composition	Each vial contains: Cephradine with Sterile Arginine eq. to Cephradine.....250mg
	Diary No. Date of R& I & fee	Dy. No. 8715 dated 27/07/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's:
	Approval status of product in Reference Regulatory Authority	Cannot be confirmed
	Me-too status	Velosef 250mg Injection Reg: No. 001870 Bristol Myer Squib Pakistan/GSK.

	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
691.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Volvocef 500mg Injection
	Composition	Each vial contains: Cephradine with Sterile Arginine eq. to Cephradine.....500mg
	Diary No. Date of R& I & fee	Dy. No. 8716 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1‘s:
	Approval status of product in Reference Regulatory Authority	Cannot be confirmed
	Me-too status	Velosef Injection Reg: No. 001866 Bristol Myer Squib Pakistan/GSK
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
692.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Volvocef 1g Injection
	Composition	Each vial contains: Cephradine with Sterile Arginine eq. to Cephradine.....1g
	Diary No. Date of R& I & fee	Dy. No. 8714 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1‘s:
	Approval status of product in Reference Regulatory Authority	Approved in National Agency for the Safety of Medicine and Health Products (ANSM), France
	Me-too status	Cannot be confirmed
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
693.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Ancef 250mg Injection
	Composition	Each vial contains: Cefuroxime sodium eq. to Cefuroxime….. 250mg
	Diary No. Date of R& I & fee	Dy.No.8712 dated 27/2/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic

	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefuroxime by M/s Villerton invest USA, MHRA Approved
	Me-too status	Zinacef 250mg Injection Reg: No. 006221 GSK
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved.	
694.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Ancef 750mg Injection
	Composition	Each vial contains: Cefuroxime sodium eq. to Cefuroxime……. 750mg
	Diary No. Date of R& I & fee	Dy. No. 8711 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: Price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefuroxime by M/s Flynn Pharma ltd, MHRA Approved
	Me-too status	Zinacef 750mg Injection Reg: No. 006222 GSK
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved.	
695.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Ancef 1.5g Injection
	Composition	Each vial contains: Cefuroxime sodium eq. to Cefuroxime…….. 1.5g
	Diary No. Date of R& I & fee	Dy. No. 8713 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefuroxime by M/s Flynn Pharma ltd, MHRA Approved
	Me-too status	Zinacef 750mg Injection Reg: No. 022104 of M/s GSK
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved.	
696.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cafizox 250mg Injection
	Composition	Each vial contains: Ceftizoxime sodium eq. to Ceftizoxime .....250 mg
	Diary No. Date of R& I & fee	Dy.No.8704 dated 27/2/2019 Rs.20,000/- 26.2.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5

	Finished product Specification	USP specifications
	Pack size & Demanded Price	1‘s: as per SRO
	Approval status of product in Reference Regulatory Authority	Cannot be confirmed
	Me-too status	Zoxi 250mg Injection Reg: No. 039105 Linz Pharmaceuticals
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
697.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cafizox 500mg Injection
	Composition	Each vial contains: Ceftizoxime sodium eq. to Ceftizoxime 500mg
	Diary No. Date of R& I & fee	Dy. No. 8705 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1‘s:
	Approval status of product in Reference Regulatory Authority	Cannot be confirmed
	Me-too status	Zoxi 500mg Injection Reg: No. 039106 Linz Pharmaceuticals
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	
698.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Cafizox 1g Injection
	Composition	Each vial contains: Ceftizoxime sodium eq. to Ceftizoxime 1g
	Diary No. Date of R& I & fee	Dy.# 8706 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1‘s:
	Approval status of product in Reference Regulatory Authority	Cannot be confirmed
	Me-too status	Zoxi 1g Injection Reg: No. 039107 Linz Pharmaceuticals
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies could not be confirmed.
	Decision: Deferred for Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board	

699.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Kafzol 500mg Injection
	Composition	Each vial contains: Cefazolin sodium equivalent to Cefazolin…….500mg
	Diary No. Date of R& I & fee	Dy. No. 8709 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1‘s: price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefazolin by M/s Sandoz, USFDA Approved
	Me-too status	Zafacain 500mg Injection Reg: No. 047441 Zafa Pharmaceutical
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved.	
700.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Kafzol 1g Injection
	Composition	Each vial contains: Cefazolin sodium equivalent to Cefazolin…….1g
	Diary No. Date of R& I & fee	Dy. No. 8710 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1‘s:
	Approval status of product in Reference Regulatory Authority	Cefazolin by M/s Sandoz, USFDA Approved
	Me-too status	Zafacain 1g Injection Reg: No. 047442 Zafa Pharmaceutical
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved.	
701.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Rome 500mg Injection (IV)
	Composition	Each vial contains: Cefepirome sulfate e.q to Cefpirome……..500 mg
	Diary No. Date of R& I & fee	Dy. No. 8707 dated 27/02/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator’s specifications
	Pack size & Demanded Price	1‘s: price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefrom Injection, ANSM (France) Approved
	Me-too status	Cefrom 500mg Injection Reg: No. 021123 Sanofi Aventis
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.

	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	
702.	Name and address of manufacturer / Applicant	M/s Amros Pharmaceuticals, A-96, S.I.T.E. Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	Rome 1g Injection (IV)
	Composition	Each vial contains: Cefepirome sulfate e.q to Cefpirome……..1g
	Diary No. Date of R& I & fee	Dy. No. 8708 dated 27/07/2019 Rs.20,000/- 26.02.2019
	Pharmacological Group	Cephelosporin Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	1's: price as per SRO
	Approval status of product in Reference Regulatory Authority	Cefrom Injection, ANSM (France) Approved
	Me-too status	Cefrom 1g Injection Reg: No. 021124 Sanofi Aventis
	GMP status	Last inspection report dated 18/07/2018 confirms the current compliance level as Good.
	Remarks of the Evaluator	
	Decision: Approved with change of brand name.	

Evaluator PEC-VIII

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

a. New cases

703.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Velotin Tablet 40mg
	Composition	"Each film coated tablet contains: Valsartan…40mg"
	Diary No. Date of R& I & fee	Dy. No. 21249 dated 13-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Dilval 40mg Tablet of Martin Dow Ltd
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved.	
704.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Velotin Tablet 80mg
	Composition	"Each film coated tablet contains: Valsartan…80mg"
	Diary No. Date of R& I & fee	Dy. No. 21250 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC

	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Velcard 80mg Tablet of M/s Paramount Pharmaceutical.
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved.	
705.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Oltrix Capsule 40mg
	Composition	"Each capsule contains: Omeprazole…40mg" (Enteric coated pellets) Source: Vision Pharmaceuticals
	Diary No. Date of R& I & fee	Dy. No. 21244 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Leprozim Capsules 40mg of Wisdom Pharmaceuticals
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved.	
706.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Pixzol 20mg/1100mg Capsule
	Composition	"Each capsule contains: Omeprazole…20mg Sodium bicarbonate…1100mg"
	Diary No. Date of R& I & fee	Dy. No.21245 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Proton Pump Inhibitors/Ant acid
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	ZoltarInsta 20mg Capsule of Pharmevo Karachi
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Decision: Approved.	
707.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Pixzol 40mg/1100mg Capsule
	Composition	"Each capsule contains: Omeprazole…40mg Sodium bicarbonate…1100mg"

	Diary No. Date of R& I & fee	Dy.No.21246dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Proton Pump Inhibitors/Ant acid
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	ZoltarInsta 20mg Capsule of Pharmevo Karachi
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Decision: Approved as per Innovator's Specifications	
708.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Swismox 400mg/250ml Injection
	Composition	"Each Injection contains: Moxifloxacin(as hydrochloride)…400mg"
	Diary No. Date of R& I & fee	Dy.No. 24095 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Moximed 400mg /250ml Infusion OF Medimarker's Hyderabad.
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator	Section approval letter is required.
	Decision: Deferred for approval of required manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	
709.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Preaed 100mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…100mg"
	Diary No. Date of R& I & fee	Dy.No.24101 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Anticonvulsant Drug
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength/dosage form)	Nurica 100mg Capsule of Macter Int. Karachi
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per Innovator's Specifications.	

710.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Preaed 25mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…25mg"
	Diary No. Date of R& I & fee	Dy.No. 24098 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Anticonvulsant Drug
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Dygab 25mg Capsules of M/s. Dyson Research Laboratories (Pvt) Ltd,
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per Innovator's Specifications.	
711.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Preaed 150mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…150mg"
	Diary No. Date of R& I & fee	Dy.No.24102 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Anticonvulsant Drug
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Dygab 150mg Capsules of M/s. Dyson Research Laboratories (Pvt) Ltd,
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per Innovator's Specifications.	
712.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Ezom 20mg Capsule
	Composition	"Each Capsule contains: Esomeprazole…20mg"
	Diary No. Date of R& I & fee	Dy.No. 24096 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength/dosage form)	Eztomac Tablets 20mg of Webros Pharmaceuticals

	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable 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. • Reference product is approved as Esomeprazole (as magnesium tri-hydrate) 40mg capsule which is different from applied formulation i.e. Esomeprazole 40mg Capsule"submit master formulation after revision.
	Decision: Deferred for the following: • **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.** • **Reference product is approved as Esomeprazole (as magnesium tri-hydrate) 40mg capsule which is different from applied formulation i.e. Esomeprazole 40mg Capsule"submit master formulation after revision.**	
713.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Preaed 50mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…50mg"
	Diary No. Date of R& I & fee	Dy.No. 24099 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength/dosage form)	Nurica 50mg Capsule of Macter Int. Karachi
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per Innovator's Specifications.	
714.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Preaed 75mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…75mg"
	Diary No. Date of R& I & fee	Dy.No. 24100 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength/dosage form)	Nurica 75mg Capsule OF Macter Int. Karachi
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Decision: Approved as per Innovator's Specifications.	
715.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Ezom 40mg Capsule

	Composition	"Each Capsule contains: Esomeprazole…40mg"
	Diary No. Date of R& I & fee	Dy.No. 24097 dated 11-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Proton Pump Inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength/dosage form)	Eztomac Tablets 40mg of Webros Pharmaceuticals
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks o Evaluator	• COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions. • Reference product is approved as Esomeprazole (as magnesium tri-hydrate) 40mg capsule which is different from applied formulation i.e. Esomeprazole 40mg Capsule"submit master formulation after revision.
	Decision: Deferred for the following: • **COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.** • **Reference product is approved as Esomeprazole (as magnesium tri-hydrate) 40mg capsule which is different from applied formulation i.e. Esomeprazole 40mg Capsule"submit master formulation after revision.**	
716.	Name and address of manufacturer / Applicant	"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Water for injection
	Composition	"Each Ampoule Contains: Water for Injection…10ml"
	Diary No. Date of R& I & fee	Dy.No. 24094 dated 11-07-2018 Rs.20,000/- 11-07-2018
	Pharmacological Group	Diluent
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's, 5's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength/dosage form)	Water for Injection of Healthtek Karachi
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator	• Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same. • Mention type of primary packaging material of applied formulation whether it is type I, II or III. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/ manufacturing facility.
	Decision: Deferred for the following: • **Step of terminal sterilization has not been mentioned in manufacturing outline. Clarify or justify the same.** • **Mention type of primary packaging material of applied formulation whether it is type I, II or III.**	

	• **Approval of required manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/ manufacturing facility.**	
717.	**Name and address of manufacturer / Applicant**	**"M/s Swiss Pharmaceuticals Pvt Ltd. A-159, S.I.T.E Super Highway, Karachi, Pakistan"**
	Brand Name +Dosage Form + Strength	Preaed 300mg Capsule
	Composition	"Each Capsule Contains: Pregabalin…300mg"
	Diary No. Date of R& I & fee	Dy.No. 24103 dated 11-07-2018 Rs.20,000/- Dated 11-07-2018
	Pharmacological Group	Anti-epileptic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	14's, 28's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Nurica 300mg Capsule of Macter Int. Karachi
	GMP status	GMP Inspection conducted on 15-09-17 concluded that firm is operating at an acceptable level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per Innovator's Specifications.	
718.	Name and address of manufacturer / Applicant	"M/s Global Pharmaceuticals Pvt Ltd Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Globutol 400mg Tablet
	Composition	"Each Film Coated Tablet Contains: Ethambutol hydrochloride…400mg"
	Diary No. Date of R& I & fee	Dy.No.21049 dated 12-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Antimycobacterials
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in Health Canada
	Me-too status (with strength/dosage form)	Etham Tablets 400mg of M/s Pacific Pharma,
	GMP status	Conclusion: Inspection date: 11 & 24-10-2018.On the basis of findings, panel unanimously decided to recommend the issuance of GMP certificate.
	Remarks of Evaluator	
	Decision: Approved.	
719.	Name and address of manufacturer / Applicant	"M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad. **By:** M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Cef-X 400mg Capsule
	Composition	"Each Capsule Contains: Cefixime (as trihydrate)…400mg"
	Diary No. Date of R& I & fee	Dy.No.21096 dated 12-06-2018 Rs.50,000/- Dated 12-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5

	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	5's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength/dosage form)	Stlicef Capsules 400mg of Treat Pharma
	GMP status	M/s Max Pharmaceuticals: Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.

Remarks of Evaluator:

Remarks	**Response**
Submit latest GMP inspection report of Applicant.	GMP Inspection conducted on 05-06-2018 concluded that the M/s Karsons Pharmaceuticals is complying cGMP as of today. However compliance of the observations is advised to be submitted alongwith an action plan as on earliest.
Evidence of section approval of manufacturer.	Firm has submitted letter of CLB dated 22nd of June, 2011confirming approval of Capsule (cephalosporin) section in the name of M/s Max Pharmaceuticals:
Detail about number of sections & number of already approved contracts of applicant.	M/s Karsons Pharmaceuticals has submitted a Letter of CLB bearing No. F.1-9/2011-Lic, dated 13th of April, 2017 confirming approval of following four section in the name of firm: Tablet Section General Capsule Section (General) Cream/Ointment/Gel Section (General) Dry Powder For Suspension Section (General) Firm has further submitted that we have four approved sections but we don't have any approved contract.

Decision: Approved.

720.	Name and address of manufacturer / Applicant	"M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad **By:** M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Cef-X 200mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Cefixime(as trihydrate)…200mg"
	Diary No. Date of R& I & fee	Dy.No.21095 dated 12-06-2018 Rs.50,000/- 12-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	5's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength/dosage form)	F-Saf Plus 200mg Suspension of Saaaf Pharmaceuticals
	GMP status	M/s Max Pharmaceuticals: Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.

Remarks of Evaluator

Remarks	**Response**
Evidence of section approval of manufacturer.	Firm has submitted letter of CLB dated 22nd of June, 2011confirming approval of Dry Powder Suspension (cephalosporin) Section in the name of M/s Max Pharmaceuticals:

Decision: Approved.

721.	Name and address of manufacturer / Applicant	"M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad **By:** M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Cef-X 100mg/5ml Dry Suspension
	Composition	"Each 5ml Contains: Cefixime(as trihydrate)…100mg"
	Diary No. Date of R& I & fee	Dy.No.21094 dated 12-06-2018 Rs.50,000/- 12-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in EMA
	Me-too status (with strength/dosage form)	Stlicef Dry Suspension 100mg/5ml of Treat Pharma
	GMP status	M/s Max Pharmaceuticals: Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of evaluator :	

Remarks	**Response**
Evidence of section approval of manufacturer.	Firm has submitted letter of CLB dated 22nd of June, 2011confirming approval of Dry Powder Suspension (cephalosporin) Section in the name of M/s Max Pharmaceuticals:

Decision: Approved.

722.	Name and address of manufacturer / Applicant	"M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By: M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Tri-Zone 1000mg IV Injection
	Composition	"Each Vial Contains: Ceftriaxone (as sodium)…1000mg"
	Diary No. Date of R& I & fee	Dy.No.21099 dated 12-06-2018 Rs.50,000/- 12-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Rocephin 1 g I.V by Roche (Pak) Ltd.
	GMP status	M/s Max Pharmaceuticals: Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	

Remarks	**Response**
Evidence of section approval of manufacturer.	Firm has submitted letter of CLB dated 11th of April, 2018 confirming approval of Dry Powder for Injection (cephalosporin) Section in the name of M/s Max Pharmaceuticals:
Mention type of glass container for applied formulation.	Tri-Zone 1000mg IV Injection is preserve in tight, single dose glass containers, preferably of type I glass, & stored at controlled room temperature.

Decision: Approved.

723.	Name and address of manufacturer / Applicant	"M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By: M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Tri-Zone 500mg IV Injection
	Composition	"Each Vial Contains: Ceftriaxone as sodium…500mg"
	Diary No. Date of R& I & fee	Dy.No. 21098 dated 12-06-2018 Rs.50,000/- 12-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Signum 500mg Injection IV of Cherwel pharmaceuticals.
	GMP status	M/s Max Pharmaceuticals: Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	

Remarks	**Response**
Evidence of section approval of manufacturer.	Firm has submitted letter of CLB dated 11th of April, 2018 confirming approval of Dry Powder for Injection (cephalosporin) Section in the name of M/s Max Pharmaceuticals:
Mention type of glass container for applied formulation.	Tri-Zone 500mg IV Injection is preserve in tight, single dose glass containers, preferably of type I glass, & stored at controlled room temperature.

Decision: Approved.

724.	Name and address of manufacturer / Applicant	"M/s Karsons Pharmaceuticals. Plot No.1, Street No. SS-3, National Industrial Zone, Rawat, Islamabad By: M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name +Dosage Form + Strength	Tri-Zone 250mg IM Injection
	Composition	"Each Vial Contains: Ceftriaxone as sodium…250mg"
	Diary No. Date of R& I & fee	Dy.No.21097 dated 12-06-2018 Rs.50,000/- 12-06-2018
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Abex 250mg Injection IM of Semos Pharma
	GMP status	M/s Max Pharmaceuticals: Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks Of Evaluator	

Remarks	**Response**
Evidence of section approval of manufacturer.	Firm has submitted letter of CLB dated 11th of April, 2018 confirming approval of Dry Powder for Injection (cephalosporin) Section in the name of M/s Max Pharmaceuticals:
Mention type of glass	Tri-Zone 1000mg IV Injection is preserve in tight, single dose glass

	container for applied formulation.	containers, preferably of type I glass, & stored at controlled room temperature.
	Decision: Approved.	
725.	Name and address of manufacturer / Applicant	"M/s Ray Pharma PvT Ltd. S-58, S.I.T.E Karachi, Pakistan"
	Brand Name +Dosage Form + Strength	Loprost 15µg/ml Eye Drops
	Composition	"Each ml Contains: Latanoprost…15µg"
	Diary No. Date of R& I & fee	Dy.No. 21050 dated 12-06-2018 Rs.20,000/- Dated 12-06-2018
	Pharmacological Group	Prostaglandin analogues
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	2.5ml: Rs.450.0/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Latim Eye Drops 2.5ml of Macquin's Karachi Each ml contains: Latanoprost …..……0.05 mg
	GMP status	GMP Inspection conducted on 14-03-2018 concluded that firm is operating a good level of GMP compliance.
	Remarks Of Evaluator:	

Remarks	Response
Mention type of type primary packaging material for applied formulation.	LDPE Bottle
Clarification regarding method used for sterilization of applied formulation is required.	Filter sterilization

	Decision: Approved as per Innovator's Specifications.	
726.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name +Dosage Form + Strength	Neobeta 2.5mg Tablet
	Composition	"Each Tablet Contains: Nebivolol (as hydrochloride)…2.5mg"
	Diary No. Date of R& I & fee	Dy.No.21231 dated 13-06-2018 Rs.20,000/- 12-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	14's: Rs. 200/-
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Nebil 2.5mg Tablet of Getz Karachi
	GMP status	Panel inspection for renewal of DML conducted on 13-10-2017 recommended renewal of DML BEARING No.00616.
	Decision: Approved as per Innovator's Specifications.	
727.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name +Dosage Form + Strength	Neobeta 5mg Tablet
	Composition	"Each Tablet Contains: Nebivolvol (as hydrochloride)…5mg"
	Diary No. Date of R& I & fee	Dy.No. 21232 dated 13-06-2018 Rs.20,000/- 12-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5

	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	14's: Rs. 400/-
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength/dosage form)	Nebil 5mg Tablet of Getz Karachi
	GMP status	Panel inspection for renewal of DML conducted on 13-10-2017 recommended renewal of DML BEARING No.00616.
	Decision: Approved as per Innovator's Specifications.	
728.	Name and address of manufacturer / Applicant	"M/s Saffron Pharmaceuticals (Pvt) Ltd. 19 Km Sheikhupura Road, Faislabad"
	Brand Name +Dosage Form + Strength	Neobeta10mg Tablet
	Composition	"Each Tablet Contains: Nebivolvol (as hydrochloride)…10mg"
	Diary No. Date of R& I & fee	Dy.No.21233 dated 13-06-2018 Rs.20,000/- 12-06-2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	14's: Rs. 600/-
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength/dosage form)	Nebil 10mg Tablet of Getz Karachi
	GMP status	Panel inspection for renewal of DML conducted on 13-10-2017 recommended renewal of DML BEARING No.00616.
	Decision: Approved as per Innovator's Specifications.	
729.	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/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)

	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.**	
730.	Name and address of manufacturer / Applicant	"M/s Wilshire Laboratories Pvt Ltd. 124/1, Quaid-e-Azam Industrial Estate, KotLakhpat, Lahore"
	Brand Name +Dosage Form + Strength	Clomif 50mg Tablet
	Composition	"Each Tablet Contains: Clomiphene citrate…50mg"
	Diary No. Date of R& I & fee	Dy.No. 21256 dated 13-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Ovulatory Stimulants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20,s: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Clomidex Tablets 50 mg of CSH, Pharmaceuticals
	GMP status	GMP inspection conducted on 27-08-2018, & 05-10-2018 & 06-11-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved with USP Specifications.	
731.	Name and address of manufacturer / Applicant	"M/s Dr.Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Esoset 20mg Capsule
	Composition	"Each Capsule Contains: Esomeprazole (as magnesium trihydrate)… 20mg (Delayed Release Pellets) Source: Vision Pharmaceuticals
	Diary No. Date of R& I & fee	Dy.No. 21222 dated 13-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's: Rs. 170/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Sanamidol Capsules 20 Of Swiss Pharmaceutical Pvt Karachi
	GMP status	GMP inspection conducted on January 24th, 2019 concluded that firm is operating at satisfactory level of GMP compliance
	Remarks of Evaluator	
	Decision: Approved.	
732.	Name and address of manufacturer / Applicant	"M/s Dr.Raza Pharma. Road B-4, Plot No. 44-C, Industrial Estate, Hayatabad, Peshawar"
	Brand Name +Dosage Form + Strength	Esoset40mg Capsule
	Composition	"Each Capsule Contains: Esomeprazole (as magnesium trihydrate)… 40mg (Delayed Release Pellets) Source: Vision Pharmaceuticals
	Diary No. Date of R& I & fee	Dy.No.21223 dated 13-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished product Specifications	USP Specifications

	Pack size & Demanded Price	14's: Rs. 152/- or As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Sold Capsule 40mg of M/s Regal Pharmaceuticals.
	GMP status	GMP inspection conducted on January 24th, 2019 concluded that firm is operating at satisfactory level of GMP compliance
	Remarks of Evaluator	
	Decision: Approved.	
733.	Name and address of manufacturer / Applicant	"M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad"
	Brand Name +Dosage Form + Strength	Olsar 40mg Tablet
	Composition	"Each Film Coated Tablet Contains: Olmesartan medoxomil…40mg"
	Diary No. Date of R& I & fee	Dy.No.21229 dated 13-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10's, 14's,28's, 56's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Olmeday tablets 40mg of Werrick Pharmaceuticals
	GMP status	Panel inspection for renewal of DML conducted on 26-07-2018 recommended grant of renewal of DML by way of formulation for following sections: Tablet section general Tablet section general antibiotics Liquid syrup section
	Remarks of Evaluator	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
734.	Name and address of manufacturer / Applicant	"M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad"
	Brand Name +Dosage Form + Strength	Olsar 20mg Tablet
	Composition	"Each Film Coated Tablet Contains: Olmesartan medoxomil…20mg"
	Diary No. Date of R& I & fee	Dy.No.21228 dated 13-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10's, 14's,28's, 56's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Olmeday tablets 20mg of Werrick Pharmaceuticals
	GMP status	Panel inspection for renewal of DML conducted on 26-07-2018 recommended grant of renewal of DML by way of formulation for following sections: Tablet section general Tablet section general antibiotics Liquid syrup section
	Remarks of Evaluator	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	

735.	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	Iro-Lex Capsule 150mg
	Composition	"Each hard gelatin capsule contains: Iron Polysaccharide Complex eq to Elemental Iron…150mg"
	Diary No. Date of R& I & fee	Dy.No.21657 dated 20-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Hematinic
	Type of Form	Form-5
	Finished product Specifications	As per innovator's Specifications
	Pack size & Demanded Price	30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	IFEREX 150 - polysaccharide-iron complex capsule by M/s Nnodum Pharmaceuticals (DailyMED) .
	Me-too status (with strength and dosage form)	Ferricure 150mg Capsule by S.J & G FazulEllahie, Karachi.(Reg#050637)
	GMP status	GMP inspection conducted on 16-03-2017 concluded that firm is operating at good level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved as per Innovator's Specifications.	
736.	Name and address of manufacturer / Applicant	"M/s AGP Limited. B-23, C, S.I.T.E. Karachi"
	Brand Name +Dosage Form + Strength	Pirfeb 200mg Tablet
	Composition	"Each film coated tablet contains: Pirfenidone…200mg"
	Diary No. Date of R& I & fee	Dy.No. 23810 dated 10-07-2018 Rs.20,000/- 08-07-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	30's: Rs. 822/-
	Approval status of product in Reference Regulatory Authorities	Approved in Japan & India (as provided by the firm)
	Me-too status (with strength/dosage form)	Pirfenex tablet of highnoon Laboratories (as provided by firm)
	GMP status	GMP Inspection conducted on 7th May, 2018 concluded that overall GMP of plant was noted good.
	Remarks of Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Mention type of primary packaging material. • In labeling you have mentioned BP specifications for Pirfenidone, provide evidence of its BP monograph
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared / approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable.** • **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 evidence is not verifiable or otherwise submit Application alongwith stability studies & requisite Form.** • **Mention type of primary packaging material for applied formulation.** • **In labeling you have mentioned BP specifications for Pirfenidone, provide evidence of its BP monograph.**	

737.	Name and address of manufacturer / Applicant	"M/s AGP Limited. B-23, C, S.I.T.E. Karachi"
	Brand Name +Dosage Form + Strength	Vilza 50mg Tablet
	Composition	"Each tablet contains: Vildagliptin…50mg"
	Diary No. Date of R& I & fee	Dy.No. 23809 dated 10-07-2018 Rs.20,000/- 09-07-2018
	Pharmacological Group	Oral hypoglycemic agent (Dipeptidyl peptidase 4 (DPP-4) inhibitors)
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	28's: Rs. 2,112/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Galvus Tablets 50mg Of Novartis Pharma
	GMP status	GMP Inspection conducted on 7th May, 2018 concluded that overall GMP of plant was noted good.
	Remarks of Evaluator	
	Decision: Approved as per Innovator's Specifications.	
738.	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	Cholesrol 20mg capsule
	Composition	"Each capsule contains: Fluvastatin(as sodium)…20mg"
	Diary No. Date of R& I & fee	Dy.No. 23826 dated 10-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	28's : As per SRO or Rs. 849.55/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Farmastin Capsules 20mg of Farmaceutics Int. Karachi
	GMP status	GMP Inspection conducted on 08-02-18 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	
	Decision: Approved.	
739.	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	Cholesrol 40mg capsule
	Composition	"Each capsule contains: Fluvastatin (as sodium)…40mg"
	Diary No. Date of R& I & fee	Dy.No. 23827 dated 10-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	28's : As per SRO or Rs. 1699.03/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Liproscot-F Capsule 40mg of Scotmann Pharmaceuticals
	GMP status	GMP Inspection conducted on 08-02-18 concluded that firm is operating at satisfactory level of GMP compliance.

	Remarks of Evaluator	
	Decision: Approved.	
740.	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	Cholesvel 10mg Tablet
	Composition	"Each tablet contains: Lercanidipine(as hydrochloride) …10mg"
	Diary No. Date of R& I & fee	Dy.No. 23824 dated 10-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Selective Calcium Channel Blockers With Mainly Vascular Effects
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	10's : As per SRO or Rs.140.53/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	GMP Inspection conducted on 08-02-18 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of evaluator	One tablet contains 10 mg of lercanidipine hydrochloride, which is equivalent to 9.4 mg of lercanidipine.
	Decision: Deferred for the following: • **For evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, Or otherwise submission of application alongwith stability studies & requisite Form.** • **For correction of applied formulation "Lercanidipine (as hydrochloride) 10mg Tablet" in line with reference product i.e. "Lercanidipine hydrochloride 10mg Tablet.**	
741.	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	Cholesvel 20mg Tablet
	Composition	"Each tablet contains: Lercanidipine(as hydrochloride)…20mg"
	Diary No. Date of R& I & fee	Dy.No. 23812 dated 10-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Selective Calcium Channel Blockers With Mainly Vascular Effects
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	10's : As per SRO or Rs.140.53/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	Could not be confirmed
	GMP status	GMP Inspection conducted on 08-02-18 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	One tablet contains 20 mg of lercanidipine hydrochloride, which is equivalent to 18.8 mg of lercanidipine.
	Decision: Deferred for the following: • **For evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, Or otherwise submission of application alongwith stability studies & requisite Form.** • **For correction of applied formulation "Lercanidipine (as hydrochloride) 20mg Tablet" in line with reference product i.e. "Lercanidipine hydrochloride 20mg Tablet.**	

742.	Name and address of manufacturer / Applicant	"M/s Trison Research Labs 27-A, Punjab Small Industries Estate, Sargodha"
	Brand Name +Dosage Form + Strength	Trizid 600mg Tablet
	Composition	"Each film coated tablet contains: Linezolid…600mg"
	Diary No. Date of R& I & fee	Dy.No. 23812 dated 10-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	10's: As per SRO or Rs.200/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	LinzolTablet 600 mg of M/s Regal Pharmaceuticals,
	GMP status	Panel inspection conducted on 22-08-2017 & 12-10-2017 recommended grant of renewal of DML by the way of formulation for following sections: General tablet section. General capsule section General dry Powder suspension section.
	Decision: Registration Board decided to approve applied drug product as per Innovator's specifications & with a condition that manufacturer shall use Linezolid polymorphic form II to keep applied formulation in-line with innovator Product.	
743.	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	Aloc-D tablet
	Composition	"Each film coated tablet contains: Fexofenadine hydrochloride…60mg Pseudoephedrine hydrochloride(as extended release)…120mg"
	Diary No. Date of R& I & fee	Dy.No. 24091 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Second-Generation Antihistamine/Sympathomimetic Drug
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	10's : As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in TGA(bilayer tablet)(EXPORT ONLY) However, applicant has provided sehat .com photocopy as evidence.
	Me-too status (with strength/dosage form)	Fexofin –D Tablets of Bio-Labs (Pvt) Ltd.
	GMP status	GMP Inspection conducted on 19-07-17 concluded that firm is operating at good level of GMP compliance.
	Remarks of Evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable & submit master formulation & manufacturing method in line with reference product.. • Evidence of purchase of required manufacturing equipment i.e tablet bilayer machine.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as from provided evidence extended release of Pseudoephedrine hydrochloride is not verifiable & submit master formulation & manufacturing method in line with reference product.**	

	• **Evidence of purchase of required manufacturing equipment.**	
744.	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	Tyladol CF
	Composition	"Each 5ml contains: Paracetomol…80mg Pseudoephedrine hydrochloride…15mg Chlorpheniramine maleate…1mg"
	Diary No. Date of R& I & fee	Dy.No. 24093 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Analgesic, antipyretic/sympathomimetic drug/First-Generation Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturers Specifications
	Pack size & Demanded Price	60ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	Reltus C&F of Pharmatech Pakistan (as provided by the firm)
	GMP status	GMP Inspection conducted on 19-07-17 concluded that firm is operating at good level of GMP compliance.
	Remarks of evaluator	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm. • Mention type of primary packaging material for applied formulation.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm as provided evidence is not verifiable.** • **Mention type of primary packaging material for applied formulation.**	
745.	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	Tyladol CF tablet
	Composition	"Each tablet contains: Paracetomol…600mg Pseudoephedrine hydrochloride…60mg Chlorpheniramine maleate…4mg"
	Diary No. Date of R& I & fee	Dy. No 24092 dated 11-07-2018 Rs.20,000/- 10-07-2018
	Pharmacological Group	Analgesic, antipyretic/ sympathomimetic drug/ First-Generation Antihistamine
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	50's: as per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status (with strength and dosage form)	Registration Number 024908 Local/Imported

		Local Brand Name Reltus C&F Tablets Composition / Generic Paracetamol BP.....600mg Pseudoephedrine Hcl BP.60mg Chlorpheniramine Maleate BP.4mg Manufacturer Name Pharmatec Pakistan (Pvt) Ltd, Manufacturer Address D-86/A, S.I.T.E, Karachi-75700
	GMP status	GMP Inspection conducted on 19-07-17 concluded that firm is operating at good level of GMP compliance.
	Remarks of 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 the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
746.	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	Tacrim Ointment 0.1%
	Composition	"Each gram contains: Tacrolimus (as monohydrate)… 1mg
	Diary No. Date of R& I & fee	Dy.No. 23977 dated 11-07-2018 Rs.20,000/- 27-06-2018
	Pharmacological Group	Immunosuppressant
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10gm,30gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength/dosage form)	Aimus Ointment of Aims Pharmaceuticals
	GMP status	GMP Inspection conducted on 08-7-2019 & 25-7-2019 concluded that firm was operating at satisfactory level of GMP compliance.
	Remarks of evaluator	
	Decision: Approved as per innovator's specifications.	
747.	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	Micona H Cream 2%
	Composition	"Each gram contains: Miconazole nitrate…20mg Hydrocortisone…. 10mg"
	Diary No. Date of R& I & fee	Dy.No. 23973 dated 11-07-2018 Rs.20,000/- 28-06-2018
	Pharmacological Group	Antifungal /Corticosteroid
	Type of Form	Form-5
	Finished product Specifications	BP Specifications
	Pack size & Demanded Price	10gm, 15gm: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA(EMC)
	Me-too status (with strength/dosage form)	Microalcort Cream of Elko Karachi
	GMP status	GMP Inspection conducted on 08-07-2019 & 25-07-2019 concluded that firm was operating at satisfactory level of GMP

		compliance.
	Decision: Approved as per innovator's specifications.	
748.	Name and address of manufacturer / Applicant	"M/s Hicon Pharmaceuticals. 131-Industrial Estate, Hayatbad"
	Brand Name +Dosage Form + Strength	Olsar 10mg Tablet
	Composition	"Each Film Coated Tablet Contains: Olmesartan Medoxomil…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21227 dated 13-06-2018 Rs.20,000/- 13-06-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10's, 14's,28's, 56's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA(emc)
	Me-too status (with strength/dosage form)	Oscord 10mg Tablet of Hilton Pharma (Pvt.) Limited Karachi
	GMP status	Panel inspection for renewal of DML conducted on 26-07-2018 recommended grant of renewal of DML by way of formulation for following sections: Tablet section general Tablet section general antibiotics Liquid syrup section
	Remarks of Evaluator	
	Decision: Approved with Japanese Pharmacopoeia Specifications.	
749.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Zitek 30mg Tablet
	Composition	"Each Modified Release Tablet Contains: Gliclazide…30mg"
	Diary No. Date of R& I & fee	Dy.No. 21086 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Oral hypoglycemic
	Type of Form	Form-5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10's,20's,14's,28's, 30's, 56's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Glinext 30mg of M/s. Novamed 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:

Remarks	Response
Applied formulation is a modified release tablet but it does not contain any ingredient for modified release, clarify/justify.	-----
Submit master formulation & manufacturing method in-line with innovator.	------
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	Firm has submitted letter of CLB bearing No. No. F.-20/99-Lic(Vol-I) dated 21st of February,2018 confirming approval of Tablet General Section (revised) in the

	facility.	name of M/s Innvotek Pharmaceuticals.
	Decision: Registration Board decided to defer the case for clarification regarding modified release polymer/ingredient & submission of master formulation & manufacturing method for applied formulation in line with innovator product.	
750.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Foril 15/850 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone (as hydrochloride)…15mg Metformin hydrochloride…850mg"
	Diary No. Date of R& I & fee	Dy.No. 21085 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Oral hypoglycemic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's, 28,s, 10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	PioGet-M 15mg/850mg Tablet of Platinum 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
	Decision: Approved.	
751.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Foril 15/500 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Pioglitazone (as hydrochloride)…15mg Metformin hydrochloride…500mg"
	Diary No. Date of R& I & fee	Dy.No. 21084 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Oral hypoglycemic
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	14's, 28,s, 10's, 20's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength/dosage form)	Glet Tablet 15/500mg of Brookes 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.	
752.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Zitek 60mg Tablet
	Composition	"Each Modified Release Tablet Contains: Gliclazide…60mg"

	Diary No. Date of R& I & fee	Dy.No. 21087 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Oral hypoglycemic
	Type of Form	Form-5
	Finished product Specifications	BP specifications
	Pack size & Demanded Price	10's,20's,14's,28's, 30's, 56's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Glinext 60mg of M/s. Novamed 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

Remarks	Response
Applied formulation is a modified release tablet but it does not contain any ingredient for modified release, clarify/justify.	-----
Submit master formulation & manufacturing method in-line with innovator.	------
Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	Firm has submitted letter of CLB bearing No. No. F.-20/99-Lic(Vol-I) dated 21st of February,2018 confirming approval of Tablet General Section (revised) in the name of M/s Innvotek Pharmaceuticals.

Decision: Registration Board decided to defer the case for clarification regarding modified release polymer/ingredient & submission of master formulation & manufacturing method for applied formulation in line with innovator product.

753.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Paglin 0.5mg Tablet
	Composition	"Each Tablet Contains: Repaglinide…0.5mg"
	Diary No. Date of R& I & fee	Dy.No. 21088 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10's,20's,30's, 50's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Repag 0.5mg Tablet of Getz Pharma
	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

Remarks	Response
Reference product in approved as uncoated tablet but you have applied with coating. Submit master formulation & manufacturing method either in-line with reference product along with requisite fee or	Applicant has submitted fee challan of Rupee 5000/- dated 27-08-2019 for revision of formulation from film coated to uncoated tablet and Revised master

	evidence of approval of applied drug product as coated tablet.	formulation & manufacturing method.
	Decision: Approved.	
754.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Paglin 1mg Tablet
	Composition	"Each Tablet Contains: Repaglinide…1mg"
	Diary No. Date of R& I & fee	Dy.No. 21089 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10's,20's,30's, 50's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Repag 1mg Tablet of Getz Pharma
	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	

Remarks	**Response**
Reference product in approved as uncoated tablet but you have applied with coating. Submit master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet.	Applicant has submitted fee challan of Rupee 5000/- dated 27-08-2019 for revision of formulation from film coated to uncoated tablet and Revised master formulation & manufacturing method

	Decision: Approved.	
755.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Paglin 2mg Tablet
	Composition	"Each Tablet Contains: Repaglinide…2mg"
	Diary No. Date of R& I & fee	Dy.No. 21090 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Blood glucose lowering drugs
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10's,20's,30's, 50's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength/dosage form)	Repag 2mg Tablet of Getz Pharma
	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	

Remarks	**Response**
Reference product in approved as uncoated	Applicant has submitted fee challan of

	tablet but you have applied with coating. Submit master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet.	Rupee 5000/- dated 27-08-2019 for revision of formulation from film coated to uncoated tablet and Revised master formulation & manufacturing method	
	Decision: Approved.		

756.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Anamont 10mg Chewable Tablet
	Composition	"Each film coated Tablet Contains: Montelukast (as sodium)…10mg"
	Diary No. Date of R& I & fee	Dy.No. 21083 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	Leukotriene receptor antagonists
	Type of Form	Form-5
	Finished product Specifications	USP specifications
	Pack size & Demanded Price	10's,20's,30's, 50's: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status (with strength and dosage form)	MonteNovex 10mg Tablet of M/s Herbion Pakistan.
	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:

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.	Applicant has submitted fee challan of Rupee 5000/- dated 27-08-2019 for revision of formulation from chewable tablet to film coated and Revised master formulation & manufacturing method. Is it required fee for this revision?

Decision: Approved.

757.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Aceril-H 2.5/12.5 mg Tablet
	Composition	"Each Tablet Contains: Ramipril…2.5mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No. 21091 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	ACE inhibitors/Thiazide diuretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	14's,28's,20's,20's,30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in EMA
	Me-too status (with strength and dosage form)	Ramy Plus 2.5/12.5 Tablet of Getz Pharma (Pvt) Ltd, 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: **Remarks** / **Response** Reference product in approved as uncoated tablet but you have applied with coating. Submit master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet. / Applicant has submitted fee challan of Rupee 5000/- dated 27-08-2019 for revision of formulation from film coated to uncoated tablet and Revised master formulation & manufacturing method	
	Decision: Approved as per innovator's specification.	
758.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Aceril-H 5/12.5 mg Tablet
	Composition	"Each Tablet Contains: Ramipril…5mg Hydrochlorothiazide…12.5mg"
	Diary No. Date of R& I & fee	Dy.No.21092 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	ACE inhibitors/ Thiazide diuretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	14's,28's,20's,20's,30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in EMA
	Me-too status (with strength and dosage form)	Ramy Plus 5/12.5 Tablet of Getz Pharma (Pvt) Ltd, 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 **Remarks** / **Response** Reference product in approved as uncoated tablet but you have applied with coating. Submit master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet. / Applicant has submitted fee challan of Rupee 5000/- dated 27-08-2019 for revision of formulation from film coated to uncoated tablet and Revised master formulation & manufacturing method	
	Decision: Approved as per innovator's specification.	
759.	Name and address of manufacturer / Applicant	"M/s Innvotek Pharmaceuticals. 35-Industrial Triangle, Kahuta Road, Islamabad"
	Brand Name +Dosage Form + Strength	Aceril-H 5/25 mg Tablet
	Composition	"Each Tablet Contains: Ramipril…5mg Hydrochlorothiazide…25mg"
	Diary No. Date of R& I & fee	Dy.No.21093 dated 12-06-2018 Rs.20,000/- 11-06-2018
	Pharmacological Group	ACE inhibitors/ Thiazide diuretic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specification
	Pack size & Demanded Price	14's, 28's, 20's, 20's, 30's: As per SRO

	Approval status of product in Reference Regulatory Authorities	Approved in EMA
	Me-too status (with strength/dosage form)	Ramy Plus 5/25 Tablet of Getz Pharma (Pvt) Ltd, 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:	

Remarks	**Response**
Reference product in approved as uncoated tablet but you have applied with coating. Submit master formulation & manufacturing method either in-line with reference product along with requisite fee or evidence of approval of applied drug product as coated tablet.	Applicant has submitted fee challan of Rupee 5000/- dated 27-08-2019 for revision of formulation from ilm coated to uncoated tablet and Revised master formulation & manufacturing method.

Decision: Approved as per innovator's specification.

760.	Name and address of manufacturer / Applicant	M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab.
	Brand Name +Dosage Form + Strength	Clofen 50mg Tablet
	Composition	"Each Tablet Contains: Clomiphene citrate…50mg"
	Diary No. Date of R& I & fee	Dy.No. 5549 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018
	Pharmacological Group	Ovulatory Stimulants
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 100,s: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status (with strength and dosage form)	Clomidex Tablets 50 mg of CSH, Pharmaceuticals
	GMP status	GMP inspection conducted on 26-05- 2017, concluded that firm was GMP Compliant at the time of inspection.
	Remarks of Evaluator:	

Remarks	**Response**
5 % overage is added in master formulation.	Applicant has submitted master formulation without overage

Decision: Approved with USP Specifications.

761.	Name and address of manufacturer / Applicant	M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab.
	Brand Name +Dosage Form + Strength	Aceclo 100mg Tablet
	Composition	"Each film coated tablet contains: Aceclofenac…100mg"
	Diary No. Date of R& I & fee	Dy.No 5548 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 30's, 100,s: As per PRC
	Approval status of product in Reference	Approved in MHRA

	Regulatory Authorities	
	Me-too status (with strength and dosage form)	Rumanac 100mg Tablet OF Noahemis Karachi
	GMP status	GMP inspection conducted on 26-05- 2017, concluded that firm was GMP Compliant at the time of inspection.
	Remarks of Evaluator: **Remarks** / **Response** 5 % overage is added in master formulation. / Applicant has submitted master formulation without overage	
	Decision: Approved with USP Specifications.	
762.	Name and address of manufacturer / Applicant	M/s Pharma Lord (Pvt) Ltd, 12 KM, Lahore Raod, Layyah, Punjab.
	Brand Name +Dosage Form + Strength	Flubri 100mg Tablet
	Composition	"Each film coated tablet contains: Flurbiprofen…100mg"
	Diary No. Date of R& I & fee	Dy.No. 5547 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specifications	USP Specifications
	Pack size & Demanded Price	10's, 30's, 100,s: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Novacid 100 mg Tablets of Novae Pharmaceuticals
	GMP status	GMP inspection conducted on 26-05- 2017, concluded that firm was GMP Compliant at the time of inspection.
	Remarks of Evaluator: **Remarks** / **Response** 5 % overage is added in master formulation. / Applicant has submitted master formulation without overage	
	Decision: Approved with USP Specifications.	
763.	Name and address of Manufacturer / Applicant	M/s Winthrox Laboratories, K-219-A, SITE, Superhighway, Phase-II, Karachi.
	Brand Name + Dosage Form + Strength	Janvia Tablet 50mg/1000mg
	Composition	Each film coated tablet contains: Sitagliptin (as phosphate monohydrate)…50mg Metformin hydrochloride…. 1000mg
	Diary No. Date of R&I & fee	Duplicate Dossier
	Pharmacological Group	Anti-Diabetic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Registration Number 059952 Local/Imported Local Brand Name Janumet 1gm Tablets Composition / Generic Sitagliptin……50mgMetformin……..1000mg

		Manufacturer Name WilshireLaboratories(Pvt)Ltd; Manufacturer Address 124/1 Industrial Estate, KotLakhpat, Lahore.
	GMP status	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year.
	Remarks of Evaluator	
	Decision: Approved as per innovator's specification.	
764.	Name and address of Manufacturer / Applicant	M/s Winthrox Laboratories, K-219-A, SITE, Superhighway, Phase-II, Karachi.
	Brand Name + Dosage Form + Strength	Nitewin 60mg Tablets
	Composition	"Each film coated Tablet Contains: Dapoxetine as hydrochloride…60mg"
	Diary No. Date of R&I & fee	Duplicate Dossier
	Pharmacological Group	Genito urinary system and sex hormones
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	10's : Rs. 850/-
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Could not be confirmed
	GMP status	Certificate of cGMP is issued to the firm based on inspection conducted on 16-08-2018 & is valid for a period of one year.
	Remarks of Evaluator	
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
765.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Velotin Tablet 160mg
	Composition	"Each film coated tablet contains: Valsartan…160mg"
	Diary No. Date of R& I & fee	Dy. No. 21251 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status (with strength and dosage form)	Velcard 160mg Tablet of M/s Paramount Pharmaceutical
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator	

Remarks	**Response**
Submit outline of manufacturing method, because under this heading you have submitted instructions.	Applicant has submitted outline of manufacturing method.

	Decision: Approved.	
766.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Velotin Tablet 320mg

	Composition	"Each film coated tablet contains: Valsartan…320mg"
	Diary No. Date of R& I & fee	Dy. No. 21252 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form-5
	Finished product Specifications	USP Specification
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in TGA
	Me-too status (with strength and dosage form)	Valtec High 320mg Tablet of Tabros Karachi.
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator: **Remarks** / **Response** Submit outline of manufacturing method, because under this heading you have submitted instructions. / Applicant has submitted outline of manufacturing method.	
	Decision: Approved.	
767.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Urocon Tablet 5mg
	Composition	"Each film coated tablet contains: Solifenacin Succinate…5mg"
	Diary No. Date of R& I & fee	Dy. No. 21248 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	Type of Form	Form-5
	Finished product Specifications	Manufacturer Specifications
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status (with strength and dosage form)	Solfin Tablet 5 mg of M/s Regal Pharmaceuticals
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator **Remarks** / **Response** Submit outline of manufacturing method, because under this heading you have submitted instructions. / Applicant has submitted outline of manufacturing method.	
	Decision: Approved as per innovator's specification.	
768.	Name and address of manufacturer / Applicant	"M/s. Nawan Laboratories (Pvt) Ltd. 136 sector 15 Korangi Industrial Area Karachi."
	Brand Name +Dosage Form + Strength	Urocon Tablet 10mg
	Composition	"Each film coated tablet contains: Solifenacin Succinate…10mg"
	Diary No. Date of R& I & fee	Dy. No. 21247 dated 13-06-2018 Rs.20,000/- Dated 13-06-2018
	Pharmacological Group	Drugs for urinary frequency and incontinence
	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 USFDA
	Me-too status (with strength and dosage form)	Solfin Tablet 10 mg of M/s Regal Pharmaceuticals
	GMP status	GMP Inspection conducted on 30-04-2018 concluded that firm is operating at satisfactory level of GMP compliance.
	Remarks of Evaluator:	

Remarks	**Response**
Submit outline of manufacturing method, because under this heading you have submitted instructions.	Applicant has submitted outline of manufacturing method.

Decision: Approved as per innovator's specification.

b. Deferred cases

769.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quid-e-azam Industrial Estate, KotLakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Namsal Injection 0.009g/ml
	Diary No. Date of R& I & fee	Diary No: 9434: 20-07-17; Rs: 20,000/-
	Composition	Each ml contains: Sodium Chloride…. 0.009gm
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	40ml,50ml,100ml ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Flow NS IV Infusion Injectable of Mediflow (100ml)
	GMP status	GMP inspection conducted on 18-05-2017 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Separate application for each volume. Mention type of primary packaging material. (Applicant has selected the filled volume "100ml" & type I glass as container closure system).
	Previous Decision	Registration Board in its 283rd meeting deferred the case for the following: Deferred for confirmation whether manufacturing facility of Liquid injectables is approved for " Small Volume Parenterals" or " Large Volume Parenterals"

Evaluation by PEC:

Firm has replied as follow:

Please note that we already hold registration of our different liquid injections with different pack sizes including 1ml, 3ml, 50ml,100ml, 250ml, 300ml, for your ready reference following documents are attached:

- Approval of our liquid Injection section.
- Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml.
- Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size.
- Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size.
- Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size.
- Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size.

Sr.#	Reply of the Firm	Evaluation by PEC:
1	Approval of our liquid Injection section.	Applicant has submitted photocopy of Letter of CLB bearing a number No.F.1-65/84- Lic(Vol-II) (M-227)
2	Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml.	Applicant has submitted Photocopy of Registration Letter dated 16th of March 2004, for Adios Injection (100ml), Neumo Injection (100ml), Quash Injection (50ml, 100ml).
3	Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size.	Firm has submitted Photocopy of Registration Letter dated 09th of May 2017, for Palzic Injection (250ml).
4	Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size.	Firm has submitted Photocopy of Registration Letter dated 08th of January 2018, for Volinza Injection (300ml).
5	Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size.	Firm has submitted Photocopy of Registration Letter dated 24th of October 2017, for Zwitter Injection (3ml).
6	Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size.	Firm has submitted Photocopy of Registration Letter dated 18th of August 2011, for Zyster Injection (1ml).

Previous Decision:
Registration board in its 289th meeting decided as follow:
Registration Board decided to defer the case for clarification regarding approval of required manufacturing facility & equipment for applied drug product from Licensing Divisions.

Evaluation By PEC:
Firm has submitted panel inspection report for grant of additional sections of dry powder injection(cephalosporin), Liquid injection(general), Powder Injection(general) & injectable (Psychotropic), wherein it was stated that the firm has also provided a double door dry heat sterilizer for sterilization of glass vials & ampoules for their liquid injectable preparations.

Decision: Approved with USP Specifications.

770.		
	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quid-e-azam Industrial Estate, KotLakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Namsal Injection 0.009g/ml
	Diary No. Date of R& I & fee	Diary No: 9432: 20-07-17; Rs: 20,000/-
	Composition	Each ml contains: Sodium Chloride…. 0.009gm
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	2ml,5ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Engsol Injection 0.90% w/v of English pharma(5ml)
	GMP status	GMP inspection conducted on 18-05-2017 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Separate application for each applied volume. Mention type of primary packaging material. (Applicant has selected the filled volume "5ml" & type I glass as container closure system).

	Previous Decision	Registration Board in its 283rd meeting deferred the case for the following: Deferred for confirmation whether manufacturing facility of Liquid injectables is approved for " Small Volume Parenterals" or " Large Volume Parenterals"
	Evaluation by PEC: Firm has replied as follow: Please note that we already hold registration of our different liquid injections with different pack sizes including 1ml, 3ml, 50ml,100ml, 250ml, 300ml, for your ready reference following documents are attached: • Approval of our liquid Injection section. • Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml. • Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size. • Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size. • Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size. • Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size.	
	Previous Decision: Registration board in its 289th meeting decided as follow: Registration Board decided to defer the case for clarification regarding approval of required manufacturing facility & equipment for applied drug product from Licensing Divisions.	
	Evaluation By PEC: Firm has submitted panel inspection report for grant of additional sections of dry powder injection(cephalosporin), Liquid injection(general), Powder Injection(general) & injectable (Psychotropic), wherein it was stated that the firm has also provided a double door dry heat sterilizer for sterilization of glass vials & ampoules for their liquid injectable preparations.	
	Decision: Approved with USP Specifications.	
771.	Name and address of manufacturer / Applicant	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quid-e-azam Industrial Estate, KotLakhpat, Lahore.
	Brand Name +Dosage Form + Strength	Namsal Injection 0.009g/ml
	Diary No. Date of R& I & fee	Diary No: 9433: 20-07-17; Rs: 20,000/-
	Composition	Each ml contains: Sodium Chloride…. 0.009gm
	Pharmacological Group	Electrolyte
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	10ml,20ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Engsol Injection 0.90% w/v of English Pharma(10ml)
	GMP status	GMP inspection conducted on 18-05-2017 with conclusive remarks that firm is operating at satisfactory level of GMP compliance.
	Remarks of the Evaluator.	Separate application for each applied volume. Mention type of primary packaging material. (Applicant has selected the filled volume "10ml" & type I glass as container closure system).
	Previous Decision	Registration Board in its 283rd meeting deferred the case for the following: Deferred for confirmation whether manufacturing facility of Liquid injectables is approved for " Small Volume Parenterals" or " Large Volume Parenterals"

	Evaluation by PEC: Firm has replied as follow: Please note that we already hold registration of our different liquid injections with different pack sizes including 1ml, 3ml, 50ml,100ml, 250ml, 300ml, for your ready reference following documents are attached: • Approval of our liquid Injection section. • Registration letter issued by Ministry of Health for our products (Adios, Neumo, & Quash) with pack sizes of 100ml & 50ml. • Registration Letter issued by DRAP for our product Palzic Injection with 250ml pack size. • Registration Letter issued by DRAP for our Product Volinza Injection with 300ml pack size. • Registration Letter issued by DRAP for our Product Zwitter Injection with 3ml pack size. • Registration Letter issued by DRAP for our Product Xyster Injection with 1ml pack size	
	Previous Decision: Registration board in its 289th meeting decided as follow: Registration Board decided to defer the case for clarification regarding approval of required manufacturing facility & equipment for applied drug product from Licensing Divisions.	
	Evaluation By PEC: Firm has submitted panel inspection report for grant of additional sections of dry powder injection(cephalosporin), Liquid injection(general), Powder Injection(general) & injectable (Psychotropic), wherein it was stated that the firm has also provided a double door dry heat sterilizer for sterilization of glass vials & ampoules for their liquid injectable preparations.	
	Decision: Approved with USP Specifications.	
772.	Name and address of Manufacturer / Applicant	M/s Ameer& Adnan Pharmaceuticals, Raiwind Road, Lahore.
	Brand Name +Dosage Form +Strength	Adospa Injection 20mg/ml
	Composition	Each ml contains: Drotaverin hydrochloride…20mg
	Diary No. Date of R&I & fee	DyNo.473; 12-03-2015; Rs. 20,000/-
	Pharmacological Group	Anesthetic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack Size & Demanded Price	(2ml); As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Spastop 40mg/2ml of City Pharma, Karachi
	GMP status	GMP inspection conducted on 05-01-2018 with conclusive remarks that firm has maintained conformance to cGMP in the manufacturing and quality control operations on the day of inspection.
	Remarks of Evaluator	Registration Board in its 284th decided as follow: Evidence of approval of applied formulation in reference regulatory authorities/agencies in applied strength i.e. Drotaverin hydrochloride…40mg/2ml which were declared/approved by the Registration Board in its 275th meeting is required.
	Previous Decision	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies in applied strength i.e. Drotaverin hydrochloride…40mg/2ml which were declared/approved by the Registration Board in its 275th meeting is required.
	Evaluation by PEC	Following reference for drotaverine 40mg/2ml injection in three European countries along with reference weblink. 1. NO-SPA 40 mg solution for injection by Sanofi Aventis (OGYEI Hungary Approved)

		(Link:https://www.ogyei.gov.hu/gyogyszeradatbazis/index.php?action=show_details&item=11235) Date of access: 09-11-2018 2. NO-SPA 40 mg / 2 ml solution for injection by Sanofi Romania (NAMMD Romania Approved) (Link:https://www.anm.ro/_/_RCP/RCP_6973_10.10.14.pdf) Date of access: 09-11-2018 3. No-Spa 20 mg/ml solution for injection by Chinoin Pharmaceutical and Chemical Works Co. Ltd (Executive Agency For Medicinal Products, Bulgaria Approved) (Link:http://www.bda.bg/images/stories/documents/register/drugs/details/lf2120.htm) Date of access: 09-11-2018
	Decision: Approved as per innovator's specification.	

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

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

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

773.	Name and address of manufacturer/ Applicant	M/s. Macquin's International, Karachi
	Brand Name +Dosage Form+Strength	Ocu-Drozol Eye drop (5ml)
	Diary No. Date of R&I &fee	DiaryNo: duplicate dossier
	Composition	Each ml contains: Dorzolamide (as hydrochloride)….. 20mg Timolol (as maleate)…. 5mg
	Pharmacological Group	Anti-gluocoma
	Type of Form	Form-5
	Finished Product Specification	USP specification
	Pack size &Demanded Price	5ml : As Per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA
	Me-too status	Dorlol Dye Drops of Genix Karachi
	GMP status	GMP Inspection conducted on 29-01-2018 concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator.	Submit manufacturing method & master formulation
	Previous decision	Registration board in its 289th meeting decided as follow: Deferred for Submission of manufacturing method & master formulation for applied formulation.
	Evaluation by PEC	Applicant has submitted master formulation & manufacturing method for applied formulation.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
774.	Name and address of manufacturer/ Applicant	M/s Semos Pharmaceuticals, Plot # 11, Sector 12-A, North Karachi. 75850, Pakistan
	Brand Name +Dosage Form+Strength	Pyrol Forte Suspension
	Diary No. Date of R&I &fee	DyNo.9063; 18-07-2017; Rs. 20,000/-

	Composition	Each 5 ml contains: Paracetamol … 250mg
	Pharmacological Group	Anti-glaucoma
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specifications
	Pack size &Demanded Price	60ml,90ml,120ml,450ml; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Parasol Plus Suspension of Z-JANS Pharmaceuticals
	GMP status	GMP inspection conducted on 07-10-17 with conclusive remarks that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator.	Evidence of section approval is required.
	Previous decision	Registration board in its 284th meeting decided as follow: Deferred for evidence of required manufacturing facility for applied formulation.
	Evaluation by PEC	Applicant has submitted letter of CLB bearing number No. F-2-1/93-Lic(Vol-III) dated 14th of December 2015 confirming liquid syrup general section of M/s Semos Pharmaceuticals, Plot # 11, Sector 12-A, North Karachi. 75850, Pakistan
	Decision: Approved with Int. Ph. Specifications.	

775.	Name and address of manufacturer / Applicant	"M/s Genome Pharmaceuticals Pvt Ltd. Plot # 16/I-Phase IV, Industrial Estate, Hattar, KPK By Skims Pharmaceuticals, 10/B Value Addition city, Khurrianwala, Faisalabad"
	Brand Name +Dosage Form + Strength	Levetram 100mg Syrup
	Composition	"Each ml contains: Levetiracetam…100mg"
	Diary No. Date of R& I & fee	Dy.No 5522 dated 15-02-2018 Rs. 50,000/- Dated 15-02-2018
	Pharmacological Group	Antiepileptic
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Levixa 100mg/ml Oral Solution of High-Q Pharmaceuticals,
	GMP status	
	Remarks of the Evaluator	M/s. Skims Pharmaceuticals has submitted section approval letter for Oral Liquid General section. Type of Primary Packaging material.
	Previous decision	Registration Board in its 289th meeting deferred the case for the following: For clarification regarding Type of Primary Packaging material of applied drug product.
	Remarks of Evaluator	Applicant has submitted amber glass bottle as type of primary packaging material for applied formulation.
	Decision: Approved.	
776.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Toplan Injection 200mg
	Composition	"Each vial contains: Teicoplanin…200mg"
	Diary No. Date of R& I & fee	Dy No. 6188: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-biotic

	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Planin 200mg Injection of S.J &G. FazulEllahie, Karachi .
	GMP status	GMP Inspection conducted on 03-01-2018 concluded that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Type of primary packaging material
	Previous decision: Registration Board in its 289th meeting deferred the case for the following: • Mention type of primary packaging material for applied formulation. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying thesection/manufacturing facility.	
	Evaluation by PEC: Applicant has submitted following: • Applicant has submitted type I glass vial with bromobutyl rubber stopper & plastic flip-off top seal.	
	Decision: Deferred for evidence of approval of required section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	
777.	Name and address of manufacturer / Applicant	"M/s Zafa Pharmaceuticals Laboratories Private Limited. L1/B Block-22, Federal B industrial Area, Karachi"
	Brand Name +Dosage Form + Strength	Toplan Injection 400mg
	Composition	"Each vial contains: Teicoplanin…400mg"
	Diary No. Date of R& I & fee	Dy No. 6187: 20-02-18 ; Rs. 20,000
	Pharmacological Group	Anti-biotic
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	14's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Teicon Injection 400mg Of Al Habib Pharmacueticals Karachi
	GMP status	GMP Inspection conducted on 03-01-2018 concluded that firm is operating at good level of GMP compliance.
	Remarks of the Evaluator	• Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility. • Type of primary packaging material
	Previous decision: Registration Board in its 289th meeting deferred the case for the following: • Mention type of primary packaging material for applied formulation. • Approval of section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying thesection/manufacturing facility.	

	Evaluation by PEC: Applicant has submitted following: • Applicant has submitted type I glass vial with bromobutyl rubber stopper & plastic flip-off top seal.	
	Decision: Deferred for evidence of approval of required section/manufacturing facility by the Central Licensing Board. However, you may submit panel inspection report for renewal of DML verifying the section/manufacturing facility.	
778.	Name and address of manufacturer / Applicant	"M/s Bloom Pharmaceuticals Pvt Ltd. Plot # 30, Phase I & II, Industrial Estate, Hattar, Pakistan"
	Brand Name +Dosage Form + Strength	Blufen 200mg Suspension
	Composition	"Each 5ml contains: Ibuprofen…200mg"
	Diary No. Date of R& I & fee	Dy.No 5494 dated 15-02-2018 Rs. 20,000/- Dated 15-02-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	60ml, 90ml, 120ml: As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Brofanic DS Oral liquid suspension of M/s Regal Pharmaceuticals.
	GMP status	GMP Inspection conducted on 07-04-2018concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator	2% overage
	Previous Decision(M-289th RB):	Deferred for justification on scientific grounds regarding addition of 2% overage in master formulation.
	Evaluation by PEC	Applicant has submitted master formulation without overage.
	Decision: Approved.	
779.	Name and address of manufacturer / Applicant	"M/s Wilson's Pharmaceuticals. 387-388, I-9, Industrial Area, Islamabad"
	Brand Name +Dosage Form + Strength	Talergin-EB 20mg Tablets
	Composition	Each Film Coated Tablet Contains: Ebastine…20mg
	Diary No. Date of R& I & fee	Dy No. 6190: 19-02-18 ; Rs. 20,000
	Pharmacological Group	H1 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturers Specifications
	Pack size & Demanded Price	10's, 20's, 30's: As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Lobastin Tablet 20mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	Overall the firm was found to be operating at a very good level of CGMP Compliance at the time of inspection.
	Remarks of the Evaluator	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting, as the provided evidence is not verifiable.
	Previous Decision (M-289th)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275thmeeting.
	Evaluation by PEC	Applicant has submitted following: Applied formulation is approved in Sweden under the brand name Ebastin Orifarm 20 mg film-coated tablet.
	Decision: Approved with Japanese Pharmacopoeia specifications.	

780.	Name and address of Manufacturer / Applicant	M/s Searl Company Limited F-319 SITE Karachi.
	Brand Name +Dosage Form +Strength	C-Flexin tablet 250mg
	Composition	Each film coated tablet contains: Ciprofloxacin (as hydrochloride)… 250mg
	Diary No. Date of R&I & fee	DyNo.2920; 16-05-2017; Rs. 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Ciprobid tablet 250mg of Nova pharmaceuticals
	GMP status	GMO Certificate issued on 18-05-2018 with following sections: 1- Tablet (General) 2- Capsule (General) 3- Injectable (Liquid/Ampoule) 4- Oral Liquid Syrup(General) 5- Dry Powder sachet(General) 6- Liquid ORS(General) Conclusion: Overall the firm was operating under good level of CGMP.
	Remarks of Evaluator	
	Previous Decision	Registration Board in its 290th Meeting deferred the case for the following: For confirmation of same already registered product.
	Evaluation by PEC	Applicant The Searl Company Limited Karachi has submitted an undertaking that applied formulation is not registered with us before.
	Decision: Approved.	
781.	Name and address of Manufacturer / Applicant	M/s Searl Company Limited F-319 SITE Karachi.
	Brand Name +Dosage Form +Strength	C-Flexin tablet 500mg
	Composition	Each film coated tablet contains: Ciprofloxacin (as hydrochloride)… 500mg
	Diary No. Date of R&I & fee	DyNo.2919; 16-05-2017; Rs. 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Ciprobid tablet 500mg of Nova pharmaceuticals
	GMP status	Same as recorded above
	Remarks of Evaluator	
	Previous Decision	Registration Board in its 290th Meeting deferred the case for the following: For confirmation of same already registered product.
	Evaluation by PEC	Applicant The Searl Company Limited Karachi has submitted an undertaking that applied formulation is not registered with us before.
	Decision: Approved.	

782.	Name and address of Manufacturer / Applicant	M/s Searl Company Limited F-319 SITE Karachi.
	Brand Name +Dosage Form +Strength	C-Flexin tablet 750mg
	Composition	Each film coated tablet contains: Ciprofloxacin (as hydrochloride)… 750mg
	Diary No. Date of R&I & fee	DyNo.2917; 16-05-2017; Rs. 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer's Specification
	Pack Size & Demanded Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Ciprobid tablet 750mg of Nova pharmaceuticals
	GMP status	Same as recorded above
	Remarks of Evaluator	
	Previous Decision	Registration Board in its 290th Meeting deferred the case for the following: For confirmation of same already registered product.
	Evaluation by PEC	Applicant The Searl Company Limited Karachi has submitted an undertaking that applied formulation is not registered with us before.
	Decision: Approved.	
783.	Name and address of Manufacturer / Applicant	M/s Searl Company Limited F-319 SITE Karachi.
	Brand Name +Dosage Form +Strength	C-Flexin XR tablet 500mg
	Composition	Each extended release tablet contains: Ciprofloxacin (as Ciprofloxacin hydrochloride monohydrate or sesquihydrate & ciprofloxacin base)… 500mg
	Diary No. Date of R&I & fee	DyNo.2918; 16-05-2017; Rs. 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Cipvax XR 500mg Tablets of Genome pharmaceuticals
	GMP status	Same as recorded above
	Remarks of Evaluator	
	Previous Decision	Registration Board in its 290th Meeting deferred the case for the following: For confirmation of same already registered product.
	Evaluation by PEC	Applicant The Searl Company Limited Karachi has submitted an undertaking that applied formulation is not registered with us before.
	Decision: Approved.	
784.	Name and address of Manufacturer / Applicant	M/s Searl Company Limited F-319 SITE Karachi.
	Brand Name +Dosage Form +Strength	C-Flexin XR tablet 1000mg
	Composition	Each extended release tablet contains: Ciprofloxacin (as Ciprofloxacin hydrochloride monohydrate & sesquihydrate & ciprofloxacin base)… 1000mg
	Diary No. Date of R&I & fee	DyNo.2916; 16-05-2017; Rs. 20,000/-
	Pharmacological Group	Antibiotic
	Type of Form	Form-5

	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	10's, 14's, 28's; As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Novidat XR 1000mg Tablets of Sami Pharmaceuticals
	GMP status	Same as recorded above
	Remarks of Evaluator	
	Previous Decision	Registration Board in its 290th Meeting deferred the case for the following: For confirmation of same already registered product.
	Evaluation by PEC	Applicant The Searl Company Limited Karachi has submitted an undertaking that applied formulation is not registered with us before.
	Decision: Approved.	
785.	Name and address of Manufacturer/Applicant	"M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name + Dosage Form + Strength	Sitamin Ds 50/500 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Sitagliptin (as phosphate monohydrate)…50mg Metformin hydrochloride…500mg"
	Diary No. D of R & I & Fee	Dy No. 16879; 07-05-18: Rs.20,000
	Pharmacological group	Anti-diabetic
	Type of Form	Form 5
	Finished product Specifications	Innovator's Specifications
	Pack Size & demanded price	14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Sita Plus 50/500 Tablet of PharmEvo (Pvt.) Ltd, Karachi
	GMP Status	---------
	Remarks of Evaluator	• Latest GMP inspection report is required.
	Previous Decision(M-290)	Registration board in its 290th meeting decided as follow: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Decision: Approved.	
786.	Name and address of Manufacturer/Applicant	"M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name + Dosage Form + Strength	Sitamin Ds 50/1000 mg Tablets
	Composition	"Each Film Coated Tablet Contains: Sitagliptin (as phosphate monohydrate)…50mg Metformin hydrochloride…1000mg"
	Diary No. D of R & I & Fee	Dy No. 16880; 07-05-18: Rs.20,000
	Pharmacological group	Anti-diabetic
	Type of Form	Form 5
	Finished product Specifications	Innovator's Specifications
	Pack Size & demanded price	14's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Gliptin Plus Tablet of Genix Pharma Karachi
	GMP Status	------
	Remarks of Evaluator	• Latest GMP inspection report is required.

	Previous Decision(M-290)	• Registration board in its 290 meeting decided as follow: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Decision: Approved.	
787.	Name and address of Manufacturer/Applicant	"M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name + Dosage Form + Strength	Maxadol 50mg Tablets
	Composition	Each Film Coated Tablet Contains: Tramadol Hydrochloride…50mg
	Diary No. D of R & I & Fee	Dy No. 16878; 07-05-18: Rs.20,000
	Pharmacological group	Analgesic
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack Size & demanded price	20's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Registration Number: 024457 Brand Name: Tramed- Tablets Each tablet contains:- Tramadol HCl ……50mg Manufacturer Name: Platinum Pharmaceuticals (Pvt) Ltd,
	GMP Status	----------
	Remarks of Evaluator	• Latest GMP inspection report is required.
	Previous Decision(M-290)	• Registration board in its 290 meeting decided as follow: Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Decision: Approved.	
788.	Name and address of Manufacturer/Applicant	"M/s Max Pharmaceuticals. Plot # 12, St. No. N-7, National Industrial Zone, Rawat, Islamabad"
	Brand Name + Dosage Form + Strength	Uperacid 40mg Capsule
	Composition	"Each Delayed Release Capsule Contains: Omeprazole …40mg" (Enteric Coated Pellets Source: Vision Pharmaceuticals)
	Diary No. D of R & I & Fee	Dy No. 16876 ; 07-05-18: Rs.20,000
	Pharmacological group	PPIs
	Type of Form	Form 5
	Finished product Specifications	USP Specifications
	Pack Size & demanded price	14's, 10's: As per SRO
	Approval status of product in reference regulatory authorities	Approved in US-FDA
	Me-too status	Omefin 40 mg Capsule of Mafins Karachi
	GMP Status	
	Remarks of Evaluator	COA, GMP, STABility Studies of pellets manufacturer& GMP Inspection report of firm is required.
	Previous Decision(M-290)	• Registration board in its 290 meeting decided as follow: COA, GMP of pellets manufacturer and stability studies of three batches of pellets conducted in accordance with zone IV-A conditions.

		Reference of the case would be sent to QA & LT Division to conduct GMP inspection of Firm on priority.
	Evaluation by PEC	Applicant has submitted following: Source of pellets: VIsision Pharmaceuticals. Firm has submitted GMP inspection report conducted on 26-06-19 concluded that firm is operating at satisfactory level of GMP compliance.
	Decision: Approved.	

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

a. Deferred cases:

789.	Name and Address of Manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt.) Ltd., 641-A Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	ZAFLAM 75mg SR Capsule
	Diary No. Date of R & I & fee	Dy No. 3517;25-01-2019; Rs.20,000/-
	Composition	Each Capsule Contains: Diclofenac sodium…….75mg (as sustained release pellets) Source of pellets: M/s Vision Phrma Islamabad.
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	20's: As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Diclomax SR Capsules 75mg;United Kingdom, Itlay (as provided by the firm)
	Me-too Status	Dicloyan-S Roryan Pharmaceutical Industries (Pvt) Ltd Pakistan.
	GMP Status	Letter Issuance Date : 8th January, 2019
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable.
	Previous decision	Registration Board in its 288th meeting deferred the case for the following: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable.
	Remarks of Evaluator	Firm has submitted that applied formulation is approved in MHRA of UK under name Diclomax SR. 1. Name of the medicinal product Diclomax SR. 2. Qualitative and quantitative composition Each Diclomax SR capsule contains diclofenac sodium 75mg.
	Decision: Approved as per innovator's specification.	
790.	Name and Address of Manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt.) Ltd., 641-A Sundar Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	ZAFLAM RETARD 100mg Capsule
	Diary No. Date of R & I & fee	Dy No. 3511;25-01-2019; Rs.20,000/-
	Composition	Each Capsule Contains: Diclofenac sodium …….100mg (as sustained release pellets) Source of pellets: M/s Vision Phrma Islamabad.
	Pharmacological Group	NSAID
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	20's/ As per SRO
	Approval Status of Product in Reference Regulatory Authorities.	Diclomax Retard Capsules 100mg;United Kingdom, Itlay (as provided by the firm)
	Me-too Status	Dicloyan-S Roryan Pharmaceutical Industries (Pvt) Ltd Pakistan.
	GMP Status	Letter Issuance Date : 8th January, 2019
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/ agencies which were declared/approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable.
	Previous decision	Registration Board in its 288th meeting deferred the case for the following: Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable.
	Remarks of Evaluator	Firm has submitted that applied formulation is approved in MHRA of UK under Brand Name Diclomax Retard. 1. Name of the medicinal product Diclomax Retard. 2. Qualitative and quantitative composition Each Diclomax Retard capsule contains diclofenac sodium 100mg.
	Decision: Approved as per innovator's specification.	
791.	Name and address of manufacturer / Applicant	M/s Zamko Pharmaceuticals (Pvt.) Ltd., 641-A Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	MYCIN Capsule 500mg
	Diary No. Date of R& I & fee	Dy No. 3549;25-01-2019; Rs.20,000/-
	Composition	Each Hard Capsule contains: Fosfomycin calcium.....500mg
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Ph,Eur
	Pack size & Demanded Price	10's : As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in Spain FOSFOSINA 500mg Hard capsules; SPAIN
	Me-too status	Osfocin Capsule 500mg of Krka Pak, Karachi
	GMP status	Letter Issuance Date : 8th January, 2019
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting as the provided evidence is not verifiable.
	Previous decision	Registration Board in its 288th meeting deferred the case for the following: For evidence of approval of applied formulation i.e. Fosfomycin calcium 500mg capsule in reference regulatory authorities/agencies which were adopted by Registration Board in its 275th meeting.
	Evaluation by PEC	Firm has submitted that applied formulation is approved in Spain under Brand Name FOSFOCINA 500 mg Cápsulas. *PHOSPHOCINE 500 mg CAPSULES* *The active substance is calcium phosphomycin (DOE). Each capsule contains 500 mg of fosfomycin calcium*
	Decision: Approved as per innovator's specification.	

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

a. New Cases

792.	Name and address of manufacturer / Applicant	"M/s Cherished Pharmaceuticals Pvt Ltd. 10 km, Sunder Raiwind Road, Sunder Industrial Estate, Lahore, Pakistan"
	Brand Name +Dosage Form + Strength	Ivergold Super Injection
	Composition	"Each ml Contains: Ivermectin…20mg Clorsulon…100mg"
	Diary No. Date of R& I & fee	Dy.No 6116 dated 19-02-2018 Rs. 20,000/- Dated 19-02-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	Decontrolled
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Ivo mex C3 Injection of Attabak (not verifiable)
	GMP status	GMP Inspection conducted on 07-04-2018concluded that firm is operating at satisfactory level of GMP Compliance.
	Remarks of the Evaluator	Submit outline of manufacturing process Mention type of primary packaging material.
	Decision: Deferred for following: **Submit outline of manufacturing method for applied formulation.** **Mention type of primary packaging material for applied formulation.**	

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

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

i. Human

793.	Name and address of Applicant	"M/s Health Services. Office A4, 3rd Floor, Building # 8, Civic Centre, Bahria Town, Phase IV, Islamabad By: M/s BiemHacSanayiVeTicaret A.S. Turgut Reis, Caddesi No. 21,0657 Tandogan-Anakara, Turkey"
	Detail of Drug Sale License	**Address:**."M/s Health Services. Office A4, 3rd Floor, Building # 8, Civic Centre, Bahria Town, Phase IV, Islamabad **Validity:** 11/02/2019 **Status:** Licence to sell as a "Distributer"
	Name and address of manufacturer	M/s BiemHacSanayiVeTicaret A.S. Turgut Reis, Caddesi No. 21,0657 Tandogan-Anakara, Turkey"
	Name and address of marketing authorization holder	MM/s BiemHacSanayiVeTicaret A.S. Turgut Reis, Caddesi No. 21,0657 Tandogan-Anakara, Turkey"
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.31028 Dated 14/09/2018
	Fee including differential fee	Rs. 50,000/- Dated 11/09/2018, Rs. 50,000/- 14/09/2018,
	Brand Name +Dosage Form + Strength	Beastin 100mg IV Powder for Concentrate for Solution for Infusion
	Composition	"Each Vial Contains: Bendamustine Hydrochloride…100mg"
	Finished Product Specification	Manufacturer's Specifications

	Pharmacological Group	Alkylating Agent
	Shelf life	36 months
	Demanded Price	Rs:17000/-
	Pack size	
	International availability	Approved in USFDA.
	Me-too status	Couldn't be confirmed
	Detail of certificates attached	Original GMP and Free sale Certificate Certificate No. 2018-1468 Certified by: Republic of Turkey,Turkish Medicines and Medical Devices Agency, Ministry of Health Issued date: 13/04/2018 Validity: 13/04/2020 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 GMP and Free Sale Certificate.
	Remarks of the Evaluator.	
	Evaluation by PEC:	
	Decision: Deferred for following reasons: • **Submission of Orginal Legalized GMP and Free sale certificate, as provided one is not legalized.** • **Letter of authorization/Agreement between importer and exporter.**	
794.	Name and address of Applicant	Genix Pharma (Pvt) ltd. 44, 45-B Korangi Creek Road, Karachi, 75190, Pakistan.
	Detail of Drug Sale License	**Address:**Genix Pharma (Pvt) ltd. 44, 45-B Korangi Creek Road, Karachi, 75190, Pakistan. **Validity:** 23/05/2020 **Status:** Drug License by way of Wholesale
	Name and address of manufacturer	Yichang Humanwell Pharmaceutical Co., Ltd., No. 19 of Dallan road, Yichange Developing Zone, Hubei Province, China.
	Name and address of marketing authorization holder	Yichang Humanwell Pharmaceutical Co., Ltd., No. 19 of Dallan road, Yichange Developing Zone, Hubei Province, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.15723 Dated 27/04/2018
	Fee including differential fee	Rs. 50,000/- Dated 20/04/2018
	Brand Name +Dosage Form + Strength	Refent Injection 1mg
	Composition	Each vial contains: Remifentanil hydrochloride….1mg (freeze-dried powder for injection)
	Finished Product Specification	Innovator's specifications
	Pharmacological Group	Anaesthetic
	Shelf life	2 years
	Demanded Price	As per SRO
	Pack size	5's: As Per SRO
	International availability	Approved in US-FDA
	Me-too status	N/A
	Detail of certificates attached	**Origional legalized CoPP:** Certificate No: 20170063 Certified by: Hubei Food & Drug Administration No. 19 Gongzheng Road Wu Chang District, Wuhan City, China. Issued date: 18/12/2017

		Free sale in exporting country: Confirms the free sale of the product in exporting country. GMP: The facilities and operations conform to GMP as recommended by WHO as per CoPP. **legalized Free sale Certificate:** Certificate No: 2017-63 Certified by: Hubei Food & Drug Administration. Issued date: 06/12/2017 Validity: 2years **legalized GMPCertificate:** Certificate No: HB20170318 Certified by: Hubei Province Food & Drug Administration. Issued date: 04/02/2017 Validity: valid until 03-02-2022 **Letter of authorization:** Genix Pharma (Pvt) ltd &YichangHumanwell Pharmaceutical.
	Remarks of the Evaluator. **Remarks** / **Response** Submit stability Studies both accelerated & real time of three batches of applied formulation as per Zone VI-A conditions as submitted stability studies are not according to Zone IVa conditions. / Applicant has submitted that Product is unstable at 30C it has to be stored between 2- 25C) they have submitted stability study data at following conditions: Real Time: 25ºC ± 2ºC / 60% ± 5%RH Accelerated:30ºC ±2ºC / 65% ± 5%RH	
	Previous decision (M-289th)	**Deferred for the following:** • For clarification regarding storage conditions of Innovator product. • For submission of stability study data both accelerated & real time for two more batches of applied drug product.
	Evaluation by PEC	Applicant has submitted following: 1. Label of innovator Product Ultiva Confirming storage at 2-25ºC. 2. stability studies data both accelerated & real time for three batches of applied drug productfor 24months on above stated condition of temperature & humidity.
	Decision: Approved as per innovator's specification.	

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

i. Deferred cases

795.	Name and address of manufacturer / Applicant	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.
	Brand Name +Dosage Form + Strength	Helisopt Ophthalmic Suspension
	Composition	Each ml ophthalmic suspension contains: Brinzolamide..…. …10mg Timolol(as maleate)….5mg
	Diary No. Date of R& I & fee	Duplicate dossier
	Pharmacological Group	Carbonic Anhydrase Inhibitor, Beta-adrenergic blocking agent.
	Type of Form	Form-5D
	Finished product Specifications	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in	Approved in TGA

	Reference Regulatory Authorities	
	Me-too status (with strength and dosage form)	N/A
	GMP status	GMP compliant dated 10-08-2017.

STABILITY STUDY DATA			
Drug	Helisopt Ophthalmic Suspension		
Name of Manufacturer	M/s Helix Pharma, Hakimsons House, A/56, S.I.T.E, Manghopir Road, Karachi.		
Manufacturer of API	**Timolol (as maleate):** M/s. Gangwal Chemicals Pvt. Ltd., Plot No. N-5 Mide, Tarapur Boisar, District: Thane 01 506, India **Brinzolamide:** M/s. Century Pharmaceuticals 103 to 106, GIDC, Halol, 389 350, Dist: PANCHMAHAL, Gujrat State, India.		
API Lot No.	**Timolol (as maleate):** (Batch No. TMM-051656. Mfg date: May 2016, Quantity: 2kgs). **Brinzolamide:** (Batch No.07111004-BA. Mfg date: March 2016, Quantity: 80grams).		
Description of Pack (Container closure system)	(5ml) LDPE bottle		
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(on going) Accelerated: 0,3,6 Months		
Batch No.	TF 001	TF 002	TF 003
Batch Size	01 Litters	01 Litters	01 Litters
Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	25-08-2017	25-08-2017	25-08-2017
No. of Batches	03		
Date of Submission	Dy No.12219, 03-04-18		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Timolol (as maleate):** Copy of GMP certificate bearing a number NEW-WHO-GMP/CERT/KD/50623/2016/11/17467 issued to M/s. Gangwal Chemicals by Food & Drug Administration Maharashtra, India. Valid until 02-12-2018. **Brinzolamide:** Copy of GMP certificate bearing a number 1707219 issued to M/s. Century Pharmaceuticals by Food & Drug Control Administration, Gujarat state India. Valid until 06-07-2019.
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.	**Timolol (as maleate):** Copy of Form 5 (license to import Drugs) issued by ADC, DRAP, Karachi dated 04-07-2016 has been submitted. Copy of commercial invoice has been submitted. **Brinzolamide:** Copy of Form 6 (license to import Drugs for clinical trial examination) issued by ADC, DRAP, Karachi dated 21-09-2016 has been submitted. Copy of ADC attested commercial invoice has been submitted.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR & REPLIES OF APPLICANT

. The firm has claimed Manufacturer's Specifications and the product is not present in available USP & BP.
. Submit raw data sheets of analytical method of applied formulation.
. Commitment to follow Drug Specification Rules, 1978.
. Commitment to continue real time stability studies till the proposed/assigned shelf life.
. Latest GMP inspection report conducted within the period of last one year.
. Chromatographic conditions in the finished product testing method submitted in dossier is different to that submitted with stability studies. Clarify/Justify.
Applicant has submitted that "We have applied for product dossier file on 20-04-2012, at that time, we did not have HPLC complies Software 21CFR but now we have all HPLCs complies with software 21CFR and we are working on HPLC with software 21CFR for new product's stability studies. Therefore you found the difference in chromatographic conditions & current chromatographic conditions upon which stability studies are performed are following: wavelength 280nm & flow rate 1ml/minute".

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Helisopt Ophthalmic Suspension (Brinzolamide/Timolol) by M/s. Helix Pharma , Karachi.

Reference No: F.13-11/2017-PEC (Vol.I) dated 10th December, 2018.
Investigation Date and Time: 18th December, 2018 (Forenoon).
Investigation Site: Factory premises of M/s. Helix Pharma, Karachi.

Background:

Chairman Registration Board considered the applications of M/s Helix Pharma, Karachi for registration of Helisopt Ophthalmic Suspension each ml of which contain Brinzolamide 10mg and Timolol (as maleate) 5mg 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. Abdul Waheed, Assistant Director, CDL, DRAP, Karachi
2. Mr. Adnan Rizvi, Director DTL Sindh, Karachi (Member Registration Board)
3. Dr. Affan Ali Qureshi, Assistant Director, CDL, DRAP, Karachi.

Scope of investigation:

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

Tools for Investigation:

The investigation was conducted by using a structured questionnaire of DRAP. For objective evidence physical inspection of the facilities for manufacturing and quality control, material used and retained, personnel

involved, ongoing studies, printed data and integrity and security of data in respective databases were also audited. The details of investigation may be summarized as under:

Helisopt Ophthalmic Suspension

S.No.	Question	Observation by panel
1	Do you have documents confirming the import of API ?	The firm has imported 80g Brinzolamide from M/s Century Pharmaceuticals Limited, India vide invoice no. EXP16087 dated 2-09-2016 and 4.0 kg from M/s Gangwal Chemical Pvt. Ltd. India vide invoice No. EXP-T/030/16-17 dated 05.01.2017 and obtained approval from DRAP Karachi
2	What was the rationale behind selecting the particular manufacturers of APIs?	There is proper vendor qualification being implemented by the firm which include a desktop audit by means of a questionnaire which is filled by the manufacturer, GMP Status, provision of DMF etc. The firms were evaluated on above mentioned criteria and selected
3	Do you have documents confirming the import of API reference standard and impurity standards?	The firm has documents confirming the import of both APIs USP reference standard and impurity standards.
4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for both APIs, working standards and their impurities.
5	Do you have any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	The firm has GMP certificate of Brinzolamide and timolol manufacturers issued by Food and Drug Control Administration, Gujrat State, India and Food and Drug Administration, Mahrashtra, India respectively.
6	Do you use API manufacturer method of testing?	The firm has used USP method of testing for both APIs.
7	Do you have stability studies reports on API?	The firm has accelerated stability studies reports of six months on both APIs and five years and four years real time stability studies reports on the Brinzolamide and Timolol respectively.
8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified.
9	Do you have method for quantifying the impurities in the API?	The firm has USP method for quantifying the impurities in the API.
10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of API and reference standard of both APIs.
11	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients.
12	Do you have documents confirming the import of the used excipients?	The firm has documents confirming the procurement of all excipients used.
13	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.
14	Do you have written and authorized protocols for the development of API ophthalmic	The firm has written and authorized protocols for the product development.

<table>
<tr><td></td><td>suspension?</td><td></td></tr>
<tr><td>15</td><td>Have you performed Drug-excipient compatibility studies?</td><td>Drug-excipients compatibility studies were not performed as the firm has used the same excipients as of innovator.</td></tr>
<tr><td>16</td><td>Have you performed comparative dissolution studies?</td><td>N/A</td></tr>
<tr><td>17</td><td>Do you have product development (R&D) section</td><td>The firm has product development (R&D) section with equipment for manufacturing of ophthalmic suspension dosage form. The analytical part is performed on equipment of routine quality control tests.</td></tr>
<tr><td>18</td><td>Do you have necessary equipment available in product development section for development of API ophthalimic suspension?</td><td>The firm has necessary equipment for product development of API ophthalmic suspensions. The product in question has been developed while using some equipment of commercial manufacturing also. Furthermore, the analytical part has been performed via the routine quality control equipment. Firm has already placed orders for procurement of other equipment for this section.</td></tr>
<tr><td>19</td><td>Are the equipment in product development section qualified?</td><td>The available equipment in product development section are qualified.</td></tr>
<tr><td>20</td><td>Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?</td><td>The firm has SOP for the maintenance/calibration/requalification of equipment used on PD section.</td></tr>
<tr><td>21</td><td>Do you have qualified staff in product development section with proper knowledge and training in product development?</td><td>The firm has qualified staff which include One Chemist and One Pharmacist in product development section with relevant work experience.</td></tr>
<tr><td>22</td><td>Have you manufactured three stability batches for the stability studies of API ophthalmic suspension as required?</td><td>The firm has manufactured three consecutive stability batches for the accelerated and real time stability studies of Helisopt ophthalmic suspension packed in LDPE bottles of 5ml each.
<table>
<tr><td>Batch No.</td><td>Batch Size</td><td>Mfg Date</td></tr>
<tr><td>TF 001</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 002</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
<tr><td>TF 003</td><td>1000ml (180 bottles)</td><td>07-2017</td></tr>
</table></td></tr>
<tr><td>23</td><td>What was the criteria for fixing the batch size of stability batches?</td><td>The criteria for fixing the batch size of stability batches is the number of bottles per testing and the number of bottles required for whole stability testing.</td></tr>
<tr><td>24</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. Necessary log books of equipment used has been available with the firm.</td></tr>
<tr><td>25</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocol for stability testing of stability batches in which the stability conditions are:
Real Time: 30°C and 65% RH
Accelerated: 40°C and 75% RH,
however, the firm has used LDPE container for the product in question for which ICH guidelines and WHO recommends 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies.</td></tr>
<tr><td>26</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated their own method for testing of stability batches. The method is supported by impurities standards spiking studies, forced degradation, hence capable of quantifying the degradation products in their ophthalmic suspension kept on stability testing.</td></tr>
<tr><td>27</td><td>Do you have method transfer studies in case when the method</td><td>Not Applicable</td></tr>
</table>

	of testing being used by your firm is given by any other lab?	
28	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of API and the finished drug?	The firm has proper documents confirming the qualification of equipment / instruments being used in the test and analysis of API and finished drug.
29	Do your method of analysis stability indicating?	The firm's method of analytical testing has stability indicating parameters.
30	Do your HPLC software is 21CFR compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31	Can you show Audit Trail reports on API testing?	The firm showed the audit trail reports on API testing.
32	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
33	Do you have commitment batches kept on stability testing?	The firm has completed accelerated stability testing on the three stability batches. The real time stability testing is in progress on all the three stability batches. Currently 12 months studies have been completed with satisfactory results.
34	Do you have valid calibration status for the equipment used in API ophthalmic suspensions production in analysis?	The firm has valid calibration status for the equipment used in helisopt ophthalmic suspension production and analysis.
35	Do proper and continuous monitoring and control are available for stability Chamber?	Continuous power supply and monitoring are available for stability chambers.
36	Do related manufacturing area, equipment, personnel and utilities be Rated as GMP compliant?	The related manufacturing area, equipment, personnel and utilities be rated as GMP compliant.

Discussion:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Helisopt Ophthalmic Suspension is verifiable to satisfactory level.
2. Furthermore, the firm has conducted the stability studies as per their protocol which is 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies, whereas, the recommended stability conditions for products packed in semi-permeable containers are 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies. However, 30°C and 65% RH for real time and 40°C and 75% RH for accelerated stability studies may be used for semi-permeable containers provided the calculated water loss multiplied with the corresponding factor may not exceed 5% of initial, which is considered as significant change.
3. In this case the firm has not calculated water loss at any stage, so no comparison can be made between the reference and alternative relative humidity as mentioned in ICH Q1A (R2) (2.2.7.3. Drug products packaged in semi-permeable containers).
4. On risk-based approach the data evaluated during inspection does not show any deviation in the critical tests throughout the study period which may be altered if the water has lost more than the prescribed limits.
5. The related manufacturing area, equipment, personnel and utilities are GMP compliant and suited for the manufacturing of Helisopt Ophthalmic Suspension.

Recommendations:

The firm may be granted necessary registration of Helisopt Ophthalmic Suspension in their name with the direction to conduct stability studies on their commitment batches as per ICH guidelines i.e. 30°C and 35% RH for real time and 40°C and 25% RH for accelerated stability studies and submit the data to the Drug Registration Board.

Previous Decision:
Registration Board in its 287th meeting decided as follow:
Registration Board deferred the case for submission of stability data at next time point of long term stability studies along with assessment of water loss rate for applied container closure system as per ICH Q1A (R2) guidelines for "Stability Testing of New drug substances and products."

Evaluation by PEC:

Applicant has submitted results of Water loss test in the form of graphs conducted on following newly manufactured batches of applied formulation.

Sr. No.	Batch No.	Batch Size.
1.	TF004	90 bottles
2.	TF005	90 bottles
3.	TF006	90 bottles

Decision:

Deferred for submission of formula by which results of moisture loss from the semipermeable container are calculated as well as submit details of readings used to plot the graph, as only graphs are submitted.

796.	Name and address of manufacturer / Applicant	Genix Pharma (Pvt.) Ltd, Karachi
	Brand Name +Dosage Form + Strength	Empag M 12.5mg + 1000mg Tablets
	Composition	Each Extended Release Film Coated Tablet Contains: - Empagliflozin ……12.5mg Metformin hydrochloride…1000mg
	Diary No. Date of R& I & fee	Dy No.34140; 15-10-2018: 50,000/- ; 09-10-18
	Pharmacological Group	Anyti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 14's, 20's, 28's, 30's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (Synjardy XR Tablet)
	Me-too status	N/A
	GMP status	In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other CGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an satisfactory level of compliance with CGMP GUIDLINES as of today. The management was also suggested to further strengthen stability and analytical sections

STABILITY STUDY DATA

Drug	Empag M 12.5mg /1000mg Tablets
Name of Manufacturer	Genix Pharma (Pvt.) Ltd, Karachi
Manufacturer of API	**For Empagliflozin:** M/s WIS Pharmatech Co., Ltd. Factory, Manufactured by M/s Ruyuan HEC Pharm Co., Ltd. China has been submitted. **For Metformin HCl:** M/s Wanbury Limited, India
API Lot No.	Empagliflozin: Lot #: EGLZ-RD20171101A Metformin Hydrochloride Lot #: MT00600118
Description of Pack (Container closure system)	Alu /alu Blister Pack in Unit carton
Stability Storage Condition	Accelerated:40˚C ± 2˚C/75%±5% RH

	Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 6 (Months) Real Time: 6 (Months)		
Frequency	Accelerated: 0,1,2,3,4,6 (Months) Real Time: 0,3,6,9,12,18,24 (Months)		
Batch No.	18SB-103-01	18SB-104-02	18SB-105-03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	04-2018	04-2018	04-2018
Date of Initiation	26-06-2018		
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Photocopy of COAs of Empagliflozin &Metformin hydrochloride for following batches have been submitted. **Particulars Batch No.** Empagliflozin EGLZ-RD20171101A Metformin Hydrochloride MT00600118
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Applicant has submitted the following: **For Empagliflozin:** GMP Certificate No: 2018024 Issued to: Ruyuan HEC Pharm Co., LTD Issued by: Shaoguan Food & Drug Administration Validity: Until 18-12-2019 **For Metformin HCl:**
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted the following: **For Empagliflozin:** Copy of commercial Invoice declaring following information on it: Invoice No: WIS170152 Attested by: ADC Karachi Attested on: 07-12-2017 Quantity: 0.75 Kg From: M/s WIS Pharmatech Co., Ltd. Factory, Manufactured by M/s Ruyuan HEC Pharm Co., Ltd. China. **For Metformin HCl:** Copy of commercial Invoice declaring following information on it: Invoice No: EXP/92001577/ 17-18 Attested by: ADC Karachi Attested on: 30-1-2018 Quantity: 5000 Kg

		From: M/s Wanbury Limited, India.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
Data for Exemption from onsite investigation		
Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their Product "WYMLY Tablets 25mg (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).
2.	Documents for the procurement of API with approval from DRAP (in case of import).	Applicant has submitted the following: **For Empagliflozin:** Copy of commercial Invoice declaring following information on it: Invoice No: WIS170152 Attested by: ADC Karachi Attested on: 07-12-2017 Quantity: 0.75 Kg From: M/s WIS Pharmatech Co., Ltd. Factory, Manufactured by M/s Ruyuan HEC Pharm Co., Ltd. China has been submitted. **For Metformin HCl:** Copy of commercial Invoice declaring following information on it: Invoice No: EXP/92001577/ 17-18 Attested by: ADC Karachi Attested on: 30-1-2018 Quantity: 5000 Kg From: M/s Wanbury Limited, India

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td><u>For Empagliflozin:</u>
The firm has submitted copy of letters from M/s Ruyuan HEC Pharm Co., Ltd. China in the name of M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following reference standards.<table><tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th></tr><tr><td>Working standard</td><td>EGLZ-WS201612101</td><td>2gm</td></tr></table><u>For Metformin HCl:</u>
M/s USP 7135 English Muffin Way Frederick, MD 21704, USA in the name of M/s Genix Pharma (Pvt.) Ltd, Karachi, declaring the submission of following reference standards.<table><tr><th>Particulars</th><th>Batch No.</th><th>Quantity</th></tr><tr><td>Working standard</td><td>--------</td><td>200mg</td></tr></table></td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Applicant has submitted the following:
<u>For Empagliflozin:</u>
GMP Certificate No: 2018024
Issued to: Ruyuan HEC Pharm Co., LTD
Issued by: Shaoguan Food & Drug Administration
Validity: Until 18-12-2019
<u>For Metformin HCl:</u></td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted photocopy of “SOP for Selection of manufacturer for Vendor Certification.
SOP No: QA/SOP/SY/037 with effective date 07-10-2016.
Version no: 01
Copy of “Vendor’s Audit form” filled for M/s Ruyuan HEC Pharm Co., Ltd. China.
Copy of “Vendor’s Audit form” filled for M/s Wanbury Limited. India.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Photocopy of COAs of Empagliflozin, working standards and impurity standards issued by M/s Ruyuan HEC Pharm Co., Ltd. China. & M/s USP 7135 English Muffin Way Frederick, MD 21704 is submitted. Detail is as under :<table><tr><th>Particulars</th><th>Batch No</th></tr><tr><td>Empagliflozin</td><td>EGLZ-RD20171101A</td></tr><tr><td>Metformin Hydrochloride</td><td>MT00600118</td></tr><tr><td colspan="2">Working Standards</td></tr><tr><td>Empagliflozin</td><td>EGLZ-WS201612101</td></tr><tr><td>Metformin HCl</td><td>R069H0</td></tr><tr><td colspan="2">Impurity Standards</td></tr><tr><td>Melamine</td><td>GIM492</td></tr><tr><td>Metformin Related Compound A</td><td>R072Y0</td></tr></table></td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Purchase Order/Invoices for the procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted photocopy of List of qualified staff involved in product development comprising of 04 members.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
</table>

<table>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of Development Protocol for Lab scale batch manufacturing of Empag-M Tablets (12.5mg + 1000mg).

The master formulation and manufacturing method mentioned in development protocol is same as that of reference product.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Record and Batch Packaging Record of the following 03 Batches:
<table>
<tr><th>BATCH NO</th><th>BATCH SIZE</th><th>MFG DATE</th></tr>
<tr><td>18SB-103-01</td><td>1500 Tablets</td><td>04-2018</td></tr>
<tr><td>18SB-104-02</td><td>1500 Tablets</td><td>04-2018</td></tr>
<tr><td>18SB-105-03</td><td>1500 Tablets</td><td>04-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has attached Record of remaining quantities of stability batches</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>The firm has submitted photocopies of digital printouts of graphical chart for Real Time and Accelerated Conditions starting from 01-03-2018 to 31-10-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td><u>For Empagliflozin:</u>
The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Empagliflozin.
<u>For Metformin HCl:</u>
The firm has submitted photocopy of raw material specifications, raw material testing procedures and report for Metformin HCl.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure (QC-FPNS-135 issued on 10-04-2018) for Empag M Tablets (12.5mg + 1000mg) along with Stability Study Report of stability batches.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td><u>For Empagliflozin:</u>
The firm has submitted photocopy of Empagliflozin 06 Months Accelerated (40oC+2 oC, RH 75+5%) Data of 03 Batches of from M/s Ruyuan HEC Pharm Co., Ltd. China.
<u>For Metformin HCl:</u>
Metformin HCl 06 Months Accelerated (40oC+2 oC, RH 75+5%) and 72Months Real Time Stability Study (30oC+2 oC, RH 65+5%) of Metformin HCl from M/s Wanbury Limited. India.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopies of its own Analytical reports for all excipients used in product development of Empag-M Tablets.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has stated that the composition of developed product is similar to the innovator’s product formulation, no ingredient which could have adverse effects over product’s in-vivo performance is used during product development therefor, it is presumed that used inactive ingredients are compatible with the active (Empagliflozin+ Metformin HCl) & also with each other and this is ensured by satisfactory results from formal stability studies.</td></tr>
</table>

<table>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted F2 factor protocol (QC/PRO/CD/21) & reports dated 03-12-2018. The details of reference product & Sample product are as follows:
<table>
<tr><th>feature</th><th>Reference product</th><th>Product of M/S Genix Pharma</th></tr>
<tr><td>Brand name</td><td>Synjardy Tablet 5mg/1000mg</td><td>Empag-M Tablets 5mg +1000mg</td></tr>
<tr><td>Batch No</td><td>605012</td><td>18SB-097-01</td></tr>
<tr><td>Expiry Date</td><td>12-2020</td><td>04-2020</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 :

Sr. No.	Deficiencies	Justification
1.	You are acquiring Metformin Hcl from M/s Wanbury, a pharmaceutical unit located in Maharashtra state of India as per commercial invoice, but submitted GMP certificate is of another site of same manufacturer located in Andhra-Pardesh. Submit GMP certificate of desired site.	M/s Wanbury, Head office located in Maharashtra state while manufacturing unit located in Andhra-Pardesh. This address is also mentioned on commercial invoice, COA and GMP. Reference attached (Annexure point no. 1)
2.	You have procured four lots of Metformin Hcl as per invoice; also submit the record about which lot is used in the manufacturing of trial batches.	The batch number MT00600118 is used. COAs and BMRs are attached for reference. Annexure point No.2
3.	COA for one lot of Metformin Hcl is submitted, but you have procured four lots, as per submitted commercial invoice, clarify/justify	Genix Pharma is also manufacturing other combination products like Metformin Hcl and Sitagliptin Phosphate Tablets Range. That's why Metformin Hcl is used from commercial material.
4.	How would you have come to know about batch number of Empagliflozin, one of the APIs of applied drug product, as it is not mentioned on commercial invoice. Clarify/Justify.	The clarification letter from supplier with purchase invoice is attached as reference (Annexure Point no 4)
5.	What analytical method you are using for test/ Analysis of applied drug product either in-house or supplier.	The in-house validated method is used for analysis of finished product (Annexure Point no 5)
6.	Evidence of procurement of reference product Synjardy XR?	Purchase invoice attached (Annexure Point no 6)
7.	Submit Raw data sheets for dissolution and assay testing along with chromatograms at every time points because raw data sheet submit separately which are difficult to understand.	Complete dissolution and assay testing along with chromatograms are attached in file (Annexure Point no 7)
8.	In dissolution testing, Empagliflozin is quantified by HPLC & Metformin Hcl is quantified by UV method as per your FPP Specification. Justify.	Empagliflozin cannot be detectable due to its lowest concentration with respect to metformin Hcl. That's why dissolution is conducted on HPLC while Metformin Hcl can be detected

		without any interference. Dissolution of Metformin Hcl extended release tablets are also given in USP by Spectroscopy method.
9.	Submit spectrums for dissolution testing of metformin Hcl, if you have quantified it on UV.	UV data of Metformin Hcl is attached in separate file (Annexure Point no 7)
10.	In dissolution testing, Empagliflozin is quantified by HPLC & Metformin Hcl is quantified by UV Spectrophotometric Method as per your FPP Specification, but all chromatog-Uiorams for dissolution testing shows peaks for both APIs. Clarify/Justify.	The dissolution of Empagliflozin was conducted as per assay method that's why tablets contained to APIs showing its absorbance Metformin Hcl and Empagliflozin.
11.	Date acquired 29th of June 2018 on chromatograms for run of sample of content uniformity test at initial studies of trial no 18SB-112-01CU03 of applied drug product is not verifiable from the submitted audit trial reports some others chromatograms are not verifiable form submitted audit trial reports. Clarify/Justify	Audit Trial reports of content uniformity are attached (Annexure Point no 11)
12.	Details of equipment used for applying layer of Empagliflozin over Metformin Hcl Extended release core, is required to be submitted	(Attached in Annexure Point no 12)

Previous Decision:
Registration Board in its 289th decided as follow:
Deferred for clarification regarding compensation of manufacturing loss during coating of API(Empagliflozin) over extended release core(Metformin hydrochloride) as there is no any overage mentioned in master formulation to compensate for manufacturing/process loss of API during coating.

Evaluation by PEC
Applicant has clarified that they have added 10% overage in master formulation of applied formulation.

Decision: Registration Board decided to approve registration of "Empag M 12.5mg + 1000mg XR Tablets" by Genix Pharma (Pvt.) Ltd, 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.**

c. Verification of stability study data

797.	Name and address of manufacturer / Applicant	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Apiban 2.5mg tablet
	Composition	Each film coated tablet contains: Apixaban …… 2.5mg
	Diary No. Date of R& I & fee	Dy. No. 97; 01-08-2016; Rs.20,000/- (01-08-2016)
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's,20's, 30's
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Not available
	GMP status	GMP certificate based upon evaluation conducted on 6-7-2017
	Remarks of the Evaluator	• Firm has submitted Form 5-D (dated 20-12-2017) alongwith differential fee of Rs. 30,000/- • Stability data as per directions of 251st meeting of Registration Board shall be submitted.
	Previous Decision	Registration Board in its 277th meeting deferred the case for submission of stability studies data as per directions of 251st meeting of Registration Board.
	Evaluation by PEC	Now the firm has submitted stability studies of the applied formulation.

STABILITY STUDY DATA

Drug	Apiban 2.5mg tablet		
Name of Manufacturer	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.		
API Lot No.	Lot No. 1704002291		
Description of Pack (Container closure system)	Alu-alu blister		
Stability Storage Condition	Real Time: 30ºC ± 2ºC / 65% ± 5%RH Accelerated:40ºC ±2ºC / 75% ± 5%RH		
Time Period	Accelerated: 06month Real Time: 06month		
Frequency	Accelerated: 0,3,6 (Month) Real Time: 0,3,6 (Month)&ongoing		
Batch No.	RD-18101	RD-18102	RD-18103
Batch Size	7,600 Tabs	7,600 Tabs	7,600 Tabs
Manufacturing Date	02-05-2018	02-05-2018	02-05-2018
Date of Initiation	06-2018	06-2018	06-2018
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted Photocopy of COA of Apixaban having following information on it. **For API Apixaban:** **Batch No**: 1704002291

		Manufacturer:M/s Alembic Pharmaceuticals Limited, India.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted following: **<u>Copy of GMP certificate for Apixaban Manufacturer:</u>** Issued To: M/s. Alembic Pharmaceuticals, India. Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India. Issued On: 02 August, 2016 Valid up till: 01-08-2018.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted ADC attested invoice stating following information on it: **<u>For Apixaban:</u>** **Invoice #:** 90046555 (dated: 20-09-2017) **Manufacturer of API**: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India. **Quantity of API**: 1kg **Lot No.** 1704002291 **Cleared on/Attested on**: 16-01-18
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

Data for exemption from On-site investigation of submitted stability data
Apixaban 2.5mg Tablets

Administrative Portion

01	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has quoted the onsite panel inspection for Nebvax (Nebivolo + Valsartan) 5/80mg Tablet, Daplozmet 5/850mg Tablet &Daplozmet 5/1000mg Tablet conducted on 1st January, 2019 & presented in 288th RB meeting as a reference inspection for instant dosage form.

1.	Is your HPLC software 21CFR compliant?	Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available.
2.	Is proper and continuous monitoring and control available for stability chamber?	Yes, monitoring and control was available for the stability chambers provided. Firm was advised to install alarm

<table>
<tr><td></td><td></td><td><table><tr><td></td><td></td><td>system in stability chamber and perform challenge test.</td></tr></table></td></tr>
<tr><td>02</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Applicant has submitted ADC attested invoice stating following information on it:
<u>For Apixaban:</u>
Invoice #: 90046555 (dated: 20-09-2017)
Manufacturer of API: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India.
Quantity of API: 1kg
Lot No. 1704002291
Cleared on/Attested on: 16-01-18</td></tr>
<tr><td>03</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>.</td></tr>
<tr><td>04</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has submitted following:
<u>Copy of GMP certificate for Apixaban Manufacturer:</u>
Issued To: M/s. Alembic Pharmaceuticals, India.
Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India.
Issued On: 02 August, 2016
Valid up till: 01-08-2018.</td></tr>
<tr><td>05</td><td>Mechanism for Vendor pre-qualification.</td><td>Firm has submitted Vendor Qualification Flow Chart.</td></tr>
<tr><td>06</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td><u>For API Apixaban:</u>
Photocopy of COA of Batch No. 1704002291 issued by M/s Alembic Pharmaceuticals Limited, India is submitted.
<u>Working standards:</u>
The firm has submitted the copy of COA of working Standards (Apixaban) Batch No. WS/APN/001, Quantity 0.2gm, provided by the API Manufacturer - M/s Alembic Pharmaceuticals Limited, India is submitted.</td></tr>
<tr><td>07</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted documents for procurement of excipients used in product development.</td></tr>
<tr><td>08</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted list of 06 qualified person working in R&D section.</td></tr>
<tr><td colspan="3">PRODUCTION DATA</td></tr>
<tr><td>09</td><td>Authorized Protocols / SOP for the development & stability testing of trial batches.</td><td>The firm has submitted copy of generalized SOP with the title ‘Product Design & Development’, Effective Date: 10th April,2017, & Analytical method for testing of API & FPP.</td></tr>
<tr><td>10</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided batch manufacturing record of all the three batches<table><tr><th colspan="4">Apixaban 2.5mg Tablets</th></tr><tr><th>BATCH NO.</th><th>BACH SIZE</th><th>MFG. STARTED</th><th>MFG. COMPLETED</th></tr><tr><td>RD-18101</td><td>7,600 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr><tr><td>RD-18102</td><td>7,600 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr><tr><td>RD-18103</td><td>7,600 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr></table></td></tr>
<tr><td>11</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Apixaban 2.5mg Tablets; Stability Pack Size : 2 x 14’s)

• RD-18101: Batch Size : 7,600 Tablets</td></tr>
</table>

		Number of tablets blistered: 400 12 Packs placed on stability (Accelerated: 03 Packs, Real Time : 09 Packs), out of which 01 pack are remaining **Accelerated** and 06 Packs remaining **Real Time.** • **RD-18102: Batch Size : 7,600 Tablets** **Number of tablets blistered: 400** 12 Packs placed on stability (Accelerated: 03 Packs, Real Time : 09 Packs), out of which 01 pack are remaining **Accelerated** and 06 Packs remaining **Real Time.** • **RD-18103: Batch Size : 7,600 Tablets** **Number of tablets blistered: 400** 12 Packs placed on stability (Accelerated: 03 Packs, Real Time : 09 Packs), out of which 01 pack are remaining **Accelerated** and 06 Packs remaining **Real Time.**
QA/QC DATA		
12	Record of Digital data logger for temperature and humidity monitoring of stability chambers (Real Time and Accelerated)	Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period.
13	Method used for analysis of API along with COA.	Firm has provided the method used for analysis of API along with its certificate of analysis.
14	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Firm has provided method used for analysis of FPP and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 06 months Real Time Stability Data.
15	Reports of stability studies of API from manufacturer.	**APIXABAN:** The firm has submitted copy of **Accelerated 06 Months** (40°C ± 2°C & 75±5%RH) stability study reports of 03 batches of Apixaban from M/s Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Village Karakhadi, Taluk-Padra, District-Panchmahal Vadodara-391450, Gujarat, India.
16	Analysis reports for excipients used.	The firm has submitted copy of COAs for the excipients used in the applied formulation.
17	Drug-excipients compatibility studies.	The firm has submitted Drug-excipients compatibility studies
18	Record of comparative dissolution data.	Firm has submitted comparative dissolution profile with the reference product Eliquis 2.5mg Tablet, Bristol-Myers Squibb, USA.
19	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.

FEATURE	REFERENCE PRODUCT	PRODUCT OF HIGHNOON
BRAND NAME	Eliquis 2.5mg Tabs.	Apixaban 2.5mg Tabs.
BATCH #	AAM5629	RD-18102
MFG/EXPIRY	Mfg. Date: 08-2016 Exp. Date: 07-2019	Mfg. Date: 05-2018 Exp. Date: 05-2020

Evaluation by PEC:

Sr.#	Deficiencies	Justification
1.	Documents for the procurement of reference standard and impurity standards are not submitted, clarify/Justify	The related substances in API % FPP are evaluated by the validated method the related substance is calculated by relative retention time which does not require impurity standard. For

		identification of the known impurities (Impurity A, Impurity B, Impurity C, Impurity D) the relative retention time (i.e. with reference to Apixaban: Impurity A= about 2.19; Impurity B= about 0.45; Impurity C= about 1.26; Impurity D= about 2.82; Apixaban= about 1.00) is used. The API Manufacturer testing procedure and highnoon method of testing for finished product are attached for reference A-1.
2.	Batch size for each of three trials is 3800 tablets as per you reconciliation sheet; out of which 400 tablets are blistered, 350 tablets were kept on stability. Justify/clarify that 350 tablets are sufficient for test/ analysis of each of the trials at all time points up till proposed shelf life. Moreover, where the remaining tablets which were not blistered were kept?	Total Tablets required for Dissolution=6 Disintegration=6 Assay/Purity=30 Total Tablets=42 Total Intervals (Real Time Stability)=6 Total Intervals (Accelerated Stability)=2 Total Intervals=8 Total Tablets Required=8*42=336 So total 350 tablets are placed in stability and the no of required tablets for testing are 336 and remaining quantities of the tablets are with the product Development Department.
3.	Analytical method used for test/analysis of applied drug product is in house or supplier, Clarify.	The method is in-house and is validated. The analytical method validation report was submitted in file no.1, Annex 13. However a copy of report is enclosed.
4.	Submit stability data of API by its manufacturer, as it is not submitted.	The stability data is enclosed.
5.	Time intervals for sampling in CDP are 10, 20, 30, & 45 minutes, which are different from that recommended by guidelines, clarify/justify.	As per item 10.3.3 of WHO Technical Report series No.992, 2015, Annes& Multisource (generic) pharmaceutical products; guidelines on registration requiremets to establish interchangeability. "10.3.3 Disssolution profile comparison for biowavers based on dose-proportionality of formulation As for biowaivers based on BCS, a model independent mathematical approach (e.g. F2 test) can used for comparing the dissolution profiles fo two products. The dissolution of the two products (reference strength and additional strength) should be measured under the same test condition. The dissolution sampling times for both reference strength and additional strength profiles should be the same for example. • Fro immediate release products 5,10,15,20,30,45 and 60 minutes. • For 12 hour extended release products 1,2,4,6,8 and 12 hours • For 24 hour extended release products 1,2,4,6,8,16 and 24 hours.
6.	Evidence of purchase of reference product eliquis for CDP.	Receipt for Eliquis purchase (enclosed)
7.	Submit chromatograms for 3rd month accelerated stability studies for all three trial batches.	The chromatograms are attached in Annexure 16 of already submitted file NO.2. However copies

		of chromatogram for 3rd month accelerated stability studies for all three trial batches are attached for your reference.
8.	According to information on chromatograms: In initial studies of batch 18101, Assay is performed on 29th May, 2018 & dissolution on 2nd June 2018, clarify/justify before further processing of the case.	Due to overload of work the testing of batch was planned in parts according to the availability of the equipment. Therefore after performing assay testing on 29th of May, 2018 dissolution testing was planned on 2nd June 2018.

Previous Decision (M-289 RB meeting):

Registration Board decided to defer the case for confirmation of audit trail of HPLC analysis for stability studies of all three trial batches of applied product & clarification about how it is possible for all three trials of both stregths of Apiban tablet 2.5mg & 5mg to have same audit trial in terms of date & time at all time intervals for all injections of sample & standard, by Area FID.

Decision: Registration Board decided to approve registration of "Apiban 2.5mg Tablet and Apiban 5mg Tablet" by M/s Highnoon Laboratories, Lahore. **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.**

798.	Name and address of manufacturer / Applicant	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Apiban 5mg tablet
	Composition	Each film coated tablet contains: Apixaban …… 5mg
	Diary No. Date of R& I & fee	Dy. No. 96; 01-08-2016; Rs.20,000/- (01-08-2016)
	Pharmacological Group	Antithrombotic agents
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's,20's, 30's
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Not available
	GMP status	GMP certificate based upon evaluation conducted on 06-7-2017
	Remarks of the Evaluator	• Firm has submitted Form 5-D (dated 20-12-2017) alongwith differential fee of Rs. 30,000/- • Stability data as per directions of 251st meeting of Registration Board shall be submitted.
	Previous Decision	Registration Board in its 277th meeting deferred the case for submission of stability studies data as per directions of 251st meeting of Registration Board.
	Evaluation by PEC	Now the firm has submitted stability studies of the applied formulation.

STABILITY STUDY DATA

Drug	Apiban 5mg tablet
Name of Manufacturer	M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore.
API Lot No.	**Lot No.** 1704002291
Description of Pack (Container closure system)	2×14's: Alu-alu blister
Stability Storage Condition	Real Time: 30°C ± 2°C / 65% ± 5%RH Accelerated:40°C ±2°C / 75% ± 5%RH
Time Period	Accelerated: 6 Month Real Time: 6 Month
Frequency	Accelerated: 0,3,6 (Month)

	Real Time: 0,3,6 (Month)		
Batch No.	RD-18092	RD-18093	RD-18094
Batch Size	3800 Tablets	3800 Tablets	3800 Tablets
Manufacturing Date	05, 2018	05, 2018	05, 2018
Date of Initiation	06, 2018	06, 2018	06, 2018
No. of Batches	03		
Date of Submission			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Applicant has submitted Photocopy of COA of Apixaban having following information on it. **For API Apixaban:** **Batch No**: 1704002291 **Manufacturer:**M/s Alembic Pharmaceuticals Limited, India.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Firm has submitted following: **Copy of GMP certificate for Apixaban Manufacturer:** Issued To: M/s. Alembic Pharmaceuticals, India. Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India. Issued On: 02 August, 2016 Valid up till: 01-08-2018.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Applicant has submitted ADC attested invoice stating following information on it: **For Apixaban:** **Invoice #:** 90046555 (dated: 20-09-2017) **Manufacturer of API**: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India. **Quantity of API**: 1kg **Lot No.** 1704002291 **Cleared on/Attested on**: 16-01-18
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

<table>
<tr><th colspan="3">Data for exemption from On-site investigation of submitted stability data
Apixaban 5mg Tablets</th></tr>
<tr><th colspan="3">Administrative Portion</th></tr>
<tr><td>01</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>Firm has quoted the onsite panel inspection for Nebvax (Nebivolo + Valsartan) 5/80mg Tablet, Daplozmet 5/850mg Tablet &Daplozmet 5/1000mg Tablet conducted on 1st January, 2019 & presented in 288th RB meeting as a reference inspection for instant dosage form.
<table>
<tr><td>1.</td><td>Is your HPLC software 21CFR compliant?</td><td>Audit trail was active on all HPLC systems used in the method validation and stability study. Individual user log in and IDs were available.</td></tr>
<tr><td>2.</td><td>Is proper and continuous monitoring and control available for stability chamber?</td><td>Yes, monitoring and control was available for the stability chambers provided. Firm was advised to install alarm system in stability chamber and perform challenge test.</td></tr>
</table></td></tr>
<tr><td>02</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>Applicant has submitted ADC attested invoice stating following information on it:
<u>For Apixaban:</u>
Invoice #: 90046555 (dated: 20-09-2017)
Manufacturer of API: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India.
Quantity of API: 1kg
Lot No. 1704002291
Cleared on/Attested on: 16-01-18</td></tr>
<tr><td>03</td><td>Documents for the procurement of reference standard and impurity standards.</td><td></td></tr>
<tr><td>04</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has submitted following:
<u>Copy of GMP certificate for Apixaban Manufacturer:</u>
Issued To: M/s. Alembic Pharmaceuticals, India.
Issued By: Food & Drug Administration, Gandhinagar, Gujrat State, India.
Issued On: 02 August, 2016
Valid up till: 01-08-2018.</td></tr>
<tr><td>05</td><td>Mechanism for Vendor pre-qualification.</td><td>Firm has submitted Vendor Qualification Flow Chart.</td></tr>
<tr><td>06</td><td>Certificate of analysis of the API, reference standards and impurity standards.</td><td><u>For API Apixaban:</u>
Photocopy of COA of Batch No. 1704002291 issued by M/s Alembic Pharmaceuticals Limited, India is submitted.
<u>Working standards:</u>
The firm has submitted the copy of COA of working Standards (Apixaban) Batch No. WS/APN/001, Quantity 0.2gm, provided by the API Manufacturer – M/s Alembic Pharmaceuticals Limited, India is submitted.</td></tr>
<tr><td>07</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted documents for procurement of excipients used in product development.</td></tr>
</table>

<table>
<tr><td>08</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted list of 06 qualified person working in R&D section.</td></tr>
<tr><td colspan="3">PRODUCTION DATA</td></tr>
<tr><td>09</td><td>Authorized Protocols / SOP for the development & stability testing of trial batches.</td><td>The firm has submitted copy of generalized SOP with the title ‘Product Design & Development’, Effective Date: 10th April, 2017, & Analytical method for testing of API & FPP.</td></tr>
<tr><td>10</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided complete batch manufacturing record of all the three batches
<table>
<tr><th colspan="4">Apixaban 2.5mg Tablets</th></tr>
<tr><th>BATCH NO.</th><th>BACH SIZE</th><th>MFG. STARTED</th><th>MFG. COMPLETED</th></tr>
<tr><td>RD-18092</td><td>3,800 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
<tr><td>RD-18093</td><td>3,800 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
<tr><td>RD-18094</td><td>3,800 Tabs</td><td>02-05-2018</td><td>03-05-2018</td></tr>
</table></td></tr>
<tr><td>11</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Apixaban 5mg Tablets; Stability Pack Size : 2 x 7’s)
• RD-18092: Batch Size : 3,800 Tablets
Number of tablets blistered: 400
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 01 pack are remaining Accelerated and 12 Packs remaining Real Time.
• RD-18093: Batch Size : 3,800 Tablets
Number of tablets blistered: 400
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 01 pack are remaining Accelerated and 12 Packs remaining Real Time.
• RD-18094: Batch Size : 3,800 Tablets
Number of tablets blistered: 400
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 01 pack are remaining Accelerated and 12 Packs remaining Real Time.</td></tr>
<tr><td colspan="3">QA/QC DATA</td></tr>
<tr><td>12</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (Real Time and Accelerated)</td><td>Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td>13</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</td></tr>
<tr><td>14</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>Firm has provided method used for analysis of FPP and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 06 months Real Time Stability Data.</td></tr>
<tr><td>15</td><td>Reports of stability studies of API from manufacturer.</td><td>APIXABAN: The firm has submitted copy of Accelerated 06 Months (40°C ± 2°C & 75±5%RH) stability study reports of 03 batches of Apixaban from M/s Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Village Karakhadi, Taluk-Padra, District-Panchmahal Vadodara-391450, Gujarat, India.</td></tr>
<tr><td>16</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Drug-excipients compatibility studies</td></tr>
</table>

<table>
<tr><td>18</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Eliquis 5mg Tablet, Bristol-Myers Squibb, USA.
<table>
<tr><th>FEATURE</th><th>REFERENCE PRODUCT</th><th>PRODUCT OF HIGHNOON</th></tr>
<tr><td>BRAND NAME</td><td>Eliquis 5mg Tabs.</td><td>Apixaban 5mg Tabs.</td></tr>
<tr><td>BATCH NO.</td><td>AAX1407</td><td>RD-18093</td></tr>
<tr><td>MFG. / EXPIRY DATE</td><td>Mfg. Date: 01-2018
Exp. Date: 12-2020</td><td>Mfg. Date: 05-2018
Exp. Date: 05-2020</td></tr>
</table></td></tr>
<tr><td>19</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.</td></tr>
</table>

Evaluation by PEC:

Sr.#	Deficiencies	Justification
1.	Submit Valid copy of GMP certificate of API Manufacturer issued by concerned regulatory authority of country of origin, as it is not valid now.	The GMP certificate for Apixaban (1809992) issued to alembic pharmaceutical Ltd, Valid up to 05-09-2021 is attached.
2.	Batch size for each of three trials is 7600 tablets as per your reconciliation sheet; out of which 400 tablets are blistered, 364 tablets were kept on stability. Justify/clarify that 364 tablets are sufficient for test/ analysis of each of the trials at all time points up till proposed shelf life. Moreover, where the remaining tablets which were not blistered were kept?	Total Tablets required for Dissolution=6 Disintegration=6 Assay/Purity=30 Total Tablets=42 Total Intervals (Real Time Stability)=6 Total Intervals (Accelerated Stability)=2 Total Intervals=8 Total Tablets Required=8*42=336 So total 364 tablets are placed in stability and the no of required tablets for testing are 336 and remaining quantities of the tablets are with the Product Development Department.
3.	Documents for the procurement of following excipients; macrogol 600, lactose anhydrous, polysorbate 80, titanium dioxide, iron oxide yellow, colloidal silicon dioxide are not submitted.	All the above excipients are procured from local vendors and their COAs are submitted in Annex 12 of already submitted file 1. The copies of COAs for your reference are enclosed.
4.	Submitted stability data of API by its Manufacturer, as it is not submitted.	The stability data is enclosed.
5.	Trial RD-18092 , RD-18093 & RD-18094 is prepared on 2nd May 2018 & assay testing is carried out on 29th May 2018 & dissolution on 2nd June 2018 as per information on chromatograms, Clarify/Justify,	Due to overload of work the testing of batch was planned in parts according to the availability of the equipment. Therefore after performing assay testing on 29th of May, 2018 dissolution testing was planned on 2nd June 2018.
6.	Chromatograms for Trial RD-18092 & RD-18093 at initial studies are not of applied drug product instead they are of some other formulation & contain a different batch number, Clarify/Justify before further processing of case.	The batch numbers mentioned on sample chromatograms are as per batch numbers were mentioned collectiverly because same standard is used against multiple samples analysed on same day. As products development has developed different formulations other thatn those formulation submitted, so batch numbers of those trials (formulation) were also mentioned on standards.
7.	Chromatogram for blank solution for trial 18093 at 6th month Accelerated Stability Studies shows some upward & downward peaks.	Based on your query we reviewed chromatogram of blank. As the diluents may have very minor residues therefore for the ease of review its scale

	Clarify/Justify	is normalized at 1 mAU along Y axis whereas in sample chromatogram due the very high concentration of solute its scale is normalized at 80 mAU along y-axis. So the baseline looks like that due to low scale)1/80th of the scale used for sample.) For understanding thechromatogram of blank solution normalized at 80 mAU is attached check A-4.
8.	Baseline for reference standards is not stable. Clarify/Justify.	Based on your we reviewed all datat and we found that in the chromatogram of reference solution of related substances, there is low concentration , its scale is normalized at 10mAU along Y axis whereas in sample chromatogram due to very high concentration its scale is noramlized at 1700mAU along y-axis. So the baseline looks like that at low scale. For understanding the chromatogram of reference solution narmalized at 1700mau is attached.
9.	Date & time for both strengths of Apixaban 2.5mg & 5mg tablet are same as per chromatograms & Audit trail. Justify/Clarify.	As the manufacturing of both strengths of Apixaban2.Smg &5mg are same as well as testing procedure is also same so we planned their analysis at same date and time

Decision: Registration Board decided to defer the case for confirmation of audit trail of HPLC analysis For stability studies of all three trial batches of applied product & clarification about how it is possible for all three trials of both strengths of Apiban tablet 2.5mg & 5mg to have same audit trial in terms of date & time at all-time intervals for all injections of sample & standard, by Area FID.

INSPECTION REPORT OF HIGHNOON LABORATORIES LTD, LAHORE

General Information

Name of Manufacturer	M/s Highnoon Laboratories Ltd.
Physical Address	17.5 km Multan Road, Lahore
DML No. and Validity	DML by way of formulation. No. 00155 Date of renewal: 20-08-2015
Date of Inspection	26th July, 2019
Purpose of Inspection	Panel inspection for verification of authenticity of stability data for purpose of registration of drugs with reference to DRAP Islamabad letter No. F.13-11/2017-PEC (Vol.I) dated 24th June, 2019
Name of Inspectors	i. Ms Haleema Sharif (Assistant Director PEC, Respective Evaluator, PE&R, DRAP Islamabad) ii. Ms UzmaBarkat (Area Federal Inspector of Drugs, Lahore)
Name of firm representatives accompanying during inspection	i. Dr SaleemAkhter (Director, Quality Operations) ii. Dr AhsanZameerSiddiqi (Associate Director Quality Control & Validation) iii. Ms IrumNaila (Associate Director Regulatory Affairs) iv. Ms NoureenAfzal (Head of Product Development) v. Mr Fahd Ali (Manager Stability) vi. Mr Muhammad Asif (Manager Quality Control)

Background:

M/s Highnoon Laboratories, 17.5 Km, Multan Road, Lahore applied for registration ofApiban 2.5mg & 5mg Tabletswith following composition:

1. Apiban 2.5mg tablet
Each film coated tablet contains:
Apixaban …… 2.5mg

2. Apiban 5mg tablet
Each film coated tablet contains:

Apixaban …… 5mg

Registration Board constituted a two member panel for on-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents, import of API, quality, specification, test analysis, facilitiesetc. Panel was requested to conduct inspection of the firm to verify the submitted data by the firm and to submit a report on approved format for further consideration of case by the Registration Board alongwith the clarification of following point.

a. For confirmation of audit trail of HPLC analysis for stability studies of all three trial batches of applied product & clarification as all three trials of both strengths of Apiban tablet 2.5mg & 5mg have same audit trial in terms of date &time at all-time intervals for all injections of sample & standard.

Scope of Inspection:

On-site investigation to confirm the genuineness/authenticity of submitted stability data and associated documents, import of API, quality, specification, test/ analysis, facilities, etc.

Tools for Inspection:

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

Details of Investigation

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of API including approval from DRAP?	Firm had submitted the AD attested commercial invoiceconfirming the import of API having following detail on it. **For Apixaban:** **Invoice #:** 90046555 (dated: 20-09-2017) **Manufacturer of API**: M/s. Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Vill. Karakhadi, Tal.Padra, Dist. Vadodara-391450, Gujarat, India. **Quantity of API**: 1kg **Lot No.** 1704002291 **Cleared on/Attested on**: 16-01-18
2.	What was the rationale behind selecting the particular manufacturer of API?	Firm has a vendor approval system and according to the firm, the rationale behind selecting the manufacturer is its GMP status and evaluation as per SOP for vendor approval.
3.	Do you have documents confirming the import of reference standard of Apixabanand impurity standards?	**For Working Standard:** • The firm informed that working standard was imported alongwith APIand had presented COA of Apixaban working standard during the visit. **For Impurity standard:** • Firm did not procure impurity standards.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	**For API & Working Standard:** The firm has submitted COAs of following: • Apixaban API • Apixaban working standard **For Impurity standard:** Impurity standards were not procured by the firm. Firm stated that impurity profiling has been carried out through Area normalization method which does not require impurity standard. (Firm informed that the related substances in API % FPP are

		evaluated by the validated method the related substance is calculated by relative retention time which does not require impurity standard. For identification of the known impurities (Impurity A, Impurity B, Impurity C, Impurity D) the relative retention time (i.e. with reference to Apixaban: Impurity A= about 2.19; Impurity B= about 0.45; Impurity C= about 1.26; Impurity D= about 2.82; Apixaban= about 1.00) is used.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has submitted following: **<u>Copy of GMP certificate for Apixaban Manufacturer:</u>** **Issued To**: M/s. Alembic Pharmaceuticals, India. **Issued By**: Food & Drug Administration, Gandhinagar, Gujrat State, India. **Issued On**: 02 August, 2016 **Valid up till**: 01-08-2018.
6.	Do you use API manufacturer's method of testing for testing of API?	Yes, firm used API manufacturer`s method of testing for testing of API
7.	Do you have stability studies reports on API?	**For Apixaban:** The firm has submitted copy of **Accelerated 06 Months** (40°C ± 2°C & 75±5%RH)& real time stability study reports of 03 batches of Apixaban API from M/s Alembic Pharmaceuticals Ltd., India, Survey No. 842, 843, Village Karakhadi, Taluk-Padra, District-Panchmahal Vadodara-391450, Gujarat, Indiaaccording to zone IV-A conditions.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes, stability testing had been performed as per Stability Indicating Method (SIM) and impurities/ related substances/degradation products had been quantified.
9.	Do you have method for quantifying the impurities in the API?	Yes, firm had method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had someremaining quantities of the API &working standard.
11.	Have you used pharmaceutical grade excipients?	The firm had used pharmaceutical grade excipients as indicated from the COAs of excipients submitted by firm.
12.	Do you have documents confirming the import of the used excipients?	The firm had submitted documents confirming import as well as purchase of the excipients from local vendors.
13.	Do you have test reports and other records on the excipients used?	Yes, the firm had test reports and other record of the excipients used.
14.	Do you have written and authorized protocols for the development of Apiban 2.5mg & 5mg Tablet.	Yes, the firm had written and authorized protocols for the development of both products.
15.	Have you performed Drug-excipients compatibility studies?	Yes, firm had performed drug excipient compatibility studies and all excipients were found compatible with the APIs as per the report provided.
16.	Have you performed comparative	Firm had performed comparative dissolution profile with the

	dissolution studies?	following reference product: **Eliquis 2.5mg Tablet, Bristol-Myers Squibb, USA.** Batch No:AAM5629 Mfg. Date: 08-2016 Exp. Date: 07-2019 **Eliquis 5mg Tablet, Bristol-Myers Squibb, USA.** Batch No:AAX1407 Mfg. Date: 01-2018 Exp. Date: 12-2020
17.	Do you have product development (R&D) section?	Yes, firm hada product development(PD) department.
18.	Do you have necessary equipment available in product development section for development of Apiban 2.5mg & 5mg Tablet?	Yes, firm had necessary equipment available in product development section for development Apiban 2.5mg Tablet and Apiban 5mg Tablet.
19.	Are the equipments in product development section qualified?	The equipment in product development section were qualified as informed by the firm. Equipment qualification protocols were available. Two protocols were randomly selected and scrutinized.
20.	Do you have proper maintenance/calibration/re-qualification program for the equipment used in PD section?	Yes, firm hada maintenance / calibration / re-qualification program for the whole facility including equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	Yes, firm had qualified and trainedstaff in product development section. Training record was available.
22.	Have you manufactured three stability batches for the stability studies of **Apiban 2.5mg & 5mg Tablet** as required?	The firm had manufactured three stability batches for the stability studies of **Apiban 2.5mg and 5mg Tablet**
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 tablets per testing frequency and number of testing frequencies / intervals) and minimum working capacity of equipment.
24.	Do you have complete record of production of stability batches?	Yes, firm had complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	Yes, firm had protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm had developed an In-house method for testing of finished product for stability studies. The firm hadalso provided during the visit, the analytical method validation protocol and report.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	The method for testing of the product was developed and validated in the firm's premises.
28.	Do you have documents confirming the qualification of equipments/instruments being	Yes, firm had documents confirming the qualification of equipment / instruments used in the test and analysis of API and finished drug product.

<table>
<tr><td></td><td>used in the test and analysis of APIs and the finished drug?</td><td></td></tr>
<tr><td>29.</td><td>Is your method of analysis stability indicating?</td><td>Yes, firm’s method of analysis was stability indicating and the record of testing of stability batches was available. The firm had conducted impurity testing through area normalization method.
The firm has also performed forced degradation studies & found that applied formulation i.e. Apiban 2.5mg & 5mg Tabletis sensitive to oxidation.</td></tr>
<tr><td>30.</td><td>Is your HPLC software 21CFR compliant?</td><td>Audit trail was active on all HPLC systems used in the stability studies. Individual user log in and IDs were available. Also, the record from logbooks was randomly checked and found verifiable onsite. A complete trail of such testing was found available and verifiable. Certificate of Compliance/Declaration of Software Quality form system manufacturers was available.</td></tr>
<tr><td>31.</td><td>Can you show Audit Trail reports on Apiban 2.5mg & 5mg Tablet testing?</td><td>Audit trail reports were available and randomly checked. It was verifiable from log books and system software.</td></tr>
<tr><td>32.</td><td>Do you have some remaining quantities of degradation products and stability batches?</td><td>The firm had remaining quantities of stability batches which were placed for ongoing real time stability studies.</td></tr>
<tr><td>33.</td><td>Do you have stability batches kept on stability testing?</td><td>The firm had completed the accelerated stability testing on the three stability batches ofApiban 2.5mg Tablet and Apiban 5mg Tablet. The firm hadstability batcheskept on ongoing real time stability testing which were shown during inspection.</td></tr>
<tr><td>34.</td><td>Do you have valid calibration status for the equipments used in production and analysis?</td><td>The firm has valid calibration status for the equipments used in production and analysis of Apiban 2.5mg & 5mg Tablet.</td></tr>
<tr><td>35.</td><td>Is proper and continuous monitoring and control are available for stability chamber?</td><td>Continuous power supply with back up from generator and UPS are available for stability chambers to address the problem of interrupted power supply or load shedding. Digital data loggers were available for continuous monitoring of temperature and humidity conditions of stability chambers.
Firm was advised to install alarm system in stability chamber and perform challenge test.

Capacity of stability chambers provided by the firm is as follows:
<table>
<tr><td>Stability Chamber</td><td>Available Capacity (samples)</td><td>Utilized Capacity (samples)</td></tr>
<tr><td>Accelerated Stability</td><td>500</td><td>300</td></tr>
<tr><td>Long Term Stability</td><td>5000</td><td>3500</td></tr>
</table></td></tr>
<tr><td>36.</td><td>Is related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?</td><td>The related facilities of Highnoon Laboratories Ltd., Lahorewere GMP compliant.The firm had valid GMP certificate issued by Drug Regulatory Authority of Pakistan.</td></tr>
<tr><td>37.</td><td>For confirmation of audit trail of HPLC analysis for stability studies of all three trial batches of applied product & clarification as all three trials of both strengths of Apiban</td><td>Audit trail reports of HPLC analysis for both strengths of Apiban tablet 2.5mg & 5mg were found verifiable onsite. Audit trail reports were available and randomly checked. It was verifiable from log books and system software. Date and time was found to be same for standard chromatograms in case same standard</td></tr>
</table>

	tablet 2.5mg & 5mg have same audit trial in terms of date &time at all-time intervals for all injections of sample & standard	injections were applicable for both strengths during a sequential analysis run on the same HPLC system.

CONCLUSION

Based on the documents reviewed, areas inspected and technical personnel met, and considering the findings of the inspection, the panel is of the view that the genuineness / authenticity of stability data submitted by M/s Highnoon Laboratories Ltd., 17.5 km Multan Road, Lahore for registration of Apiban 2.5mg Tablet and Apiban 5mg Tablet is verifiable to a satisfactory level.

Decision: Registration Board decided to approve registration of "Apiban 2.5mg Tablet and Apiban 5mg Tablet" by M/s Highnoon Laboratories, Lahore. 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.

Case No. 05: Registration applications of local manufacturing of human drugs submitted on CTD Format.

a. New cases

799.	Name, address of Applicant / Marketing Authorization Holder	M/s Roche Pakistan limited, Ist floor, 37-B, Block-6, P.E.C.H.S, Karachi.
	Name, address of Manufacturing site.	**M/s Roche, Germany** **Site** / **Responsibility** Excella GmbH & Co. KG, Nürnberger Strasse 12, 90537 Feucht Germany — Manufacturing and analytical release testing Delpharm Milano, S.r.l.a, Via Carnevale 1, 20090 Segrate (MI) Italy — Analytical stability testing, primary and secondary packaging and release of Finished Drug Product F. Hoffmann□La Roche Ltd, Viaduktstrasse 33, CH□4051 Basel Switzerland — Release of Finished Drug Product
	Status of the applicant	□ Manufacturer □ **Importer** □ Is involved in none of the above (contract giver) Firm has submitted agreement for contract manufacturing
	Intended use of pharmaceutical product	□ Domestic sale □ Export sale □ **Domestic sales**
	Dy. No. and date of submission	Dy. No. 5564: 08-05-2019
	Details of fee submitted	PKR 50,000/-: 07-05-2019
	The proposed proprietary name / brand name	**Alecensa Capsule 150 mg**
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Alectinib …… 150mg
	Pharmaceutical form of applied drug	Hard gelatin capsule (White to yellowish white, Size 1capsules with ALE printed in black ink on the cap & 150mg printed in black ink on the body.)
	Pharmacotherapeutic Group of (API)	Anti-neoplastic

	Reference to Finished product specifications	In-House
	Proposed Pack size	4's
	Proposed unit price	To be provided
	The status in reference regulatory authorities	Approved by USFDA
	For generic drugs (me-too status)	N/A
	Name and address of API manufacturer.	**Responsibility** / **Site** / **Address** Manufacture (synthesis), Release and Stability Testing — Evonik Corp. — 1650 Lilly Road Lafayette, IN 47909 USA Manufacture (milling), Release Testing, Packaging — Catalent Micron Technologies, Inc.a — 333 Phoenixville Pike Malvern, PA 19355 USA
	Stability Studies of Drug Substance (Conditions & duration of Stability studies)	30□C/75% RH 40□C/75% RH for 48 months
	Comparative Dissolution Profile Data (Details of reference product & study)	N/A It is innovator Product
	Process validation data of product	Submitted
	Analytical method validation/verification of product	Submitted
	Stability studies of product	Submitted

Summary of Evaluation:

DRUG PRODUCT NAME AND STRENGTH:
Alecensa 150mg hard Capsule
APPLICANT:
M/s Roche Pharmaceuticals (Importer)

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No. 5564 dated 08-05-2019 , 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 Roche Pakistan limited, Ist floor, 37-B, Block-6, P.E.C.H.S, Karachi.**
	1.3.2	Name, address and contact details of Manufacturing site. **Site** / **Responsibility** Excella GmbH & Co. KG Nürnberger Strasse 12 90537 Feucht Germany — Manufacturing and analytical release testing

			Delpharm Milano, S.r.l.a Via Carnevale 1 20090 Segrate (MI) Italy	Analytical stability testing, primary and secondary packaging and release of Finished Drug Product	
			F. Hoffmann□La Roche Ltd Viaduktstrasse 33 CH□4051 Basel Switzerland	Release of Finished Drug Product	
	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. Drug sale license by way of whole sale Validity: 02-08-2019 Address: M/s Roche Pakistan limited. Drug sale license by way of whole sale Validity: 01-08-2019 Address: M/s Roche Pakistan limited.			
	1.3.5	Evidence of approval of manufacturing facility / Approved Section from Licensing Authority. N/A, Imported Product			
	1.3.6	List of already approved registered drugs in this section. Submitted			
	1.3.7	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance Provided			
	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)** □ 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. Alectinib			
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each capsule contains: Alectinib …… 150mg			
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance. Alecensa Capsule 150 mg			

	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. 224(4 packs of 56) hard capsule
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) L01XE36 Alectinib
	1.5.6	Pharmacopoeial reference / Status of applied formulation Innovator
	1.5.7	Route of administration Oral
	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. N/A
	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. Approved by USFDA.
	1.5.10	Dosage form of applied drug Capsule
	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 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).
	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 Not Applicable
	1.6.2	Appendix Not Applicable
	1.6.3	Electronic Review Package Submitted
	1.6.4	QIS (Quality Information Summary) Submitted
	1.6.5	Drug Substance related Document including following: a. Name and address of API manufacturer. Evonik Corp 1650 Lilly Road, Lafayette, IN 47909, USA b. Approval of manufacturing facility of API by regulatory body of country and validity. Not Applicable c. Vendor qualification / audit is □ Document based □ Site inspection based d. Reason for point c.
	Original, legalized CoPP: It has following information on it: **Certificate No**. 190041202 **Issued by**: Swiss Agency For Therapeutic Products **Free Sale In Exporting Country:** Product is actually on the market in the exporting country. **GMP:** Facilities & Operations confirm to GMP as recommended by World Health Organizations.	

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	**Drug substance (API)** General information *Submitted* Manufacture *Submitted* Characterization *Submitted* Control of drugsubstance *Submitted* Reference standards *Submitted* Container closure system *Submitted* Stability *Submitted*
	Comments
	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 Submittted
	Comments
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***
	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** ***Submitted***
	3.2.S.2.5	**Process Validation and/or Evaluation** ***Not applicable***
	The alectinib HCl manufacturing process involves neither aseptic processes nor sterilization processes. The ICH Q11 guideline states that for non-sterile chemical entity Drug Substance processes, results of process validation studies are not normally included in the dossier. Therefore, no information is provided in this section.	
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***
		Comments
	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
		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***
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***	
	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 ***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***
		Comments
	3.2.P.3.2	**Batch formula** ***Submitted***
		Comments
	3.2.P.3.3	**Description of manufacturing process and process controls** ***Submitted***
		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***
		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** ***Submitted***
	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***
		Comments
	3.2.P.5.6	**Justification of specifications** ***Submitted***
		Comments
3.2.P.6	**Reference Standards or Materials** ***Submitted***	
	Comments	
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***
		Comments
	3.2.P.8.2	**Post-approval Stability Protocol and Stability Commitment** ***Submitted***
		Comments
	3.2.P.8.3	**Stability** ***Submitted***

Decision: Approved as per innovator's specification.

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

a. New cases

803.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore By M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	Ceftam 2gm IV Dry Injection
	Composition	Each Vial Contains: Cefoperazone as Sodium…1g Sulbactam as Sodium…1g
	Diary No. Date of R& I & fee	Dy No. 18678: 23.05.2018 PKR 50,000/-: 23.05.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	1's vial; Rs. 350/-
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Ectafin Injection 2gm IV. Reg. No. 80027
	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. The firm M/s Vega Pharmaceuticals was inspected on 17.07.2017, wherein GMP was rated as good.
	Remarks of the Evaluator.	• The firm M/s Reko Pharmacal Pvt Ltd submitted that there is no product approved for contract manufacturing. • The firm M/s Reko Pharmacal Pvt Ltd submitted list of 04 products applied for contract manufacturing. However, there are six products mentioned in the contract manufacturing agreement. • The firm M/s Reko Pharmacal Pvt Ltd submitted list of 09 approved sections. However, 08 sections have been mentioned in the GMP inspection report. • The firm has submitted copy of contract manufacturing agreement between applicant and manufacturer.
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Vega Pharmaceuticals Pvt Ltd. Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
804.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore By M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	CEFTOX 1g IV Dry Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…1g
	Diary No. Date of R& I & fee	Dy No. 18785: 23.05.2018 PKR 50,000/-: 23.05.2018
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; Rs. 321/-
	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	As above
	Remarks of the Evaluator.	• As above
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Vega Pharmaceuticals Pvt Ltd. Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
805.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore By M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	CEFTOX 500mg IV Dry Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…500mg
	Diary No. Date of R& I & fee	Dy No. 18784: 23.05.2018 PKR 50,000/-: 23.05.2018
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; Rs. 170/-
	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	As above
	Remarks of the Evaluator.	• As above
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Vega Pharmaceuticals Pvt Ltd. Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
806.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Pvt Ltd. 13-Km, Multan Road, Lahore By M/s Vega Pharmaceuticals Pvt Ltd. Plot No. 4, 30-Km Pharma City, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	CEFTOX 250mg IM Dry Injection
	Composition	Each Vial Contains: Ceftriaxone Sodium Eq. to Ceftriaxone…250mg
	Diary No. Date of R& I & fee	Dy No. 18783: 23.05.2018 PKR 50,000/-: 23.05.2018
	Pharmacological Group	Third generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; Rs. 101/-
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IM). US-FDA approved
	Me-too status	Unixone Inj.(ceftriaxone Sodium) 250mg IM. R.No.82556
	GMP status	As above
	Remarks of the Evaluator.	• As above
	Decision: Registration Board deferred the case for assessment and confirmation of manufacturing capacity of M/s Vega Pharmaceuticals Pvt Ltd. Lahore by panel to be constituted by Chairman Registration Board for further granting contract manufacturing permission as the firm has already been granted approval for contract manufacturing of numerous products.	
807.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cestar Dry Powder for oral suspension 100mg/5ml
	Composition	Each 5ml contains: Cefixime as trihydrate…..100mg
	Diary No. Date of R& I & fee	Dy No. 18679: 22.05.2018 PKR 20,000/-: 22.05.2018

	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 100ml, 120ml; As per PRC
	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	GMP inspection of M/s Daneen Pharma Pvt. Ltd by Panel of Inspectors dated 08-03-2019 shows that firm compliant to GMP and Quality control operation (Only dry powder injection section (Cephalosporin) was operational at the time of inspection.
	Remarks of the Evaluator.	• The firm has mentioned powder for suspension, but granulation process has been mentioned in the manufacturing outlines. The firm did not clarify the same. • The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved.	
808.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Cestar Dry Powder for oral suspension 200mg/5ml
	Composition	Each 5ml contains: Cefixime as trihydrate…..200mg
	Diary No. Date of R& I & fee	Dy No. 18676: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 100ml, 120ml; As per PRC
	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	As above
	Remarks of the Evaluator.	• The firm has mentioned powder for suspension, but granulation process has been mentioned in the manufacturing outlines. The firm did not clarify the same. • The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	
809.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kingrox 125mg/5ml Dry powder suspension
	Composition	Each 5ml contains: Cefuroxime axetil eq to Cefuroxime…125mg (150mg)
	Diary No. Date of R& I & fee	Dy No. 18679: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	Second-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	ZINNAT cefuroxime (as axetil) 125 mg/5mL granules for oral suspension bottle. **TGA** approved The dosage form has been mentioned as "Suspension, powder for".
	Me-too status	Kefzy Suspension 125mg/5ml. Reg. No. 82756

	GMP status	As above
	Remarks of the Evaluator.	• The firm applied for powder for suspension, with granulation process mentioned in the manufacturing outlines. The firm later on revised it to granules for suspension without submission of any fee. • The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	
810.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kingrox Injection 750mg
	Composition	Each vial contains: Cefuroxime Sodium eq to Cefuroxime…750mg
	Diary No. Date of R& I & fee	Dy No. 18680: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	Second-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per registration; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Cefuroxime 750 mg powder for solution/suspension for injection. **MHRA** approved
	Me-too status	Rokky Injection 750mg. Reg. No. 84891
	GMP status	As above
	Remarks of the Evaluator.	The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	
811.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kinglex capsules 250mg
	Composition	Each capsule contains: Cephalexin as monohydrate…250mg
	Diary No. Date of R& I & fee	Dy No. 18681: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Cefalexin 250 mg Capsules [contains Cefalexin (Monohydrate) equivalent to 250 mg of Cefalexin]. Approved by MHRA
	Me-too status	Lexofin Capsule 250mg by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80026
	GMP status	As above
	Remarks of the Evaluator.	The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	
812.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kinglex dry powder suspension 125mg/5ml
	Composition	Each 5ml contains: Cephalexin as monohydrate…125mg
	Diary No. Date of R& I & fee	Dy No. 18682: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	60ml, 90ml, 100ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	GENRX CEPHALEXIN cefalexin (as monohydrate) 125mg/5mL powder for suspension. **TGA** approved
	Me-too status	Pefalex Suspension 125mg. Reg. No. 80049
	GMP status	As above
	Remarks of the Evaluator.	• The firm has applied for powder for suspension, but granulation process has been mentioned in the manufacturing outlines. The firm revised it to granule for suspension without submission of any fee. • The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	
813.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Kinglex dry powder suspension 250mg/5ml
	Composition	Each 5ml contains: Cephalexin as monohydrate…250mg
	Diary No. Date of R& I & fee	Dy No. 18683: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 100ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	GENRX CEPHALEXIN cefalexin (as monohydrate) 250mg/5mL powder for suspension. **TGA** approved
	Me-too status	Pefalex Suspension 250mg. Reg. No. 80050
	GMP status	As above
	Remarks of the Evaluator.	• The firm has applied for powder for suspension, but granulation process has been mentioned in the manufacturing outlines. The firm revised it to granule for suspension without submission of any fee. • The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	
814.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	D-Clor 125mg/5ml Dry powder suspension
	Composition	Each 5ml contains: Cefaclor monohydrate eq to cefaclor…..125mg
	Diary No. Date of R& I & fee	Dy No. 18677: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	Second-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Cefaclor 125mg/5ml powder for Suspension. MHRA approved
	Me-too status	Eclor Oral 125mg/5ml Dry Suspension. R.No. 83946
	GMP status	As above
	Remarks of the Evaluator.	• The firm has applied for powder for suspension, but granulation process has been mentioned in the manufacturing outlines. The firm revised it to granule for suspension without submission of any fee. • The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	

815.	Name and address of manufacturer / Applicant	M/s Daneen Pharma Pvt Ltd. 27, Sundar industrial Estate, Sundar Raiwind Road, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	D-Clor 250mg/5ml Dry powder suspension
	Composition	Each 5ml contains: Cefaclor monohydrate eq to cefaclor…..250mg
	Diary No. Date of R& I & fee	Dy No. 18678: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	Second-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Cefaclor 250mg/5ml powder for Suspension. MHRA approved
	Me-too status	Eclor Oral Suspension 250mg/5ml Dry Suspension. Reg. No. 83945
	GMP status	As above
	Remarks of the Evaluator.	• The firm has applied for powder for suspension, but granulation process has been mentioned in the manufacturing outlines. The firm revised it to granule for suspension without submission of any fee. • The firm has submitted latest Form 5 duly signed by all concerned persons.
	Decision: Approved	
816.	Name and address of manufacturer / Applicant	Glitz Pharma Plot No. 265, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Atom 40 mg Capsule
	Composition	Each capsule contains: Atomoxetine hydrochloride eq. to Atomoxetine…..40mg
	Diary No. Date of R& I & fee	Dy No. 2732: 19.01.2018 PKR 20,000/-: 17.01.2018
	Pharmacological Group	Centrally acting sympathomimetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per Policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	ATAMA 40 mg hard capsules. **MHRA** approved
	Me-too status	Doqaz 40mg Capsule. Reg. No. 79926
	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	•
	Decision: Approved with change of brand name.	
817.	Name and address of manufacturer / Applicant	Glitz Pharma Plot No. 265, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Basinol 2.5mg Tablet
	Composition	Each film-coated tablet contains: Bisoprolol fumarate……..2.5mg
	Diary No. Date of R& I & fee	Dy No. 2733: 19.01.2018 PKR 20,000/-: 17.01.2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 14's, 28's, 30's, 50's, 100's; As per Policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	Bisoprolol 2.5 mg Film-coated Tablet. **MHRA** approved
	Me-too status	Bisfat Tablets 2.5mg. Reg. No. 77054

	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	•
	Decision: Approved	
818.	Name and address of manufacturer / Applicant	Glitz Pharma Plot No. 265, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Exocib 60mg Tablet
	Composition	Each film-coated tablet contains: Etorcoxib……..60mg
	Diary No. Date of R& I & fee	Dy No. 2728: 19.01.2018 PKR 20,000/-: 17.01.2018
	Pharmacological Group	Coxibs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed USP specifications. The product is not available in USP, BP, IP and JP
	Pack size & Demanded Price	10's, 20's, 14's, 28's, 30's, 50's, 100's; As per Policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	Etoricoxib 60 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Eto 60 mg Tablet. Reg. No. 78176
	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications and testing method. The firm did not submit the same.
	Decision: Approved with innovator's specifications	
819.	Name and address of manufacturer / Applicant	Glitz Pharma Plot No. 265, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Rivar G 20mg Tablet
	Composition	Each film-coated tablet contains: Rivaroxaban……..20mg
	Diary No. Date of R& I & fee	Dy No. 2738: 19.01.2018 PKR 20,000/-: 17.01.2018
	Pharmacological Group	Factor Xa inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	10's, 20's, 14's, 28's, 30's, 50's, 100's; As per Policy of DRAP
	Approval status of product in Reference Regulatory Authorities.	Rivaroxaban 20 mg film-coated tablets. **MHRA** approved
	Me-too status	Rivaxo 20mg film-coated Tablet. Reg. No. 80791
	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
820.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	L-Zolid Dry Suspension 100mg/5ml
	Composition	Each 5ml contain: Linezolid…..100mg
	Diary No. Date of R& I & fee	Dy No. 1070: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	Other antibacterials
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities.	ZYVOX® (linezolid) oral suspension (dry). MHRA approved
	Me-too status	Nezolid 100mg Suspension. Reg. No. 50326
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
821.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Trans Injection 500mg/5ml
	Composition	Each 5ml vial contains: Tranexamic acid…..500mg
	Diary No. Date of R& I & fee	Dy No. 1060: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	Antifibrinolytics
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TRANEXAMIC ACID IV APOTEX tranexamic acid 500 mg/5 mL solution for injection vial. TGA approved
	Me-too status	Enxamin Injection 500mg. Reg. No. 52925
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	• The firm submitted Rs. 5000/- without any reason.
	Decision: Deferred for confirmation of approval of manufacturing facility / section (i.e. General vial section) from Licensing Division DRAP.	
822.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Amika Injection 500mg/2ml
	Composition	Each 2ml vial contains: Amikacin as sulphate…..500mg
	Diary No. Date of R& I & fee	Dy No. 1103: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	Other aminoglycosides
	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.	Amikacin 250mg/ml Injection (2ml). MHRA approved
	Me-too status	Enxamin Injection 500mg. Reg. No. 52925
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	• The firm has applied for 500mg/2ml injection, while the master Formula contains amikacin sulphate 250mg per 2 ml vial. Correction along with adjustment of weight as per salt factor is required in master Formula. • The firm submitted Rs. 5000/-. • Undertaking at the end of Form 5 is missing.
	Decision: Deferred for confirmation of approval of manufacturing facility / section (i.e. General vial section) from Licensing Division DRAP.	

823.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Glimefold Tablet 1/500mg
	Composition	Each film-coated tablet contains: Glimepiride……..1mg Metformin as HCl….500mg
	Diary No. Date of R& I & fee	Dy No. 1094: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	Sulfonylureas + Biguanides
	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	Diabold Plus Tablet (film-coated). Reg. No. 76011 GPRIDE-M SR 1/500mg tablet (bilayer). Reg. No. 76306
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	• Undertaking at the end of Form 5 is missing.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting** • **Revision of salt form of Metformin HCl in line with the reference product.** • **Submission of undertaking at the end of Form 5.**	
824.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Glimefold Tablet 2/500mg
	Composition	Each film-coated tablet contains: Glimepiride……..2mg Metformin as HCl….500mg
	Diary No. Date of R& I & fee	Dy No. 1095: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	Sulfonylureas + Biguanides
	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	Diabold Plus Tablet (film-coated). Reg. No. 76012 GPRIDE-M SR 2/500mg tablet (bilayer). Reg. No. 76307
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	• Undertaking at the end of Form 5 is missing.
	Decision: Deferred for the following: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275thmeeting** • **Revision of salt form of Metformin HCl in line with the reference product.** • **Submission of undertaking at the end of Form 5.**	
825.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	W-Mide Tablet 100mg
	Composition	Each film-coated tablet contains: Lacosamide……100mg
	Diary No. Date of R& I & fee	Dy No. 1087: 08.01.2018 PKR 20,000/-: 08.01.2018

	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	VIMPAT® (lacosamide) film coated tablet, for oral use, CV. USFDA approved
	Me-too status	Lacolit Tablet (film-coated). Reg. No. 77127
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
826.	Name and address of manufacturer / Applicant	Weather Folds Pharmaceuticals Plot No. 12 Street # N-3 National Industrial Zone (RCCI) Rawat Islamabad Pakistan
	Brand Name +Dosage Form + Strength	Thiofold Tablet 4mg
	Composition	Each uncoated tablet contains: Thiocolchicoside ……4mg
	Diary No. Date of R& I & fee	Dy No. 1059: 08.01.2018 PKR 20,000/-: 08.01.2018
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	THIOCOLCHICOSIDE EG 4 mg, scored tablet. **ANSM** approved
	Me-too status	Myolax Tablets. Reg. No. 74170
	GMP status	The firm was inspected on 15.09.2017 with the following conclusion: Overall the firm was GMP Compliant as per DRAP Guidelines.
	Remarks of the Evaluator.	• The firm revised the formulation to uncoated tablet without submission of fee. • Revision of manufacturing outlines is required accordingly. • Undertaking at the end of Form 5 is missing.
	Decision: Deferred for following: • **Submission of fee for revision of formulation** • **Submission of manufacturing outlines** • **Submission of undertaking**	
827.	Name and address of manufacturer / Applicant	M/s Asian Continental Pvt Ltd. Continental House, D-133, Tipu Sultan Road, Scheme-I, Karachi
	Brand Name +Dosage Form + Strength	Viscon Liquid
	Composition	Each 10ml contains: Sodium Alginate…500mg Sodium Bicarbonate…267mg Calcium Carbonate…160mg
	Diary No. Date of R& I & fee	Dy No. 18782: 23.05.2018 PKR 20,000/-: 23.05.2018
	Pharmacological Group	Gastro-oesophageal reflux suppressant (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Gaviscon Cool Liquid. MHRA approved
	Me-too status	Ul-Nil Suspension. Reg. No. 52470

	GMP status	The firm was inspected on 25.06.2019, wherein the GMP level was rated as GOOD
	Remarks of the Evaluator.	The firm has applied for oral liquid; however, the product is internationally and locally available/registered is suspension. The firm replied that the application is based on the brand leader available in Pakistan. Gaviscon liquid manufactured by Reckeitt Benckiser Pakistan has not mentioned suspension in bottle label. Although the formulation of applied product is suspension. The firm requested to change syrup /iquid to suspension.
	Decision: Approved with innovator's specifications	
828.	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	Epilev 250mg Tablet
	Composition	Each film-coated tablet contains: Levetiracetam…250mg
	Diary No. Date of R& I & fee	Dy No. 25465: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 250 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 250mg Tablets. Reg. No. 84220
	GMP status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP.
	Remarks of the Evaluator.	•
	Decision: Approved	
829.	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	Epilev 500mg Tablet
	Composition	Each film-coated tablet contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 25466: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other Antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84221
	GMP status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP.
	Remarks of the Evaluator.	•
	Decision: Approved	
830.	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	Epilev 750mg Tablet
	Composition	Each film-coated tablet contains: Levetiracetam…750mg
	Diary No. Date of R& I & fee	Dy No. 25468: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antiepileptics

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 750 mg film-coated tablets. **MHRA** approved
	Me-too status	Levotam film-coated 750mg Tablets. Reg. No. 55641
	GMP status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP.
	Remarks of the Evaluator.	•
	Decision: Approved	
831.	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	Epilev XR 500mg Tablet
	Composition	Each extended release tablet contains: Levetiracetam…500mg
	Diary No. Date of R& I & fee	Dy No. 25467: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's; As per DPC
	Approval status of product in Reference Regulatory Authorities.	KEPPRA XR (levetiracetam) film-coated extended-release tablets, for oral use. **MHRA** approved
	Me-too status	Lerace XR Tablet. Reg. No. 70417
	GMP status	The firm was inspected on 10.07.2018, wherein the firm was considered to be operating at good level of compliance with GMP.
	Remarks of the Evaluator.	•
	Decision: Approved	
832.	Name and address of manufacturer / Applicant	Rock Pharmaceutical laboratories (Pvt.) Ltd., 134-B & 135-B Noweshera Industrial Estate, Risalpur
	Brand Name +Dosage Form + Strength	Zes Capsule 40mg
	Composition	Each capsule contains: Omeprazole (as enteric coated pellets)…..40mg
	Diary No. Date of R& I & fee	Dy No. 2675: 26.01.2017 PKR 100,000/-: 26.01.2017
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Losec 40 mg hard gastro-resistant capsules. Approved by **MHRA**
	Me-too status	Omecap Capsule. Reg. No. 84494
	GMP status	The firm was inspected on 18.07.2018, wherein grant of GMP certificate was recommended. Source of pellets: not provided
	Remarks of the Evaluator.	• The firm submitted stability data of imported pellets of Asian Pharmacoat (Pvt) Ltd, Hyderabad, India, which has already been approved for Zes 20mg capsules. • Latest GMP of the source of pellets is required. • The pellets have been tested as per in-house specifications.
	Decision: Deferred for GMP certificate of the source of pellets and clarification regarding testing of pellets as per in-house specifications.	

833.	Name and address of manufacturer / Applicant	Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	DiSita Tablets 100mg
	Composition	Each film-coated tablet contains: Sitagliptin (as phosphate monohydrate)……...100mg
	Diary No. Date of R& I & fee	Dy No. 18955: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	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.	JANUVIA® (sitagliptin) Tablets, film-coated. **USFDA** approved
	Me-too status	Duvel 100mg Tablet. Reg. No. 79616
	GMP status	The firm was inspected on 15-16.01.2018, wherein grant of GMP certificates was recommended.
	Remarks of the Evaluator.	•
	Decision: Approved	
834.	Name and address of manufacturer / Applicant	Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	DiSita Tablets 50mg
	Composition	Each film-coated tablet contains: Sitagliptin (as phosphate monohydrate)……...50mg
	Diary No. Date of R& I & fee	Dy No. 18952: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	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.	JANUVIA® (sitagliptin) Tablets, 50mg film-coated. **USFDA** approved
	Me-too status	Duvel 50mg Tablet. Reg. No. 79615
	GMP status	As above
	Remarks of the Evaluator.	•
	Decision: Approved	
835.	**Name and address of manufacturer / Applicant**	**Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore**
	Brand Name +Dosage Form + Strength	DiSita Tablets 25mg
	Composition	Each film-coated tablet contains: Sitagliptin (as phosphate monohydrate)……...25mg
	Diary No. Date of R& I & fee	Dy No. 18956: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Dipeptidyl peptidase 4 (DPP-4) inhibitors
	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.	JANUVIA® (sitagliptin) Tablets, 25mg film-coated. USFDA approved
	Me-too status	Duvel 25mg Tablet. Reg. No. 79614
	GMP status	As above
	Remarks of the Evaluator.	•
	Decision: Approved	
836.	Name and address of manufacturer / Applicant	Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	DiSita Plus Tablets 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. 18951: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2x7's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/500mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/500mg Tablets. Reg. No. 53099 (does not depict hydrate form).
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised Sitagliptin to Sitagliptin (as phosphate monohydrate) in label claim along with submission of Rs. 5000/- fee
	Decision: Approved with innovator's specifications	
837.	Name and address of manufacturer / Applicant	Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	DiSita Plus Tablets 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. 18953: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2x7's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/1000mg Tablets. Reg. No. 53100 (does not depict hydrate form).
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised Sitagliptin to Sitagliptin (as phosphate monohydrate) in label claim along with submission of Rs. 5000/- fee.
	Decision: Approved with innovator's specifications	
838.	Name and address of manufacturer / Applicant	Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	DiVilda Plus Tablets 50mg/500mg
	Composition	Each film-coated tablet contains: Vildagliptin……...50mg Metformin HCl…..500mg
	Diary No. Date of R& I & fee	Dy No. 18957: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm ahs claimed in-house specifications
	Pack size & Demanded Price	2x7's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/500 vildagliptin 50 mg/metformin hydrochloride 500 mg film coated tablet by Novartis Pharmaceuticals Australia Pty Ld. **TGA** approved
	Me-too status	Galmet 50mg/500mg Tablet by Vision Pharma. Reg No. 81905
	GMP status	As above
	Remarks of the Evaluator.	• The firm mentioned "each tablet contains". However, coating

		compositions and process has been mentioned in manufacturing outlines. Upon clarification the firm submitted that it was atypoghrapical mistake. • The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with innovator's specifications	
839.	Name and address of manufacturer / Applicant	Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	DiVilda Plus Tablets 50mg/850mg
	Composition	Each film-coated tablet contains: Vildagliptin……...50mg Metformin HCl…..850mg
	Diary No. Date of R& I & fee	Dy No. 18958: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm ahs claimed in-house specifications
	Pack size & Demanded Price	2x7's; leader price
	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	As above
	Remarks of the Evaluator.	• The firm mentioned "each tablet contains". However, coating compositions and process has been mentioned in manufacturing outlines. Upon clarification the firm submitted that it was atypoghrapical mistake. • The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with innovator's specifications	
840.	Name and address of manufacturer / Applicant	Remington Pharmaceuticals Industries (Pvt.) Ltd., 18-km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	DiVilda Plus Tablets 50mg/1000mg
	Composition	Each film-coated tablet contains: Vildagliptin……...50mg Metformin HCl…..1000mg
	Diary No. Date of R& I & fee	Dy No. 18954: 24.05.2018 PKR 20,000/-: 24.05.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	???
	Pack size & Demanded Price	2x7's; leader price
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/1000 vildagliptin 50 mg/metformin hydrochloride 1000 mg film coated tablet. **TGA** approved
	Me-too status	Valiant-M Tablets by Ferozsons Labs., Nowshehra. Reg No. 77485
	GMP status	As above
	Remarks of the Evaluator.	• The firm mentioned "each tablet contains". However, coating compositions and process has been mentioned in manufacturing outlines. Upon clarification the firm submitted that it was atypoghrapical mistake. • The approved shelf-life of the product in 18 months in TGA Australia
	Decision: Approved with innovator's specifications	
841.	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	Ranitid 300mg Tablet

	Composition	Each Film Coated Tablet Contains: Ranitidine as HCL…300mg
	Diary No. Date of R& I & fee	Dy No. 25418: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; As per PAC
	Approval status of product in Reference Regulatory Authorities.	Ranitidine 300mg film coated tablets. **MHRA** approved
	Me-too status	Ranidol Tablets 300mg. Reg. No. 79258
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 12.12.2017.
	Remarks of the Evaluator.	
	Decision: Approved	
842.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Pequit 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Quetiapine as Fumarate…25mg
	Diary No. Date of R& I & fee	Dy No. 23631: 09.07.2018 PKR 20,000/-: 09.07.2018
	Pharmacological Group	Anti-psychotic
	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.	Quetiapine 25 mg film-coated tablets. MHRA approved
	Me-too status	Qupixan Tablet 25 mg. Reg. No. 81960
	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	
843.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Pequit 100mg Tablet
	Composition	Each film coated tablet contains: Quetiapine as fumarate….. 100mg
	Diary No. Date of R& I & fee	Dy No. 23632: 09.07.2018 PKR 20,000/-: 09.07.2018
	Pharmacological Group	Anti-psychotic
	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.	Quetiapine 100mg film-coated tablets. MHRA Approved
	Me-too status	Qupixan Tablet 100 mg. Reg. No. 81961
	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	

844.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Pequit 150mg XR Tablet
	Composition	Each film coated extended release tablet contains: Quetiapine as fumarate….. 150mg
	Diary No. Date of R& I & fee	Dy No. 23633: 09.07.2018 PKR 20,000/-: 09.07.2018
	Pharmacological Group	Anti-psychotic
	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.	Alaquet XL 150 MG prolonged-release tablets. MHRA Approved
	Me-too status	Ziapine XR 150mg Oral Tablets. Reg. No. 78755
	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	
845.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Pequit 200mg XR Tablet
	Composition	Each film coated extended release tablet contains: Quetiapine as fumarate….. 200mg
	Diary No. Date of R& I & fee	Dy No. 23634: 09.07.2018 PKR 20,000/-: 09.07.2018
	Pharmacological Group	Anti-psychotic
	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.	Alaquet XL 200 MG prolonged-release tablets. MHRA Approved
	Me-too status	Ziapine XR 200mg Oral Tablets. Reg. No. 78754
	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	
846.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Pequit 300mg XR Tablet
	Composition	Each film coated extended release tablet contains: Quetiapine as fumarate….. 300mg
	Diary No. Date of R& I & fee	Dy No. 23635: 09.07.2018 PKR 20,000/-: 09.07.2018
	Pharmacological Group	Anti-psychotic
	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.	Alaquet XL 300 MG prolonged-release tablets. MHRA Approved
	Me-too status	Ziapine XR 300mg Oral Tablets. Reg. No. 78753
	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	
847.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate,Raiwind,Lahore
	Brand Name +Dosage Form + Strength	Pequit 400mg XR Tablet
	Composition	Each film coated extended release tablet contains: Quetiapine as fumarate….. 400mg
	Diary No. Date of R& I & fee	Dy No. 23636: 09.07.2018 PKR 20,000/-: 09.07.2018
	Pharmacological Group	Anti-psychotic
	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.	Alaquet XL 400 MG prolonged-release tablets. MHRA Approved
	Me-too status	Evokalm XR 400mg Tablet. Reg. No. 61340
	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	
848.	Name and address of manufacturer / Applicant	M/s AGP Limited. B-23, S.I.T.E. Karachi
	Brand Name +Dosage Form + Strength	Emerep 40mg Capsule
	Composition	Each Capsule Contains: Aprepitant…40mg
	Diary No. Date of R& I & fee	Dy No. 15151: 24.04.2018 PKR 20,000/-: 24.04.2018
	Pharmacological Group	Other antiemetics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's; Rs. 2545.52/-
	Approval status of product in Reference Regulatory Authorities.	EMEND (aprepitant) 40mg capsules, for oral use. USFDA approved.
	Me-too status	Apreon 40mg Capsules. Reg. No. 68201
	GMP status	GMP granted on the basis of inspection dated 16.10.2018
	Remarks of the Evaluator.	Decision was not recorded in 289th meeting of RB.
	Decision: Approved	
849.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Vision Pharmaceuticals. Plot # 22,23, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Winzek 40mg IV sterile powder for injection
	Composition	Each vial contains: Omeprazole as sodium……40mg
	Diary No. Date of R& I & fee	Dy No. 18781: 23.05.2018 PKR 50,000/-: 23.05.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1's vial; As per SRO
	Approval status of product in Reference Regulatory Authorities.	OMEPRAZOLE SANDOZ IV omeprazole (as sodium) 40mg powder for injection vial. **TGA** approved
	Me-too status	Somezol Injection. Reg. No. 45386
	GMP status	The firm (M/s Winthrox Pharma) was inspected on on 14.09.2017, wherein the GMP of the firm was rated as GOOD.

	Remarks of the Evaluator.	• The firm submitted that they have never applied for contract manufacturing before this. • The firm submitted list of 07 product applied for contract manufacturing. • The firm submitted list of 06 approved sections and 04 additional approved section. • First page of Form 5 was from vision Pahrmaceuticals which was not signed. The firm M/s Winthrox Laboratories submitted Form 5 now. • The firm mentioned the dosage form as injection. Upon clarification, the firm revised the dosage form to sterile powder for injection.
	Decision: Approved with innovator's specifications.	
850.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Prega 50mg Capsule
	Composition	Each capsule contains: Pregabalin…50mg
	Diary No. Date of R& I & fee	Dy No. 23260: 05.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 50 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	The firm was inspected on 29.06.2017, wherein the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications	
851.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Prega 75mg Capsule
	Composition	Each capsule contains: Pregabalin…75mg
	Diary No. Date of R& I & fee	Dy No. 23261: 05.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 75 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 75mg Capsule. Reg. No. 82186
	GMP status	The firm was inspected on 29.06.2017, wherein the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
852.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Prega 100mg Capsule
	Composition	Each capsule contains: Pregabalin…100mg
	Diary No. Date of R& I & fee	Dy No. 23262: 05.07.2018 PKR 20,000/-: 03.07.2018

	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 100 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 100mg Capsule. Reg. No. 82185
	GMP status	The firm was inspected on 29.06.2017, wherein the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
853.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Prega 150mg Capsule
	Composition	Each capsule contains: Pregabalin…150mg
	Diary No. Date of R& I & fee	Dy No. 23262-B: 05.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 150 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 150mg Capsule. Reg. No. 82184
	GMP status	The firm was inspected on 29.06.2017, wherein the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
854.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Prega 200mg Capsule
	Composition	Each capsule contains: Pregabalin…200mg
	Diary No. Date of R& I & fee	Dy No. 23263: 05.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 200 mg Capsules, Hard. **MHRA** approved
	Me-too status	Gabica 200mg Capsules. Reg. No. 47367
	GMP status	The firm was inspected on 29.06.2017, wherein the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
855.	Name and address of manufacturer / Applicant	M/s Mega Pharmaceuticals Limited. 27-km, Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Prega 300mg Capsule
	Composition	Each capsule contains: Pregabalin…300mg
	Diary No. Date of R& I & fee	Dy No. 23264: 05.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5

	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	14's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 300 mg Capsules, Hard. **MHRA** approved
	Me-too status	Gabica 300mg Capsules. Reg. No. 47368
	GMP status	The firm was inspected on 29.06.2017, wherein the panel recommended issuance of GMP certificate.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
856.	Name and address of manufacturer / Applicant	Jaskan Pharmaceuticals (Pvt.) Limited Plot No. 50, Sunder Inustrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Amsart 5/80mg Tablet
	Composition	Each film-coated tablet contains: Amlodipine as besilate….5mg Valsartan…….80mg
	Diary No. Date of R& I & fee	Dy No. NIL: 03.08.2016 (duplicate dossier, form 5 freshly signed) PKR 140,000/-: 03.08.2016 (for 07 prodcuts)
	Pharmacological Group	Antihypertensives
	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.	Exforge film-coated tablet 5/80mg. **TGA** approved
	Me-too status	VALTAN -M 85 PLUS TABLET. Reg. No. 77204
	GMP status	The firm was inspected on 13.03.2018, wherein resumption of production was recommended by the panel.
	Remarks of the Evaluator.	
	Decision: Approved	
857.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Mactum 250mg Injection
	Composition	Each Vial Contains: Ceftazidime as pentahydrate…250mg
	Diary No. Date of R& I & fee	Dy No. 25452: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Fortum® 250 mg powder for solution for injection (vial). **MHRA** approved
	Me-too status	Fortez Injection 250mg IM/IV. Reg. No. 82751
	GMP status	The firm M/s Himed Pharma was inspected on 27.04.2018, wherein grnat of DML was recommended for 4 sections. GMP of manufacturer: The firm M/s Medpharm Research Lab was inspected on 12.04.2019, wherein GOOD level of GMP compliance has been reported, however, some advices were also given in the report to the firm for up gradation.
	Remarks of the Evaluator.	• First page of Form 5 shall be signed by the applicant, not manufacturer. The firm (applicant) submitted revised Form 5. • The firm submitted list of 04 approved sections. • The firm submitted that no product has been approved for contract manufacturing. • The firm submitted list of 20 applied products for contract

		manufacturing.
	Decision: Approved	
858.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Mactum 500mg Injection
	Composition	Each Vial Contains: Ceftazidime as pentahydrate…500mg
	Diary No. Date of R& I & fee	Dy No. 25453: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Fortum® 500 mg powder for solution for injection (vial). **MHRA** approved
	Me-too status	Fortez Injection 500mg IM/IV. Reg. No. 82750
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
859.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Mactum 1g Injection
	Composition	Each Vial Contains: Ceftazidime as pentahydrate…1g
	Diary No. Date of R& I & fee	Dy No. 25454: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Fortum® 500 mg powder for solution for injection (vial). **MHRA** approved
	Me-too status	Fortez Injection 500mg IM/IV. Reg. No. 82750
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
860.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Maxofen 250mg IV Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Diary No. Date of R& I & fee	Dy No. 25459: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IV). **US-FDA** approved
	Me-too status	Ceftirains 250mg (ceftriaxone Sodium) I.V Injection. Reg. No. 78655
	GMP status	As for above case

	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
861.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Maxofen 500mg IV Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 25461: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	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	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
862.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Maxofen 1g IV Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…1g
	Diary No. Date of R& I & fee	Dy No. 25463: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Rocephin 1 g Powder for solution for injection or infusion (vial). MHRA approved.
	Me-too status	Cytozon Injection 1gm I.V. Reg. No. 84897
	GMP status	As for above case
	Remarks of the Evaluator.	As for above case
	Decision: Approved	
863.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Maxofen 2g IV Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…2g
	Diary No. Date of R& I & fee	Dy No. 25464: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Rocephin 2 g Powder for solution for injection or infusion (vial). MHRA approved.
	Me-too status	Cytozon Injection 2gm I.V. Reg. No. 84896
	GMP status	As for above case
	Remarks of the Evaluator.	As for above case

	Decision: Approved with change of brand name	
864.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	M-Trex 250mg IM Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…250mg
	Diary No. Date of R& I & fee	Dy No. 25458: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg (IM). **US-FDA** approved
	Me-too status	Unixone Injection (ceftriaxone Sodium) 250mg IM. Reg. No. 82556
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
865.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	M-Trex 500mg IM Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 25460: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 500mg (IM). **US-FDA** approved
	Me-too status	Wincef 500 mg (**Ceftriaxone sodium)** IM injection by Wnsfeild Pharmaceuticals. Reg. No. 68371
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
866.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	M-Trex 1g IM Injection
	Composition	Each Vial Contains: Ceftriaxone as Sodium…1g
	Diary No. Date of R& I & fee	Dy No. 25460: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Rocephin 1 g Powder for solution for injection or infusion (vial). MHRA approved
	Me-too status	Esticef 1g Powder for Injection IM. Reg. No. 85082

	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
867.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	M-Tax 250mg Injection
	Composition	Each Vial Contains: Cefotaxime as Sodium…250mg
	Diary No. Date of R& I & fee	Dy No. 25455: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CEFOTAXIMA NORMON 250 mg POWDER AND SOLVENT FOR SOLUTION INJECTABLE IV EFG. CIMA approved
	Me-too status	Varxiame 250mg IM/IV Injection. Reg. No. 49270
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
868.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	M-Tax 500mg Injection
	Composition	Each Vial Contains: Cefotaxime as Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 25456: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Cefotaxime 500 mg powder for solution for injection. MHRA approved
	Me-too status	Varxiame 500mg IM/IV Injection. Reg. No. 49271
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
869.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	M-Tax 1g Injection
	Composition	Each Vial Contains: Cefotaxime as Sodium…1g
	Diary No. Date of R& I & fee	Dy No. 25457: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	CEFOTAXIME INJECTION cefotaxime 1g (as sodium) powder for injection IV. TGA approved
	Me-too status	Taxosa 1g injection. Reg. No. 85076

	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
870.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Mepime 500g Injection
	Composition	Each Vial Contains: Cefepime as HCl…500g
	Diary No. Date of R& I & fee	Dy No. 25445: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Fourth-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use. USFDA Approved
	Me-too status	Cefevial Injection 500mg IV Reg. No. 80029
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
871.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Mepime 1g Injection
	Composition	Each Vial Contains: Cefepime as HCl…1g
	Diary No. Date of R& I & fee	Dy No. 25446: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Fourth-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use. USFDA Approved
	Me-too status	Cefevial Injection 1g IV Reg. No. 80030
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
872.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Roxim DS 100mg/5ml
	Composition	Each 5ml Contains: Cefixime as Trihydrate…100mg
	Diary No. Date of R& I & fee	Dy No. 25449: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30ml (after reconstituition); As per PRC
	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	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
873.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Roxim DS 200mg/5ml
	Composition	Each 5ml Contains: Cefixime as Trihydrate…200mg
	Diary No. Date of R& I & fee	Dy No. 25450: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30ml (after reconstituition); As per PRC
	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	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
874.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Roxim 400mg Capsule
	Composition	Each Hard Gelatin Capsule Contains: Cefixime as Trihydrate…400mg
	Diary No. Date of R& I & fee	Dy No. 25451: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	5's; As per PRC
	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	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved	
875.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Fasten 1g Injection
	Composition	Each Vial Contains: Cefoparazone as Sodium…500mg Salbactum as Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 25447: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per PRC
	Approval status of product in	Sulperazon Injection. PMDA Approved

	Reference Regulatory Authorities.	
	Me-too status	Ectafin Injection 1gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80028
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
876.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan; Contract manufacturing By Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore"
	Brand Name +Dosage Form + Strength	Fasten 2g Injection
	Composition	Each Vial Contains: Cefoparazone as Sodium…1g Salbactum as Sodium…1g
	Diary No. Date of R& I & fee	Dy No. 25448: 23.07.2018 PKR 50,000/-: 13.07.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Approved in 03 European countries, i.e., Czech Republic, Poland and Slovakia
	Me-too status	Ectafin Injection 2gm IV by Hi-Medic Pharmaceuticals (Pvt) Ltd. Reg. No. 80027
	GMP status	As for above case
	Remarks of the Evaluator.	• As for above case
	Decision: Approved with change of brand name	
877.	Name and address of manufacturer / Applicant	M/s Hi-Med Pharmaceuticals. 208C Sunder Industrial Estate, Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Hivirin 200mg Capsule
	Composition	Each Hard Gelatin Capsule Contains: Ribavirin…200mg
	Diary No. Date of R& I & fee	Dy No. 25686: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	Third generation cephalosporins and beta-lactamase inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	REBETOL® (ribavirin USP) Capsules. USFDA approved
	Me-too status	RIVAB 200mg Capsule. Reg. No. 83984
	GMP status	The firm M/s Himed Pharma was inspected on 27.04.2018, wherein grant of DML was recommended for 4 sections.
	Remarks of the Evaluator.	• Form 5 and all relevant documents are from Medpharm Research Lab, which should be from Hi-Med Pharma. The firm was asked for clarification. The firm did not reply.
	Decision: Deferred for submission of documents	
878.	Name and address of manufacturer / Applicant	Medpharm Research Lab. 28-KM, Ferozpur Road, Lahore
	Brand Name +Dosage Form + Strength	Desmed 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 25286: 20.07.2018 PKR 20,000/-: 20.07.2018
	Pharmacological Group	Other antihistamines for systemic use

	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Desloratadine 5 mg film-coated tablets by Bristol Laboratories Ltd. **MHRA** approved
	Me-too status	Larinex Tablets 5mg by Getz Pharma. Reg. No. 39175
	GMP status	The firm M/s Medpharm Research Lab was inspected on 12.04.2019, wherein GOOD level of GMP compliance has been reported, however, some advices were also given in the report to the firm for up gradation.
	Remarks of the Evaluator.	
	Decision: Approved	
879.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Aksozine L Syrup
	Composition	Each 5ml contains: Levocetirizine dihydrochloride…2.5mg
	Diary No. Date of R& I & fee	Dy No. 23076: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Antihistamines for systemic use
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	30ml, 60ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	XYZAL (levocetirizine dihydrochloride) oral solution 0.5mg/ml. **USFDA** approved
	Me-too status	Lecetzi Syrup. Reg. No.79521
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature is placed on Form 5. • Filling and packing processes are missing in the manufacturing outlines.
	Decision: Deferred for submission of manufacturing outlines	
880.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Ketotin 1mg Tablet
	Composition	Each tablet contains: Ketotifen as hydrogen fumarate…1mg
	Diary No. Date of R& I & fee	Dy No. 23077: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	3x10's; as per SRO
	Approval status of product in Reference Regulatory Authorities.	ZADITEN Tablets 1mg by Alfasigma S.p.A. **MHRA** approved
	Me-too status	Ketovent Tablets 1mg by Barrett Hodgson Pakistan (Pvt) Ltd. Reg No. 30977
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature is placed on Form 5.
	Decision: Approved	
881.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Promazine Syrup 5mg/5ml

	Composition	Each 5ml contains: Promethazine HCl…5mg
	Diary No. Date of R& I & fee	Dy No. 23078: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Phenothiazine derivatives
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 120ml; as per SRO
	Approval status of product in Reference Regulatory Authorities.	Phenergan Elixir 5mg/5ml Oral Solution. **MHRA** approved
	Me-too status	Cofinol syrup. Reg No. 82278
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature are placed on Form 5. • The reference product is in the form of Exilir oral solution. • Filling and packing processes are missing in the manufacturing outlines.
	Decision: Deferred for submission of manufacturing outlines	
882.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Fexofin Tablets 60mg
	Composition	Each film-coated tablet contains: Fexofenadine HCl…60mg
	Diary No. Date of R& I & fee	Dy No. 23083: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	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.	FEXOTABS fexofenadine hydrochloride 60mg tablet blister pack.TGA approved
	Me-too status	Vigil Tablets by Tabros Pharma. Reg. No. 39776
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature are placed on Form 5. • The firm revised the formulation in line with the refrence product along with submission of Rs. 5000/- fee.
	Decision: Approved	
883.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Fexofin Tablets 120mg
	Composition	Each film-coated tablet contains: Fexofenadine HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 23084: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	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.	Fexofenadine 120 mg film-coated tablets by Teva UK Limited. **MHRA** approved
	Me-too status	Fenadrin Tablets 120mg by Noa Hemis Pharma. Reg. No. 42118

	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature are placed on Form 5. • The firm revised the formulation in line with the refrence product along with submission of Rs. 5000/- fee.
	Decision: Approved	
884.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Fexofin Tablets 180mg
	Composition	Each film-coated tablet contains: Fexofenadine HCl…180mg
	Diary No. Date of R& I & fee	Dy No. 23085: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	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.	Fexofenadine 180 mg film-coated tablets. **MHRA** approved
	Me-too status	Fenadrin Tablets 180mg by Noa Hemis Pharma. Reg. No. 42119
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature are placed on Form 5. • The firm revised the formulation in line with the refrence product along with submission of Rs. 5000/- fee.
	Decision: Approved	
885.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Fexofin 30mg/5ml suspension
	Composition	Each 5ml contains: Fexofenadine HCl…30mg
	Diary No. Date of R& I & fee	Dy No. 23082: 04.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TELFAST ORAL LIQUID fexofenadine hydrochloride 6 mg/mL oral suspension bottle. **TGA** approved
	Me-too status	Reliefex Suspension. Reg. No. 755802
	GMP status	The firm was inspected on 24.04.2017, wherein renewal of DML was recommended.
	Remarks of the Evaluator.	• Stamped signature is placed on Form 5. • Filling and packing process is missing in the manufacturing outlines.
	Decision: Deferred for submission of manufacturing outlines	
886.	Name and address of manufacturer / Applicant	M/s Welwink Pharmaceuticals. Factory G.T. Road, Industrial Estate, Gujranwala Cantt
	Brand Name +Dosage Form + Strength	Antrosit 30mg Injection
	Composition	Each Vial Contains: Artesunate…30mg
	Diary No. Date of R& I & fee	Dy No. 25782: 24.07.2018 PKR 20,000/-: 24.07.2018

	Pharmacological Group	Artemisinin and derivatives, plain
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed IP specs. Available in USP
	Pack size & Demanded Price	1 vial with relevant solvent; As per PRC
	Approval status of product in Reference Regulatory Authorities.	WHO prequalified
	Me-too status	Artebrain Injection 30mg. Reg. No. 85071
	GMP status	The firm was inspected on 20.12.2017 with the following conclusion: "Reference to previous inspection it was found that the firm rectified most of the shortcomings pointed out during last inspection. Panel advised the firm to continue the up gradation of building and system to maintain the GMP, which is a continuous process. Firm undertook to further upgrade the manufacturing & QC facility and documentation in the light of advices given by inspecting panels of experts. The panel concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section for which the firm was advised to provide liquid particle counter and TOC at earliest."
	Remarks of the Evaluator.	• The firm has mentioned Ms. Aamna Shah as QCM, however, Form 5 has been signed by Mr. Aftab Hussain as QCM. The firm was asked for proof of approval of Ms. Aamna Shah as QCM by the Licensing Division. The firm submitted revised Form 5.
	Decision: Approved with USP sepcifications	
887.	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	Qutamed 25mg Tabl et
	Composition	Each film-coated tablet contains: Quetiapine as fumarate….25mg
	Diary No. Date of R& I & fee	Dy No. 19162: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® (quetiapine fumarate) tablets, for oral use film-coated. **USFDA** approved
	Me-too status	Qupixan Tablet 25 mg film coated. Reg No. 81960
	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 revised quetiapine to quetiapine as fumarate in label claim along with submission of Rs. 5000/- fee. The name of signatory is not present on first page of Form 5.
	Decision: Approved	
888.	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	Qutamed 100mg Tablet
	Composition	Each film-coated tablet contains: Quetiapine as fumarate….100mg
	Diary No. Date of R& I & fee	Dy No. 19157: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Antipsychotics
	Type of Form	Form 5

	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® (quetiapine fumarate) tablets, for oral use film-coated. **USFDA** approved
	Me-too status	Qupixan Tablet 100 mg film coated. Reg No. 81961
	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 revised quetiapine to quetiapine as fumarate in label claim along with submission of Rs. 5000/- fee. The name of signatory is not present on first page of Form 5.
	Decision: Approved	
889.	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	Manufacturer specs
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® (quetiapine fumarate) tablets, for oral use film-coated. **USFDA** approved
	Me-too status	Qupixan Tablet 100 mg film coated. Reg No. 81961
	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.
	Decision: Deferred for the following: • **Clarification of 11mg/tab of API in Master Formula.** • **Revision of formulation in line with the reference product along with submission of applicable fee.**	
890.	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	Manufacturer specs
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	SEROQUEL® (quetiapine fumarate) tablets, for oral use film-coated. **USFDA** approved
	Me-too status	Qupixan Tablet 100 mg film coated. Reg No. 81961

	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.
	Decision: Deferred for the following: • **Clarification of 11mg/tab of API in Master Formula.** • **Revision of formulation in line with the reference product along with submission of applicable fee.**	
891.	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.
	Decision: Deferred for clarification of mentioning enteric film-coated tablet	
892.	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	Dulax-M 30mg Capsule
	Composition	Each capsule contains: Duloxetine as HCl (enteric coated pellets)…….30mg
	Diary No. Date of R& I & fee	Dy No. 19159: 25.05.2018 PKR 20,000/-: 25.05.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Dutor 30 mg gastro-resistant capsules, hard. **MHRA** approved
	Me-too status	Oxcym DR 30 mg Capsule. Reg. No. 53101
	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. Source of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.

	Remarks of the Evaluator.	• The name of signatory is not present on the Form 5. • The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under discussion. • The pellets have been tested with in-house specifications. • The assay is based on Duloxetine HCl, not free base.
	Decision: Approved	
893.	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…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.
	Decision: Deferred for revision of salt form in line with the reference product along with submission of applicable fee.	
894.	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	Hilixophin 2g IV Injection
	Composition	Each Vial Contains: Ceftriaxone as sodium…..2g
	Diary No. Date of R& I & fee	Dy No. 19161: 25.05.2018 PKR 20,000/-: 25.05.2018
	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 2 g powder for solution for injection/infusion. MHRA approved
	Me-too status	Cefast 2g Injection I.V. Reg. No. 82281
	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 submitted revised form 5, mentioning ceftriaxone as sodium instead of 'ceftriaxone sodium' in label claim. The name of signatory is not present on the revised form 5.
	Decision: Approved	
895.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip Capsule 150mg
	Composition	Each capsule contains: Pregabalin……. 150mg

	Diary No. Date of R& I & fee	Dy No. 6905: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	1x14's; Rs. 385/-
	Approval status of product in Reference Regulatory Authorities.	Alzain 150 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 150mg Capsule. Reg. No. 82184
	GMP status	• The 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). The firm further requested to process their cases..
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
896.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip Capsule 300mg
	Composition	Each capsule contains: Pregabalin……. 300mg
	Diary No. Date of R& I & fee	Dy No. 6886: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	1x14's; Rs. 630/-
	Approval status of product in Reference Regulatory Authorities.	Alzain 300 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 300mg Capsule. Reg. No. 82183
	GMP status	As for previous case
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
897.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip Capsule 100mg
	Composition	Each capsule contains: Pregabalin……. 100mg
	Diary No. Date of R& I & fee	Dy No. 6862: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	1x14's; Rs. 315/-
	Approval status of product in Reference Regulatory Authorities.	Alzain 100 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 100mg Capsule. Reg. No. 82185
	GMP status	As for previous case
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
898.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip Capsule 50mg
	Composition	Each capsule contains: Pregabalin……. 50mg

	Diary No. Date of R& I & fee	Dy No. 6853: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	1x14's; Rs. 220/-
	Approval status of product in Reference Regulatory Authorities.	Alzain 75 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	As for previous case
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
899.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Linagrip Capsule 75mg
	Composition	Each capsule contains: Pregabalin……. 75mg
	Diary No. Date of R& I & fee	Dy No. 6854: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	1x14's; Rs. 270/-
	Approval status of product in Reference Regulatory Authorities.	Alzain 75 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 75mg Capsule. Reg. No. 82186
	GMP status	As for previous case
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications	
900.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	AJCIP Tablet 500mg
	Composition	Each film-coated tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin……. 500mg
	Diary No. Date of R& I & fee	Dy No. 6855: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; Rs. 320/-
	Approval status of product in Reference Regulatory Authorities.	Ciprofloxacin 500 mg film-coated Tablets. **MHRA** approved
	Me-too status	Cibo 500mg Tablet. Reg. No. 81583
	GMP status	As for previous case
	Remarks of the Evaluator.	• The firm did not mention the strength in label claim. Upon clarification, the firm provide the strength as 500mg. • The firm corrected the label to "Each film-coated tablet contains" with submission of Rs. 5000/- fee.
	Decision: Approved	
901.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	AJCIP Tablet 250mg
	Composition	Each film-coated tablet contains: Ciprofloxacin HCl eq. to Ciprofloxacin…….250mg

	Diary No. Date of R& I & fee	Dy No. 6857: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; Rs. 170/-
	Approval status of product in Reference Regulatory Authorities.	CIPRO® 250mg film-coated tablets. **USFDA** approved
	Me-too status	Cipra 250mg Tablet. Reg. No. 82229
	GMP status	As for previous case
	Remarks of the Evaluator.	• The firm did not mention the strength in label claim. Upon clarification, the firm provide the strength as 250mg. • The firm corrected the label to "Each film-coated tablet contains" with submission of Rs. 5000/- fee.
	Decision: Approved	
902.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Levtitam Tablet 500mg
	Composition	Each film-coated tablet contains: Levetiracetam…….500mg
	Diary No. Date of R& I & fee	Dy No. 6858: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; Rs. 435/-
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 500 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 500mg Tablets. Reg. No. 84221
	GMP status	As for previous case
	Remarks of the Evaluator.	• The firm corrected the label to "Each film-coated tablet contains" with submission of Rs. 5000/- fee.
	Decision: Approved	
903.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Levtitam Tablet 250mg
	Composition	Each film-coated tablet contains: Levetiracetam…….250mg
	Diary No. Date of R& I & fee	Dy No. 6863: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	3x10's; Rs. 765/-
	Approval status of product in Reference Regulatory Authorities.	Levetiracetam 250 mg film-coated tablets. **MHRA** approved
	Me-too status	Leveticam film-coated 250mg Tablets. Reg. No. 84220
	GMP status	As for previous case
	Remarks of the Evaluator.	• The firm corrected the label to "Each film-coated tablet contains" with submission of Rs. 5000/- fee.
	Decision: Approved	

904.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Clovatis Tablet 90mg
	Composition	Each film-coated tablet contains: Daclatasvir as dihydrochloride…….90mg
	Diary No. Date of R& I & fee	Dy No. 6851: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Antivirals for treatment of HCV infections
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x14's; Rs……./-
	Approval status of product in Reference Regulatory Authorities.	DAKLINZA (daclatasvir) tablets, for oral use. **USFDA** approved **with box warning.**
	Me-too status	**Could not be confirmed**
	GMP status	As for previous case
	Remarks of the Evaluator.	• The firm corrected the label to "Each film-coated tablet contains" with submission of Rs. 5000/- fee. • Clarification is required about the demanded price. The firm did not clarify the same. • Stability studies data as per decision of 278th meeting of registration Board was asked from the firm. The firm submitted that they will submit the stability data before marketing the product.
	Decision: Deferred for the following: • **Clarification about the demanded price.** • **Stability studies data as per decision of 278th meeting of registration Board.**	
905.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Domper Tablet 10mg
	Composition	Each film-coated tablet contains: Domperidone as maleate…….10mg
	Diary No. Date of R& I & fee	Dy No. 6851: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Propulsives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	5x10's; Rs. 215/-
	Approval status of product in Reference Regulatory Authorities.	Domperidone 10mg Tablets. **MHRA** approved
	Me-too status	Kohidone 10mg Tablet Reg. No. 70705
	GMP status	As for previous case
	Remarks of the Evaluator.	• The firm corrected the label to "Each film-coated tablet contains" with submission of Rs. 5000/- fee. • In the coating composition, the firm mentioned hydrogen peroxide. Justification about the stability of such solution and safety of hydrogen peroxide. The firm replied that it is used in very small amount for stability purpose.
	Decision: Approved	
906.	**Name and address of manufacturer / Applicant**	**M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, Khyber Pakhtunkhwa**
	Brand Name +Dosage Form + Strength	Olnz Capsule
	Composition	Each Capsule Contains: Olanzapine…12mg Fluoxetine as HCl…25mg
	Diary No. Date of R& I & fee	Dy No. 25808: 26.07.2018 PKR 20,000/-: 26.07.2018

	Pharmacological Group	Antipsychotics and selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	SYMBYAX (olanzapine and fluoxetine) capsules by Eli Lilly and Company. Approved by **US-FDA**
	Me-too status	Olanco Capsules. Reg. No. 79387
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator.	•
	Decision: Approved	
907.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, Khyber Pakhtunkhwa
	Brand Name +Dosage Form + Strength	Diclo 50mg Tablet
	Composition	Each Film Coated Tablet Contains: Diclofenac Potassium…50mg
	Diary No. Date of R& I & fee	Dy No. 25807: 26.07.2018 PKR 20,000/-: 26.07.2018
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diclofenac Potassium 50 mg film-coated Tablets. **MHRA** approved
	Me-too status	Arnil-P 50mg film-coated tablets. Reg # 82129
	GMP status	The firm was last inspected on 27.06.2019, wherein GMP was rated satisfactory.
	Remarks of the Evaluator.	• Form 5 had not been signed. The firm submitted duly signed form 5.
	Decision: Approved with change of brand name.	
908.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals. Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, Khyber Pakhtunkhwa
	Brand Name +Dosage Form + Strength	Colomat 1 MIU Injection
	Composition	Each Vial Contains: Colistimethate Sodium (Lyophilized Powder)…1 MIU
	Diary No. Date of R& I & fee	Dy No. 25806: 26.07.2018 PKR 20,000/-: 26.07.2018
	Pharmacological Group	Polymyxins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Colistimethate Sodium 1 Million I.U. Powder for Solution for Injection (lyophilized powder in glass vial). Approved by **MHRA**
	Me-too status	Colistat powder for Injection. Reg. No. 76160
	GMP status	The firm was last inspected on 13.02.2018, wherein it was concluded that "Overall the firm was in good working condition with proper documentation, adequate Equipments both in production and quality control and qualified staff for performing the manufacturing and analysis of the manufactured products in accordance with the cGMP guidelines. Some of the minor shortcomings as described above were identified to the firm for immediate rectification. Based on the premises inspected, the qualified staff met and documentation reviewed, it is concluded that M/s Aulton Pharma Industrial Estate Hatter operate at good level of compliance with cGMP guidelines".

	Remarks of the Evaluator.	• Undertaking was not signed. The firm submitted duly signed form 5.
	Decision: Deferred for submission of undertaking	
909.	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	Delorat 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 25803: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's; As per PAC
	Approval status of product in Reference Regulatory Authorities.	Desloratadine 5 mg film-coated tablets by Bristol Laboratories Ltd. **MHRA** approved
	Me-too status	Larinex Tablets 5mg by Getz Pharma. Reg. No. 39175
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 12.12.2017.
	Remarks of the Evaluator.	•
	Decision: Approved	
910.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Estate Hattar
	Brand Name +Dosage Form + Strength	Cefpro 125mg/5ml Suspension
	Composition	Each 5ml Reconstituted Suspension Contains: Cefprozil…125mg
	Diary No. Date of R& I & fee	Dy No. 25959: 27.07.2018 PKR 20,000/-: 27.07.2018
	Pharmacological Group	Second-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefzil® (CEFPROZIL) for Oral Suspension 125 mg/5 mL and 250 mg/5 mL. Discontinued in **USFDA** not for safety or efficacy reasons.
	Me-too status	Cefzil Suspension 125mg. Reg. No. 34391
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 12.12.2017.
	Remarks of the Evaluator.	• The reference product contains cefprozil as monohydrate. The firm submitted revised form 5 with correct label claim along with adjustment of weight of API in Master Formula as per equivalency factor. • Undertaking at the end of Form 5 was missing. The firm submitted revised form 5.
	Decision: Approved	
911.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar
	Brand Name +Dosage Form + Strength	Lupus 200mg Tablet
	Composition	Each Film Coated Tablet Contains: Hydroxychloroquine Sulphate…200mg
	Diary No. Date of R& I & fee	Dy No. 25962: 27.07.2018 PKR 20,000/-: 27.07.2018
	Pharmacological Group	Aminoquinolines
	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.	PLAQUENIL® HYDROXYCHLOROQUINE SULFATE TABLETS, USP. USFDA approved.
	Me-too status	Cefzil Suspension 125mg. Reg. No. 34391
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 12.12.2017.
	Remarks of the Evaluator.	Undertaking at the end of Form 5 was missing. The firm submitted revised Form-5.
	Decision: Approved	
912.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Sepgen 1000mg Dry Powder Injection
	Composition	Each Vial Contains: Cefepime as HCl and L-arginine…1000mg
	Diary No. Date of R& I & fee	Dy No. 25675: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	Fourth generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's glass vial; as per PRC
	Approval status of product in Reference Regulatory Authorities.	MAXIPIME (cefepime hydrochloride) for injection, for intravenous or intramuscular use. USFDA approved
	Me-too status	Cefevial Injection 1.0gm IV. Reg. No. 80030 (does not depict L-argenine)
	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	• The firm submitted revised Form 5, wherein name of signatory is not present on Form 5. • The reference product contains Cefepime as HCl monohydrate. Correction along with adjustment of its weight as per salt factor in Master Formula was asked from the firm. The firm did not revise the same.
	Decision: Deferred for revision of salt form in line with the reference product	
913.	Name and address of manufacturer / Applicant	M/s Semos Pharmaceuticals Pvt Ltd. Plot No. 11, Sector 12-A, North Karachi, Krachi-75850, Pakistan
	Brand Name +Dosage Form + Strength	Delor 5mg Tablet
	Composition	Each Film Coated Tablet Contains: Desloratadine…5mg
	Diary No. Date of R& I & fee	Dy No. 25675: 24.07.2018 PKR 20,000/-: 24.07.2018
	Pharmacological Group	Other antihistamines for systemic use
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	10's20's, 30's, 50's, 100,s; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Desloratadine 5 mg film-coated tablets by Bristol Laboratories Ltd. **MHRA** approved
	Me-too status	Larinex Tablets 5mg by Getz Pharma. Reg. No. 39175
	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	The firm submitted revised updated Form 5, wherein name of signatory is not present on Form 5.
	Decision: Approved with innovator's specifications	
914.	Name and address of manufacturer / Applicant	M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Coryton-H Tablet

	Composition	Each Film Coated Tablet Contains: Losartan Potassium…50mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy No. 25677: 24.07.2018 PKR 20,000/-: 19.07.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's; as per brand leader
	Approval status of product in Reference Regulatory Authorities.	FORTZAAR 50 mg / 12.5 mg film-coated tablets. **ANSM** approved
	Me-too status	Rosar-H Tablets. Reg. No. 64218
	GMP status	Certificate of GMP Issued on 08.05.2018.
	Remarks of the Evaluator.	• Name of signatory is missing at first place in Form 5; mentioned along with signature.
	Decision: approved	
915.	Name and address of manufacturer / Applicant	M/s Brookes Pharma Pvt Ltd. 58 & 59, Sector 15, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Coryton-H DS Tablet
	Composition	Each Film Coated Tablet Contains: Losartan Potassium…100mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy No. 25678: 24.07.2018 PKR 20,000/-: 19.07.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs) and diuretics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's; as per brand leader
	Approval status of product in Reference Regulatory Authorities.	FORTZAAR 50 mg / 12.5 mg film-coated tablets. **ANSM** approved
	Me-too status	Lotass Plus 100mg/25mg Tablet. Reg. No. 76788
	GMP status	Certificate of GMP Issued on 08.05.2018.
	Remarks of the Evaluator.	Name of signatory is missing at first place in Form-5; mentioned along with signature.
	Decision: Approved	
916.	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	Bolive 2.5mg Tablet
	Composition	Each tablet contains: Nebivolol HCl eq to Nebivolvol…2.5mg
	Diary No. Date of R& I & fee	Dy No. 22942: 03.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Beta blocking agents, selective
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications.
	Pack size & Demanded Price	10's; 14's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	BYSTOLIC® (nebivolol) tablets, for oral use (2.5mg, 5mg, 10mg, 20mg). **TGA** approved
	Me-too status	Bynevol 2.5mg Tablet. Reg. No. 80561
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 15.09.2017.
	Remarks of the Evaluator.	The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5. Name of signatory is missing at first

		place in Form 5; mentioned along with signature
	Decision: Approved	
917.	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	Ftaft EC 500mg Tablet
	Composition	Each enteric coated tablet contains: Naproxen…500mg
	Diary No. Date of R& I & fee	Dy No. 22942: 03.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Propionic acid derivatives.
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	Naproxen 500 mg Gastro-resistant Tablets. **MHRA** approved
	Me-too status	Naps 500mg Tablet. Reg. No. 83344
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 15.09.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5. Name of signatory is missing at first place in Form 5; mentioned along with signature • The firm mentioned term EC in the brand name and applied for enteric coated tablet. Upon clarification, the firm submitted label claim as "Each enteric coated tablet contains". However, no coating compostion and coating process has been submitted.
	Decision: Deferred for submission of correct master formula and manufacturing outlines.	
918.	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	Ftaft SR 750mg Tablet
	Composition	Each sustained release tablet contains: Naproxen…750mg
	Diary No. Date of R& I & fee	Dy No. 22941: 03.07.2018 PKR 20,000/-: 03.07.2018
	Pharmacological Group	Propionic acid derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm claimed in-house specifications.
	Pack size & Demanded Price	10's; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	PROXEN SR 750 naproxen sustained release 750mg tablets bottle. **TGA** approved
	Me-too status	Provin-SR Tablet 750mg. Reg. No. 69462
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 15.09.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5. Name of signatory is missing at first place in Form 5; mentioned along with signature.
	Decision: Approved with change of brand name.	
919.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B, Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zodip-V Plus 5/160/12.5 mg Tablet
	Composition	Each Tablet Contains:

		Amlodipine as besylate…5mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy No. 25680: 24.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets. **US-FDA** approved
	Me-too status	Exforge HCT 5/160/12.5MG film coated tablets. Reg. No. 69548
	GMP status	GMP certificate issued on 23.05.2018
	Remarks of the Evaluator.	• The firm had mentioned amlodipine in label claim. In the revised Form 5, they corrected it to amlodipine as besylate in master formula. • However, it was 'amlodipine as besylate' in Master formula. The firm did not revise it to amlodipine besilate. • The firm has mentioned coating composition in Master formula. However, the label claim was "each tablet contains". The firm revised 'Each tablet contains' to 'Each film-coated tablet contains' in Form 5. • Blistering/packaging process is missing in the manufacturing outlines.
	Decision: Deferred for the following: • **Revision of 'amlodipine as besylate' to 'amlodipine besylate' in Master formula** • **Submission of complete manufacturing outlines.**	
920.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B, Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zodip-V Plus 10/160/12.5 mg Tablet
	Composition	Each Tablet Contains: Amlodipine as besylate…10mg Valsartan…160mg Hydrochlorothiazide…12.5mg
	Diary No. Date of R& I & fee	Dy No. 25682: 24.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved
	Me-too status	Exforge HCT 10/160/12.5MG film coated tablets. Reg. No. 69550
	GMP status	GMP certificate issued on 23.05.2018
	Remarks of the Evaluator.	• The firm had mentioned amlodipine in label claim. In the revised Form 5, they corrected it to amlodipine as besylate in master formula. • However, it was 'amlodipine as besylate' in Master formula. The firm did not revise it to amlodipine besilate. • The firm has mentioned coating composition in Master formula. However, the label claim was "each tablet contains". The firm revised 'Each tablet contains' to 'Each film-coated tablet contains' in Form 5. • Blistering/packaging process is missing in the manufacturing outlines.

	Decision: Deferred for the following: • **Revision of 'amlodipine as besylate' to 'amlodipine besylate' in Master formula** • **Submission of complete manufacturing outlines.**	
921.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-1/B, Block-22, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Zodip-V Plus 10/160/25 mg Tablet
	Composition	Each Tablet Contains: Amlodipine…10mg Valsartan…160mg Hydrochlorothiazide…25mg
	Diary No. Date of R& I & fee	Dy No. 25682: 24.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Antihypertensive
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	EXFORGE HCT® Tablets by Novartis Pharmaceuticals Corporation. **US-FDA** approved
	Me-too status	Exforge HCT 10/160/25MG film coated tablets. Reg. No. 69551
	GMP status	GMP certificate issued on 23.05.2018
	Remarks of the Evaluator.	• The firm had mentioned amlodipine in label claim. In the revised Form 5, they corrected it to amlodipine as besylate in master formula. • However, it was 'amlodipine as besylate' in Master formula. The firm did not revise it to amlodipine besilate. • The firm has mentioned coating composition in Master formula. However, the label claim was "each tablet contains". The firm revised 'Each tablet contains' to 'Each film-coated tablet contains' in Form 5. • Blistering/packaging process is missing in the manufacturing outlines.
	Decision: Deferred for the following: • **Revision of 'amlodipine as besylate' to 'amlodipine besylate' in Master formula** • **Submission of complete manufacturing outlines.**	
922.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceuticals Laboratories Private Limited. L-4/1, A & B Block-21, Federal B industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Pantazaf 40mg Tablet
	Composition	Each Tablet Contains: Pantoprazole as Sodium Sesquihydrate…40mg
	Diary No. Date of R& I & fee	Dy No. 25681: 24.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; As per PRC
	Approval status of product in Reference Regulatory Authorities.	PROTONIX (pantoprazole sodium) delayed-release tablets, for oral use. **US-FDA** approved
	Me-too status	Pantberg Tablet. Reg. No. 79782
	GMP status	GMP certificate issued on 15-05-2018
	Remarks of the Evaluator.	• Deatil of Form 5 after point No. 18 were missing. The firm submitted complete updated form 5 duly signed by all concerned persons. • The firm was asked to revise 'Pantoprazole as Sodium Sesquihydrate' to 'Pantoprazole Sodium Sesquihydrate' in

		Master Formula only. The firm did not revise the same. • The firm has mentioned enteric coating composition in Master formula. However, the label claim was "each tablet contains". The firm revised 'Each tablet contains' to 'Each enteric-coated tablet contains' in Form 5. • Blistering/packaging process is missing in the manufacturing outlines.
	Decision: Deferred for the following: • **Revision of 'Pantoprazole as Sodium Sesquihydrate' to 'Pantoprazole Sodium Sesquihydrate' in Master formula** • **Submission of complete manufacturing outlines.**	
923.	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	Azimit 250mg Tablet
	Composition	Each film-coated tablet contains: Azithromycin as dihydrate…250mg
	Diary No. Date of R& I & fee	Dy No. 23236: 05.07.2018 PKR 20,000/-: 05.07.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	6's, 10's; As per SRO
	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 250mg Tablets. Reg. No. 85507
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
924.	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	Azimit 500mg Tablet
	Composition	Each film-coated tablet contains: Azithromycin as dihydrate…500mg
	Diary No. Date of R& I & fee	Dy No. 23237: 05.07.2018 PKR 20,000/-: 05.07.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	6's, 10's; As per SRO
	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 has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
925.	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	Spasmit 50mg Tablet
	Composition	Each sugar-coated tablet contains: Eperisone HCl…50mg
	Diary No. Date of R& I & fee	Dy No. 23240: 05.07.2018 PKR 20,000/-: 05.07.2018

	Pharmacological Group	Muscle relaxants, centrally acting agents
	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.	Eperisone hydrochloride tablet 50 mg **sugar coated**. PMDA approved
	Me-too status	Peson Tablet 50 mg. Reg. No. 81955
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5. • The firm revised the formulation to sugar-coated tablet in line with the reference product along with submission of Rs. 5000/- fee. Revision of manufacturing outlines is required.
	Decision: Approved with innovator's specifications	
926.	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	Migesim 85/500MG Tablet
	Composition	Each film coated tablet contains: Sumatriptan as succinate…85mg Naproxen Sodium…500mg
	Diary No. Date of R& I & fee	Dy No. 23239: 05.07.2018 PKR 20,000/-: 05.07.2018
	Pharmacological Group	Selective serotonin (5HT1) agonists and Propionic acid derivatives
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2's, 6's, 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	TREXIMET (sumatriptan and naproxen sodium) tablets, film coated. PMDA approved
	Me-too status	Peson Tablet 50 mg. Reg. No. 81955
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved with innovator's specifications	
927.	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	Itomit Tablet 50mg
	Composition	Each film-coated tablet contains: Itopride HCl…..50mg
	Diary No. Date of R& I & fee	Dy No. 23238: 05.07.2018 PKR 20,000/-: 05.07.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Itopride hydrochloride tablet 50 mg by Shiseido Pharmaceutical Co., Ltd. **PMDA** approved
	Me-too status	Itoride Tablet by Lexicon Pharmaceutical. Reg No. 42040
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved with innovator's specifications	

928.	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	Metromit 200mg/5ml Suspension
	Composition	Each 5ml Contains: Metronidazole Benzoate Eq. to Metronidazole…200mg
	Diary No. Date of R& I & fee	Dy No. 25421: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	60ml, 90ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Flagyl S 200mg/5ml Oral Suspension. **MHRA** approved
	Me-too status	Lagyn Suspension. Reg No. 84625
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved with innovator's specifications	
929.	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	Xantix 4mg Tablet
	Composition	Each Tablet Contains: Tizanidine as HCl…4mg
	Diary No. Date of R& I & fee	Dy No. 25420: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Muscle relaxants, centrally acting agents
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ZANAFLEX® (tizanidine hydrochloride) tablets, uncoated for oral use. **USFDA** approved
	Me-too status	Dyzo Tablet. Reg No. 84426
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
930.	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	Vanesten 1 Tablet
	Composition	Each Tablet Contains: Clotrimazole…500mg
	Diary No. Date of R& I & fee	Dy No. 25419: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MYCOHYDRALIN 500 mg, vaginal tablet. **ANSM** approved
	Me-too status	CANESTTEN-VAGINAL TAB 500mg. Reg No. 7293
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.

	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
931.	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	Salbeta 2mg/5ml Syrup
	Composition	Each 5ml Contains: Salbutamol Sulphate eq. to Salbutamol…2mg
	Diary No. Date of R& I & fee	Dy No. 25424: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	60ml, 120ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Salbutamol Syrup 2mg/5ml (sugar-free syrup). **MHRA** approved
	Me-too status	Salbax 2mg/5ml Syrup. Reg No. 82210
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
932.	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	Terbutamit 0.3mg/ml Syrup
	Composition	Each ml Contains: Terbutaline Sulphate…0.3mg
	Diary No. Date of R& I & fee	Dy No. 25423: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Selective beta-2-adrenoreceptor agonists
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bricanyl 0.3 mg/ml Syrup. **MHRA** approved
	Me-too status	Butali Liquid Syrup. Reg No. 79712
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved with innovator's specifications	
933.	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	Risplax 1mg Tablet
	Composition	Each film coated tablet contains: Risperidone…1mg
	Diary No. Date of R& I & fee	Dy No. 25431: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	3x6's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Risperdal® 1mg film coated Tablets. **MHRA** approved
	Me-too status	Neo-Risp Tablet 1mg, film-coated. Reg No. 85184

	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
934.	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	Risplax 2mg Tablet
	Composition	Each film coated tablet contains: Risperidone…2mg
	Diary No. Date of R& I & fee	Dy No. 25432: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x6's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Risperdal® 2mg film coated Tablets. **MHRA** approved
	Me-too status	Neo-Risp Tablet 2mg, film-coated. Reg No. 85185
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
935.	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	Risplax 3mg Tablet
	Composition	Each film coated tablet contains: Risperidone…3mg
	Diary No. Date of R& I & fee	Dy No. 25433: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antipsychotics
	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.	Risperdal® 3mg film coated Tablets. **MHRA** approved
	Me-too status	Neo-Risp Tablet 3mg, film-coated. Reg No. 85186
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
936.	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	Risplax 4mg Tablet
	Composition	Each film coated tablet contains: Risperidone…4mg
	Diary No. Date of R& I & fee	Dy No. 25434: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other antipsychotics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in	Risperdal® 4mg film coated Tablets. **MHRA** approved

	Reference Regulatory Authorities.	
	Me-too status	Neo-Risp Tablet 4mg, film-coated. Reg No. 85187
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
937.	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	Verine 40mg Tablet
	Composition	Each tablet contains: Drotaverine HCl…40mg
	Diary No. Date of R& I & fee	Dy No. 25429: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Apporved in three EMA states as un-coated tablets in Hungary (both coated and uncoated), Romania & Slovakia (both coated and uncoated).
	Me-too status	Spasmostar Tablets. Reg No. 78711
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved with innovator's specifications	
938.	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	Verine Forte 80mg Tablet
	Composition	Each tablet contains: Drotaverine HCl…80mg
	Diary No. Date of R& I & fee	Dy No. 25429: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Drugs for functional gastrointestinal disorders
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Apporved in three EMA states as un-coated tablets in Hungary (both coated and uncoated), Lithuania & Slovakia (uncoated).
	Me-too status	Spasmostar Forte Tablets. Reg No. 78710
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved with innovator's specifications	
939.	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	Zincwim 10mg/5ml Syrup
	Composition	Each 5ml Contains: Zinc Sulphate Monohydrate Eq. to Elemental Zinc…10mg
	Diary No. Date of R& I & fee	Dy No. 25425: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other mineral supplements

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Available in IP as solution (Available strengths: 10 mg or 20 mg of zinc per 5 mL)
	Me-too status	Zevro Syrup 10mg. Reg. No. 77058
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
940.	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	Zincwim 20mg/5ml Syrup
	Composition	Each 5ml Contains: Zinc Sulphate Monohydrate Eq. to Elemental Zinc…20mg
	Diary No. Date of R& I & fee	Dy No. 25426: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Other mineral supplements
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml, 90ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Available in IP as solution (Available strengths: 10 mg or 20 mg of zinc per 5 mL)
	Me-too status	Xink 20mg Oral Solution (zinc sulfate as monohydrate). Reg. No. 82715
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	
941.	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	Danso 2mg/ml Injection
	Composition	Each ml Contains: Ondansetron as Hydrochloride dihydrate…2mg
	Diary No. Date of R& I & fee	Dy No. 25427: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	The claimed BP specifications. Available in USP
	Pack size & Demanded Price	2mlx5's, 4mlx5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 2mg/ml Solution for Injection or Infusion (2ml, 4ml ampule). MHRA approved.
	Me-too status	Ondenles 8mg Injection (4ml). Reg. No. 80548 Adosetron 4mg Injection (2ml). Reg. No. 78789
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	• The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5. • The firm was asked to clarify the pack size as you can get one filled volume (either 4ml or 2 ml) per registration. The firm did not respond to the clarification. • Revise 'Ondansetron as Hydrochloride dihydrate' to

		"Ondansetron Hydrochloride dihydrate' in master Formula only.
	Decision: Deferred for the following: • **Clarify the pack size as you can get one filled volume (either 4ml or 2 ml) per registration** • **Revise 'Ondansetron as Hydrochloride dihydrate' to "Ondansetron Hydrochloride dihydrate' in master Formula only.**	
942.	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	Danso 4mg Tablet
	Composition	Each film coated tablet contains: Ondansetron as Hydrochloride dihydrate…4mg
	Diary No. Date of R& I & fee	Dy No. 25428: 23.07.2018 PKR 20,000/-: 23.07.2018
	Pharmacological Group	Serotonin (5HT3) antagonists
	Type of Form	Form 5
	Finished Product Specification	The claimed BP specifications. Available in USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 4 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Ondan Tablet film-coated 4mg. Reg No. 82656
	GMP status	The firm has been issued GMP certificate on the basis of inspection dated 03.11.2017.
	Remarks of the Evaluator.	Form 5 had not been signed. The applicant/signatory's name was missing in Form 5. The firm submitted revised form 5.
	Decision: Approved	

b. Deferred cases

943.	Name and address of manufacturer / Applicant	M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan
	Brand Name+ Dosage Form + Strength	Pendic Gel 1%
	Composition	Each gram contains: Diclofenac diethylamine 11.6 mg eq. to Diclofenac sodium…..10mg
	Diary No. Date of R & I & Fee	Dy No. 15585: 07.03.2019 Rs. 20,000/-: 07.03.2019
	Pharmacological Group	Corticosteroids, potent (group III) in combination with other dermatological and retinoids for topical use
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack Size & Demanded Price	30g; as per SRO
	Approval Status of product in Reference Regulatory Authorities	VOLTAREN OSTEO GEL diclofenac diethylamine 11.6mg/g (1.16%) tube. **USFDA** approved. With no equivalency.
	Me-too Status	Dicmaf 1% Gel. With label claim "each gram contains: Diclofenac Diethylamine 11.6 mg eq. to Diclofenac Sodium.10 mg". Reg No. 79899
	GMP Status	New License
	Remarks of the Evaluator	• The compositions depict that the product is emulsion. Clarify.
	Previous decision	The Board in its 289th meeting deferred the case for clarification about the compositions.
	Evaluation by PEC	• The firm submitted that they have applied for emulgel as per reference product.
	Decision: Approved	

944.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Clarip Tablet 500mg
	Composition	Each film-coated tablet contains: Clarithromycin…..500mg
	Diary No. Date of R& I & fee	Dy No. 14987: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 500 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Clarital 500mg Tablet. Reg. No. 85500
	GMP status	The firm was inspected on 31.01.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	• The firm submitted updated Form 5. First page of Form 5 is missing.
	Previous decision	• The Board in its 289th meeting deferred the case for submission of updated Form 5.
	Evaluation by PEC	• The firm submitted Form 5 (first page).
	Decision: Approved	
945.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Clarip Tablet 250mg
	Composition	Each film-coated tablet contains: Clarithromycin…..250mg
	Diary No. Date of R& I & fee	Dy No. 14986: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 250 mg Film-coated Tablets. **MHRA** approved
	Me-too status	Clarital 250mg Tablet. Reg. No. 85501
	GMP status	The firm was inspected on 31.01.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	• The firm submitted updated Form 5. First page of Form 5 is missing.
	Previous decision	• The Board in its 289th meeting deferred the case for submission of updated Form 5.
	Evaluation by PEC	• The firm submitted Form 5 (first page).
	Decision: Approved	

946.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	J-Artan Tablet 25mg
	Composition	Each film-coated tablet contains: Losartan Potassium…..25mg
	Diary No. Date of R& I & fee	Dy No. 14990: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cozaar® 25 mg film-coated tablets. MHRA approved
	Me-too status	Lotass 25mg Tablet. Reg. No. 66802
	GMP status	The firm was inspected on 31.01.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	The firm submitted updated Form-5. First page of Form 5 is missing.
	Previous decision	• The Board in its 289th meeting deferred the case for submission of updated Form 5.
	Evaluation by PEC	• The firm submitted Form-5 (first page).
	Decision: Approved	
947.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	J-Artan Tablet 50mg
	Composition	Each film-coated tablet contains: Losartan Potassium…..50mg
	Diary No. Date of R& I & fee	Dy No. 14991: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Angiotensin II receptor blockers (ARBs), plain
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cozaar® 50 mg film-coated tablets. MHRA approved
	Me-too status	Lotass 50mg Tablet. Reg. No. 66803
	GMP status	The firm was inspected on 31.01.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	• The firm submitted updated Form 5. First page of Form 5 is missing.
	Previous decision	• The Board in its 289th meeting deferred the case for submission of updated Form 5.
	Evaluation by PEC	• The firm submitted Form 5 (first page).
	Decision: Approved	
948.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Clarip Dry Suspension 250mg/5ml

	Composition	Each 5ml contain: Clarithromycin…..250mg
	Diary No. Date of R& I & fee	Dy No. 14984: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 250mg/5ml granules for oral suspension. MHRA approved
	Me-too status	KETEK 250 mg/5ml Oral Suspension. Reg. No. 84173 (does not depict granules)
	GMP status	The firm was inspected on 31.01.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	• The firm submitted updated Form 5. First page of Form-5 is missing.
	Previous decision	• The Board in its 289th meeting deferred the case for submission of updated Form 5.
	Evaluation by PEC	• The firm submitted Form 5 (first page).
	Decision: Approved with the condition that the firm will manufacture micropellets in-house.	
949.	Name and address of manufacturer / Applicant	M/s Norwich Pharmaceuticals, Plot No. 220, Industrial Triangle, Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Furox Powder for oral suspension 125mg/5ml
	Composition	Each 5ml contain: Cefuroxime as axetil…… 125mg
	Diary No. Date of R& I & fee	Dy No. 3372: 24.01.2019 PKR 20,000/-: 24.01.2019
	Pharmacological Group	First-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zinnat granules for Suspension 125mg/5ml. MHRA approved
	Me-too status	Kefzy Suspension 125mg/5ml. Reg. No. 82756
	GMP status	New DML
	Remarks of the Evaluator.	The reference product contains granules for oral suspension. However, the provided master formula and manufacturing outlines does not depict granule formation. The firm was asked for justification/ clarification. The firm provided another reference product, which could be verified.
	Previous decision	• The Board in its 289th meeting deferred the case for confirmation of approval status in reference regulatory authorities.
	Evaluation by PEC	• The firm submitted that the dosage form is granule for suspension with submission of Rs. 5000/-.
	Decision: Approved	
950.	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/-.
	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.	

951.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Ranx 1000mg Tablet
	Composition	Each film-coated tablet contains: Ranolazine…1000mg
	Diary No. Date of R& I & fee	Dy No. 15780: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other cardiac preparations
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	RANEXA® (ranolazine) 1000mg extended-release tablets, film-coated. **USFDA** approved
	Me-too status	Ranzol-XR 1000mg Tablet. Reg. No. 61010
	GMP status	The firm was inspected on 17.01.2019 with the following recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator.	• The firm revised the formulation from film-coated to film coated, extended release tablet (in line with the reference product) along with submission of Rs. 5000/- fee. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for clarification of finished product specifications.

	Evaluation by PEC	• The firm has claimed innovator's specifications
	Decision: Approved	
952.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Nicoran 20mg Tablet
	Composition	Each tablet contains: Nicorandil…20mg
	Diary No. Date of R& I & fee	Dy No. 15786: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	30's, 60's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	IKOREL Nicorandil 20mg tablet un-coated. **TGA** approved
	Me-too status	Nicogina 20mg Tablet. Reg. No. 67050
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised the label claim to un-coated tablet with submission of Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.
	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	•**Decision: Approved**	
953.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Nicoran 10mg Tablet
	Composition	Each tablet contains: Nicorandil…10mg
	Diary No. Date of R& I & fee	Dy No. 15785: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	BP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	IKOREL Nicorandil 10mg tablet un-coated. **TGA** approved
	Me-too status	Nicogina 10mg Tablet. Reg. No. 67049
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised the label claim to un-coated tablet with submission of Rs. 5000/- fee. • Undertaking at the end of revised form is missing. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.
	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	•**Decision: Approved**	

954.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 90mg Tablet
	Composition	Each film-coated, extended release tablet contains: Diltiazem HCl…90mg
	Diary No. Date of R& I & fee	Dy No. 15795: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Tildem retard 90mg tablet. **MHRA** approved
	Me-too status	DIACORD SR 90MG TAB. Reg. No. 13369
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised the label claim to extended release tablet with submission of Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.
	Evaluation by PEC	• The firm submitted the manufacturing outlines. • The reference product (Tildem retard 90mg tablet) is in the form of special membrane coating.
	Decision: Deferred for further delibration of the formulation	
955.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 120mg Tablet
	Composition	Each film-coated, extended release tablet contains: Diltiazem HCl…120mg
	Diary No. Date of R& I & fee	Dy No. 15796: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	Available in USP as extended release
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	CARDIZEM® 120mg tablet un-coated. **USFDA** approved
	Me-too status	Calzem-SR 120mg Tablet. Reg. No. 57741 (does not depict salt form)
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised the label claim to extended release tablet with submission of Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.
	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	•**Decision: Deferred for further delibration of the formulation as per previous case of 90mg strength**	

956.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Liptin-M 50/500mg Tablet
	Composition	Each film-coated tablet contains: Sitagliptin as phophpahte monohydrate…50mg Metformin HCl…500mg
	Diary No. Date of R& I & fee	Dy No. 15787: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/500mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/500mg Tablets. Reg. No. 53099
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised Sitagliptin to Sitagliptin as phophpahte monohydrate (Form 5, master Formula, weight adjustment as per slat factor) in line with the reference product along with submission Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.
	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	•**Decision: Approved**	
957.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Liptin-M 50/1000mg Tablet
	Composition	Each film-coated tablet contains: Sitagliptin as phophpahte monohydrate …50mg Metformin HCl…1000mg
	Diary No. Date of R& I & fee	Dy No. 15788: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Combinations of oral blood glucose lowering drugs
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (sitagliptin and metformin HCl) tablet, 50/1000mg film-coated. **USFDA** approved
	Me-too status	Neoglip 50/1000mg Tablets. Reg. No. 53100
	GMP status	As above
	Remarks of the Evaluator.	• The firm revised Sitagliptin to Sitagliptin as phophpahte monohydrate (Form 5, master Formula, weight adjustment as per slat factor) in line with the reference product along with submission Rs. 5000/- fee. • Blistering and packing steps are missing. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.

	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	•**Decision: Approved**	
958.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 90mg Capsule
	Composition	Each capsule contains: Diltiazem HCl (as sustained release pellets)…90mg
	Diary No. Date of R& I & fee	Dy No. 15797: 27.04.2018 PKR 20,000/-: 27.04.2018 PKR 5,000/-: 29.04.2019 PKR 80000/- 19.07.2019
	Pharmacological Group	Other vasodilators used in cardiac diseases
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Angitil SR 90mg MR capsules. **MHRA** approved
	Me-too status	TIAZEM SR 90MG CAP. Reg No. 10863
	GMP status	As above
	Remarks of the Evaluator.	• The firm has revised formulation in line with the reference product without submission of Rs. 5000/- fee. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019. • The pellets have been tested /analysed with unknown specifications. • The long term stability of pellets has been conducted at 25±2 C, 65±5 RH. • Differential fee for imported pellets is required. • GMP certificate of source of pellets is required.
	Previous decision	The Board in its 289th meeting deferred the case for: • The reference for specifications of pellets. • The long term stability of pellets shall be conducted in zone IV-A. • Differential fee for imported pellets is required. • GMP certificate of source of pellets is required.
	Evaluation by PEC	• The firm submitted the reference for pellets. It is pertinent to mention that the dissolution specifications are different from those of USP (mentioned for capsule). • The firm submitted the stability data of the pellets as per Zone IV-A. • The firm submitted Rs. 80000/- differential fee. • The firm M/s Titan Laboratories Pvt. Ltd. Distric Rigad (source of pellets) has been issued GMP certificate by the FDA of Maharashtra State of India, which is valid till 18.10.2019.
	•**Decision: Deferred for clarification regarding the specification of pellets.**	
959.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Diltcontin 180mg Capsule
	Composition	Each capsule contains: Diltiazem HCl (as sustained release pellets)…180mg
	Diary No. Date of R& I & fee	Dy No. 15798: 27.04.2018 PKR 20,000/-: 27.04.2018 PKR 80000/- 19.07.2019
	Pharmacological Group	Other vasodilators used in cardiac diseases

	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Angitil SR 180mg MR capsules. **MHRA** approved
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 17.01.2019 with the following recommendations: Based on the evaluation of the firm and findings of the inspection, the firm was found to be operating at satisfactory level of GMP compliant at the time of inspection. However, firm has received approval for changes in layout plan vide letter no F.1-51/2004-Lic dated 16-08-2018 whereby after revision three sections were approved in layout. At the time of inspection, it was noted that some changes in production are had been done as per approved layout. Some changes were yet to be done. Firm was advised to inform licensing Division Drap, Islamabad upon completion of the proposed changes for further processing.
	Remarks of the Evaluator.	• The firm has revised formulation in line with the reference product without submission of Rs. 5000/- fee. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019. • The pellets have been tested /analysed with unknown specifications. • The long term stability of pellets has been conducted at 25±2 C, 65±5 RH. • Differential fee for imported pellets is required. • GMP certificate of source of pellets is required.
	Previous decision	The Board in its 289th meeting deferred the case for: • The reference for specifications of pellets. • The long term stability of pellets shall be conducted in zone IV-A. • Differential fee for imported pellets is required. • GMP certificate of source of pellets is required.
	Evaluation by PEC	• The firm did not submit the reference for pellets. It is pertinent to mention that the dissolution specifications are different from those of USP (mentioned for capsule). • The firm submitted the stability data of the pellets as per Zone IV-A. • The firm submitted Rs. 80000/- differential fee. • The firm M/s Titan Laboratories Pvt. Ltd. District Rigad (source of pellets) has been issued GMP certificate by the FDA of Maharashtra State of India, which is valid till 18.10.2019.
	•Decision: Deferred for clarification regarding the specification of pellets.	
960.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Prostem 400mcg capsule
	Composition	Each capsule contains: Tamsulosin HCl (modified release pellets)…400mcg
	Diary No. Date of R& I & fee	Dy No. 15776: 27.04.2018 PKR 20,000/-: 27.04.2018 PKR 80000/- 19.07.2019

	Pharmacological Group	Drugs used in benign prostatic hypertrophy
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FLOMAX® (tamsulosin hydrochloride, USP) Capsules, for oral use. **USFDA** approved
	Me-too status	Tamsolin 0.4mg Capsule. Reg. No. 50392
	GMP status	As above
	Remarks of the Evaluator.	• The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 18.01.2019. • Blistering and packing steps are missing in the manufacturing outlines. • The firm has revised the salt form of API and formulation in line with the reference product with submission of Rs. 5000/- fee. • The pellets have been tested with in-house specifications. • The long term stability of pellets has been conducted at 25±2 C, 65±5 RH. • Differential fee for imported pellets is required.
	Previous decision	The Board in its 289th meeting deferred the case for : • Submission of complete manufacturing outline. • The long term stability of pellets shall be conducted in zone IV-A. • Differential fee for imported pellets is required. • GMP certificate of source of pellets is required.
	Evaluation by PEC	• The firm submitted in-house specifications for finished product. It is pertinent to mention that the dissolution specifications of pellets are different from those of USP (mentioned for capsule). • The firm submitted the stability data of the pellets as per Zone IV-A. • The firm submitted Rs. 80000/- differential fee. • The firm M/s RA CHEM PHARMA LIMITED, Telangana, India (source of pellets) has been issued GMP certificate by the Drug control Administration, Government of Telangana of Maharashtra State of India, which is valid for one year from the date of issue (13.04.2018).
	•**Decision: Deferred for clarification regarding the specification of pellets.**	
961.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Clowin 50mg tablet
	Composition	Each tablet contains: Clomiphene citrate…50mg
	Diary No. Date of R& I & fee	Dy No. 15781: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GENRX CLOMIPHENE clomifene citrate 50mg tablet, un-coated. **TGA** approved
	Me-too status	OVA-MIT TABLETS. Reg. No. 20404

	GMP status	As above
	Remarks of the Evaluator.	• Blistering and packing steps are missing in the manufacturing outlines. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.
	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	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.	
962.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Clowin 50mg capsule
	Composition	Each capsule contains: Clomiphene citrate…50mg
	Diary No. Date of R& I & fee	Dy No. 15782: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Ovulation stimulants, synthetic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications
	Pack size & Demanded Price	10's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	PROLIFEN CAP. Reg. No. 10250
	GMP status	As above
	Remarks of the Evaluator.	• Blistering and packing steps are missing in the manufacturing outlines. • The firm has changed its name to "Horizon Healthcare (Pvt.) Ltd Plot No. 33 Sundar Industrial Estate, Lahore and submitted Rs. 20000/- fee dated 31.01.2019.
	Previous decision	The Board in its 289th meeting deferred the case for: • Submission of complete manufacturing outlines. • Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board
	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	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.	
963.	Name and address of manufacturer / Applicant	M/s Wellness Pharmaceuticals Pvt Ltd. Plot No 33, Sundar Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Jmslim 120mg capsule
	Composition	Each capsule contains: Orlistat…120mg
	Diary No. Date of R& I & fee	Dy No. 15775: 27.04.2018 PKR 20,000/-: 27.04.2018
	Pharmacological Group	Peripherally acting antiobesity products
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's, 14's, 30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Beacita 120mg Capsules, hard. **MHRA** approved

	Me-too status	Xenical Capsule. Reg. No. 42142
	GMP status	As above
	Remarks of the Evaluator.	• Diltiazem HCl has been mentioned in the filling step of manufacturing outlines • Blistering and packing steps are missing in the manufacturing outlines.
	Previous decision	The Board in its 289th meeting deferred the case for submission of complete manufacturing outlines.
	Evaluation by PEC	• The firm submitted the manufacturing outlines.
	Decision: Deffered for submission of all requirements of orlistat pellets including stability data.	
964.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Menem Powder for solution for injection 500mg
	Composition	Each vial contains: Meropenemas as trihydrate……500mg
	Diary No. Date of R& I & fee	Dy No. 9524: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MERREM® IV (meropenem for injection) 500mg, for intravenous use. **US-FDA** approved
	Me-too status	Engpan Injection 500mg. Reg. No. 64555
	GMP status	The firm (M/s Winthrox Pharma) was inspected on on 14.09.2017, wherein the GMP of the firm was rated as GOOD. The firm M/s Global Pharma was was inspected on 11. & 24.10.2018, wherein issuance of GMP certificate was recommended.
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, the firm revised it to Powder for solution for injection.
	Previous decision	The Board in its 289th meeting deferred the case for: • List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required.
	Evaluation by PEC	• The firm submitted that they have never applied for contract manufacturing before this. • The firm submitted list of 07 product applied for contract manufacturing. • The firm submitted list of 06 approved sections and 04 additional approved section.
	•**Decision: Approved**	

965.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Menem Powder for solution for injection 1g
	Composition	Each vial contains: Meropenem as trihydrate……1g
	Diary No. Date of R& I & fee	Dy No. 9523: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	MERREM® IV (meropenem for injection) 1g, for intravenous use. **US-FDA** approved
	Me-too status	Meropeon Injection 1g. Reg. No. 78145
	GMP status	The firm (M/s Winthrox Pharma) was inspected on on 14.09.2017, wherein the GMP of the firm was rated as GOOD. The firm M/s Global Pharma was inspected on 11. & 24.10.2018, wherein issuance of GMP certificate was recommended.
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, the firm revised it to Powder for solution for injection.
	Previous decision	The Board in its 289th meeting deferred the case for: • List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required.
	Evaluation by PEC	• The firm submitted that they have never applied for contract manufacturing before this. • The firm submitted list of 07 product applied for contract manufacturing. • The firm submitted list of 06 approved sections and 04 additional approved section.
	•**Decision: Approved**	
966.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tazowin Powder for solution for injection 4.5g
	Composition	Each vial contains: Piperacillin as sodium……4g Tazobactam as sodium……0.5g
	Diary No. Date of R& I & fee	Dy No. 9523: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Piperacillin and beta-lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for injection, for intravenous use. **US-FDA** approved
	Me-too status	Tanzo Injection. Reg. No. 39439
	GMP status	The firm (M/s Winthrox Pharma) was inspected on on 14.09.2017, wherein the GMP of the firm was rated as GOOD. The firm M/s Global Pharma was inspected on 11. & 24.10.2018, wherein issuance of GMP certificate was recommended.
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, the firm now revised it to Powder for solution for injection
	Previous decision	The Board in its 289th meeting deferred the case for: • List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required.
	Evaluation by PEC	• The firm submitted that they have never applied for contract manufacturing before this. • The firm submitted list of 07 product applied for contract manufacturing. • The firm submitted list of 06 approved sections and 04 additional approved section.
	•**Decision: Approved**	
967.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Tazowin Powder for solution for injection 2.25g
	Composition	Each vial contains: Piperacillin as sodium……2g Tazobactam as sodium……0.25g
	Diary No. Date of R& I & fee	Dy No. 9521: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Piperacillin and beta-lactamase inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	ZOSYN® (piperacillin and tazobactam) for injection, for intravenous use. **USFDA** approved
	Me-too status	Tanzo Injection. Reg. No. 39593
	GMP status	The firm (M/s Winthrox Pharma) was inspected on on 14.09.2017, wherein the GMP of the firm was rated as GOOD. The firm M/s Global Pharma was inspected on 11. & 24.10.2018, wherein issuance of GMP certificate was recommended.
	Remarks of the Evaluator.	• Tazowin 2.5 has been mentioned on fee challan instead of Tazowin 2.25 • List of already approved product for contact manufacturing

		of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, the firm revised it to Powder for solution for injection.
	Previous decision	The Board in its 289th meeting deferred the case for: • List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required.
	Evaluation by PEC	• The firm submitted that they have never applied for contract manufacturing before this. • The firm submitted list of 07 product applied for contract manufacturing. • The firm submitted list of 06 approved sections and 04 additional approved section.
	•**Decision: Approved**	
968.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt) Ltd. K-219-A, SITE, Super Highway, Phase-II, Karachi-Contract Manufacturing by: M/s Global Pharmaceuticals (Pvt) ltd. Plot No. 204-205, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Imicil Powder for solution for injection
	Composition	Each vial contains: Imipenem as monohydrate…..500mg Cilastin as sodium……500mg
	Diary No. Date of R& I & fee	Dy No. 9520: 14.03.2018 PKR 50,000/-: 13.03.2018
	Pharmacological Group	Carbapenems
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's vial; As per DRAP policy
	Approval status of product in Reference Regulatory Authorities.	PRIMAXIN® (imipenem and cilastatin) for Injection, for intravenous use. **USFDA** approved
	Me-too status	Imclas Injection IV. Reg. No. 48341
	GMP status	The firm (M/s Winthrox Pharma) was inspected on on 14.09.2017, wherein the GMP of the firm was rated as GOOD. The firm M/s Global Pharma was inspected on 11. & 24.10.2018, wherein issuance of GMP certificate was recommended.
	Remarks of the Evaluator.	• List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required. • List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required. • The firm has mentioned the dosage form as injection. However, the firm revised it to Powder for solution for injection.
	Previous decision	The Board in its 289th meeting deferred the case for: • List of already approved product for contact manufacturing of M/s Winthrox Laboratories is required.

		• List of product applied for contact manufacturing by M/s Winthrox Laboratories is required. • List of all approved sections of M/s Winthrox Laboratories is required.
	Evaluation by PEC	• The firm submitted that they have never applied for contract manufacturing before this. • The firm submitted list of 07 product applied for contract manufacturing. • The firm submitted list of 06 approved sections and 04 additional approved section.
	•**Decision: Approved**	
969.	Name and address of manufacturer / Applicant	Semos Pharmaceutical Private Limited. Plot No. 11, sector 12-A, North Karachi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Soxitil DS Suspension 100mg/5ml
	Composition	Each 5ml contain: Cefpodoxime (as Proxetil) USP……..100mg
	Diary No. Date of R& I & fee	Dy No. 3463: 26.01.2018 PKR 20,000/-: 26.01.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per Policy
	Approval status of product in Reference Regulatory Authorities.	**Could not be confirmed**
	Me-too status	Qink Dry Suspension. Reg. No. 53636
	GMP status	The firm was inspected on 19.09.2017, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	
	Previous decision	The Board in its 287th meeting deferred the case for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC	The product is available as Vantin (cefpodoxime proxetil for oral suspension, USP) 50mg, 100mg base in USFDA (**in the form of granules**), which was not discontinued or withdrawn for safety or efficacy reasons.
	Decision: Deferred for revision of formulation in line with the reference product.	
970.	Name and address of manufacturer / Applicant	Zafa Pharmaceutical Laboratories (Private) Limited A-46, SITE North Karachi
	Brand Name +Dosage Form + Strength	Dydrone Tablet 10mg
	Composition	Each film-coated tablet contains: Dydrogesterone…….10mg
	Diary No. Date of R& I & fee	Dy No. 9283: 13.03.2018 PKR 20,000/-: 12.03.2018
	Pharmacological Group	Progestogens
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	Duphaston 10 mg film-coated tablets. Approved in **Belgium**
	Me-too status	D-Gest 10mg Tablets. Reg. No. 77100
	GMP status	The firm was inspected on 07.02.2019, wherein the GMP was rated as GOOD
	Remarks of the Evaluator.	• The firm submitted that they will use trans-isomer of API.

	Previous decision	• The Board deferred the case for proof of approval of the section
	Evaluation by PEC	• The firm submitted copy of approval letter dated 22.10.2008, wherein the firm has been granted **Tablet (Hormone)** section.
	Decision: Approved	
971.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gabitin Capsule 300mg
	Composition	Each tablet contains: Gabapentin…….300mg
	Diary No. Date of R& I & fee	Dy No. 6859: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; Rs. 180/-
	Approval status of product in Reference Regulatory Authorities.	Gabapentin 300mg Capsules. **MHRA** approved
	Me-too status	Pentowan 300mg Capsule. Reg. No. 82103
	GMP status	The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production.
	Remarks of the Evaluator.	•
	Previous decision	Registration Board in its 288th meeting deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications.
	Evaluation by PEC	• The 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). • The firm further requested to process their cases.
	Decision: Approved	
972.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Gabitin Capsule 100mg
	Composition	Each tablet contains: Gabapentin…….100mg
	Diary No. Date of R& I & fee	Dy No. 6850: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; Rs. 90/-
	Approval status of product in Reference Regulatory Authorities.	Gabapentin 100mg Capsules. **MHRA** approved
	Me-too status	Pentowan 100mg Capsule. Reg. No. 79688
	GMP status	The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production.
	Remarks of the Evaluator.	•
	Previous decision	Registration Board in its 288th meeting deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications.
	Evaluation by PEC	•
	Previous decision	Registration Board in its 288th meeting deferred the case on the request of M/s AJM Pharma to hold evaluation of their

		registration applications.
	Evaluation by PEC	• The 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). • The firm further requested to process their cases.
	Decision: Approved	
973.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Aplodine Tablet 10mg
	Composition	Each tablet contains: Amlodipine as besilate…….10mg
	Diary No. Date of R& I & fee	Dy No. 6856: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Selective calcium channel blockers with mainly vascular effects
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	12x0's; Rs. 290/-
	Approval status of product in Reference Regulatory Authorities.	NORVASC® (amlodipine besylate) 10mg Tablets for oral administration. **USFDA** approved
	Me-too status	NORVASC 10MG TAB. Reg. No. 11826
	GMP status	The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production.
	Remarks of the Evaluator.	•
	Previous decision	Registration Board in its 288th meeting deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications.
	Evaluation by PEC	• The 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). • The firm further requested to process their cases.
	Decision: Approved	
974.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Aplodine Tablet 5mg
	Composition	Each tablet contains: Amlodipine as besilate…….5mg
	Diary No. Date of R& I & fee	Dy No. 6887: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Selective calcium channel blockers with mainly vascular effects
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x10's; Rs. 160/-
	Approval status of product in Reference Regulatory Authorities.	NORVASC® (amlodipine besylate) 5mg Tablets for oral administration. **USFDA** approved
	Me-too status	NORVASC 5MG TAB. Reg. No. 11825
	GMP status	The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production.
	Remarks of the Evaluator.	•
	Previous decision	Registration Board in its 288th meeting deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications.

	Evaluation by PEC	• The 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). • The firm further requested to process their cases.
	Decision: Approved	
975.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Levtitam 500mg/5ml Syrup
	Composition	Each 5ml contain: Levetiracetam…….500mg
	Diary No. Date of R& I & fee	Dy No. 6849: 22.02.2018 PKR 20,000/-: 16.02.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	30ml; Rs. 210/-
	Approval status of product in Reference Regulatory Authorities.	Desitrend 100 mg/ml oral solution. **MHRA** approved
	Me-too status	Eplipsa 100mg/ml Oral Solution. Reg. No. 82200
	GMP status	The firm was inspected on 14.11.2014, wherein the panel recommended the resumption of production.
	Remarks of the Evaluator.	•
	Previous decision	Registration Board in its 288th meeting deferred the case on the request of M/s AJM Pharma to hold evaluation of their registration applications.
	Evaluation by PEC	• The 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). • The firm further requested to process their cases.
	Decision: Approved	
976.	Name and address of manufacturer / Applicant	Aspin Pharma (Pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi 74900, Pakistan
	Brand Name +Dosage Form + Strength	Athrocin DS
	Composition	Each 5ml contains: Azithromycin as dihydrate……200mg
	Diary No. Date of R& I & fee	Dy No. 9296: 13.03.2018 PKR 20,000/-: 13.03.2018
	Pharmacological Group	Macrolides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	15ml, 25ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 200 mg/5 ml Suspension. **MHRA** approved
	Me-too status	Chemzee Dry Powder Suspension. Reg. No. 35875
	GMP status	The firm was inspected on 20.02.2018, wherein the GMP level was rated as satisfactory.
	Remarks of the Evaluator.	• The USP has specified Amperometric electrochemical detector with Dual glassy carbon Electrode. The firm was asked for provision of the same. The firm did not respond. • The firm has mentioned the dosage form as suspension instead of dry suspension in Form 5.
	Previous decision	The Board in its 289th meeting deferred the case for provision of Amperometric electrochemical detector with Dual glassy carbon Electrode

	Evaluation by PEC	The firm submitted that the revised monograph of USP 42, which has referred to UV detector. The firm has attached copy of the monograph. However, the evaluator has access to USP 41 only, wherein the monograph has referred to Amperometric electrochemical detector with Dual glassy carbon Electrode.
	Decision: Deferred for further delibration	
977.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals, Factory Plot # 122, Block B, Phase V, Industrial Estate, Hattar, District Haripur, Pakistan
	Brand Name +Dosage Form + Strength	Nelfi 250mg tablet
	Composition	Each film-coated tablet contains: Nelfinavir as Mesylate…..250mg
	Diary No. Date of R& I & fee	Dy No. 39451: 30.11.2018 PKR 20,000/-: 30.11.2018
	Pharmacological Group	Protease inhibitors
	Type of Form	Form 5
	Finished Product Specification	IP
	Pack size & Demanded Price	As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	VIRACEPT® (nelfinavir mesylate) film-coated Tablets, for oral use USFDA approved
	Me-too status	NELFIN–250 Tablets. Reg. No.41115
	GMP status	The firm was inspected on 04.09.2018 & 26.09.2018 with the conclusion: As per observation made, facilities of production and quality control inspected, technical staff employed and keeping in view the overall GMP compliance status of the firm, the panel unanimously recommends the renewal of DML 000614 by way of formulation granted to M/s Welmark KPK.
	Remarks of the Evaluator.	• The firm revised Nelfinavir Mesylate to Nelfinavir as Mesylate in Form 5 without any fee.
	Previous decision	• The Board in its 289 meeting deferred the case for submission of fee.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee.
	Decision: Approved	
978.	Name and address of manufacturer / Applicant	Berlex Lab. International, 10 Km Nangshah Chowk Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Parolex Tablet 20mg
	Composition	Each film-coated tablet contains: Paroxetine as HCl…….20mg
	Diary No. Date of R& I & fee	Dy No. 33094: 04.10.2018 PKR 20,000/-: 29.03.2017 (**Duplicate Dossier**)
	Pharmacological Group	Selective serotonin reuptake inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Paroxetine 20 mg Film-coated tablets. MHRA approved
	Me-too status	Frais Tablet 20mg. Reg. No. 82658 (Does not depict hemihydrate)
	GMP status	The firm was inspected on 05.07.2018, wherein the panel recommended renewal of DML
	Remarks of the Evaluator.	• The firm was asked to revise the label claim in Form 5 to "Each film-coated tablet contains" with submission of applicable fee. The firm revised the label claim without submission of fee.

		• The reference product contains Paroxetine as HCl hemihydrate. Correct the label claim to Paroxetine as HCl hemihydrate and master formula to Paroxetine HCl hemihydrate. However, the firm did not revise the same.
	Previous decision	• The Board in its 288th meeting deferred the case for revision of salt forms of the API in the formulation as per the reference product along with submission of fee for revision of formulation.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee. • Revision of salt form in label claim to Paroxetine as HCl hemihydrate and master formula to Paroxetine HCl hemihydrate along with adjustment of weight as per salt factor is required.
	Decision: Deferred for revision of salt form in label claim to Paroxetine as HCl hemihydrate and in master formula to Paroxetine HCl hemihydrate along with adjustment of weight as per salt	
979.	Name and address of manufacturer / Applicant	Berlex Lab. International, 10 Km Nangshah Chowk Karachi Road, Multan
	Brand Name +Dosage Form + Strength	Tramalex Plus Tablet
	Composition	Each film-coated tablet contains: Tramadol HCl……37.5 Paracetamol……..325
	Diary No. Date of R& I & fee	Dy No. 33096: 04.10.2018 PKR 20,000/-: 29.03.2017 (**Duplicate Dossier**)
	Pharmacological Group	Opioids in combination with non-opioid analgesics
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x5's; Rs. 100/-
	Approval status of product in Reference Regulatory Authorities.	ULTRACET (tramadol hydrochloride and acetaminophen) tablets, for oral use by Janssen Pharms **US-FDA** approved
	Me-too status	Tril-P Tablet by Linta Pharmaceuticals. Reg. No. 78181
	GMP status	The firm was inspected on 05.07.2018, wherein the panel recommended renewal of DML
	Remarks of the Evaluator.	• The firm was asked to revise the formulation to film-coated tablet along with correction in label claim, Master Formula and manufacturing outlines and submission of applicable fee. However, the firm only revised label claim in Form 5 and did not submit any fee.
	Previous decision	The Board in its 288th meeting deferred the case for submission of fee for revision of formulation.
	Evaluation by PEC	• The firm submitted Rs. 5000/- fee. • Revision of Master Formula and manufacturing outlines required.
	Decision: Deferred for revision of Master Formula and manufacturing outlines for film-coated tablet.	
980.	Name and address of manufacturer / Applicant	Winthrox Laboratories, (Pvt) Ltd., K-219-A, SITE, Super Highway, Phase-II, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Windic SR Tablet 100mg
	Composition	Each sustained release tablet contains: Diclofenac sodium……100mg
	Diary No. Date of R& I & fee	Dy No. 6874: 22.02.2018 PKR 20,000/-: 21.02.2018 PKR 5,000/-: 08.03.2019
	Pharmacological Group	Acetic acid derivatives and related substances
	Type of Form	Form 5
	Finished Product Specification	USP

	Pack size & Demanded Price	As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Dicloflex Retard 100 mg prolonged release tablet. **MHRA** approved
	Me-too status	Diclorax 100mg Tablet. Reg. # 85498
	GMP status	The firm was inspected on 14.09.2017, wherein the GMP of the firm was rated as GOOD.
	Remarks of the Evaluator.	• The firm revised the formulation to sustained release tablet with submission of Rs. 5,000/- fee. • The revised coating composition has HPMC 15cp as binder. The reference product contains sub-coat of Copovidone and Sucrose, and Pigmented film coat of Opadry 02B24025. The dossier does not depict the same. • The firm was asked about the use of sustained release polymer in composition, i.e., how the drug release was sustained/extended. The firm did not justify the same. The firm has mentioned HMPC K100 and HPMC K4 as binder.
	Prevoius decision	The Board in its 289th meeting deferred the case for further clarification from the firm.
	Evaluation by PEC	The firm revised the composition and manufacturing outlines.
	Decision: Approved	

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

a. New DML

The firm has been granted New section in 263rd meeting of CLB held on 11.06.2018. The firm has applied for 10 molecules (10 products).		
981.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Heptapar Syrup
	Composition	Each 5ml Contains: L-Ornithine-L-Aspartate…300mg Nicotinamide…24mg Riboflavin Phosphate Sodium…0.765mg
	Diary No. Date of R& I & fee	Dy.No. 13646: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Amino acid and vitamins
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	60ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	New section
	Remarks of the Evaluator.	• Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking. • Proof of International availability of same dosage form with same strength and same salt forms in reference regulatory authority as defined in 275th meeting of the Registration Board. • Evidence of approval of me-too product with the same strength.
	Decision: Deferred 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.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	

982.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Hi-Sonic Suspension
	Composition	Each 5ml Contain: Sucralfate…1g
	Diary No. Date of R& I & fee	Dy.No. 13649: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Other drugs for peptic ulcer and gastro-oesophageal reflux disease (GORD)
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	60ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Antepsin® 1g/5ml Oral Suspension. MHRA approved
	Me-too status	Gastromed Oral Suspension 1gm/5ml. Reg. No. 82601
	GMP status	New section
	Remarks of the Evaluator.	• Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking.
	Decision: Approved with innovator's specifications.	
983.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Irofort Syrup
	Composition	Each 15ml Contains: Iron Protein Succinylate Eq. to Iron…40mg
	Diary No. Date of R& I & fee	Dy.No. 13648: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Iron preparations
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	60ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Perital Syrup. Reg. No. 23915
	GMP status	New section
	Remarks of the Evaluator.	• Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking.
	Decision: Approved with innovator's specifications.	
984.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Appegor-V Syrup
	Composition	Each 10ml Contains: Pizotifen as Hydrogen Maleate…0.5mg Thiamine Hcl…1.75mg Riboflavin Phosphate…2.62mg Pyridoxine Hcl…1.54mg Nicotinamide…10.50mg
	Diary No. Date of R& I & fee	Dy.No. 13645: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Other antimigraine preparations with vitamins
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	60ml, 120ml; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed

	Me-too status	MOSEGOR V SYP. Reg. No. 7449. (The strengths could not be verified)
	GMP status	New section
	Remarks of the Evaluator.	• Proof of International availability of same dosage form with same strength and same salt forms in reference regulatory authority as defined in 275th meeting of the Registration Board. • Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking
	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.	
985.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Hilax Syrup
	Composition	Each 5ml Contains: Lactulose…3.35g
	Diary No. Date of R& I & fee	Dy.No. 13647: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Osmotically acting laxatives
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & demanded price	60ml, 120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Duphalac (Lactulose 3.335 g/5 ml) clear, viscous liquid. MHRA approved
	Me-too status	Kohilac Syrup (Lactulose……3.35g). Reg. No. 55593
	GMP status	New section
	Remarks of the Evaluator.	• The quantity of API in applied and me-too product are different than that of international reference product. • Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking • The firm was asked to provide source of lactulose. The firm submitted Fresenius Kabi, Austria. • The firm was asked to submit manufacturing outlines. The firm submitted that they will refill it.
	Decision: Deferred for revision of quanitity of API from 3.35g to 3.335g along with submission of fee for revision of strength.	
986.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Cetum Syrup
	Composition	Each 5ml Contains: Piracetam…1g
	Diary No. Date of R& I & fee	Dy.No. 13653: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Other psychostimulants and nootropics
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Medipil Syrup. Reg. No. 49548
	GMP status	New section
	Remarks of the Evaluator.	• Proof of International availability of same dosage form with same strength and same salt forms in reference regulatory authority as defined in 275th meeting of the Registration

		Board. • Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking.
	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.	
987.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Acemax Syrup
	Composition	Each 5ml Contains: Acefylline Piperazine…45mg Diphenhydramine HCl…8mg
	Diary No. Date of R& I & fee	Dy.No. 13650: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	diphenhydramine, combinations
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	120ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	M-Cefyl Syrup. Reg. No. 69348
	GMP status	New section
	Remarks of the Evaluator.	• Proof International availability of same dosage form with same strength and same salt forms in reference regulatory authority as defined in 275th meeting of the Registration Board. • Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking. • In the revised master formula, the firm revised to Diphenhydramine Hcl to Diphenhydramine as Hcl, which is against the me-too product.
	Decision: Deferred 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.** • **Revision of salt form as per reference (if any) and me-too products.**	
988.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Spasnil Syrup
	Composition	Each 5ml Contains: Hyoscine Butyl Bromide…5mg
	Diary No. Date of R& I & fee	Dy.No. 13651: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Other antiemetics
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	60ml; As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Spacure Syrup (Hyoscine-N Butylbromide). Reg. No. 70564
	GMP status	New section
	Remarks of the Evaluator.	• Proof of International availability of same dosage form with same strength and same salt forms in reference regulatory authority as defined in 275th meeting of the Registration Board. • Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking.

	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.	
989.	**Name and address of manufacturer / Applicant**	**M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore**
	Brand Name +Dosage Form + Strength	Tussicol Syrup
	Composition	Each 5ml Contains: Dextromethorphan…7.5mg Carbinoxamine Maleate…1.25mg Pseudoephedrine Hcl…30mg Guaifensin…50mg
	Diary No. Date of R& I & fee	Dy.No. 13654: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Opium alkaloids and derivatives + Aminoalkyl ethers + Sympathomimetics + Guaifensin
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	30 ml; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	New section
	Remarks of the Evaluator.	• Proof of International availability of same dosage form with same strength and same salt forms in reference regulatory authority as defined in 275th meeting of the Registration Board. • Proof of me-too product (Name and registration number) approved by DRAP. • Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking.
	Decision: Deferred 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.** • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
990.	Name and address of manufacturer / Applicant	M/s Pakheim International Pharma Pvt Ltd. 28 Km, Feroze Pur Road, Lahore
	Brand Name +Dosage Form + Strength	Hi-Mark Syrup
	Composition	Each ml Contains: Levetiracetam…100mg
	Diary No. Date of R& I & fee	Dy.No. 13652: 07.03.2018 Rs. 20,000/-: 07.03.2018
	Pharmacological Group	Other antiepileptics
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & demanded price	30ml, 60ml; as per PRC
	Approval status of product in Reference Regulatory Authorities.	KEPPRA (levetiracetam) oral solution. USFDA approved
	Me-too status	Eplipsa 100mg/ml Oral Solution. Reg No. 82200
	GMP status	New section
	Remarks of the Evaluator.	• Name of signatory is missing on Form 5. • Undertaking at the end of Form had not been signed by the concerned persons. The firm provided signed undertaking.
	Decision: Approved with innovator's specifications.	

b. New/Additional section(s)

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

a. New Cases

991.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Iverlon Super Injection 100ml
	Composition	Each ml contains: Ivermectin…20mg Clorsulon…100mg
	Diary No. Date of R& I & fee	Dy No. 22521: 28.06.2018 PKR 20,000/-: 28.06.2018
	Pharmacological Group	Anthelmintics (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	100ml vial; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	IVOCLOR INJECTION (50ml). Reg. No. 043275 (does not depict vial/ampule)
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended.
	Remarks of the Evaluator.	•
	Decision: Approved with box warning	
992.	**Deleted due to duplications**	
993.	Name and address of manufacturer / Applicant	M/s Leads Pharma Pvt Ltd. 81-A, Street # 6, I-10/3, Islamabad
	Brand Name +Dosage Form + Strength	Meloxin 20mg Injection
	Composition	Each ml Contains: Meloxicam…20mg
	Diary No. Date of R& I & fee	Dy No. 23075: 04.07.2018 PKR 20,000/-: 04.07.2018
	Pharmacological Group	Oxicams
	Type of Form	Form 5
	Finished Product Specification	BP (Vet)
	Pack size & Demanded Price	Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Metrym Injection. Reg. No. 44961
	GMP status	The firm was inspected on 29.11.2018 and 01.01.2019, wherein grant of GMP certificate was recommended.
	Remarks of the Evaluator.	• The firm has submitted latest updated Form 5 duly filled and signed by all concerned persons.
	Decision: Approved	
994.	**Name and address of manufacturer / Applicant**	**M/s Noble Pharma. B-1 Old Industrial Area, Mirpur, Azad Kashmir**
	Brand Name +Dosage Form + Strength	Nobicomb Suspension
	Composition	Each 5ml Contains Oxyclozanide…150mg Levamisole as HCL…75mg
	Diary No. Date of R& I & fee	Dy No. 21496: 14.06.2018 PKR 20,000/-: 14.06.2018
	Pharmacological Group	Anthelmintics (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	100ml, 150ml, 500ml, 1000ml; Decontrolled
	Approval status of product in Reference	NA

	Regulatory Authorities.	
	Me-too status	COMBAT ORAL DRENCH. Reg. No. 043275 (does not depict suspension form)
	GMP status	The firm was inspected on 16.11.2018, wherein the FIDreported average level of GMP compliance.
	Remarks of the Evaluator.	• The firm was asked to revise levamesol as HCl to levamesol HCl in Form 5. The firm did not revise thye same. Revision is required. • The firm was asked to justify the statement "Appropirate overage is added to compensate the potency loss on storage". The firm removed the statement in revised master formula. However, in the revised master formula, the quantities of API do not correspond to the batch size. • The firm was asked to provide reference for finished product specifications. The firm did not provide the same.
	Decision: Deferred for the following: • **Revise levamesol as HCl to levamesol HCl in Form 5** • **Correct Master Formula with the quantities of API/addtiives corresponding to the batch size**	

b. Deferred Cases

995.	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	Hepahil 100mg/ml Injection (50ml)
	Composition	Each ml contains: 2-Methyl 2-Phenoxy propionic acid…..100mg
	Diary No. Date of R& I & fee	Dy No. 15838: 27.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Liver tonic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	HEPASEL INJECTION. Reg. No. 46518 (30ml, 50ml, 100ml)
	GMP status	The firm was inspected on 19.07.2017, wherein the GMP was rated as satisfactory.
	Remarks of the Evaluator.	• The firm revised the API from salt form to free acid without submission of applicable fee. • Filling and packing are missing.
	Previous decision	The Board in its 290th meeting deferred the case for the following: • Submission of fee for revision of salt form • Submission of manufacturing outlines.
	Evaluation by PEC	The firm submitted Rs. 5000/- fee and revised the manufacturing outlines
	Decision: Approved with innovator's specifications.	
996.	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	Hepahil 100mg/ml Injection (100ml)
	Composition	Each ml contains: 2-Methyl 2-Phenoxy propionic acid….. 100mg
	Diary No. Date of R& I & fee	Dy No. 15839: 27.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Liver tonic
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications

	Pack size & Demanded Price	100ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	HEPASEL INJECTION. Reg. No. 46518 (30ml, 50ml, 100ml)
	GMP status	The firm was inspected on 19.07.2017, wherein the GMP was rated as satisfactory.
	Remarks of the Evaluator.	• The provided me-too doesnot have salt form of API. Proof of approval of me-too product with same dosage form, strength and salt forms by DRAP is required. Otherwise, revise the salt form in line with the reference product along with submission of applicable fee. • Filling and packing are missing.
	Previous decision	The Board in its 290th meeting deferred the case for the following: • Submission of fee for revision of salt form • Submission of manufacturing outlines.
	Evaluation by PEC	The firm submitted Rs. 5000/- fee and revised the manufacturing outlines
	Decision: Approved with innovator's specifications.	
997.	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	Ketohil 100mg/ml Injection (20ml)
	Composition	Each ml contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy No. 15840: 27.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	20ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	KETOJECT INJECTION. Reg. No. 43141 (10ml, 20ml, 50ml, 100ml)
	GMP status	The firm was inspected on 19.07.2017, wherein the GMP was rated as satisfactory.
	Remarks of the Evaluator.	• Filling and packing are missing.
	Previous decision	The Board in its 290th meeting deferred the case for submission of manufacturing outlines.
	Evaluation by PEC	The firm submitted the manufacturing outlines
	Decision: Approved with innovator's specifications.	
998.	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	Ketohil 100mg/ml Injection (50ml)
	Composition	Each ml contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy No. 15841: 27.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	50ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	KETOJECT INJECTION. Reg. No. 43141 (10ml, 20ml, 50ml, 100ml)

	GMP status	The firm was inspected on 19.07.2017, wherein the GMP was rated as satisfactory.
	Remarks of the Evaluator.	• Filling and packing are missing.
	Previous decision	The Board in its 290th meeting deferred the case for submission of manufacturing outlines.
	Evaluation by PEC	The firm submitted the manufacturing outlines
	Decision: Approved with innovator's specifications.	
999.	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	Ketohil 100mg/ml Injection (100ml)
	Composition	Each ml contains: Ketoprofen…100mg
	Diary No. Date of R& I & fee	Dy No. 15842: 27.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer specifications
	Pack size & Demanded Price	100ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	KETOJECT INJECTION. Reg. No. 43141 (10ml, 20ml, 50ml, 100ml)
	GMP status	The firm was inspected on 19.07.2017, wherein the GMP was rated as satisfactory.
	Remarks of the Evaluator.	• Filling and packing are missing.
	Previous decision	The Board in its 290th meeting deferred the case for submission of manufacturing outlines.
	Evaluation by PEC	The firm submitted the manufacturing outlines
	Decision: Approved with innovator's specifications.	
1000.	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	BIO-BIOTIC-500 LIQUID
	Composition	Each 1000 ml contains Tylosin Tartrate---------- 100g Doxycycline HCl---------- 200g Bromhexine HCL--------- 3g Colistin Sulphate---------- 480 MIU
	Diary No. Date of R & I & Fee	Dy No. 11657: 06.03.2019 Rs. 20,000/-: 01.03.2019
	Pharmacological Group	Antibiotic + Expectorant
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100 ml, 500 ml, 1 Litre, 2.5 Litre, 5 Litre : As per Policy of MoH
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	BRONCHOTIL LIQUID. Reg No. 058880
	GMP Status	New License (Inspection Date: 04.10.2018 & 05.11.2018)
	Remarks of the Evaluator	• The firm revised doxycycline to doxycycline HCl in Form 5 along with submission Rs. 5000/- fee. Revision of doxycycline to doxycycline HCl in master formula and manufacturing outlines is required.
	Previous decision	The Board in its 290th meeting deferred the case for revision of doxycycline to doxycycline HCl in master formula and manufacturing outlines.

	Evaluation by PEC	• The firm revised doxycycline to doxycycline HCl in master formula and manufacturing outlines.
	Decision: Approved with innovator's specifications.	
1001.	**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	FLOXYCOL-PLUS ORAL LIQUID
	Composition	Each 100 ml contains :- Enrofloxacin…….10g Colistin Sulphate…….52 MIU
	Diary No. Date of R & I & Fee	Dy No. 11631: 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
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	BIO-ENROCOLIS. Reg. No. 73916
	GMP Status	New License (Inspection Date: 04.10.2018 & 05.11.2018)
	Remarks of the Evaluator	• Undertaking at the end of Form 5 is missing.
	Previous decision	The Board in its 290th meeting deferred the case for submission of undertaking at the end of Form 5.
	Evaluation by PEC	The firm submitted undertaking at the end of Form 5.
	Decision: Approved with innovator's specifications.	
1002.	Name and address of manufacturer / Applicant	M/s Vetec Laboratories, Plot No. 20, Street S-5, National Industrial Zone, Rawat, Rawalpindi
	Brand Name + Dosage Form + Strength	SE-COLIFLOR LIQUID
	Composition	Each 100 ml contains:- Florfenicol……23g Colistin Sulphate……50 MIU
	Diary No. Date of R & I & Fee	Dy No.11702: 06.03.2019 Rs. 20,000/-: 01.03.2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed In-house specification
	Pack Size & Demanded Price	100 ml, 500 ml, 1 Litre, 2.5 Litre, 5 Litre : As per Policy of MoH
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	MAXIFLOR-PLUS LIQUID. Reg No. 075617
	GMP Status	New License (Inspection Date: 04.10.2018 & 05.11.2018)
	Remarks of the Evaluator	• Adjust the strength of API in line with the reference product along with submission of applicable fee.
	Previous decision	The Board in its 290th meeting deferred for adjustment of the strength of API in line with the reference product along with submission of applicable fee.
	Evaluation by PEC	The firm submitted the following me-too: FLORIN LIQUID. Reg. No. 78238
	Decision: Approved with innovator's specifications.	
1003.	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	DOXYTIL-T
	Composition	Each 100 ml contain: Doxycycline Hyclate…….20g Tylosin Tartrate……..10g

	Diary No. Date of R & I & Fee	Dy No. 11650; 06.03.2019 Rs. 20,000/-: 01.03.2019
	Pharmacological Group	Antibacterials
	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
	Approval Status of product in Reference Regulatory Authorities	N/A
	Me-too Status	TETRAMAC LIQUID. Reg No. 043175
	GMP Status	New License (Inspection Date: 04.10.2018 & 05.11.2018)
	Remarks of the Evaluator	• Undertaking at the end of Form 5 is missing.
	Previous decision	The Board in its 290th meeting deferred the case for submission of undertaking at the end of Form 5.
	Evaluation by PEC	The firm submitted undertaking at the end of Form 5.
	Decision: Approved with innovator's specifications.	
1004.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36-Km, Multan Road Lahore
	Brand Name +Dosage Form + Strength	Trypnil Granules for Injection
	Composition	Each 2.36gm Sachet contains: Diminazene Diaceturate…1.05g
	Diary No. Date of R& I & fee	Dy No. 22520: 28.06.2018 PKR 20,000/-: 28.06.2018
	Pharmacological Group	Trypanocidal agent (not in ATC)
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	2.36g sachet; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Could not be confirmed
	GMP status	The firm was inspected on 05.03.2018, 17.08.2018 & 16.10.2018 wherein Renewal of DML was recommended.
	Remarks of the Evaluator.	•
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1005.	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
	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
	Approval status of product in Reference Regulatory Authorities.	NA
	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.
	Decision: Deferred for submission of fee for revision of strength of API.	

Case no. 04 Registration applications of categories to be considered on priority

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

k. Export facilitation

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

i. Human

1006.	Name and address of Applicant	Aster Life Sciences 32-Babar Block, New Garden Town, Lahore
	Detail of Drug Sale License	No. 05-352-0065-013801D, valid till 29.11.2019 Address: 32-Babar Block, New Garden Town, Lahore
	Name and address of Manufacturer	Panacea Biotec Limited, Vill. Malpur, Baddi, Distt. Solan, Himachal Pradesh-173205, India
	Name and address of marketing authorization holder	M/s Panacea Biotech Ltd., Village Malpur, Baddi, Distt. Solan-173205, Himachal Pradesh, India
	Name of exporting country	India
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No. 25111: 19.07.2018
	Fee including differential fee	PKR 50,000/-: 19.07.2018
	Brand Name +Dosage Form + Strength	PacliAll Lyophilzed Powder for Injectable Suspension
	Composition	Each vial contains: Paclitaxel USP…..100mg Human Albumin USP……..900mg
	Pharmacological Group	Taxanes
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per policy
	Approval status of product in Reference Regulatory Authorities.	ABRAXANE® for Injectable Suspension (paclitaxel protein-bound particles for injectable suspension, albumin-bound). Label claim; Each single-use vial contains 100mg of paclitaxel (bound to human albumin) and approximately 900 mg of human albumin (containing sodium caprylate and sodium acetyltryptophanate) **USFDA approved with box warning.**
	Me-too status	ONCOTAXEL 100MG. Reg. No. 78156 (does not depict protein bounding).
	Detail of certificate attached	• Original, legalized COPP, valid till 11.02.2020 issued by **State Drug Controller Distt. Solan Himachal Pradesh** is attached. • Original, legalized FSC, valid till 10.10.2020 issued by **State Drug Controller Distt. Solan Himachal Pradesh** is attached. • Original legalized GMP certificate valid until 11.02.2020 issued by **Health and Family Welfare Department, Himachal Pradesh Baddi Distt. Solan** is attached. • Original legalized Sole agent letter is provided which is valid till 31.03.2021.
	Remarks of the Evaluator.	• It has been mentioned in the COPP, SmPC and composition that the product contains Chloroform and Ethanol. Upon clarification, the firm submitted that these solvents are subsequently removed during the process. The level of these solvent in final drug product are controlled to concentrations much below the allowable limits as per ICH Q3C guidelines. • The label claim of reference product is "Each single-use vial contains 100mg of paclitaxel (bound to human albumin) and approximately 900mg of human albumin (containing sodium caprylate and sodium acetyltryptophanate)". However, the

		applied product has label claim "Each vial contains 100 mg of paclitaxel and 900mg of human albumin USP". • In the reference product, human albumin has been stabilized by sodium caprylate and sodium acetyltryptophanate. Clarification was asked for such stabilization of your product. The firm submitted that the albumin contains such stabilizing agents. The firm submitted COA of albumin (API) from CSL Behring, Switzerland, mentioning sodium caprylate and sodium acetyltryptophan.
	Previous decision	The Board in its 289th meeting deferred the case for further deliberation.
	Evaluation by PEC	•
	Decision: Approved with Innovator's specifications as per Policy for inspection of Manufacturer abroad.	

ii. Veterinary

Case no. 05 Registration applications of import cases

a. New Cases (Human)

b. New Cases (Veterinary)

1007.	Name and address of Applicant	M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No.23255: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Amoxcol Powder
	Composition	Each 1000g Contains: Amoxicillin Trihydrate…200 g Colistin Sulphate…1000 MIU
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 9625/-
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	Could not be confirmed
	Detail of certificate attached	• Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 24.07.2018. Only brand name has

		been mentioned without label claim. • Legalized copy of GMP certificate issued by Department of Animal Health of Vietnam for five years from 23.1.2017. • Letter of authorization is provided.
	Remarks of the Evaluator.	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • The firm has provided stability summary sheets, wherein description, loss on drying and assay have been performed as per Zone IV-A. However, USp general chapter has mentioned description, identification, assay and impurities for universal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Decision: Deferred for the following: • **Submission of testing method and certificate of analysis.** • **Submission of Original legalized and vlaid FSC with label claim of the product.**	
1008.	Name and address of Applicant	M/s Schiwo Pakistan. Office No. 10, First Floor, City Plaza, Khanewal Road, Chowk Rasheedabad, Multan, Punjab
	Detail of Drug Sale License	Address: 11G, Shah Rukh e Alam Colony, District Multan Godown: House No. 24/C, Loha Market, Vehari Road, Near Metro Station, People Colony Multan License No. 04-361-0171-0926D vaild till: **26.08.2019**
	Name and address of Manufacturer	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Raod No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name and address of marketing authorization holder	M/s Asifac Viet Pharma Co. Ltd. 220 Pham The Hein St.,Dist.8, Ho Chi Minh City, Vietnam Factory: Road No. 5, Giang Dien Industrial Zone, Trang Bom Dist., Dong Nai.
	Name of exporting country	Vietnam
	Type of Form	Form 5A
	Diary No. Date of R& I	Dy No.23258: 05.07.2018
	Fee including differential fee	PKR 100,000/-: 05.07.2018
	Brand Name +Dosage Form + Strength	Asi-Tydox Plus Powder
	Composition	Each 1000g Contains: Tylosin Tartrate…100g Doxycycline Hyclate…200g
	Pharmacological Group	Antibiotics
	Finished Product Specification	Not provided
	Pack size & Demanded Price	1 kg; Rs. 10500/-
	Approval status of product in	NA

	Reference Regulatory Authorities.	
	Me-too status	TYLODOX 100/200 W.S. POWDER. Reg No. 43595
	Detail of certificate attached	• Legalized copy of FSC issued by Department of Animal Health of Vietnam valid for two years from 30.07.2018. Only brand name has been mentioned without label claim. • Legalized copy of GMP certificate issued by Department of Animal Health of Vietnam for five years from 23.1.2017. • Letter of authorization is provided.
	Remarks of the Evaluator.	• First page of Form 5A was from manufacturer not importer and had not been signed. The firm submitted revised first page of Form 5. • The firm was asked to submit certificate of analysis. The firm did not submit the same. • Only brand name has been mentioned without label claim. • The firm has provided stability summary sheets, wherein description, identification, loss on drying and assay have been performed as per Zone IV-A. However, USP general chapter has mentioned description, identification, assay and impurities for universdal tests. Furthermore, USP has mentionedadditional tests for powder as: "Oral powders should indicate: "For Oral Use Only". Tests that are considered specific to the type of powders include: Minimum Fill (755) and volatile content ((731) and (921)). Minimum Fill (755) has specifications that apply to oral powders. On the basis of the nature of the article and scientific criteria, additional tests may apply, including pH in an aqueous solution, powder fineness, microbial limits, and others.
	Decision: Deferred for the following: • **Submission of testing method and certificate of analysis.** • **Submission of Original legalized and vlaid FSC with label claim of the product.**	

c. Deferred cases
i. Human
ii. Veterinary

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
1009.	M/s Wilshire Laboratories (Pvt) Ltd. 124/1, Quaid-e-Azam Industrial Estate, Kot Lukhpat, Lahore	Velbuvir tablet 400/100 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 / 75% ± 5% RH Accelerated: 40˚C ± 2˚C / 75% ± 5% RH
Time Period	Real time: 6 months Accelerated:6 months
Frequency	Accelerated: 0,1,2,3,4 & 6 (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. No.	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. No	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 manufacturer issued by regulatory authority of country of origin?	Firm had GMP certificate of Velpatasvir manufacturer issued by regulatory authority of India and GMP 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.

Prevoius 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)". **Decision: The Board aftrer thorough deliberation decided to defer the case for scientific justification from the firm regarding anomalous release profile of the formulation.**

Evaluator PEC-X

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

a. New cases

1010.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name+Dosage Form + Strength	Anol Tablet
	Composition	Each film coated tablet contains: Tramadol HCL USP…..37.5mg Paracetamol USP…325mg
	Diary No. Date of R& I & fee	Dy. No 19984 Dated 01-06-2018, Rs. 20,000/- dated 01-06-2018
	Pharmacological Group	Opioid & Analgesic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & 20's
	Approval status of product in Reference Regulatory Authorities.	Tramadol hydrochloride/Paracetamol 37.5 mg/325 mg film-coated tablets of Ireland
	Me-too status	Tramapar Tablets (053192)
	GMP status	DML No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance"
	Remarks of the Evaluator	
	Decision: Approved	
1011.	Name and address of Manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt. Ltd, 16/I, Phase IV, Industrial Estate Hattar Pakistan
	Brand Name+ Dosage Form +Strength	Terbiz 250mg Tablets
	Composition	Each tablet contains: Terbinafine……. 250mg
	Diary No, Date of R & I & fee	Dy. No. 22429 dated 27-06-2018 Rs 20,000/-Dated 26-06-18
	Pharmacological Group	Antifungal
	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.	Terbinafine 250 mg tablets of M/s Milpharm Limited United Kingdom

	Me-too status	LAMISIL SANDOZ 250MG TAB Each tablet contains:- TERBINAFINE 250mg
	GMP Status	DML No. 000454 by way of formulation dated 27-10-2015 GMP Inspection dated 29-03-2017 by panel is recommended.
	Remarks of the Evaluator	
	Decision: Approved	
1012.	Name and address of Manufacturer / Applicant	M/s Genome Pharmaceuticals Pvt. Ltd, 16/I, Phase IV, Industrial Estate Hattar Pakistan
	Brand Name + Dosage Form + Strength	Atorid 10mg/5mg Tablets
	Composition	Each film coated tablet contains: Atorvastatin as calcium…….10mg Amlodipine as besylate……5mg
	Diary No, Date of R & I & fee	Dy. No. 22428 dated 27-06-2018 Rs 20,000/-Dated 26-06-18
	Pharmacological Group	Statin/Calcium channel blocker
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1x7'S & As per SRO
	Approval Status of product in Reference Regulatory Authorities.	**AMLODIPINE BESYLATE AND ATORVASTATIN CALCIUM (USFDA)**
	Me-too status	CADUET 5MG/10MG TABLETS of M/s Pfizer
	GMP Status	DML No. 000454 by way of formulation dated 27-10-2015 GMP Inspection dated 29-03-2017 by panel is recommended.
	Remarks of the Evaluator	
	Decision: Approved	
1013.	Name and address of Manufacturer / Applicant	M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi
	Brand Name + Dosage Form + Strength	Bronchi 200 Sachet
	Composition	Each sachet contains: **Acetylcysteine** …….200mg
	Diary No, Date of R & I & fee	Dy. No. 22178 dated 26-06-2018 Rs20,000/-Dated 25-06-18
	Pharmacological Group	Mucolytic agent
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	10 sachet pack in unit carton 20 sachet pack in unit carton 30 sachet pack in unit carton
	Approval Status of product in Reference Regulatory Authorities.	Acetylcysteine 200 mg Powder for Oral Solution (UK)
	Me-too status	FLUIMUCIL SACHETS 200 of M/s ZAMBON GROUP SPA
	GMP Status	GMP Certificate dated 04th June 2018 shows that firm complying with cGMP
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications and change of brand name	

1014.	Name and address of Manufacturer / Applicant	M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi
	Brand Name + Dosage Form + Strength	20OSB Capsule (20mg/1100mg)
	Composition	Each OSB capsule contains: Omeprazole USP……..20mg Sodium Bicarbonate USP…….1100mg
	Diary No, Date of R & I & fee	Dy. No. 22181 dated 26-06-2018 Rs20,000/- Dated 25-06-18
	Pharmacological Group	PPI's/ systemic and urinary alkalinizer
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	7's, 10's & 14's
	Approval Status of product in Reference Regulatory Authorities.	**ZEGERID (USFDA)**
	Me-too status	Omega Rapid Capsules.20/1100 of M/s FerozesonsLabs
	GMP Status	GMP Certificate dated 04th June 2018 shows that firm complying with cGMP
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
1015.	Name and address of Manufacturer / Applicant	M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi
	Brand Name + Dosage Form + Strength	40OSB Capsule (40mg/1100mg)
	Composition	Each OSB capsule contains: Omeprazole USP……..40mg Sodium Bicarbonate USP…….1100mg
	Diary No, Date of R & I & fee	Dy. No. 22182 dated 26-06-2018 Rs20,000/-Dated 25-06-18
	Pharmacological Group	PPI's/ systemic and urinary alkalinizer
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	7's & 14's
	Approval Status of product in Reference Regulatory Authorities.	**ZEGERID (USFDA)**
	Me-too status	Omefast Plus Capsule of M/s EfrozeChemicalIndustries
	GMP Status	GMP Certificate dated 04th June 2018 shows that firm complying with cGMP
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
1016.	Name and address of Manufacturer / Applicant	M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi
	Brand Name + Dosage Form + Strength	CIBACIN 500mg Tablets
	Composition	Each film coated tablet contains: Azithromycin USP……500mg
	Diary No, Date of R & I & fee	Dy. No. 22180 dated 26-06-2018 Rs20,000/-Dated 25-06-18
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP

	Pack Size & Demanded Price	Rs. 45.83/- per tablet, Pack of 6's Rs.270/- & Pack of 10's Rs. 440/-
	Approval Status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Biozith Tablets by M/s. Bio Labs (Pvt) Ltd, (R.No.069912)
	GMP Status	GMP Certificate dated 04th June 2018 shows that firm complying with cGMP
	Remarks of the Evaluator	
	Decision: Approved	
1017.	Name and address of manufacturer/Applicant	Applicant: M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi Manufacturer: ISIS Pharmaceuticals & Chemical works 25/1-3, sector 12-c, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	C-PAT 0.2% Ophthalmic solution
	Composition	Each ml contains: Olopatadine HCl USP eq. to Olopataine……..2mg
	Diary No. Date of R& I & fee	Dy. No 22174 Dated 26-06-2018, Rs. 50,000/- dated 25-06-2018
	Pharmacological Group	Antihistamines
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml: Rs. 395/-
	Approval status of product in Reference Regulatory Authorities.	**OLOPATADINE HYDROCHLORIDE (USFDA)**
	Me-too status	Olotek-DS 0.2% Eye Drops of M/s Innvotek Pharmaceuticals
	GMP status	GMP certificate dated 27th July, 2017 shows firm (ISIS Pharmaceuticals & Chemical..) complying with cGMP)
	Remarks of the Evaluator	Firm has submitted the currect GMP inspection report of M/s ISIS Pharma dated 08-07-2019 showed good level of GMP compliance.
	Decision: Approved	
1018.	Name and address of manufacturer/Applicant	Applicant: M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi Manufacturer: ISIS Pharmaceuticals & Chemical works 25/1-3, sector 12-c, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	C-TOB-D Ophthalmic Suspension
	Composition	Each ml contains: Tobramycin USP……3mg Dexamethasone……...1mg
	Diary No. Date of R& I & fee	Dy. No 22173 Dated 26-06-2018, Rs. 50,000/- dated 25-06-2018
	Pharmacological Group	Antibiotic/Corticosteroid
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml: Rs. 280/-
	Approval status of product in Reference	**TOBRADEX (USFDA)**

	Regulatory Authorities.	
	Me-too status	Tobra –D Eye Drops of M/s Schazoo Lab. Lahore
	GMP status	GMP certificate dated 27th July, 2017 shows firm (ISIS Pharmaceuticals & Chemical..) complying with cGMP)
	Remarks of the Evaluator	
	Decision: Approved	
1019.	Name and address of manufacturer/Applicant	Applicant: M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi Manufacturer: ISIS Pharmaceuticals & Chemical works 25/1-3, sector 12-c, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	C-SYSLUB Ophthalmic Solution
	Composition	Each ml contains: Polyethylene glycol 400USP…….4mg Propylene glycol USP…….3mg
	Diary No. Date of R& I & fee	Dy. No 22175 Dated 26-06-2018, Rs. 50,000/- dated 25-06-2018
	Pharmacological Group	Lubricant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	15ml: Rs. 500/-
	Approval status of product in Reference Regulatory Authorities.	SYSTANE® Lubricant Eye Drops by Alcon Laboratories, Inc
	Me-too status	SYSTANE LUBRICANT EYE DROPS of M/s ALCON LAB.
	GMP status	GMP certificate dated 27th July, 2017 shows firm (ISIS Pharmaceuticals & Chemical..) complying with cGMP)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
1020.	Name and address of manufacturer/Applicant	Applicant: M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi Manufacturer: ISIS Pharmaceuticals & Chemical works 25/1-3, sector 12-c, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	C-MOX 0.5% Ophthalmic Solution
	Composition	Each ml contains: Moxifloxacin HCl USP eq. to Moxifloxacin….5mg
	Diary No. Date of R& I & fee	Dy. No 22176 Dated 26-06-2018, Rs. 50,000/- 25-6-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	5ml: Rs. 425/-
	Approval status of product in Reference Regulatory Authorities.	MOXIVIG 0.5%w/v eye drops, solution (UK)
	Me-too status	Opmox Eye Drop of M/s Ophth-Pharma(Pvt.)Ltd,
	GMP status	GMP certificate dated 27th July, 2017 shows firm (ISIS Pharmaceuticals & Chemical..) complying with cGMP)
	Remarks of the Evaluator	
	Decision: Approved	

1021.	Name and address of manufacturer/Applicant	Applicant: M/s CIBA Pharmaceutical Private Limited. Plot No. A-371, Nooriabad Site Industrial Area, Superhighway (Hyderabad) Karachi Manufacturer: ISIS Pharmaceuticals & Chemical works 25/1-3, sector 12-c, North Karachi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	C-VANAC 0.1% Ophthalmic Suspension
	Composition	Each ml contains: Nepafenac……1mg
	Diary No. Date of R& I & fee	Dy. No 22183 Dated 26-06-2018, Rs. 50,000/- 25-06-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	5ml: Rs. 480/-
	Approval status of product in Reference Regulatory Authorities.	NEVANAC® 1 mg/ml eye drops, suspension (UK)
	Me-too status	Neplo ophthalmic Suspension of M/s Alza Pharmaceuticals
	GMP status	GMP certificate dated 27th July, 2017 shows firm (ISIS Pharmaceuticals & Chemical..) complying with cGMP)
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
1022.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Concor (Bisoprolol hemifumarate) 2.5mg Tablet
	Composition	Each film coated tablet contains; Bisoprolol hemifumarate USP……..2.5mg
	Diary No. Date of R& I & fee	Dy. No 20082 Dated 04-06-2018, Rs. 20,000/- dated 04-06-2018
	Pharmacological Group	Beta Blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's Alu/PVC
	Approval status of product in Reference Regulatory Authorities.	Cardicor 2.5 mg film-coated tablets (UK)
	Me-too status	Bisolol Tablets 2.5mg
	GMP status	DML by way of formulation no. 000597 dated 05-07-2016 renewal of DML letter issue dated 27th January 2017. GMP inspection by area FID dated 19-07-2017 concluded that firm was considered to be operating at good level of compliance with GMP guideline.
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	
1023.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Concor (Bisoprolol hemifumarate) 10mg Tablet
	Composition	Each film coated tablet contains; Bisoprolol hemifumarate USP……..10mg
	Diary No. Date of R& I & fee	Dy. No 20079 Dated 04-06-2018, Rs. 20,000/- 04-06-2018

	Pharmacological Group	Beta Blocker
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's Alu/PVC
	Approval status of product in Reference Regulatory Authorities.	Cardicor 10 mg film-coated tablets (UK)
	Me-too status	Monocor 10mg Tablet of M/s Standpharm Pakistan
	GMP status	DML by way of formulation no. 000597 dated 05-07-2016 renewal of DML letter issue dated 27th January 2017. GMP inspection by area FID dated 19-07-2017 concluded that firm was considered to be operating at good level of compliance with GMP guideline.
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	
1024.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Zomix (Zolmitriptan) 2.5mg Tablet
	Composition	Each film coated tablet contains: Zolmitriptan USP…….2.5mg
	Diary No. Date of R& I & fee	Dy. No 20080 Dated 04-06-2018, Rs. 20,000/- dated 04-06-2018
	Pharmacological Group	selective serotonin receptor agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3's, 5's, 10's Alu-Alu
	Approval status of product in Reference Regulatory Authorities.	Zolmitriptan 2.5 mg film-coated tablets (UK)
	Me-too status	ZOMIG TABLETS 2.5MG of M/s IPR FOR ZENECA
	GMP status	DML by way of formulation no. 000597 dated 05-07-2016 renewal of DML letter issue dated 27th January 2017. GMP inspection by area FID dated 19-07-2017 concluded that firm was considered to be operating at good level of compliance with GMP guideline.
	Remarks of the Evaluator	
	Decision: Approved	
1025.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Coxibex (Celecoxib) 400mg Capsule
	Composition	Each capsule contains: Celecoxib B.P…….400mg
	Diary No. Date of R& I & fee	Dy. No 20066 Dated 04-06-2018, Rs. 20,000/- 01-06-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	10's, 20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**CELEBREX (USFDA)**
	Me-too status	

	GMP status	DML by way of formulation no. 000597 dated 05-07-2016 renewal of DML letter issue dated 27th January 2017. GMP inspection by area FID dated 19-07-2017 concluded that firm was considered to be operating at good level of compliance with GMP guideline.
	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.	
1026.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals Plot No. 224, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Etorix 30mg Tablet
	Composition	Each film coated tablet contains: Etoricoxib…….30mg
	Diary No. Date of R& I & fee	Dy. No 20063 Dated 04-06-2018, Rs. 20,000/- 01-06-2018
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	7's, 10's, 20's, 30's
	Approval status of product in Reference Regulatory Authorities.	ARCOXIA® 30 mg film-coated tablets (Netherlands)
	Me-too status	
	GMP status	DML by way of formulation no. 000597 dated 05-07-2016 renewal of DML letter issue dated 27th January 2017. GMP inspection by area FID dated 19-07-2017 concluded that firm was considered to be operating at good level of compliance with GMP guideline.
	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.	
1027.	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	ODETRO 4mg Tablet
	Composition	Each film coated tablet contains: Ondansetron (as ondansetron hydrochloride)……4mg
	Diary No. Date of R& I & fee	Dy. No 28542 Dated 24-08-2018, Rs. 20,000/- 20-08-2018
	Pharmacological Group	serotonin 5-HT_3 receptor antagonists
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 40's & 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 4 mg film-coated tablets (UK)
	Me-too status	Oniron 4mg Tablets of M/s Genome Pharmaceuticals (Pvt,) Ltd.
	GMP status	DML by way of formulation dated 21-07-2015 & GMP certificate dated 26-09-2017
	Remarks of the Evaluator	
	Decision: Approved	
1028.	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	ODETRO 8mg Tablet
	Composition	Each film coated tablet contains: Ondansetron (as ondansetron hydrochloride)……8mg
	Diary No. Date of R& I & fee	Dy. No 28543 Dated 24-08-2018, Rs. 20,000/- dated 20-08-2018
	Pharmacological Group	serotonin 5-HT_3 receptor antagonists
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's, 40's & 50's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8 mg film-coated tablets (UK)
	Me-too status	Oniron 8mg Tablets of M/s Genome Pharmaceuticals (Pvt,) Ltd.
	GMP status	DML by way of formulation dated 21-07-2015
	Remarks of the Evaluator	
	Decision: Approved	
1029.	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	QOSMET 50/850 Tablet
	Composition	Each film coated tablet contains: sitagliptin phosphate monohydrate, equivalent to sitagliptin…..50mg Metformin HCl…….850mg
	Diary No. Date of R& I & fee	Dy. No 28541 Dated 24-08-2018, Rs. 20,000/- dated 20-08-2018
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer specification's
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 40's, 50's, 60's & As per SRO.
	Approval status of product in Reference Regulatory Authorities.	JANUMET® (TGA)
	Me-too status	Treviamet 50mg/850mg Tablet of M/s Getz Pharma (Pvt) Ltd.
	GMP status	DML by way of formulation dated 21-07-2015
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1030.	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 20mg Tablet
	Composition	Each tablet contains: Telmisartan…….20mg
	Diary No. Date of R& I & fee	Dy. No 28544 Dated 24-08-2018, Rs. 20,000/- 20-08-2018
	Pharmacological Group	angiotensin receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 40's & As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Micardis 20 mg tablets (Germany)
	Me-too status	Mycardix 20mg Tablets of M/s Macer Int Katrachi
	GMP status	DML by way of formulation dated 21-07-2015
	Remarks of the Evaluator	
	Decision: Approved	

1031.	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 80mg Tablet
	Composition	Each tablet contains: Telmisartan…….80mg
	Diary No. Date of R& I & fee	Dy. No 28546 Dated 24-08-2018, Rs. 20,000/- 20-08-2018
	Pharmacological Group	angiotensin receptor blockers (ARBs)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 40's & As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Micardis 80 mg tablets (Germany)
	Me-too status	Mycardix 80mg Tablets of M/s Macer Int Katrachi
	GMP status	DML by way of formulation dated 21-07-2015
	Remarks of the Evaluator	
	Decision: Approved	
1032.	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-AM 40/10mg Tablet
	Composition	Each tablet contains: Telmisartan…….40mg Amlodipine……10mg
	Diary No. Date of R& I & fee	Dy. No 28551 Dated 24-08-2018, Rs. 20,000/- 20-8-2018
	Pharmacological Group	angiotensin receptor blockers (ARBs)/ calcium channel blockers
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 40's & As per SRO.
	Approval status of product in Reference Regulatory Authorities.	TELMISARTAN AND AMLODIPINE (USFDA)
	Me-too status	Amtas 10mg +40mg Tablet of M/s Sami Pharmaceuticals (Pvt) Ltd.
	GMP status	DML by way of formulation dated 21-07-2015
	Remarks of the Evaluator	
	Decision: Deferred for revision of formulation to bilayer tablet as per the reference product along with submission of fee for revision of formulation and evidence of bilayer tablet machine.	
1033.	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-HC 40/12.5mg Tablet
	Composition	Each tablet contains: Telmisartan……..40mg Hydrochlorothiazide ……..12.5mg
	Diary No. Date of R& I & fee	Dy. No 28547 Dated 24-08-2018, Rs. 20,000/- 20-8-2018
	Pharmacological Group	angiotensin receptor blockers (ARBs)/ diuretic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 40's & As per SRO.
	Approval status of product in Reference Regulatory Authorities.	MICARDIS HCT (USFDA)
	Me-too status	Co-Telsan 40/12.5 Tablets of M/s Hilton Pharma (Pvt) Ltd,
	GMP status	DML by way of formulation dated 21-07-2015

	Remarks of the Evaluator	
	Decision: Deferred for revision of formulation to bilayer tablet as per the reference product along with submission of fee for revision of formulation and evidence of bilayer tablet machine.	
1034.	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-HC 80/25mg Tablet
	Composition	Each tablet contains: Telmisartan……..80mg **Hydrochlorothiazide** ……..25mg
	Diary No. Date of R& I & fee	Dy. No 28549 Dated 24-08-2018, Rs. 20,000/- 20-8-2018
	Pharmacological Group	angiotensin receptor blockers (ARBs)/ diuretic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 40's & As per SRO.
	Approval status of product in Reference Regulatory Authorities.	**MICARDIS HCT (USFDA)**
	Me-too status	Co-Telsan 80/25 Tablets of M/s Hilton Pharma (Pvt) Ltd,
	GMP status	DML by way of formulation dated 21-07-2015
	Remarks of the Evaluator	
	Decision: Deferred for revision of formulation to bilayer tablet as per the reference product along with submission of fee for revision of formulation and evidence of bilayer tablet machine.	
1035.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd. K-219-A, SITE, Super highway, Phase-II Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Biocip Eye Drops
	Composition	Each ml of solution contains: Ciprofoxacin as HCL….3mg
	Diary No. Date of R& I & fee	Dy. No 17891 Dated 15-05-2018, Rs. 20,000/- 14-05-2018
	Pharmacological Group	Antibiotic (Quinolone)
	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.	Ciloxan® Eye Drops, Solution (MHRA)
	Me-too status	Prolox Eye Drops of Atco
	GMP status	GMP inspection report conducted by FID Karachi dated 09-10-2019 which conclude that overall GMP compliance level is rated as Good
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1036.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd. K-219-A, SITE, Super highway, Phase-II Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Oflolon Eye Drops
	Composition	Each ml contains: Ofloxacin as hydrochloride….3mg
	Diary No. Date of R& I & fee	Dy. No 17895 Dated 15-05-2018, Rs. 20,000/- 14-05-2018
	Pharmacological Group	Antibiotic (Quinolone)
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference	EXOCIN® 0.3% w/v Eye drops, solution (MHRA)

	Regulatory Authorities.	
	Me-too status	Taripharm Eye Drops 0.3% of Epharm
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1037.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd. K-219-A, SITE, Super highway, Phase-II Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Winlop-Fort Eye Drops
	Composition	Each ml of solution contains: Olopatadine as HCL….2mg
	Diary No. Date of R& I & fee	Dy. No 17894 Dated 15-05-2018, Rs. 20,000/- 14-05-2018
	Pharmacological Group	Anti-allergy
	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.	**PATADAY (USFDA)**
	Me-too status	Eyepat 0.2% Eye Drops of Hansel Pharma
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1038.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd. K-219-A, SITE, Super highway, Phase-II Karachi, Pakistan
	Brand Name +Dosage Form + Strength	LODOXA Eye Drops
	Composition	Each ml of solution contains: Lodoxamide as trometamol….1mg
	Diary No. Date of R& I & fee	Dy. No 17892 Dated 15-05-2018, Rs. 20,000/- dated 14-05-2018
	Pharmacological Group	Anti-allergy
	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.	**ALOMIDE (USFDA)**
	Me-too status	ALOMIDE SOLUTION of Ali Gohar & Co
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
	Tablet (General) Section:	
1039.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd. K-219-A, SITE, Super highway, Phase-II Karachi, Pakistan
	Brand Name +Dosage Form + Strength	WINTREM 40mg/240mg Tablet
	Composition	Each tablet contains: Artemether……..40mg Lumefantrine……..240mg
	Diary No. Date of R& I & fee	Dy. No 17896 Dated 15-05-2018, Rs. 20,000/- 14-05-2018
	Pharmacological Group	Antimalarials
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	1x10's, 1x8's, 2x8's, 2x6's As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation

	Me-too status	Artrine 40/240mg Tablet of M/s OBS
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1040.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories (Pvt.) Ltd. K-219-A, SITE, Super highway, Phase-II Karachi, Pakistan
	Brand Name +Dosage Form + Strength	WINTREM 80mg/480mg Tablet
	Composition	Each tablet contains: Artemether……..80mg Lumefantrine…….480mg
	Diary No. Date of R& I & fee	Dy. No 17897 Dated 15-05-2018, Rs. 20,000/- dated 14-05-2018
	Pharmacological Group	Antimalarials
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specification
	Pack size & Demanded Price	1x10's, 1x8's, 2x8's, 2x6's As per SRO
	Approval status of product in Reference Regulatory Authorities.	Artemether/Lumefantrine Tablet 80mg/480mg of M/s Novartis Pharma AG, Lichtstrasse 35, Basel, 4002, Switzerland
	Me-too status	R-Terine Forte Tablet of M/s Ardin Pharmaceuticals,
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1041.	Name and address of Applicant /manufacturer	M/s Genix Pharma Pvt. Ltd. 44, 45-B Korangi Creek Road, Karachi 75190, Pakistan Manufacturer: M/s Daneen Pharma Pvt. Ltd. 27, Sundar Industrial estate, sundar Raiwand Road, Lahore Pakistan
	Brand Name +Dosage Form + Strength	Blucef IV 250mg Powder for injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone USP…250mg
	Diary No. Date of R& I & fee	Dy. No 17986 Dated 16-05-2018, Rs. 50,000/- dated 15-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1's & 10's
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg powder for solution for injection of M/s Villerton Invest SA Luxembourg
	Me-too status	Fastrixone 250mg Injection of M/s Fassgen
	GMP status	➢ GMP inspection of M/s Genix Pharma by FID dated 10-04-2019 shows the acceptable level of compliance with cGMP guideline. ➢ GMP inspection of M/s Daneen Pharma Pvt. Ltd by Panel of Inspectors dated 08-03-2019 shows that firm compliant to GMP and Quality control operation (Only dry powder injection section (Cephalosporin) was operational at the time of inspection.
	Remarks of the Evaluator	
	Decision: Approved	

1042.	Name and address of Applicant /manufacturer	M/s Genix Pharma Pvt. Ltd. 44, 45-B Korangi Creek Road, Karachi 75190, Pakistan Manufacturer: M/s Daneen Pharma Pvt. Ltd. 27, Sundar Industrial estate, sundar Raiwand Road, Lahore Pakistan
	Brand Name +Dosage Form + Strength	Blucef IM 250mg Powder for injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone USP…250mg
	Diary No. Date of R& I & fee	Dy. No 17984 Dated 16-05-2018, Rs. 50,000/- dated 15-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1's & 10's
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg powder for solution for injection of M/s Villerton Invest SA Luxembourg
	Me-too status	Fastrixone 250mg Injection of M/s Fassgen
	Remarks of the Evaluator	
	Decision: Approved	
1043.	Name and address of Applicant /manufacturer	M/s Genix Pharma Pvt. Ltd. 44, 45-B Korangi Creek Road, Karachi 75190, Pakistan Manufacturer: M/s Daneen Pharma Pvt. Ltd. 27, Sundar Industrial estate, sundar Raiwand Road, Lahore Pakistan
	Brand Name +Dosage Form + Strength	Blucef IV 500mg Powder for injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone USP…500mg
	Diary No. Date of R& I & fee	Dy. No 17987 Dated 16-05-2018, Rs. 50,000/- dated 15-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1's & 10's
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE 500mg (USFDA)**
	Me-too status	Fastrixone 500mg Injection of M/s Fassgen
	Remarks of the Evaluator	
	Decision: Approved	
1044.	Name and address of Applicant /manufacturer	M/s Genix Pharma Pvt. Ltd. 44, 45-B Korangi Creek Road, Karachi 75190, Pakistan Manufacturer: M/s Daneen Pharma Pvt. Ltd. 27, Sundar Industrial estate, sundar Raiwand Road, Lahore Pakistan
	Brand Name +Dosage Form + Strength	Blucef IM 500mg Powder for injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone USP…500mg
	Diary No. Date of R& I & fee	Dy. No 17985 Dated 16-05-2018, Rs. 50,000/- dated 15-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1's & 10's
	Approval status of product in Reference	**CEFTRIAXONE 500mg (USFDA)**

	Regulatory Authorities.	
	Me-too status	Fastrixone 500mg Injection of M/s Fassgen
	Remarks of the Evaluator	
	Decision: Approved	
1045.	Name and address of Applicant /manufacturer	M/s Genix Pharma Pvt. Ltd. 44, 45-B Korangi Creek Road, Karachi 75190, Pakistan Manufacturer: M/s Daneen Pharma Pvt. Ltd. 27, Sundar Industrial estate, sundar Raiwand Road, Lahore Pakistan
	Brand Name +Dosage Form + Strength	Blucef IV 1g Powder for injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone USP…1g
	Diary No. Date of R& I & fee	Dy. No 17988 Dated 16-05-2018, Rs. 50,000/- dated 15-05-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1's & 10's
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE 1g (USFDA)**
	Me-too status	Rocelite Injection 1gm IV of M/s Elite
	Remarks of the Evaluator	
	Decision: Approved	
1046.	Name and address of manufacturer/Applicant	Applicant: M/s Sigma Pharma International (Pvt.) Ltd. Karachi Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Triax 250mg IV Injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…….250
	Diary No. Date of R& I & fee	Dy. No 19996 Dated 01-06-2018, Rs. 50,000/- dated 01-06-2018
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1 vial of dry powder + 1 vial of diluent
	Approval status of product in Reference Regulatory Authorities.	Ceftriaxone 250mg powder for solution for injection of M/s Villerton Invest SA Rue Edward Steichen 14 2540 Luxembourg
	Me-too status	TRAXON I.M/I.V INJECTION 250
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	

1047.	Name and address of manufacturer/Applicant	Applicant: M/s Sigma Pharma International (Pvt.) Ltd. Karachi Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Triax 500mg IV Injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…….500mg
	Diary No. Date of R& I & fee	Dy. No 19998 Dated 01-06-2018, Rs. 50,000/- dated 01-06-2018
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1 vial of dry powder + 1 vial of diluent
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE (USFDA)**
	Me-too status	TRAXON I.M/I.V INJECTION 500
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	
1048.	Name and address of manufacturer/Applicant	Applicant: M/s Sigma Pharma International (Pvt.) Ltd. Karachi Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Triax 1gm IV Injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…….1gm
	Diary No. Date of R& I & fee	Dy. No 20000 Dated 01-06-2018, Rs. 50,000/- 01-06-2018
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1 vial of dry powder + 1 vial of diluent
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE (USFDA)**
	Me-too status	CEFAXONE 1GM INJECTION of M/s High-Q
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	
1049.	Name and address of manufacturer/Applicant	Applicant: M/s Sigma Pharma International (Pvt.) Ltd. Karachi Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Triax 250mg IM Injection

	Composition	Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…….250mg
	Diary No. Date of R& I & fee	Dy. No 19995 Dated 01-06-2018, Rs. 50,000/- dated 01-06-2018
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1 vial of dry powder + 1 vial of diluent
	Approval status of product in Reference Regulatory Authorities.	CEFTRIAXONE (USFDA)
	Me-too status	TRAXON I.M/I.V INJECTION 250
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	
1050.	Name and address of manufacturer/Applicant	Applicant: M/s Sigma Pharma International (Pvt.) Ltd. Karachi Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Triax 500mg IM Injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…….500mg
	Diary No. Date of R& I & fee	Dy. No 19997 Dated 01-06-2018, Rs. 50,000/- dated 01-06-2018
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1 vial of dry powder + 1 vial of diluent
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE (USFDA)**
	Me-too status	TRAXON I.M/I.V INJECTION 500
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	
1051.	Name and address of manufacturer/Applicant	Applicant: M/s Sigma Pharma International (Pvt.) Ltd. Karachi Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Triax 1gm IM Injection
	Composition	Each vial contains: Ceftriaxone sodium eq. to ceftriaxone…….1gm

	Diary No. Date of R& I & fee	Dy. No 19999 Dated 01-06-2018, Rs. 50,000/- dated 01-06-2018
	Pharmacological Group	Antibiotic (cephalosporin)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	1 vial of dry powder + 1 vial of diluent
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE (USFDA)**
	Me-too status	CEFAXONE 1GM INJECTION of M/s High-Q
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with change in brand name	
1052.	Name and address of manufacturer/Applicant	Applicant: M/s Sigma Pharma International (Pvt.) Ltd. Karachi Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Pentale 40mg Infusion
	Composition	Each vial contains: Pantoprazole sodium equivalent to Pantoprazole…40mg
	Diary No. Date of R& I & fee	Dy. No 19994 Dated 01-06-2018, Rs. 50,000/- dated 01-06-2018
	Pharmacological Group	PPI's
	Type of Form	Form-5
	Finished product Specification	
	Pack size & Demanded Price	1 vial of dry powder + I vial of diluent
	Approval status of product in Reference Regulatory Authorities.	Pantoprazole 40 mg Powder for Solution for Injection (UK)
	Me-too status	Neege of Sami Pharma
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	Firm claim B.P. specification but applied formulation monograph is not available in B.P.
	Decision: Approved with innovator's specifications	
1053.	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	Leveron 500mg/5ml Injection
	Composition	Each 5ml contains: Levetiracetam…….500mg
	Diary No, Date of R & I & fee	Dy. No. 19982 dated 01-06-2018 Rs20,000/-Dated 31-05-18
	Pharmacological Group	Antiepileptic drugs
	Type of Form	Form-5

	Finished Product Specification	USP
	Pack Size & Demanded Price	10's (5ml ampoules)
	Approval Status of product in Reference Regulatory Authorities.	Desitrend 100 mg/ml concentrate for solution for infusion (Germany)
	Me-too status	Eplipsa 500mg/5ml Injection of M/s Helix
	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: Approved	
1054.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Gabatin 300mg Tablets
	Composition	Each film coated tablet contains: Gabapentin…….300mg
	Diary No. Date of R& I & fee	Dy. No 19701 dated 30-05-2018 Rs.20,000/- Dated 29-05-2018
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	
	Approval status of product in Reference Regulatory Authorities.	Gabapentin (USFDA) Approved
	Me-too status	Gepent 300mg Tablet of M/s Amarant Pharma
	GMP status	12-10-2018. Panel unanimously recommended the issuance of GMP Certificate.
	Remarks of the Evaluator.	
	Decision: Approved	
1055.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Gabatin 400mg Tablets
	Composition	Each film coated tablet contains: Gabapentin……..400mg
	Diary No. Date of R& I & fee	Dy. No 19702 dated 30-05-2018 Rs.20,000/- Dated 29-05-2018
	Pharmacological Group	Anticonvulsant
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	Gabapentin (USFDA) Approved
	Me-too status	Gepent 400mg Tablet of M/s Amarant Pharma
	GMP status	12-10-2018. Panel unanimously recommended the issuance of GMP Certificate.
	Remarks of the Evaluator.	
	Decision: Approved	
1056.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Artelume Tablet
	Composition	Each Tablet Contains: Artemether…….40mg Lumefantrine…….240mg
	Diary No. Date of R& I & fee	Dy. No 19703 dated 30-05-2018 Rs.20,000/- Dated 29-05-2018

	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	As per SRO.
	Approval status of product in Reference Regulatory Authorities.	WHO approved formulation
	Me-too status	Artem -DS Plus Tablets of M/s Hilton Pharma, Karachi (Reg.# 044209)
	GMP status	12-10-2018. Panel unanimously recommended the issuance of GMP Certificate.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications	
1057.	Name and address of manufacturer / Applicant	M/s Davis Pharmaceuticals Laboratories. Plot No. 121, Industrial Triangle, kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Artelume DS Tablet
	Composition	Each Tablet Contains: Artemether……80mg Lumefantrine…….480mg
	Diary No. Date of R& I & fee	Dy. No 19704 dated 30-05-2018 Rs.20,000/- Dated 29-05-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO approved formulation
	Me-too status	Marlin DS Tablet by M/s Jupiter Pharma, Islamabad Reg. No. 081928
	GMP status	12-10-2018. Panel unanimously recommended the issuance of GMP Certificate.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications	
1058.	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	Lyvox 600mg Tablet
	Composition	Each film coated tablet contains: Linezolid……600mg
	Diary No, Date of R & I & fee	Dy. No. 19993 dated 01-06-2018 Rs20,000/- 01-06-18
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	Alu-Alu Blister of 10tablets
	Approval Status of product in Reference Regulatory Authorities.	Linezolid 600 mg Film-coated Tablets (UK)
	Me-too status	Zyvoxin Tablets 600mg
	GMP Status	GMP inspection by panel dated 12-12-2017 and manufacturer overall rating Good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
1059.	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	Lyvox 400mg Tablet
	Composition	Each film coated tablet contains: Linezolid……400mg

	Diary No, Date of R & I & fee	Dy. No. 19992 dated 01-06-2018 Rs20,000/- 01-06-18
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	In-house
	Pack Size & Demanded Price	Alu-Alu Blister of 10tablets
	Approval Status of product in Reference Regulatory Authorities.	ZYVOX (USFDA)
	Me-too status	Zoxin 400mg Tablets
	GMP Status	GMP inspection by panel dated 12-12-2017 and manufacturer overall rating Good.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specifications	
1060.	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	Lamart Plus 37.5mg+325mg Tablet
	Composition	Each film coated tablet contains: Tramadol HCL……37.5mg Paracetamol……..325mg
	Diary No, Date of R & I & fee	Dy. No. 19991 dated 01-06-2018 Rs20,000/- 01-06-18
	Pharmacological Group	Opioid & Analgesic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10'S
	Approval Status of product in Reference Regulatory Authorities.	Tramadol hydrochloride/Paracetamol 37.5 mg/325 mg film-coated tablets of Ireland
	Me-too status	Tramapar Tablets (053192)
	GMP Status	GMP inspection by panel dated 12-12-2017 and manufacturer overall rating Good.
	Remarks of the Evaluator	
	Decision: Approved	
1061.	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	Lamart Capsule 50mg
	Composition	Each capsule contains: Tramadol HCL……50mg
	Diary No, Date of R & I & fee	Dy. No. 19990 dated 01-06-2018 Rs20,000/- 01-06-18
	Pharmacological Group	Opioid
	Type of Form	Form-5
	Finished Product Specification	B.P.
	Pack Size & Demanded Price	10's
	Approval Status of product in Reference Regulatory Authorities.	Tramadol 50 mg capsules, hard (UK)
	Me-too status	Himadol Capsules (037180)
	GMP Status	GMP inspection by panel dated 12-12-2017 and manufacturer overall rating Good.
	Remarks of the Evaluator	
	Decision: Approved	
1062.	Name and address of manufacturer/Applicant	M/s Sigma Pharma International (Pvt.) Ltd. Karachi Contract Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Superhighway, Karachi
	Brand Name +Dosage Form + Strength	Somep Infusion 40mg Lyophilized powder
	Composition	Each ml vial contains: Esomeprazole (as esomeprazole magnesium dihydrate)…..40mg

	Diary No. Date of R& I & fee	Dy. No 17994 Dated 16-05-2018, Rs. 50,000/- dated 16-05-2018
	Pharmacological Group	PPI's
	Type of Form	Form-5
	Finished product Specification	In-house Specification
	Pack size & Demanded Price	1's
	Approval status of product in Reference Regulatory Authorities.	Esomeprazole 40 mg powder for solution for injection/infusion (UK)
	Me-too status	Esso-40 Injection of shaigan
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1063.	Name and address of manufacturer/Applicant	M/s Sigma Pharma International (Pvt.) Ltd. Karachi Contract Manufacturer: M/s Medisure Laboratories Pakistan (Pvt.) A-115, SITE II, Super Highway, Karachi
	Brand Name +Dosage Form + Strength	Profile 40mg Infusion, Lyophilize powder
	Composition	Each 2ml contains: Omeprazole sodium equivalent to omeprazole ….40mg
	Diary No. Date of R& I & fee	Dy. No 17995 Dated 16-05-2018, Rs. 50,000/- dated 16-05-2018
	Pharmacological Group	PPI's
	Type of Form	Form-5
	Finished product Specification	In-house Specification
	Pack size & Demanded Price	1's
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40 mg Powder for Solution for Infusion (UK)
	Me-too status	Eselan Ly.Pd.Injection. 40mg Vial of M/s A.J&CO
	GMP status	Last GMP inspection dated 10-05-2017 conclusion by FID "The firm (M/s Medisure Laboratories Pakistan (Pvt.)) is holding a good level of GMP compliance at the time of inspection and committed towards continuous improvement by taking necessary steps as per GMP guidelines"
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	

b. Deferred cases

1064.	Name and address of manufacturer /Applicant	Welmark Pharmaceuticals Plot. No. 122, Block B, Phase V, Industrial Estate Hattar KPK.
	Brand Name +Dosage Form + Strength	Markcon 100mg
	Composition	Each Capsule Contains: - Itraconazole ……100mg
	Diary No. Date of R& I & fee	Dy. No. 11700: 30.03.2018 PKR 20,000/:- 30.03.2018
	Pharmacological Group	Anti-Fungal
	Type of Form	Form-5
	Finished Product Specification	Firm has claimed manufacturer 's spec.
	Pack size & Demanded Price	As per SRO,
	Approval status of product in Reference Regulatory Authorities.	Itraconazole 100 mg capsules, hard by M/s SandozLimited (MHRA Approved).
	Me-too status	Rolac 100mg Capsules of Sami Pharmaceuticals, Reg.No. 24491.
	GMP status	GMP inspection was conducted on 16.19.2017 and concluded as overall the firm was GMP compliant as per DRAP guidelines.
	Remarks of the Evaluator	The firm was asked to correct label claim as reference product contains Itraconazole 100 mg and mentioned as Itraconazole 10mg on Form-5 along with the submission of applicable fee. The firm in response submitted that it is typing mistake, whereas in rest of pages it is 100mg and submitted the revised form 5 without submitting applicable fee.

Decision of 289th meeting of Registration Board:

"Deferred for submission of applicable fee"

The firm has submitted the fee challan Rs. 5000/- and revised form-5.

Decision: Approved with innovator's specifications

1065.	Name and address of manufacturer /Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Qinreg 200mg Tablet
	Composition	Each film coated tablet contains: Hydroxychloroquine Sulphate……200mg
	Diary No. Date of R& I & fee	Dy. No. 11718: 30-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	Antimalarial
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Plaquenil 200mg Film coated tablet (MHRA Approved)
	Me-too status	HCQ 200mg tablets of GETZ (Reg. No. 045471)
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated the firm operating at fair level of compliance with GMP as of today
	Remarks of the Evaluator	The Applied formulation in reference countries agencies is film coated and firm applied for uncoated, however firm submitted formulation for film coated. The firm was asked to correct label claim and submit updated form 5. The firm in response submitted same previous form5 for uncoated and did not justify

Decision of 289th meeting of Registration Board:

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.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.

Now the firm has submitted the desire data and clarification.

Decision: Approved

1066.	Name and address of manufacturer / Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Lepride 25mg Tablets
	Composition	Each Tablet contains: Levosulpride …….25mg
	Diary No. Date of R& I & fee	Dy No. 11721: 30-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer ‘s specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Levidomed 25mg tablets of M/s Medochemie Ltd. approved by AIFA of Italy.
	Me-too status	Sulvoric 25mg of M/s High-Q, Karachi (Reg. No. 070484).
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated the firm operating at fair level of compliance with GMP as of today.
	Remarks of the Evaluator	Applied formulation in reference countries agencies is film coated and firm applied for uncoated. The firm was asked to clarify. Firm in response submitted same form5, formulation for uncoated tablets

Decision of 289th meeting of Registration Board:

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.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board

Now the firm has submitted the desire data and clarification.

Decision: Approved

1067.	Name and address of manufacturer/Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Lepride 50 mg Tablets
	Composition	Each Tablet contains: Levosulpride ……50mg
	Diary No. Date of R& I & fee	Dy No. 11719: 30-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	Antipsycotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer ‘s specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory	Levidomed 50mg tablets of M/s Medochemie Ltd. approved by AIFA of Italy.

	Authorities.	
	Me-too status	Sulvoric 50mg of M/s High-Q, Karachi (Reg.#070485)
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated as The firm operating at fair level of compliance with GMP as of today.
	Remarks of the Evaluator	Applied formulation in reference agencies is film coated and firm applied for uncoated. The firm was asked to clarify. Firm in response submitted same form5, formulation for uncoated tablets.

Decision of 289th meeting of Registration Board:

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.
- Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board.

Now the firm has submitted the desire data and clarification.

Decision: Approved with innovator's specification

1068.	Name and address of manufacturer /Applicant	Regal Pharma Plot #2A, St#S-5 National Industrial Zones, Rawat Islamabad.
	Brand Name +Dosage Form + Strength	Cine 1mg Tablet
	Composition	Each tablet contains: Cinitapride hydrogen tartrate eq. to cinitapride…1mg
	Diary No. Date of R& I & fee	Dy No. 11720: 30-03-2018 PKR 20,000/-: 28-03-2018
	Pharmacological Group	Propulsives Antidopaminergic prokinetic
	Type of Form	Form-5
	Finished Product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg uncoated tablet by ALMIRALL, SA (Spain Approved)
	Me-too status	Cidine Tablets by Highnoon Lab (Reg#052940).
	GMP status	Last inspection was conducted on 20.11.2017 by area FID, and rated as ―The firm operating at fair level of compliance with GMP as of today.
	Remarks of the Evaluator	Applied formulation in reference agencies is film coated and firm applied for uncoated. The firm was asked to clarify. Firm in response submitted same form5, formulation for uncoated tablets.

Decision of 289th meeting of Registration Board:

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.

Now the firm has submitted the desire data and clarification.

Decision: Approved

1069.	Name and address of manufacturer /Applicant	"M/s Genix Pharma Pvt. Ltd. 44, 45-B, Korangi Creek Road, Karachi, 75190, Pakistan."
	Brand Name +Dosage Form + Strength	Decon 50mcg/actuation Nasal Spray
	Composition	"Each actuation Contains: Mometasone Furoate Monohydrate Eq. to Mometasone

		Fumarate…50mcg"
	Diary No. Date of R& I & fee	Dy. No 13997 dated 13-04-2018 Rs.20,000/- 11-04-2018
	Pharmacological Group	Corticosteroid
	Type of Form	Form-5
	Finished Product Specification	The Firm has claimed manufacturer‘s specification
	Pack size & Demanded Price	Anti-allergic
	Approval status of product in Reference Regulatory Authorities.	Nasonex® 50 micrograms/actuation Nasal spray, suspension. MHRA approved.
	Me-too status	Hivate Nasal Spray By M/s Saffron Pharma Reg. No. 60352
	GMP status	16.02.2018. Satisfactory level of compliance.
	Remarks of evaluator	

Decision of 289th meeting of Registration Board:

Deferred for confirmation of manufacturing facility.

Firm has submitted the copy of last inspection report by area FID Karachi dated 10-04-2019 showing manufacturing facility of Sterile Drops (Ophthalmic, Ear and Nose) section.

Decision: Deferred for confirmation of approval of required manufacturing facility by Licensing Division.

1070.	Name and address of manufacturer /Applicant	M/s. Axis Pharmaceuticals 3-B, Value addition City, 1.5Km Khurrianwala – Sahianwala road Faisalabad.
	Brand Name +Dosage Form + Strength	Nimsulin Tablets
	Composition	Each Tablet contains; Nimesulide…….…….... 100mg
	Diary No. Date of R& I & fee	Dy No. 9981: 16.03.2018 PKR 20,000/-: 09.03.2018
	Pharmacological Group	Non-steroidal anti-inflammatory drug (NSAID) selective COX-2 inhibitors.
	Type of Form	Form-5
	Finished Product Specification	The firm has claimed manufacturer ‘s specifications.
	Pack size & Demanded Price	As per SRO, 10‘s
	Approval status of product in Reference Regulatory Authorities.	Approved by EMA.
	Me-too status	Nims Table 100mg by M/S Sami Pharmaceuticals Reg.No. 26657
	GMP status	Last inspection was conducted on 19th Sep & 3rd October 2018 by panel for the purpose of grant of GMP certificate, panel rated the firm operating at fair level of compliance with GMP and recommended for grant of GMP.
	Remarks of Evaluator	

Decision of 289th meeting of Registration Board:

Deferred for evidence of approval of applied formulation as film coated tablet by reference regulatory authorities adopted by Registration Board in its 275th meeting.

Firm has submitted the revised formulation showing that product is plain tablet instead of film coated with Rs. 5000/- fee.

Decision: Approved with innovator’s specification

1071.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Odium capsule
	Composition	Each capsule contains: Loperamide….2mg
	Diary No. Date of R& I & fee	Dy. No 17393 Dated 07-03-2019, Rs. 20,000/- 07-03-2019
	Pharmacological Group	Antidiarrheal
	Type of Form	Form 5

	Finished Product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**LOPERAMIDE HYDROCHLORIDE (USFDA)**
	Me-too status	IMODIUM 2MG CAP of M/s JOHNSON & JOHNSON KHI
	GMP status	CLB in its 267th meeting approved the new Section for Capsule general on dated 31st December 2018.
	Remarks of the Evaluator.	Annexure I-VII are not provided.
	Decision of 290th meeting of Registration Board: Deferred for submission of international availability, me-too status along with annexure I-VII. Now firm submitted the annexure and international availability also confirmed. **Decision: Approved**	
1072.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Gentle 80mg/2ml Injection
	Composition	"Each 2ml Glass Vial Contains: Gentamicin Sulphate…….80mg"
	Diary No. Date of R & I & Fee	Dy.#15530 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference Regulatory Authorities	Gentamicin Injection by M/s Fresenius Kabi USA, LLC
	Me-too Status	Genta Injections by m/s Epoch Pharma Reg. No. 47130
	GMP Status	As recorded for above application
	Remarks of the Evaluator	
Decision of 289th meeting of Registration Board: Deferred for confirmation of manufacturing facility for 2ml vial Now the firm submit letter showing the "sterile infusion/small volume vial (general) section dated 05th March 2019. **Decision: Approved with change name**		
1073.	Name and address of manufacturer / Applicant	"M/s Iqra Pharmaceuticals. Plot No. 02, Street No. S-9, National Industrial Zone, Rawat, Islamabad, Pakistan"
	Brand Name + Dosage Form + Strength	Linca 600mg/2ml Ampoule
	Composition	"Each 2ml Vial Contains: Lincomycin Hydrochloride Monohydrate Eq. to Lincomycin…600mg"
	Diary No. Date of R & I & Fee	Dy. No 15527 dated 07-03-2019 Rs.20,000/- Dated 07-03-2019
	Pharmacological Group	Antibiotic,
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack Size & Demanded Price	As per SRO.
	Approval Status of product in Reference	LINCOCIN 600mg/2ml (Vial) solution for injection by M/s Pharmacia and Upjohn (USFDA Approved).

	Regulatory Authorities	
	Me-too Status	Dds Lincomycin 600mg Injection by M/s Global Pharma, Reg. No. 32155
	GMP Status	As recorded for above application
	Remarks of the Evaluator	

Decision of 289th meeting of Registration Board:
Deferred for confirmation of manufacturing facility for 2ml vial
Now the firm submit letter showing the "sterile infusion/small volume vial (general) section dated 05th March 2019.
Decision: Approved

1074.	Name and address of manufacturer /Applicant	"M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area,Islamabad."
	Brand Name +Dosage Form + Strength	Grip 10mg/ml Oral Drops
	Composition	"Each ml Contains: - Escitalopram as (Escitalopram Oxalate) ……..10mg"
	Diary No. Date of R& I & fee	Dy. No 13989 dated 13-04-2018 Rs.20,000/- Dated 13-04-2018
	Pharmacological Group	Antidepressants
	Type of Form	Form-5
	Finished Product Specification	USP
	Pack size & Demanded Price	15ml, 30ml, 60ml. As per SRO.
	Approval status of product in Reference Regulatory Authorities.	LEXAPRO® Oral Solution 10mg/ml of M/s Lundbeck Australia
	Me-too status	Citanew Oral Drops by M/s Hilton Pharma Reg. No. 47485
	GMP status	The firm was inspected on 19.09.2017 & 21.09.2017 & concluded as: The firm operating at very good level of GMP.
	Remarks of the Evaluator	

Decision of 289th meeting of Registration Board:
Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.

Now the firm has submitted the reference of applied formulation in reference regulatory authorities.
Decision: Approved

1075.	Name and address of manufacturer / Applicant	M/s Relozon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Mecozon 500mcg tablets
	Composition	Each sugar-coated tablet contains: Mecobalamin….500mcg
	Diary No. Date of R& I & fee	Dy. No 17996 Dated 16-05-2018, Rs. 20,000/- dated 16-05-2018
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specification	JP Specification
	Pack size & Demanded Price	20's, 30's & 100's
	Approval status of product in Reference Regulatory Authorities.	Mecobalamin Tablet 500 µg "JG" PMDA
	Me-too status	Anemovit Tablet of Pharmacare
	GMP status	DML dated 21-02-2018 and Tablet (General) section , Capsule (General) Section dated 23-02-2018
	Remarks of the Evaluator	
	Decision of 290th meeting of Registration Board: **Deferred for submission of reference of applied formulation from reference regulatory authorities approved by Registration Board in its 275th meeting.**	

	Firm has submitted the international availability of the product. **Decision: Approved as said formulation is available in Japan (PMDA)**	
1076.	Name and address of manufacturer / Applicant	M/s Relozon Pharmaceuticals, 118, Sunder Industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	Duloxon 20mg Capsule
	Composition	Each capsule contains Enteric coated pellets of Duloxetine Hydrochloride eq to Duloxetine…20mg Source of Pellets M/s vision pharma
	Diary No. Date of R& I & fee	Dy. No 18000 Dated 16-05-2018, Rs. 20,000/- dated 16-05-2018
	Pharmacological Group	selective serotonin and norepinephrine reuptake inhibitor antidepressant (SSNRI)
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	10's, 14's, 28's & 30's
	Approval status of product in Reference Regulatory Authorities.	Duloxetine 20 mg gastro-resistant capsules of M/s Consilient Health Ireland
	Me-too status	Duprex Capsule 20mg of CCL
	GMP status	DML dated 21-02-2018 and Tablet (General) section, Capsule (General) Section dated 23-02-2018
	Remarks of the Evaluator	
	Decision of 290th meeting of Registration Board: **"Deferred for source of pellets"** Firm submit Source of Pellets "M/s vision pharma" **Decision: Approved**	

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

a. New DML

b. New/Additional section(s)

M/S Fahmir Pharma Pvt Ltd 26-km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura

Central Licensing Board in its 259th meeting held on 29-30th March 2018 has considered and approved the grant of drug manufacturing license by way of formulation with **Tablet (General) Section.**

Already considered molecule 3

Remaining molecule 7

Tablet (General) Section 12 Product/ 7 Molecule

1077.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km, Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	MONTIMIR 5mg Tablet
	Composition	Each film coated tablet contains: Montelukast Sodium eq. to montelukast……5mg
	Diary No. Date of R & I & fee	Dry. No. 2905 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Blister packing 2x7's & Rs. 14.571 per Tablet

	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Adkast Tablet of M/s Ameer & Adnan Pharma
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	International availability of same formulation in reference regulatory authorities approves by Registration Board in its 275th meeting is not available. M/s Fahmir Pharma submit revised form-5 with 20,000/ fee.
Decision: Registration Board approved with following composition: **Each chewable tablet contains:** **Montelukast Sodium eq. to montelukast……5mg**		
1078.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	MONTIMIR 10mg Tablet
	Composition	Each film coated tablet contains: Montelukast Sodium eq. to montelukast……10mg
	Diary No. Date of R & I & fee	Dry. No. 2897 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Blister packing 2x7's & Rs. 14.571 per Tablet
	Approval status of product in Reference Regulatory Authorities.	SINGULAIR 10-mg Film-Coated Tablets (USFDA)
	Me-too status	Remont 10mg Tablet of M/s Regent Laboratories,
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved		
1079.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	THROCIN 250mg Tablet
	Composition	Each film coated tablet contains: Clarithromycin……250mg
	Diary No. Date of R & I & fee	Dry. No. 2898 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	Antibiotic (Macrolides)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Blister packing 1x10's
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 250 mg film-coated tablets (UK)
	Me-too status	Pficid 250mg Tablet of M/s Parke Davis
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018

	Remarks	
Decision: Approved		
1080.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	THROCIN 500mg Tablet
	Composition	Each film coated tablet contains: Clarithromycin……500mg
	Diary No. Date of R & I & fee	Dry. No. 2893 dated 19-02-2019 Fee. 20,000/- 15-02-2019
	Pharmacological Group	Antibiotic (Macrolides)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Blister packing 1x10's
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 500 mg film-coated tablets (UK)
	Me-too status	Pficid 500mg Tablet of M/s Parke Davis
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved		
1081.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	Z-MYCIN 250 Tablets
	Composition	Each film coated tablet contains: Azithromycin as dihydrate……250mg
	Diary No. Date of R & I & fee	Dry. No. 7028 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	Antibiotic (Macrolides)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Blister packing 1x6's
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 250 mg film-coated tablets (UK)
	Me-too status	Myzi Tablet of M/s Pharmacare Labs,
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved		
1082.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	Z-MYCIN 500 Tablets
	Composition	Each film coated tablet contains: Azithromycin as dihydrate……500mg
	Diary No. Date of R & I & fee	Dry. No. 7029 dated 19-02-2019 Fee. 20,000/- 15-02-2019
	Pharmacological Group	Antibiotic (Macrolides)
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	Blister packing 1x6's
	Approval status of product in Reference Regulatory Authorities.	Azithromycin 500 mg film-coated tablets (UK)
	Me-too status	Biozith Tablets of M/s Bio Labs (Pvt) Ltd,
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved		
1083.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	Metomir 500,50mg Tablet
	Composition	Each film coated tablet contains: Metformin HCL……500mg Sitagliptin phosphate monohydrate eq. to sitagliptin…..50mg
	Diary No. Date of R & I & fee	Dry. No. 7038 dated 19-02-2019 Fee. 20,000/- 15-02-2019
	Pharmacological Group	Biguanide/DPP4I's (Antidiabetic)
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs
	Pack size & Demanded Price	Blister of 10's & 2x7's
	Approval status of product in Reference Regulatory Authorities.	JANUMET (USFDA)
	Me-too status	JANVIA-M Tablets of M/s 'Genix Pharma
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved with innovator's specification		
1084.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	Metomir 1000,50mg Tablet
	Composition	Each film coated tablet contains: Metformin HCL ……1000mg Sitagliptin phosphate monohydrate eq. to sitagliptin…..50mg
	Diary No. Date of R & I & fee	Dry. No. 7039 dated 19-02-2019 Fee. 20,000/- 15-02-2019
	Pharmacological Group	Biguanide/DPP4I's (Antidiabetic)
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs
	Pack size & Demanded Price	Blister of 10's & 14's
	Approval status of product in Reference Regulatory Authorities.	Janumet® 50 mg/1,000 mg film-coated tablets (The Netherlands)
	Me-too status	JANVIA-M Tablets of M/s 'Genix Pharma
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved with innovator's specification		

1085.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	Moximir 400mg Tablets
	Composition	Each film coated tablet contains: Moxifloxacin…….400mg
	Diary No. Date of R & I & fee	Dry. No. 7034 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	Antibiotic (Quinolones)
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Blister of 5's
	Approval status of product in Reference Regulatory Authorities.	Avelox 400 mg film-coated tablets of M/s Bayer plc, 400 South Oak Way
	Me-too status	Winbact 400mg Tablet of M/s Faas Pharmaceuticals
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved		
1086.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	ATOMIR 50mg Tablet
	Composition	Each tablet contains: Atenolol…….50mg
	Diary No. Date of R & I & fee	Dry. No. 7040 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	Blister of 3x10's
	Approval status of product in Reference Regulatory Authorities.	Atenolol 50 mg Tablets of UK
	Me-too status	Uminol 50mg Tablet of M/s Umema Pharma Baloochistan
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved		
1087.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	ATOMIR 100mg Tablet
	Composition	Each tablet contains: Atenolol…….100mg
	Diary No. Date of R & I & fee	Dry. No. 7041 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	Beta blocker
	Type of Form	Form 5

	Finished product Specification	USP
	Pack size & Demanded Price	Blister of 2x10's
	Approval status of product in Reference Regulatory Authorities.	Atenolol 100mg Tablets of UK
	Me-too status	Atenosap -100 Tablets of M/s Sapient Pharma,
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved		
1088.	Name and address of manufacturer / Applicant	M/s Fahmir Pharma Pvt Ltd 26km,Lahore- Jaranwala Road Main Stop Mandianwala Tehsil Sharaqpur, Dist. Sheikhupura
	Brand Name + Dosage Form + Strength	BELLA 20mg Tablet
	Composition	Each tablet contains: Piroxicam beta cyclodextrin 191.2mg eq. to Piroxicam….20mg
	Diary No. Date of R & I & fee	Dry. No. 7027 dated 19-02-2019 Fee. 20,000/- dated 15-02-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specs
	Pack size & Demanded Price	Blister of 20's
	Approval status of product in Reference Regulatory Authorities.	Approved by ANSM of France
	Me-too status	Bexagen 20mg Tablets of M/s Genesis Pharma
	GMP status	New DML No. 000880 Dated 11-04-2018, New section approval dated 11-04-2018
	Remarks	
Decision: Approved with innovator's specification		

M/s Avensis Pharmaceuticals Karachi

CLB in its 267th meeting held 31-12-2018 has considered and approved the new DML with following sections: The details of molecules and products applied are as below:

9 molecules / 11 products

Already approved products: 8

Capsule (General) Section:		
1089.	**Name and address of manufacturer / Applicant**	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Doxylin 100mg Capsule
	Composition	Each capsule contains: Doxycycline as Hyclate……..100mg
	Diary No. Date of R& I & fee	Dy. No 17406 Dated 07-03-2019, Rs. 20,000/- dated 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's '20's & 100's& As per SRO
	Approval status of product in Reference Regulatory Authorities.	Doxycycline 100mg Capsules and Vibrox 100mg Capsules (UK)

	Me-too status	VIBRAMYCIN 100MG CAP of M/s PFIZER
	GMP status	CLB in its 267th meeting approved the new Section for Capsule general on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision: Approved	
1090.	**Name and address of manufacturer / Applicant**	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Diflusis 150mg Capsule
	Composition	Each capsule contains: Fluconazole……150mg
	Diary No. Date of R& I & fee	Dy. No 17384 Dated 07-03-2019, Rs. 20,000/- dated 07-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	B.P.
	Pack size & Demanded Price	1's & 5's
	Approval status of product in Reference Regulatory Authorities.	Azocan-P (UK)
	Me-too status	DIFLUCAN 150MG CAP Each capsule contains:- FLUCONAZOLE 150mg
	GMP status	CLB in its 267th meeting approved the new Section for Capsule general on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision: Approved	
1091.	**Name and address of manufacturer / Applicant**	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	D-Fenac SR 100mg Capsule
	Composition	Each capsule contains: Diclofenac Sodium……..100mg
	Diary No. Date of R& I & fee	Dy. No 17386 Dated 07-03-2019, Rs. 20,000/- dated 07-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished Product Specification	B.P.
	Pack size & Demanded Price	20's' 30's & 100's
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	PHOGIN SR 100 CAP of M/s BROOKES
	GMP status	CLB in its 267th meeting approved the new Section for Capsule general on dated 31st December 2018.
	Remarks of the Evaluator.	International availability is not confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	

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

a. New Cases

1092.	Name and address of Applicant/ Manufacturer	M/s Vetec Laboratories Plot No. 20, street no. s-5, Rawat Industrial Zone, Rawat
	Detail of Drug Manufacturing Licence	DML by way of Formulation dated 05-03-2019 Approved Section Oral powder Section (Veterinary) Oral Liquid Section (Veterinary)
	Type of Form	Form-5
	Diary No. & Date of R& I	Dy. No 11637 Dated 06-03-2019
	Fee including differential fee	Rs. 20,000/- Dated 01-03-2019
	Brand Name +Dosage Form + Strength	BROMODOX-60 POWDER (ORAL)
	Composition	Each 100gram contains: Tylosin tartrate……..20gm Doxycycline hyclate…….40gm Colistin sulfate……10gm Bromhexine HCL…….2gm
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	1000gm, 100gm, 500gm, jars and bags
	Me-too status	BROCOTYD POWDER (Reg. 058962)
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	
1093.	Name and address of Applicant/ Manufacturer	M/s Vetec Laboratories Plot No. 20, street no. s-5, Rawat Industrial Zone, Rawat
	Detail of Drug Manufacturing Licence	DML by way of Formulation dated 05-03-2019 Approved Section Oral powder Section (Veterinary) Oral Liquid Section (Veterinary)
	Type of Form	Form-5
	Diary No. & Date of R& I	Dy. No 11629 Dated 06-03-2019
	Fee including differential fee	Rs. 20,000/- Dated 01-03-2019
	Brand Name +Dosage Form + Strength	D-tyloxine 20 Powder
	Composition	Each 1000gram contains: Tylosin tartrate……..200gm Doxycycline hyclate…….400gm Colistin sulfate……1000MIU Bromhexine HCL…….10gm
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	1000gm
	Me-too status	Monodoxwater Soluble Powder of M/s Baariq Pharmaceuticals Lhr
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	

1094.	Name and address of Applicant/ Manufacturer	M/s Vetec Laboratories Plot No. 20, street no. s-5, Rawat Industrial Zone, Rawat
	Detail of Drug Manufacturing Licence	DML by way of Formulation dated 05-03-2019 Approved Section Oral powder Section (Veterinary) Oral Liquid Section (Veterinary)
	Type of Form	Form-5
	Diary No. & Date of R& I	Dy. No 11639 Dated 06-03-2019
	Fee including differential fee	Rs. 20,000/- Dated 01-03-2019
	Brand Name +Dosage Form + Strength	SE-DOX 50 POEDER
	Composition	Each 1000gm contains: Doxycycline Hyclate…….500gm
	Finished Product Specification	In-house
	Pharmacological Group	Antibacterial
	Shelf life	2 Years
	Demanded Price	Decontrolled
	Pack size	1000gm, 500gm, 100gm
	Me-too status	SELDOX POWDER of M/s SELMOREPHARMACEUTICALS, LAHORE
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	
1095.	Name and address of Manufacturer / Applicant	M/s RAS Pharmaceuticals (Pvt.) Ltd. 25, km Lahore Road Multan
	Brand Name + Dosage Form + Strength	Amanta Ras (Oral Liquid)
	Composition	Each 100ml contains: Amantadine HCl……10gm
	Diary No, Date of R & I & fee	Dy. No. 23020 dated 03-07-2018 Rs. 20,000/-Dated 03-07-18
	Pharmacological Group	Antiviral
	Type of Form	Form-5
	Finished Product Specification	B.P.
	Pack Size & Demanded Price	100ml, 250ml, 500ml, 1 liter, 5-liter, 10 liter, 25 liter & Decontrolled
	Me-too status	
	GMP Status	DML by way of formulation dated 23-06-2015 & last GMP inspection dated 16-10-2018 by area FID shows the GMP compliance status of the applied product.
	Remarks of the Evaluator	Me-too status is not confirmed
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	
1096.	Name and address of Manufacturer / Applicant	M/s RAS Pharmaceuticals (Pvt.) Ltd. 25, km Lahore Road Multan
	Brand Name + Dosage Form + Strength	CINA-ES Oral Liquid
	Composition	Each ml contains: Enrofloxacin……75mg Sulphamethoxypyridazine……..50mg Sulphamethazine……50mg Trimethoprim…….25mg
	Diary No, Date of R & I & fee	Dy. No. 23021 dated 03-07-2018 Rs. 20,000/-Dated 03-07-18
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Manufacturer Specification

	Pack Size & Demanded Price	100ml, 250ml, 500ml, 1 liter, 5-liter, 10 liter, 25 liter & Decontrolled
	Me-too status	Sulphacina Oral Liquid of M/s Bio-Oxime Pharmaceuticals
	Remarks of the Evaluator	
	Decision: Registration Board referred the case regarding the composition to the expert working group on veterinary drugs.	
1097.	Name and address of Manufacturer / Applicant	M/s RAS Pharmaceuticals (Pvt.) Ltd. 25, km Lahore Road Multan
	Brand Name + Dosage Form + Strength	Paralyte-C Oral Powder
	Composition	Each 100gm contains: Paracetamol…….2gm Vitamin C (Ascorbic Acid). ….20gm Calcium carbonate……4.5gm Magnecium sulphate……..3.5gm Potassium chloride……..4gm
	Diary No, Date of R & I & fee	Dy. No. 23026 dated 03-07-2018 Rs. 20,000/-Dated 03-07-18
	Pharmacological Group	NSAID+ Vitamin+ electrolyte
	Type of Form	Form-5
	Finished Product Specification	Manufacturer specification
	Pack Size & Demanded Price	50gm, 100gm, 250gm, 500gm, 1kg, 2.5kg, 5kg 10kg, 25kg & Decontrolled
	Me-too status	Spin-C Powder of M/s Leads Pharma (Pvt) Ltd.
	Remarks of the Evaluator	
	Decision: Registration Board referred the case regarding the composition to the expert working group on veterinary drugs.	

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

1098.	Name and address of Applicant	M/s Roche Pakistan Limited 1st floor, 37-B, Block 6, P.E.C.H.S Karachi, 75400 Pakistan
	Detail of Drug Sale License	M/s Roche Pakistan Limited 37-C, Block 6 PECHS, Karachi Drug License by way of Wholesale No. 0750 Valid till 13-09-2020
	Name and address of manufacturer	Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan
	Name and address of marketing authorization holder	M/s Genetec, Inc (A member of the Roche Group), 1 DNA Way, South San Francisco, CA 94080 USA
	Name of exporting country	Switzerland
	Type of Form	Form-5F
	Diary No. & Date of R& I	Dy. No 1874 Dated 26-03-2019
	Fee including differential fee	Rs. 50,000/- Dated 26-03-2019
	Brand Name +Dosage Form + Strength	Xofluza 20mg Film Coated Tablet
	Composition	Each film coated tablet contains: Baloxavir Marboxil……20mg
	Finished Product Specification	In-house
	Pharmacological Group	Antiviral
	Shelf life	24 months
	Demanded Price	
	Pack size	20x2's and 20x4's

	International availability	USA
	Me-too status	No.
	Name and address of API manufacturer.	Shionogi Pharma Chemicals Co., Ltd. 224-20, Hiraishiebisuno, Kawauchi-cho, Tokushima, Tokushima 771-0132, Japan
	Stability studies	Firm has submitted three batches long term stability data 3 batches 24 months at 30^0C±75%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. BVM5-AX4X)** dated 26-07-2017 by USFDA declaring the free sale of applied product and GMP compliant status of the manufacturer i.e Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan. Certificate expiration date: January 06, 2021
	Remarks of the Evaluator.	It is submitted that applied product for registration will be imported from Switzerland, manufactured in Japan and marketing authorization holder as per submitted CoPP issued by USFDA is M/s Genetec USA. M/s Roche Pakistan submit sole agency agreement with M/s Hoffmann-La Roche Switzerland along with documents of 2009 showing that "Roche (SWX: ROG.VX; RO.S, OTCQX: RHHBY) and Genentech (NYSE: DNA) announced today (Thursday, Mar 26, 2009) that Roche has completed its acquisition of Genentech pursuant to a short-form merger in which Genentech became a wholly-owned member of the Roche Group"
	Decision: Approved as per Import Policy for inspection of finished product	
1099.	Name and address of Applicant	M/s Roche Pakistan Limited 1st floor, 37-B, Block 6, P.E.C.H.S Karachi, 75400 Pakistan
	Name and address of manufacturer	Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan
	Name and address of marketing authorization holder	M/s Genetec, Inc (A member of the Roche Group), 1 DNA Way, South San Francisco, CA 94080 USA
	Name of exporting country	Switzerland
	Type of Form	Form-5F
	Diary No. & Date of R& I	Dy. No 1874 Dated 26-03-2019
	Fee including differential fee	Rs. 50,000/- Dated 26-03-2019
	Brand Name +Dosage Form + Strength	Xofluza 40mg Film Coated Tablet
	Composition	Each film coated tablet contains: Baloxavir Marboxil……40mg
	Finished Product Specification	In-house
	Pharmacological Group	Antiviral
	Shelf life	24 months
	Demanded Price	
	Pack size	40x1's and 40x2's
	International availability	USA
	Me-too status	No.
	Name and address of API manufacturer.	Shionogi Pharma Chemicals Co., Ltd. 224-20, Hiraishiebisuno, Kawauchi-cho, Tokushima, Tokushima 771-0132, Japan
	Stability studies	Firm has submitted three batches long term stability data 3 batches 24 months at 30^0C±75%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. G9W9-YEHU)** dated 26-07-2017 by USFDA declaring the free sale of applied

		product and GMP compliant status of the manufacturer i.e Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan. Certificate expiration date: January 09, 2021
	Remarks of the Evaluator.	It is submitted that applied product for registration will be imported from Switzerland, manufactured in Japan and marketing authorization holder as per submitted CoPP issued by USFDA is M/s Genetec USA. M/s Roche Pakistan submit sole agency agreement with M/s Hoffmann-La Roche Switzerland along with documents of 2009 showing that "Roche (SWX: ROG.VX; RO.S, OTCQX: RHHBY) and Genentech (NYSE: DNA) announced today (Thursday, Mar 26, 2009) that Roche has completed its acquisition of Genentech pursuant to a short-form merger in which Genentech became a wholly-owned member of the Roche Group"

FORM 5-F ASSESMENT REPORT

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 1874 Dated 26-03-2019 PKR: 50,000/- dated 26-03-2019
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 Roche Pakistan Limited 1st floor, 37-B, Block 6, P.E.C.H.S Karachi, 75400 Pakistan
	1.3.2	Name, address and contact details of Manufacturing site. Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan Marketing Authorization Holder: M/s Genetec, Inc (A member of the Roche Group), 1 DNA Way, South San Francisco, CA 94080 USA
	1.3.3	Specify whether the Applicant is: □ Importer
	1.3.4	**Drug Sale License** Drug License by way of Wholesale No. 0750 Valid till 13-09-2020
	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. Baloxavir Marboxil
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each film coated tablet contains: Baloxavir Marboxil……20mg & 40mg

	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Xofluza 20mg & 40mg Film Coated Tablet
	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. 20x2's and 20x4's, 40x1's and 40x2's
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Antiviral (for Influenza treatment)
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	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. USA, UK approved
	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. M/s Shionogi Pharma Chemicals Co., Ltd. 224-20, Hiraishiebisuno, Kawauchi-cho, Tokushima, Tokushima 771-0132, Japan Vendor qualification / audit is □ Document based □ Site inspection based Reason for point c.
	• **Original Legalized CoPP for 20mg tablet (Certificate#. BVM5-AX4X)** dated 26-07-2017 by USFDA declaring the free sale of applied product and GMP compliant status of the manufacturer i.e Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan. Certificate expiration date: January 06, 2021 • **Original Legalized CoPP for 40mg tablet (Certificate#. G9W9-YEHU)** dated 26-07-2017 by USFDA declaring the free sale of applied product and GMP compliant status of the manufacturer i.e Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan. Certificate expiration date: January 09, 2021	

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 24 months at 30^0C±75%RH and 6 months at 40^0C±75%RH for three batches.

Module 4: (Non-clinical / Safety) Submitted
Module 5: (Clinical / Efficacy) Submitted

Decision: Approved as per Import Policy for inspection of finished products.

1100.	**Name and address of Applicant**	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Detail of Drug Sale License	Drug license by way of retail sale no. 3080 valid upto 23-May-2020
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36523 Dated 05-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 100mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide……100mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 30^0C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temoeirgen 100Mg Capsules of M/s Merixil Pharma
	Stability studies	Firm has submitted long term (36 months) at 30^oC±2^0C, 65±5%RH & accelerated (06 months) stability data at 40^oC, 75% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 05/18/124543)** dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. • Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP.	
1101.	**Name and address of Applicant**	M/s Scilife Pharma (Pvt.) Limited Plot # FD-57/58-A2, Korangi Creek Industrial park (KCIP) Karachi
	Name and address of manufacturer	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Marketing authorization holder	M/s Laboratorio Eczane Pharma S.A. Laprida 43, Avellaneda (1870), Buenos Aires Argentina
	Name of exporting country	Argentina
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 36524 Dated 05-11-2018
	Fee including differential fee	Rs. 100,000/- Dated 05-11-2018
	Brand Name +Dosage Form + Strength	TEMO 250mg Capsule (Temozolomide)
	Composition	Each capsule contains: Temozolomide……250mg
	Finished Product Specification	In-house
	Pharmacological Group	ATC Code L01AX03 alkylating agents (Anticancer)
	Shelf life	36 Months below 30^0C
	Pack size	5's
	International availability	Temozolomide (USFDA)
	Me-too status	Temonat 250mg Capsules of M/s Hakimsons
	Stability studies	Firm has submitted long term (36 months) at 30^oC±2^0C, 65±5%RH & accelerated (06 months) stability data at 40^oC, 75% RH for three batches.

	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 05/18/124543)** dated 28August 2018 by National Institute of Medicines- National Institute of Drugs Caseros Avenue 2161 Autonomous City of Buenos Aires Argentine Republic declaring the no free sale of applied product in the exporting country. • Sole agency agreement provided.
	Remarks of the Evaluator.	Submitted CoPP shows that Product is not actually on the market in the exporting country. Firm reply as under: "The manufacturer has taken exclusive registration of these products with brand name for export market only, reasoning which the said product is not available in exporting country"
	Decision: Deferred for clarification regarding non availability of product in country of origin as per submitted CoPP.	

Case no. 06 Registration applications of import cases

a. New Cases (Human)

1102.	**Name and address of Applicant**	M/s Pfizer Pakistan Limited 12, Dockyard Road, West Wharf, Karachi, Pakistan
	Detail of Drug Sale License	M/s Pfizer Pakistan Limited (Formerly Parke davis & co. Ltd.) B-2, S.I.T.E, Karachi Address of Godown 12, Dockyard Road, West Wharf, Karachi, Pakistan C-11-D, S.I.T.E, Karachi Drug License by Way of Wholesale No. 10578 valid upto 17-Feb-2020
	Name and address of manufacturer	M/s Swiss Co Services AG Bahnhofstrasse 14, Sisseln, 4334, Switzerland
	Name and address of marketing authorization holder	M/s Basilea Medical Ltd, (c/o Cox Costello & Horne Limited) Langwood House, 63-81 High Street, Rickmansworth, WD 3 1EQ Hertfordshire, United Kingdom
	Name of exporting country	UK
	Type of Form	Form-5F
	Diary No. & Date of R& I	Dy. No 7867 Dated 03-06-2019
	Fee including differential fee	Rs. 100,000/- Dated 30-05-2019
	Brand Name +Dosage Form + Strength	Cresemba 100mg Capsule
	Composition	Each Capsule contains: Isavuconazole…….100mg
	Finished Product Specification	In-house
	Pharmacological Group	Antifungal
	Shelf life	30 Months at 30^0C
	Demanded Price	As per SRO
	Pack size	14's
	International availability	Switzerland
	Me-too status	N/A
	Name and address of API manufacturer.	M/s Hovione FarmaCiencia S.A. Sete Cases, Loures, 2674-506, Portugal
	Stability studies	Firm has submitted three batches long term stability data 3 batches 30 months at 30^0C±75%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 05/18/124545)** 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 Swiss Co Services AG Bahnhofstrasse 14, Sisseln, 4334, Switzerland. • Letter of Authorization
	Remarks of the Evaluator.	

FORM 5-F ASSESMENT REPORT

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 7867 Dated 03-06-2019 PKR: 100,000/- dated 30-05-2019
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 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. M/s Swiss Co Services AG Bahnhofstrasse 14, Sisseln, 4334, Switzerland Marketing Authorization Holder: M/s Basilea Medical Ltd, (c/o Cox Costello & Horne Limited) Langwood House, 63-81 High Street, Rickmansworth, WD 3 1EQ Hertfordshire, United Kingdom
	1.3.3	Specify whether the Applicant is: □ Importer
	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: □ **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. Isavuconazole
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each Capsule contains: Isavuconazole…….100mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Cresemba 100mg Capsule
	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. 14's
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Antifungal
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	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. UK approved
	1.5.10	Dosage form of applied drug Capsule
	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. M/s Hovione FarmaCiencia S.A. Sete Cases, Loures, 2674-506, Portugal Vendor qualification / audit is □ Document based □ Site inspection based Reason for point c.
	• **Original Legalized CoPP (Certificate#. 05/18/124545)** 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 Swiss Co Services AG Bahnhofstrasse 14, Sisseln, 4334, Switzerland. • Letter of Authorization	

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 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 30 months at $30^0C \pm 75\%RH$ and 6 months at $40^0C \pm 75\%RH$ for three batches.

Module 4: (Non-clinical / Safety) Submitted
Module 5: (Clinical / Efficacy) Submitted

Decision: Approved with innovator specification

1103.	**Name and address of Applicant**	M/s Pfizer Pakistan Limited 12, Dockyard Road, West Wharf, Karachi, Pakistan
	Detail of Drug Sale License	M/s Pfizer Pakistan Limited (Formerly Parke davis & co. Ltd.) B-2, S.I.T.E, Karachi Address of Godown 12, Dockyard Road, West Wharf, Karachi, Pakistan C-11-D, S.I.T.E, Karachi Drug License by Way of Wholesale No. 10578 valid upto 17-Feb-2020
	Name and address of manufacturer	M/s Baxter Pharmaceutical solutions, LLC, 927 S. Curry Pike, 47403 Bloomington, Indiana (IN), United States
	Name and address of marketing authorization holder	M/s Basilea Medical Ltd, (c/o Cox Costello & Horne Limited) Langwood House, 63-81 High Street, Rickmansworth, WD 3 1EQ Hertfordshire, United Kingdom
	Name of exporting country	UK
	Type of Form	Form-5F

	Diary No. & Date of R& I	Dy. No 7868 Dated 03-06-2019
	Fee including differential fee	Rs. 100,000/- Dated 30-05-2019
	Brand Name +Dosage Form + Strength	Cresemba Powder for concentrate for solution for infusion
	Composition	Each vial contains: Isavuconazole…….200mg
	Finished Product Specification	In-house
	Pharmacological Group	Antifungal
	Shelf life	48 Months
	Demanded Price	As per
	Pack size	1's
	International availability	UK
	Me-too status	N/A
	Name and address of API manufacturer.	M/s Hovione FarmaCiencia S.A. Sete Cases, Loures, 2674-506, Portugal
	Stability studies	Firm has submitted three batches long term stability data 3 batches 48 months at 5^0C and 6 months at 25^0C±60%RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 05/18/124543)** 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 Baxter Pharmaceutical solutions, LLC, 927 S. Curry Pike, 47403 Bloomington, Indiana (IN), United States. • Letter of Authorization
	Remarks of the Evaluator.	

FORM 5-F ASSESMENT REPORT

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No 7868 Dated 03-06-2019 PKR: 100,000/- dated 30-05-2019
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 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. M/s Baxter Pharmaceutical solutions, LLC, 927 S. Curry Pike, 47403 Bloomington, Indiana (IN), United States Marketing Authorization Holder: M/s Basilea Medical Ltd, (c/o Cox Costello & Horne Limited) Langwood House, 63-81 High Street, Rickmansworth, WD 3 1EQ Hertfordshire, United Kingdom
	1.3.3	Specify whether the Applicant is: □ Importer
	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: □ **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. Isavuconazole
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit Each vial contains: Isavuconazole…….200mg
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trademark certification / clearance. Cresemba Powder for concentrate for solution for infusion
	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) Antifungal
	1.5.6	Pharmacopoeial reference / Status of applied formulation In-house
	1.5.7	Route of administration Infusion (IV)
	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. UK approved
	1.5.10	Dosage form of applied drug 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 & 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. M/s Hovione FarmaCiencia S.A. Sete Cases, Loures, 2674-506, Portugal Vendor qualification / audit is □ Document based □ Site inspection based Reason for point c.
	• **Original Legalized CoPP (Certificate#. 05/18/124545)** 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 Swiss Co Services AG Bahnhofstrasse 14, Sisseln, 4334, Switzerland. • Letter of Authorization	

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 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 48 months at 5^0C and 6 months at 25^0C±60%RH for three batches.

Module 4: (Non-clinical / Safety) Submitted
Module 5: (Clinical / Efficacy) Submitted

Decision: Approved with innovator specification

1104.	**Name and address of Applicant**	M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., 65 Main Boulevard Gulberg, Lahore
	Detail of Drug Sale License	Address: M/s Servier Research Pharmaceuticals, Kot abdul malik ferozwala District Sheikhupura Status: License to Sell Drugs as a Distributor valid upto 28-06-2020
	Name and address of manufacturer	M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France
	Name and address of marketing authorization holder	M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France
	Name of exporting country	France
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Duplicate dossier Dy. No 10003 Dated 28-06-2019
	Fee including differential fee	Fee slip duplicate Rs. 50,000/- Dated 24-05-2017
	Brand Name +Dosage Form + Strength	CARIVALAN 12.5mg/5mg film coated tablets
	Composition	Each film coated tablet Contains: Carvedilol…….12.5mg Ivabradine (as hydrochloride) …….5mg
	Finished Product Specification	Manufacturer specifications
	Pharmacological Group	Betablocker/cardiotonic
	Shelf life	24 months
	Demanded Price	
	Pack size	14, 28 & 56 Tablets
	International availability	France
	Me-too status	N/A
	Stability studies	Firm has submitted long term Provided data 18 months at 30^0C±65%RH and 6 months at 40^0C±75%RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP (Certificate#. 026357)** issued on 22-03-2019 by Chamber de commerce et d'Industrie de Region Paris Ile-de-Farance declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Les Laboratoires Servier Industrie, 905, route de saran 45520 Gidy France. • **Original Notarized "Letter of Authorization" from** M/s Les Laboratoires Servier Industrie, 50, rue carnot-92284 suresnes Cedex France declaring M/s Servier Research and Pharmaceuticals (Pakistan) Pvt. Ltd., Pakistan as marketing authorization holder in a territory defined as Pakistan.
	Remarks of the Evaluator.	
	Decision: Approved	
1105.	**Name and address of Applicant**	M/s Punjab Medical Services Office No. 4/5 2. Floor Jalal Center Opp. OPC Gme Gangaram Hospital Mozang Road Lahore
	Detail of Drug Sale License	Address: Punjab Medical Services Office No. 4/5 Jalal Center Opp. DPO Gate sir Ganga ram Hospital Mozang Road Lahore License no: 05-352-0063-041061D valid upto 27th Feb. 2021
	Name and address of manufacturer	M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey

	Name and address of marketing authorization holder	M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye
	Name of exporting country	Turkey
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 16281 Dated 03-05-2018
	Fee including differential fee	Rs. 100,000/- Dated 03-05-2018
	Brand Name +Dosage Form + Strength	Tirostu 12.5mg/50ml IV concentrated solution for infusion
	Composition	Each ml vial Contains: Tirofiban Hydrochloride Monohydrate ….0.281 (Equivalent to 0.25mg/ml Tirofiban)
	Finished Product Specification	*Ph. Eur.*
	Pharmacological Group	**Antithrombotic agent (**Antiplatelet Agent)
	Shelf life	24 months Do not store above 30^0C
	Demanded Price	As per SRO
	Pack size	50ml glass vial
	International availability	AGGRASTAT®*(250 micrograms/ml) concentrate for solution for infusion UK
	Me-too status	Aggrastat Injection of M/s MULLER & PHIPPS
	Stability studies	Firm has submitted long term (24 months) at 30±2ºC RH 65%± 5%± 5% & accelerated (06 months) stability data at 40± 2ºC, 75± 5% RH for three batches.
	Detail of certificates attached	• **Original Legalized CoPP (Certificate#. 2018/1369)** issued on 05-04-2018 by Republic of Turkey Ministry of Health Turkish Medicines and Medical Devices Agency declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Onko Ilac Sanayi ve Ticaret A.S Address: Gebze Organize Sanayi Bolgesi, 1700 Sokak no: 1703 Gebze Kocaeli Turkey valid until 05/04/2020. • **Original Notarized "Letter of Authorization" from** M/s Kocsel Ilac Sanayi ve Tic A.S. Kosuyolu Cad No: 34, 34781 Kosuyolu Kadikoy, Istanbul, Turkiye declaring M/s Punjab Medical Services, Pakistan authorize to perform registration procedures, sales and other similar activities concerning medicinal products for territory defined as Pakistan. Authorization valid for three years.
	Remarks of the Evaluator.	
	Decision: Approved	

b. New Cases (Veterinary)

1106.	Name and address of Applicant	M/s Vet Line International Flat No. 55/5, First floor, Main Shadman Market, Lahore
	Detail of Drug Sale License	M/s Vet Line International plot no. 939-A, Block-J, Phase-1, LDA Avenue-1, District Lahore License to sell drugs as a Distributor no. 0011000 0002836 valid up to 09-Feb-2021
	Name and address of manufacturer	M/s Bela-Pharm GmbH & Co. KG Lohner Str. 49377 Vechta Germany
	Marketing authorization holder	M/s Bela-Pharm GmbH & Co. KG Lohner Str. 49377 Vechta Germany
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 23638 Dated 09-07-2018

	Fee including differential fee	Rs. 100,000/- Dated 09-07-2018
	Brand Name +Dosage Form + Strength	Tylo-Suscit 100% Kompaktat
	Composition	Each gram granules contains: Tylosin Tartrate for animals equivalent to 924mg Tylosin……1000mg
	Finished Product Specification	B.P
	Pharmacological Group	Antibiotic
	Shelf life	24 Months
	Demanded Price	Decontrolled
	Pack size	
	International availability	Germany
	Me-too status	TYLOLINA 100% POWDER of M/s ALINA COMBINE Karachi
	Stability studies	Firm has submitted long term (24 months) at 30°C±2°C, 65±5%RH & accelerated (06 months) stability data at 40°C, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP (No. DE-NI-04-WHO-2018-0034) dated 20.04.2018**
	Remarks of the Evaluator.	
	Decision: Approved	
1107.	**Name and address of Applicant**	M/s Vet Line International Flat No. 55/5, First floor, Main Shadman Market, Lahore
	Name and address of manufacturer	M/s Bela-Pharm GmbH & Co. KG Lohner Str. 49377 Vechta Germany
	Marketing authorization holder	M/s Bela-Pharm GmbH & Co. KG Lohner Str. 49377 Vechta Germany
	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 23637 Dated 09-07-2018
	Fee including differential fee	Rs. 100,000/- Dated 09-07-2018
	Brand Name +Dosage Form + Strength	Sulphix
	Composition	Each ml solution contains: Trimethoprim……..40mg Sulfadoxine……200mg
	Finished Product Specification	B.P.
	Pharmacological Group	Antibiotic
	Shelf life	36 Months
	Demanded Price	Decontrolled
	Pack size	
	International availability	Germany
	Me-too status	
	Stability studies	Firm has submitted long term (36 months) at 30°C±2°C, 65±5%RH & accelerated (06 months) stability data at 40°C, 75±5% RH for three batches.
	Detail of certificates attached	**Original Legalized CoPP (No. DE-NI-04-WHO-2018-003) dated 16.01.2018**
	Remarks of the Evaluator.	Evidence of applied formulations already approved (generic/me-too) by DRAP/DCO not provided.
	Decision: Approved	

1108.	**Name and address of Applicant**	M/s Atzan Pharmaceuticals, commercial area aziz Bhatti town Sargodha
	Detail of Drug Sale License	DSL No. 0011000 0001644 valid up 14-Apr-2020
	Name and address of manufacturer	M/s Produlab Pharma BV Forellenweg 16 NL-4941 SJ Raamsdonksveer The Netherlands
	Marketing authorization holder	M/s Zoleant Ilac A.S Buyukdere Cad. Tekfen Towder No. 209 Kat: 8 Ofis: 31 SisIi/Istanbul/ Turkiye
	Name of exporting country	Netherland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 27418 Dated 09-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 09-08-2018
	Brand Name +Dosage Form + Strength	Tilmizole Oral Solution
	Composition	Each ml contains: Tilmicosin (as tilmicosin phosphate)……..250mg
	Finished Product Specification	Innovator specification
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	240ml PE Bottle, 960ml PE Bottle
	Me-too status	T MYCIN ORAL SOLUTION of M/s ALINA COMBINE
	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 issued** by ministry of food agriculture and livestock General Directorate of food and control Eskisehir yolu 9. Km Lodumlu Ankata/ Turkey declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Produlab Pharma BV Forellenweg 16 NL-4941 SJ Raamsdonksveer The Netherlands ➢ Legalized GMP certificate of manufacturer issued by Ministry of Economic Affairs ➢ Original sole agency agreement
	Remarks of the Evaluator.	
	Decision: Deferred for following: **i. Confirmation of regulatory status of applied product in Netherlands.** **ii. Authorization of Ministry of Economic Affairs for issuance of GMP certificate** **iii. Linkage of Marketing authorization holder with manufacturer of product** **iv. Clarification regarding import of same drug from this manufacturer by any other importer in Pakistan.**	
1109.	**Name and address of Applicant**	M/s Atzan Pharmaceuticals, commercial area aziz Bhatti town Sargodha
	Detail of Drug Sale License	DSL No. 0011000 0001644 valid up 14-Apr-2020
	Name and address of manufacturer	M/s Produlab Pharma BV Forellenweg 16 NL-4941 SJ Raamsdonksveer The Netherlands
	Marketing authorization holder	M/s Zoleant Ilac A.S Buyukdere Cad. Tekfen Towder No. 209 Kat: 8 Ofis: 31 SisIi/Istanbul/ Turkiye
	Name of exporting country	Netherland
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 27417 Dated 09-08-2018
	Fee including differential fee	Rs. 100,000/- Dated 09-08-2018
	Brand Name +Dosage Form +	Zoloxy LA Injection

	Strength	
	Composition	Each ml contains: Oxytetracycline (as oxytetracycline dihydrate)….200mg
	Finished Product Specification	Innovator specification
	Pharmacological Group	Antibacterial
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	50ml vial
	Me-too status	Retardoxi-20 La Injectable Solution of M/s ORIENT TRADERS INTERNATIONAL,
	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 issued** by ministry of food agriculture and livestock General Directorate of food and control Eskisehir yolu 9. Km Lodumlu Ankata/ Turkey declaring the free sale of applied product and GMP compliant status of the manufacturer i.e., M/s Produlab Pharma BV Forellenweg 16 NL-4941 SJ Raamsdonksveer The Netherlands ➢ Legalized GMP certificate of manufacturer issued by Ministry of Economic Affairs ➢ Original sole agency agreement
	Remarks of the Evaluator.	
	Decision: Deferred for following: **i. Confirmation of regulatory status of applied product in Netherlands.** **ii. Authorization of Ministry of Economic Affairs for issuance of GMP certificate** **iii. Linkage of Marketing authorization holder with manufacturer of product** **iv. Clarification regarding import of same drug from this manufacturer by any other importer in Pakistan.**	
1110.	Name and address of Applicant	M/s Huzaifa international commercial area, aziz Bhatti town, Sargodha, Pakistan
	Detail of Drug Sale License	DSL by way of distribution no. 0011000 0001489 valid upto20-Nov-2019
	Name and address of manufacturer	M/s Super's Diana S.L CTRA C. 17, km 17, 08150 Parets Del Valles, (Barcelona), Spain
	Marketing authorization holder	M/s Super's Diana S.L CTRA C. 17, km 17, 08150 Parets Del Valles, (Barcelona), Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 19409 Dated 30-10-2017
	Fee including differential fee	Rs. 100,000/- Dated 30-10-2017
	Brand Name +Dosage Form + Strength	ESPASMODIAN Solution for Innjection
	Composition	Each 100ml contains: Hyoscine (N-Butyl Bromide)……4gm Metamizole (Sodium)……..50gm
	Finished Product Specification	Innovator specification
	Pharmacological Group	Antispasmodic
	Shelf life	24Months
	Demanded Price	Decontrolled
	Pack size	20ml, 50ml, 100ml

	International availability	Spain
	Me-too status	N/A
	Stability studies	Firm has submitted long term (24 months) at 30ºC 65% RH & accelerated (06 months) stability data at 40ºC, 75% RH for three batches. (50ml, 100ml)
	Detail of certificates attached	Legalized GMP No. ES/073HV/17 date of inspection 16/02/2017 valid for three year from date of inspection. Legalized FSC dated 30th June 2017. Sole agency agreement between manufacturer M/s Super's Diana S.L CTRA C. 17, km 17, 08150 Parets Del Valles, (Barcelona), Spain and Importer M/s Huzaifa international commercial area, aziz Bhatti town, Sargodha, Pakistan
	Remarks of the Evaluator.	
	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. Moreover, registration status of metamizole shall also be verified as generic product.	

Evaluator PEC-I

Case 02. New DML/ New Sections

a) New Cases: -

Liquid Ampule Section 10 Molecules 12 Products		
1111.	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	Artemed 80mg Injection
	Composition	Each ml Ampoule Contains: Artemether……..80mg
	Diary No. Date of R&I &fee	Dy. No. 17139 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antimalarial
	Type of Form	Form – 5
	Finished product Specification	IP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	WHO approved formulation.
	Me-too status	PALUTHER INJECTION 80MG imported by Rhone. Reg. No.14938
	GMP status	The firm last inspected on 18-10-2018 Panel recommends Grant of Additional sections and cGMP certificate.
	Remarks of the Evaluator	
	Decision: Approved. The earlier registration (Reg. 061012) of firm's product shall stand cancelled due to none extension of contract manufacturing	
1112.	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	Margiv 50mg/ml Injection
	Composition	Each ml Ampoule contains: Dimenhydrinate……..50mg
	Diary No. Date of R&I &fee	Dy. No. 171175 dated 07-03-2019 Rs.20,000/- Dated 08-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form – 5
	Finished product Specification	USP

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Dimenhydrinate Injection of Fresenius Kabi, USFDA Approved.
	Me-too status	Corinate 50mg/ml Inj. of Asian continental (Reg#057863).
	GMP status	The firm last inspected on 18-10-2018 Panel recommends Grant of Additional sections and cGMP certificate.
	Remarks of the Evaluator	
	Decision: Approved	
1113.	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	Mecoman 500mcg /ml Injection
	Composition	Each ml Ampoule Contains: Mecobalamin…….500mcg
	Diary No. Date of R&I &fee	Dy. No. 8468 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Anti-Anemia
	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 authority	PMDA approved
	Me-too status	Methycobal Injection 500mcg/ml M/s Macter International Pvt. Ltd.
	GMP status	The firm last inspected on 18-10-2018 Panel recommends Grant of Additional sections and cGMP certificate.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification. The earlier registration (Reg. 061016) of firm's product shall stand cancelled due to none extension of contract manufacturing	
1114.	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	Water for Injection 5 ml Ampoule
	Composition	Each ampoule contains Distilled Water for Injection……5ml
	Diary No. Date of R&I &fee	Dy. No. 8460 dated 26.02.2019 Rs.20,000/- Dated 19-02-2019
	Pharmacological Group	N/A
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Sterile water for injection by M/s Pfizer Limited, (MHRA approved).
	Me-too status	Water For Injection M/s Otsuka (Pvt.) Ltd.
	GMP status	The firm last inspected on 18-10-2018 Panel recommends Grant of Additional sections and cGMP certificate.
	Remarks of the Evaluator	Duplicate dossier with photocopy challan.
	Decision: Approved. fee shall be verified as per procedure adopted by Registration Board in 285th meeting	
1115.	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	Water for Injection 10 ml Ampoule
	Composition	Each ampoule contains Distilled Water for Injection ……10ml
	Diary No. Date of R&I &fee	Dy. No. 17140 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019

	Pharmacological Group	Diluent
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Sterile water for injection by M/s Pfizer Limited, (MHRA approved).
	Me-too status	Water For Injection M/s Otsuka (Pvt.) Ltd.
	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	
1116.	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	Metramol 50mg Injection
	Composition	Each ml Ampoule Contains: Tramadol Hcl……50mg
	Diary No. Date of R&I &fee	Dy. No. 17164 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Opoid Analgesic
	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 authority	Tramadol 50 mg/ml solution for injection (MHRA Approved).
	Me-too status	Mictra Injection of M/s Bosch Pharma.
	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 with innovator's specification	
1117.	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	Mark-D3 Injection
	Composition	Each ml ampoule contains: Cholecalciferol ……..5mg
	Diary No. Date of R&I &fee	Dy. No. 17142 dated 07-03-2019 Rs.20,000/- Dated 05-03-2019
	Pharmacological Group	Analogue of Vitamin D
	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 authority	Vitamin D3 Good (ANSM).
	Me-too status	Genvit-D 5mg Injection (Reg. 61284).
	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 GMP certificate.
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification	
1118.	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	Iron-Fer 100mg /5ml Injection
	Composition	Each 5 ml Ampoule contains: Iron Sucrose…….100mg

	Diary No. Date of R&I &fee	Dy. No. 17171 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Antianemic
	Type of Form	Form – 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Venofer Injection by Vifor (MHRA Approved).
	Me-too status	Hemofer Injection I.V by M/s Barrett Hodgson Reg. No. 30955
	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. The earlier registration (Reg. 061014) of firm's product shall stand cancelled due to none extension of contract manufacturing	
1119.	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	Vita-Mark Injection 1000mcg/ml
	Composition	Each ml Ampule contains:- Vitamin B-12…….1000mcg
	Diary No. Date of R&I &fee	Dy. No. 17149 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Vitamins
	Type of Form	Form5
	Finished product Specification	USP
	Pack size & Demanded Price	01x10'S. As per SRO
	Approval status of product in Reference regulatory authority	Cyanocobalamin Injection by West-Ward Pharms Int. (USFDA).
	Me-too status	AKTIS injection by EPOCH PHARMA.
	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	
1120.	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	Vita-Comp Injection 3ml/Ampule
	Composition	Each 3ml Ampoule Contains: Vitmain B1 (Thiamine Hydrochloride)……..100mg Vitamin B6 (Pyridoxine Hydrochloride)……100mg Vitamin B12 (Cyanocobalamin)…….1000mcg
	Diary No. Date of R&I &fee	Dy. No. 17170 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Vitamin B compound.
	Type of Form	Form5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	01x25's. As per SRO
	Approval status of product in Reference regulatory authority	Neurobion solution for Injection 3ml by M/s Merck Selbstmedikation GmbH (Germany Approved).
	Me-too status	Neurolina Injection 3ml by M/s Alina Combine (Reg#076143).
	GMP status	The 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 with innovator's specification	
1121.	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	Xylomark 1% Injection
	Composition	Each ml Ampoule Contains Lidocaine Hydrochloride……..10mg
	Diary No. Date of R&I &fee	Dy. No. 17174 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Local Anesthetic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Lidocaine Hydrochloride solution for Injection 1% w/v of M/s Accord Health Care, UK (MHRA Approved).
	Me-too status	Anacaine 2% Injection of M/s Akson Pharma.
	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	Firm submitted incorrect formulation, firm has been asked to submit formulation as per reference product.
	Decision: Deferred for submission of formulation as per reference product along with fee.	
1122.	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	Xylomark 2% Injection
	Composition	Each ml Ampoule Contains Lidocaine Hydrochloride……..20mg
	Diary No. Date of R&I &fee	Dy. No. 17160 dated 07-03-2019 Rs.20,000/- Dated 06-03-2019
	Pharmacological Group	Local Anesthetic
	Type of Form	Form 5
	Finished product Specification	BP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Lidocaine Injection 2% w/v (MHRA approved).
	Me-too status	Lacain 2% Injection of M/s. Pulse 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	Firm submitted incorrect formulation, firm has been asked to submit formulation as per reference product.
	Decision: Deferred for submission of formulation as per reference product along with fee.	

Case 03. Import (Human)

1123.	**Name and address of Applicant**	McPharm International (Pvt) Ltd. 219-A, Lalazar Commercial Market, Raiwand Road, Lahore, Pakistan.
	Detail of Drug Sale License	Address: McPharm International (Pvt) Ltd. 219-A, Lalazar Commercial Market, Raiwand Road, Lahore, Pakistan. Validity: 23-12-2017 to 20-02-2020 Status: Drug License to sell drugs as distributor
	Name and address of manufacturer	Haupt pharma Munster Gmbh Schleebruggenkamp 1548159 Munster, Germany.
	Name and address of marketing authorization holder	Denk Pharma GmbH & Co. KG. Prinzregentenstr. 79 81675 Munchen, Germany.

	Name of exporting country	Germany
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No 35871 Dated 29-10-2018
	Fee including differential fee	Rs. 100,000/- Dated 29-10-2018
	Brand Name +Dosage Form + Strength	Letro-Denk 2.5mg Tablet
	Composition	Each film coated tablet Contains: Letrozole ……2.5mg
	Finished Product Specification	Manufacturer specifications
	Pharmacological Group	Aromatase inhibitor
	Shelf life	36 months: Store below 30°C.
	Pack size & Demanded Price	3x10's, As per SRO
	International availability	Letrozole 2.5mg Filmbletten, Germany.
	Me-too status	
	Stability studies	Firm has submitted long term (36 months) at 30°C,75± 5% & accelerated (06 months) stability data at 40°C±2, 75± 5% RH for three batches.
	Detail of certificates attached	Firm has submitted: certified copy of GMP certificate with original stamp and seal by Pakistan Embassy. Copy of Pakistan Embassy attested COPP and Manufacturer's Authorisation confirms free sale of product in exporting country and GMP of the manufacturer.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specification	

Evaluator PEC-XIII

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

a. New cases

1124.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Rispe tablet 1mg
	Composition	Each film-coated tablet contains:- Risperidone ……...……..1mg
	Diary No. Date of R& I & fee	Dy.No.19404;28-05-2018;Rs.20,000(28-05-2018)
	Pharmacological Group	Anti- psychotic
	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	MHRA Approved
	Me-too status	Risperin Tablet of M/s Hansel Pharmaceuticals (Reg. # 041346)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1125.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Rispe tablet 2mg
	Composition	Each film-coated tablet contains:- Risperidone ……...……..2mg
	Diary No. Date of R& I & fee	Dy.No.19412;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	Anti-psychotic
	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	MHRA Approved
	Me-too status	Risperin Tablet of M/s Hansel Pharmaceuticals (Reg. # 041347)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	Tablet section (General) is available in the firm as mentioned in the submitted 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1126.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Rispe tablet 3mg
	Composition	Each film-coated tablet contains:- Risperidone ……...……..3mg
	Diary No. Date of R& I & fee	Dy.No.19411;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	Anti-psychotic
	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	MHRA Approved
	Me-too status	Risperin Tablet of M/s Hansel Pharmaceuticals (Reg. # 041348)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1127.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Benpride tablet 50mg
	Composition	Each film-coated tablet contains:- Itopride Hydrochloride ……....50mg
	Diary No. Date of R& I & fee	Dy.No.19403;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	Propulsive/ Drugs for GIT disorders
	Type of Form	Form- 5
	Finished product Specification	Innovator's
	Pack size & Demanded Price	10's, 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	Ganaton Tablets 50mg of M/s Abbott Laboratories (Reg. # 028429)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1128.	Name and address of manufacturer / Applicant	M/s Benson Pharmaceuticals, Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Paradol 37.5mg/ 325mg Tablets
	Composition	Each film-coated tablet contains:- Tramadol Hydrochloride…….37.5mg Acetaminophen…….325mg
	Diary No. Date of R& I & fee	Dy.No.19406;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	NSAIDS
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Tramadoln Plus Tablet 37.5/ 325mg of M/s Akson Pharma (Reg. # 085459)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as

		mentioned in the submitted 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1129.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals Plot 3 Phase I-II, Block A, Industrial Estate, Hattar, KPK. Contract Manufacturer M/s Winbrains Research Laboratories, Plot # 69, Block B, Phase I- II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Drimolol Ophthalmic Drops 2% / 0.5%
	Composition	Each ml contains: Dorzolamide as Hydrochloride……..20mg Timolol as Maleate……...……..5mg
	Diary No. Date of R& I & fee	Dy.No.19400;28-05-2018; Rs.50,000 (25-05-2018)
	Pharmacological Group	Anti- glaucoma drugs
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Cosopt Ophthalmic Solution of M/s Muller & Phipps (Reg. # 025294)
	GMP status	Welwrd: Last GMP inspection was conducted on 07-05-2019 with satisfactory GMP compliance. M/s Winbrains: Last GMP inspection was conducted on 20-05-2019 on the basis of which GMP certificate has been granted.
	Remarks of the Evaluator [XIII]	• Applicants' firm has 08 approved sections and 02 approved drugs on contract basis. • M/s Winbrains has General Eye Drop section as is mentioned in the submitted GMP certificate.
	Decision: Approved	
1130.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals Plot 3 Phase I-II, Block A, Industrial Estate, Hattar, KPK. Contract Manufacturer M/s Winbrains Research Laboratories, Plot # 69, Block B, Phase I- II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Floxrin 5mg Eye Drops
	Composition	Each ml contains: Moxifloxacin as HCl…..……..5 mg
	Diary No. Date of R& I & fee	Dy.No.26338; 28-12-2017; Rs.50,000 (12-12-2017)
	Pharmacological Group	Antibiotic/ Floroquinolones
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's x 5ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Moxivig Eye Drops by MHRA UK
	Me-too status	Selmoxi Eye drops by Aulton Pharmaceuticals (Reg #

		080565)
	GMP status	Welwrd: Last GMP inspection was conducted on 07-05-2019 with satisfactory GMP compliance. M/s Winbrains: Last GMP inspection was conducted on 20-05-2019 on the basis of which GMP certificate has been granted.
	Remarks of the Evaluator [XIII]	• Applicants' firm has 08 approved sections and 02 approved drugs on contract basis. • M/s Winbrains has General Eye Drop section as is mentioned in the submitted GMP certificate.
	Decision: Approved	
1131.	Name and address of manufacturer / Applicant	M/s Welwrd Pharmaceuticals Plot 3 Phase I-II, Block A, Industrial Estate, Hattar, KPK. Contract Manufacturer M/s Winbrains Research Laboratories, Plot # 69, Block B, Phase I- II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Nepawin Eye drops (Solution)
	Composition	Each ml of solution contains: Nepafenac……..…1mg
	Diary No. Date of R& I & fee	Dy.No.26339;28-12-2017; Rs.50,000 (12-12-2017)
	Pharmacological Group	Anti-inflammatory
	Type of Form	Form- 5
	Finished product Specification	Innovator's specs
	Pack size & Demanded Price	1's x 5ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA and MHRA as ophthalmic suspension
	Me-too status	Fenap Eye Drops of M/s Valor Pharma (Reg. # 072978)
	GMP status	M/s Welwrd: Last GMP inspection was conducted on 07-05-2019 with satisfactory GMP compliance. M/s Winbrains: Last GMP inspection was conducted on 20-05-2019 on the basis of which GMP certificate has been granted.
	Remarks of the Evaluator [XIII]	• Applicants' firm has 08 approved sections and 02 approved drugs on contract basis. • M/s Winbrains has General Eye Drop section as is mentioned in the submitted GMP certificate. • The formulation has been applied as ophthalmic solution while is approved in USFDA and MHRA as ophthalmic suspension.
	Decision: Deferred as the formulation has been applied as ophthalmic "solution" while is approved in USFDA and MHRA as ophthalmic "suspension".	
1132.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals (Pvt.) Ltd, Plot No. 16/1, Phase-IV, Industrial Estate Hattar, KPK.
	Brand Name +Dosage Form + Strength	Telmizide tablets 40mg/12.5mg
	Composition	Each tablet contains: - Telmisartan ……40mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy.No.19148;25-05-2015; Rs.20,000 (24-05-2018)
	Pharmacological Group	Angiotensin II Antagonists/ Diuretic (Antihypertensive)
	Type of Form	Form- 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO

	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Telzimed Tablet 40mg/ 12.5mg of M/s Mediate Pharma (Reg. # 073592)
	GMP status	Last GMP inspection was conducted on 12-05-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Deferred for following reasons: • **The formulation is applied as uncoated tablet only while in the reference regulatory authorities, it is approved as uncoated and bi- layered tablet both.** • **Evidence of manufacturing facility of bilayered tablet.**	
1133.	Name and address of manufacturer / Applicant	M/s Genome Pharmaceuticals (Pvt.) Ltd, Plot No. 16/1, Phase-IV, Industrial Estate Hattar, KPK.
	Brand Name +Dosage Form + Strength	Telmizide tablets 80mg/12.5mg
	Composition	Each tablet contains: - Telmisartan ……80mg Hydrochlorothiazide……12.5mg
	Diary No. Date of R& I & fee	Dy.No.19149;25-05-2015; Rs.20,000 (24-05-2018)
	Pharmacological Group	Angiotensin II Antagonists/ Diuretic (Antihypertensive)
	Type of Form	Form- 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Co-TelBar 80mg/12.5mg Tablet Barrett Hodgson (Reg. # 081191)
	GMP status	Last GMP inspection was conducted on 12-05-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Deferred for following reasons: • **The formulation is applied as uncoated tablet only while in the reference regulatory authorities, it is approved as uncoated and bi- layered tablet both.** • **Evidence of manufacturing facility of bilayered tablet.**	
1134.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Myrex tablet 200mg
	Composition	Each film-coated tablet contains: Rifaximin ……....200mg
	Diary No. Date of R& I & fee	Dy.No.19172; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rixabac 200mg tablet of M/s Pharmevo (Reg.# 076260)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• The official monograph of the applied formulation is not available in USP and BP.
	Decision: Approved as per innovators' specifications.	

1135.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Myrex tablet 550mg
	Composition	Each film-coated tablet contains: Rifaximin ……..…..550mg
	Diary No. Date of R& I & fee	Dy.No.19173; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rixabac 550mg tablet of M/s Pharmevo (Reg.# 076259)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• The official monograph of the applied formulation is not available in USP and BP.
	Decision: Approved as per innovators' specifications.	
1136.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Flomax tablet 400mg
	Composition	Each film- coated tablet contains: Moxifloxacin as HCl…….400mg
	Diary No. Date of R& I & fee	Dy.No.19166; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Fluoro- quinolones
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 5's & as per DRAP policy
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Mozter 400mg tablet of M/s Jupiter Pharma (Reg. # 081920)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1137.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Mecol tablet 500 mcg
	Composition	Each film-coated tablet contains: Mecobalamin ……..…500mcg
	Diary No. Date of R& I & fee	Dy.No.19144; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Vitamin B-12 (Anti- Anaemic)
	Type of Form	Form 5
	Finished product Specification	Japanese Pharmacopoeia
	Pack size & Demanded Price	20's tablets & as per S.R.O
	Approval status of product in Reference Regulatory Authorities	Approved in PMDA Japan as sugar- coated tablet

	Me-too status	Heam 500 mcg Tablet of M/s Linear Pharma (Reg. # 081876)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• Approved in PMDA Japan as **sugar- coated** tablet**.**
	Decision: Deferred as the applied formulation is film-coated tablet while it is approved in PMDA Japan as sugar- coated tablet.	
1138.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Lorix tablet 4mg
	Composition	Each film- coated tablet contains: Lornoxicam ……4mg
	Diary No. Date of R& I & fee	Dy.No.19168; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5's, 10's tablets & 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	Nicam Tablets of M/s S.J & G Fazul Ellahie (Pvt.) Ltd,(Reg. # 061603)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1139.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Lorix tablet 8mg
	Composition	Each film- coated tablet contains: Lornoxicam ……8mg
	Diary No. Date of R& I & fee	Dy.No.19169; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Anti- inflammatory
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5's, 10's tablets & as per SRO
	Approval status of product in Reference Regulatory Authorities	Xefo 8mg tablet (Swiss Medic approved)
	Me-too status	Atcam 8mg tablet of M/s Atco (Reg. # 073723)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1140.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Ebazit tablet 10mg
	Composition	Each film-coated tablet contains: Ebastine ……..……10mg
	Diary No. Date of R& I & fee	Dy.No.19170; 25-05-2018;Rs.20,000 (25-05-2018)
	Pharmacological Group	Anti- histamine

	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's tablets & as per SRO
	Approval status of product in Reference Regulatory Authorities	ANSM Approved
	Me-too status	Bestec Tablet of M/s Shrooq Pharma (Reg. # 068173)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in Japanese Pharmacopoeia.
	Decision: Approved as per innovators' specifications.	
1141.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Ebazit tablet 20mg
	Composition	Each film-coated tablet contains: Ebastine …….....….20mg
	Diary No. Date of R& I & fee	Dy.No.19171; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Anti- histamine
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's tablets & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in France (ANSM)
	Me-too status	Bestec tablet of M/s Shrooq Pharma (Reg. # 068174)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in Japanese Pharmacopoeia.
	Decision: Approved as per innovators' specifications.	
1142.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Mutrol tablet 20mg
	Composition	Each tablet contains: Bambuterol Hydrochloride …….. 20 mg
	Diary No. Date of R& I & fee	Dy.No.19165; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Long-Acting β- Adrenoceptor Agonist (Drugs used for Obstructive Airway diseases)
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30's tablets & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Pulmitac Tablet of M/s Platinum Pharma (Reg. # 024447)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator [XIII]	• No USP, BP, IP or JP monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	

1143.	Name and address of manufacturer/ Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand name + Dosage Form+ Strength	Lacomide tablet 150mg
	Composition	Each film-coated tablet contains: Lacosamide…….150mg
	Diary No. Date of R & I & fee	Dy.No.19167; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Anticonvulsant
	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	MHRA Approved
	Me-too Status	Lacolep 150mg Tablet of M/s Hilton Pharma (Pvt.) Ltd., (Reg. # 073859)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator	• No official monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1144.	Name and address of manufacturer/ Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand name + Dosage Form+ Strength	Valsart tablet 40mg
	Composition	Each film-coated tablet contains:- Valsartan……..…..40mg
	Diary No. Date of R & I & fee	Dy.No.19174; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Angiotensin-II receptor Antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's tablets & as per SRO
	Approval status of product in Reference regulatory authorities	MHRA Approved
	Me-too Status	Diovan 40mg tablet of M/s Novartis Pharmaceuticals Pakistan Ltd. (Reg. # 080718)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator	
	Decision: Approved	
1145.	Name and address of manufacturer/ Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand name + Dosage Form+ Strength	Valsart tablet 80mg
	Composition	Each film-coated tablet contains:- Valsartan……..…..80mg
	Diary No. Date of R & I & fee	Dy.No.19175; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Angiotensin-II receptor Antagonist
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	14's, 28's tablets & as per SRO
	Approval status of product in Reference regulatory authorities	MHRA Approved
	Me-too Status	Diovan 80mg tablet of M/s Novartis Pharmaceuticals Pakistan Ltd. (Reg. # 027346)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the

		report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator	
	Decision: Approved	
1146.	Name and address of manufacturer/ Applicant	M/s Cunningham Pharma Pvt. Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore.
	Brand name + Dosage Form+ Strength	Valsart tablet 160 mg
	Composition	Each film-coated tablet contains:- Valsartan……..160mg
	Diary No. Date of R & I & fee	Dy.No.19176; 25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Angiotensin- II Antagonists
	Type of Form	Form-5
	Finished Product Specification	U.S.P.
	Pack size & Demanded Price	14's, 28's & As per SRO
	Approval status of product in Reference regulatory authorities	MHRA Approved
	Me-too Status	Diovan 160mg tablet of M/s Novartis Pharmaceuticals Pakistan Ltd. (Reg. # 027347)
	GMP status	Last GMP inspection was conducted on 12-03-2018 and the report concludes good GMP compliance. Firm was issued GMP certificate on the same date mentioned above.
	Remarks of the Evaluator	
	Decision: Approved	
1147.	Name and address of manufacturer / Applicant	M/s Linz Pharmaceuticals Pvt. Ltd., Plot No. 31-G & 31-H, Sector 15, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Qzon 2g Injection I/V
	Composition	Each vial contains: Ceftriaxone as Sodium…….2gm
	Diary No. Date of R& I & fee	Dy. No.7835; 01-03-2018;Rs.20,000/-(01-03-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	1 vial & as per PRC
	Approval status of product in Reference Regulatory Authorities	Rocephin 2g powder for Injection of M/s Roche Products Limited (MHRA Approved)
	Me-too status	Cefxone 2 gm Injection of M/s Bosch Pharma (Reg. # 055913)
	GMP status	Last GMP inspection was conducted on 21-09-2017 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has Dry powder for injectable Sterile (Cephalosporin) section as mentioned in the submitted inspection report.
	Decision: Approved	
1148.	Name and address of manufacturer / Applicant	M/s Nabiqasim Industries Pvt. Limited, 17/ 24 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lijenta tablet 5mg
	Composition	Each film- coated tablet contains: Linagliptin ……..5mg
	Diary No. Date of R& I & fee	Dy.No.15977;30-04-2018;Rs.20,000 (30-04-2018)
	Pharmacological Group	Dipeptidyl Peptidase- 4 Inhibitor (Anti- diabetic)
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	10's, 30's & as per PRC
	Approval status of product in Reference	MHRA Approved

	Regulatory Authorities	
	Me-too status	Trajenta tablet 5mg of M/s AGP Pvt. Limited, (Reg. # 078139)
	GMP status	Last inspection dated 02-08-2018 concluding acceptable level of **GMP** compliance.
	Remarks of the Evaluator [XIII]	• Firm has Tablet section as mentioned in the submitted inspection report. • Registration Board in its **289**th DRB meeting decided to refer the case to the Legal affairs Division on the issue of its **patent** rights. • No USP or BP monograph is available for the applied formulation.
	Decision: Deferred as the case has been forwarded to Legal Affairs Division for its patent rights.	
1149.	Name and address of manufacturer / Applicant	M/s Life Pharmaceutical Company, 24 III, Industrial Estate, Multan
	Brand Name +Dosage Form + Strength	Tanzen DS tablet 10mg
	Composition	Each enteric- coated tablet contains: Serratiopeptidase ……...10mg (20, 000 units)
	Diary No. Date of R& I & fee	Dy.No.9823;24-07-2017; Rs.20,000/- (21-07-2017)
	Pharmacological Group	Proteolytic enzyme
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	10's, 20's, 100's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Swelgo uncoated tablet 10mg of M/s Century Pharmaceutical (Reg. # 022607)
	GMP status	Last GMP inspection was conducted on 15-01-2018 with follow up status.
	Remarks of the Evaluator [XIII]	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting. • Me- too status of enteric- coated tablet could not be confirmed. • Molecule is under review. • GMP report needs to be submitted as compliance status could not be confirmed. • According to 245th meeting, Serratio-peptidase is a proteolytic enzyme present in silkworm gut which helps it to dissolve the cocoon. It has been used as an anti-inflammatory agent without any scientific evidence of efficacy. Takeda Pharmaceuticals, the brand leader Japanese company, had agreed for voluntary withdrawal from market in 2011. Not recommended for registration. • No USP or BP monograph is available for the applied formulation. • Section approval letter needs to be submitted. • Firm was issued first reminder letter on 29th January, 2019 and second reminder on 19th July, 2019 but still no response by the firm has been received yet.
	Decision: Deferred due to following reasons: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies**	

	which were declared/approved by the Registration Board in its 275th meeting. • **Me- too status of enteric- coated tablet could not be confirmed.** • **Molecule is under review.** • **GMP report needs to be submitted as compliance status could not be confirmed.** • **According to 245th meeting, Serratio-peptidase is a proteolytic enzyme present in silkworm gut which helps it to dissolve the cocoon. It has been used as an anti-inflammatory agent without any scientific evidence of efficacy. Takeda Pharmaceuticals, the brand leader Japanese company, had agreed for voluntary withdrawal from market in 2011. Not recommended for registration.** • **No USP or BP monograph is available for the applied formulation.** • **Section approval letter needs to be submitted.**	
1150.	Name and address of manufacturer / Applicant	M/s Biolabs (Pvt.) Limited, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Doxin tablet 2mg
	Composition	Each tablet contains: Doxazosin as Mesylate……..……...2mg
	Diary No. Date of R& I & fee	Dy.No.1634;16-02-2017; Rs.20,000 (15-02-2017)
	Pharmacological Group	Alpha- adrenorecpetor Antagonist
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & As recommended by PRC (MOH)
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Cardura tablet 2mg of M/s Pfizer (Reg. # 011743)
	GMP status	Last GMP inspection was conducted on 23-04-2019 and the report concludes a **reasonably acceptable** GMP compliance.
	Remarks of the Evaluator [XIII]	According to the latest submitted GMP inspection report, the firm was advised to: i. Remove gaps in the door and maintenance of cleaning in the area. ii. Purchase SS seamless single piece scoops to facilitate easy cleaning in RMS of Human (General). iii. Do correction of doors, improvement in change room and installation of insect cutter etc. iv. Purchase more primary reference standards along with cabinet from reliable source and more stability chambers to meet the huge volume of production. v. QA inspectors/ Officers were advised to remain more vigilant. They were also advised to adopt different color schemes of uniform for different sections. vi. Devise a validation plan for validation of all critical steps/ procedures. vii. Develop more stringent steps for complaints. viii. Increase the frequency of training on ICH, WHO and PICs.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1151.	Name and address of manufacturer / Applicant	M/s Fozan Pharmaceutical Industrial (Pvt) Ltd. 36-A Industrial Estate, Hayatabad, Peshawar Contract Manufacturer: M/s Weatherfolds Pharmaceuticals, 69/3, Phase II, Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Welgest 10mg tablet
	Composition	Each film- coated tablet contains: Dydrogesterone ……..…...10mg

	Diary No. Date of R& I & fee	Dy.No.841;05-01-2018; Rs.50,000/- (02-01-2018)
	Pharmacological Group	Progestogen
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Duphaston 10 mg film-coated tablets of M/s Mylan IRE**,** Healthcare Limited (Ireland Approved)
	Me-too status	Danilon 10mg Tablet of M/s Sami, Kar (Reg. # 076057)
	GMP status	Fozan: Last GMP inspection was conducted on 25-05-2018 and the report concludes satisfactory GMP compliance. Weatherfolds: Last GMP inspection was conducted on 20-02-2019 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• No. of drugs on contract basis are 06 products and 07 sections are available in the applicant's firm. • General tablet section is available in the manufacturer's firm as mentioned in the GMP inspection report.
	Decision: Approved	
1152.	Name and address of manufacturer / Applicant	M/s Zaynoon Pharmaceuticals Pvt. Limited, 27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Pizotifen + B- Complex Syrup
	Composition	Each 10ml contains: Pizotifen as Hydrogen Malate……0.5mg Thiamin HCl (Vit B-1)……..…1.75mg Riboflavin-5 as Phosphate (Vit B-2)……2.62mg Pyridoxine HCl (Vit B-6)……..…1.54mg Nicotinamide (Vit B-3)……..……10.50mg
	Diary No. Date of R& I & fee	Dy. No 854; 05-01-2018; Rs.20,000/- (05-01-2018)
	Pharmacological Group	Anti- migraine/ nutrient/ Supplement
	Type of Form	Form-5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	60ml , 120ml & Rs. 70/- , Rs. 120/-
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has relevant section i.e. "Oral liquid" as mentioned in the submitted GMP report. • Different **overages** have been applied. • Specifications are not claimed. • International availability could **not** be confirmed. • Me- too status could **not** be confirmed**.** • Letter was issued to the firm against its shortcoming on 6th **March**, 2019 and a reminder on 19th **July**, 2019 but still **no reply** has been received by the firm yet.
	Decision: Deferred for following reasons: • **Different overages have been applied.** • **Finished product specification to be submitted in the light of decision taken by the Registration Board in its 267th meeting.** • **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.	
1153.	Name and address of manufacturer / Applicant	M/s Zaynoon Pharmaceuticals Pvt. Limited, 27/28-B, Industrial Estate, Hayatabad, Peshawar, Pakistan
	Brand Name +Dosage Form + Strength	Zayfed-P Syrup (1.25mg+ 30mg+ 80mg/ 5ml)
	Composition	Each 5ml contains: Triprolidine ……..……..1.25mg Pseudoephedrine……..……..30mg Paracetamol ……..……..…..80mg
	Diary No. Date of R& I & fee	Dy. No 857; 05-01-2018; Rs.20,000/- (05-01-2018)
	Pharmacological Group	Decongestant and Anti- histamine
	Type of Form	Form-5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	60ml; 120ml & Rs. 40/-; Rs. 75/-
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 03-08-2017 and the report concludes satisfactory GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has Oral liquid section as mentioned in the GMP inspection report. • International availability could not be confirmed. • Me- too status could not be confirmed. • Specifications are not claimed. • Letter was issued to the firm against its shortcoming on 6th March, 2019 and a reminder on 19th July, 2019 but still no reply has been received by the firm yet.
	Decision: Deferred for following reasons: • **Finished product specification to be submitted in the light of decision taken by the Registration Board in its 267th meeting.** • **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.**	
1154.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt. Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Moxilone Eye Drops 5mg/ ml
	Composition	Each ml of solution contains: Moxifloxacin ……..5mg
	Diary No. Date of R& I & fee	Dy.No.19146;25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & as per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Moxivig 0.5% w/v Eye Drops, Solution of M/s Novartis Pharmaceuticals, UK Limited (MHRA Approved)
	Me-too status	Eyemox Eye Drops 0.5%. of M/s Vega Pharma (Reg. # **045929)**
	GMP status	Last GMP inspection was conducted on 09-102018 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 for the applied formulation is

		available in USP.
	Decision: Approved with USP specifications.	
1155.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Hydrowin Eye Drops 3mg/ ml
	Composition	Each ml of ophthalmic solution contains: Hydroxy propyl methyl cellulose….3mg
	Diary No. Date of R& I & fee	Dy.No.19145;25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Anti- allergic
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	As per SRO & as per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Softeal of M/s Sante Pvt. Limited (Reg. # 075812)
	GMP status	Last GMP inspection was conducted on 09-102018 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 international availability of the applied formulation could not be confirmed. • The applied formulation is non- pharmacopoeial.
	Decision: Deferred for following reasons: • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/ approved by the Registration Board in its 275th meeting.** • **Confirmation whether it is applied as a lubricant or as a medical device.**	
1156.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt. Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Winlop Eye Drops 1mg/ ml
	Composition	Each ml of solution contains: Olopatadine as HCl…...1mg
	Diary No. Date of R& I & fee	Dy.No.19147;25-05-2018; Rs.20,000 (25-05-2018)
	Pharmacological Group	Anti- allergic
	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	Olopat Eye Drops 0.1% of M/s Vega Pharma (Reg. # 050252)
	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 for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1157.	Name and address of manufacturer / Applicant	M/s Winthrox Laboratories Pvt. Ltd. K-219/A, S.I.T.E, Super Highway, Phase-II, Karachi, Pakistan.
	Brand Name +Dosage Form + Strength	Winxime capsule 200mg
	Composition	Each capsule contains: Cefixime as Trihydrate……....200mg
	Diary No. Date of R& I & fee	Dy.No.20325;05-06-2018; Rs.20,000 (05-06-2018)

	Pharmacological Group	Cephalosporin
	Type of Form	Form- 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	As per SRO & As per DRAP policy
	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	Cefim 200mg capsule of M/s Hilton Pharma (Reg. # 034664)
	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]	• Cephalosporin capsule section is available in the firm. • The official monograph for the applied formulation is available in JP.
	Decision: Approved with JP specifications.	
1158.	Name and address of manufacturer / Applicant	M/s Getz Pharma (Pvt.) Limited, Korangi Industrial Area, Karachi. Contract Manufacturer: M/s Herbion Pharma, Industrial Triangle, Islamabad.
	Brand Name +Dosage Form + Strength	Fexet Oral Suspension 30mg/ 5ml
	Composition	Each 5ml contains: Fexofenadine HCl…….30mg
	Diary No. Date of R& I & fee	Dy.No.15718;27-04-2018; Rs.50,000 (27-04-2018)
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1'sx 60ml & Rs. 200/-
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Fexofast Oral Suspension 30mg/ 5ml of M/s Platinum Pharma (Reg.# 055703)
	GMP status	M/s Getz: Last GMP inspection was conducted on 07-01-2019 on the basis of which GMP certificate has been granted. M/s Herbion: Last GMP inspection was conducted on 28-03-2019 and the report concludes approval of DML.
	Remarks of the Evaluator [XIII]	• M/s Herbion has General Oral Liquid section as mentioned in the submitted GMP certificate. • Number of already registered products on Contract basis is 18 and approved sections are 08.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1159.	Name and address of manufacturer / Applicant	M/s Cunningham Pharma (Pvt) Limited, Plot # 81 Sunder Industrial Estate Raiwind Road, Lahore
	Brand Name +Dosage Form + Strength	Cefotac Dry Injection 250mg IV or IM
	Composition	Each vial contains: Cefotaxime as Sodium……...250mg
	Diary No. Date of R& I & fee	Dy.No.15767; 27-04-2018; Rs.20,000 (27-04-2018)
	Pharmacological Group	3rd Generation Cephalosporin Antibiotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 8ml Glass vial & as per DRAP policy
	Approval status of product in Reference Regulatory Authorities	Claforan 250mg Injection by M/s Sanofi Aventis (Approved in Netherland)
	Me-too status	Sefotex Injection 250mg (IV/IM) of M/s Advanced Pharma (Reg.# 065363)

	GMP status	Last GMP inspection was conducted on 31-01-2018 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	Firm has Dry powder Injection (Cephalosporin) Section as is mentioned in the submitted section approval letter.
	Decision: Approved	
1160.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar, Haripur
	Brand Name +Dosage Form + Strength	S- Glip tablet 2.5mg
	Composition	Each film-coated tablet contains: Saxagliptin (as Hydrochloride)……..…..2.5mg
	Diary No. Date of R& I & fee	Dy.No.26251;31-07-2018; Rs.20,000 (13-07-2018)
	Pharmacological Group	Anti-diabetic/ DPP- 4 Inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO & as fixed by Govt.
	Approval status of product in Reference Regulatory Authorities	Onglyza 2.5mg film-coated tablet of M/s AstraZeneca, UK Limited (MHRA Approved)
	Me-too status	Saxagen 2.5mg Tablet of M/s Genix Pharma (Reg. # 076644)
	GMP status	Last GMP inspection was conducted on 26-09-2018 and the report concludes of DML.
	Remarks of the Evaluator [XIII]	The applied formulation is non-pharmacopoeial.
	Decision: Registration Board was apprised with reference to EMA Publis assessment report that Saxagliptin is prone to undergo an intra-molecular cyclisation reaction in solution & solid states to form a cyclic amidine. The tablet formulation was developed using active an active coating process to minimize this formation. Saxagliptin was embedded within a film coat of Opadry spray coated onto inert core tablets. During the coating process, Saxagliptin free base is converted in-situ into hydrochloride salt. **Considering the above facts Registration Board deferred the case for clarification to avoid cyclisation process.**	
1161.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar, Haripur
	Brand Name +Dosage Form + Strength	S- Glip tablet 5mg
	Composition	Each film-coated tablet contains: Saxagliptin (as Hydrochloride)……..……..5mg
	Diary No. Date of R& I & fee	Dy.No.26252;31-07-2018; Rs.20,000 (13-07-2018)
	Pharmacological Group	Anti- diabetic/ DPP- 4 Inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO & as fixed by Govt.
	Approval status of product in Reference Regulatory Authorities	Onglyza 5mg film-coated tablet of M/s AstraZeneca, UK Limited (MHRA Approved)
	Me-too status	Saxagen 5mg Tablet of M/s Genix Pharma (Reg. # 076643)
	GMP status	Last GMP inspection was conducted on 26-09-2018 and the report concludes of DML.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Registration Board was apprised with reference to EMA Publis assessment report that Saxagliptin is prone to undergo an intra-molecular cyclisation reaction in solution & solid states to form a cyclic amidine. The tablet formulation was developed using active an active coating process to minimize this formation. Saxagliptin was embedded within a film coat of Opadry spray coated onto inert core tablets. During the coating process, Saxagliptin free base is converted in-situ into hydrochloride salt. **Considering the above facts Registration Board deferred the case for clarification to avoid**	

	cyclisation process.	
1162.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar, Haripur
	Brand Name +Dosage Form + Strength	Fluwel 75mg capsule
	Composition	Each capsule contains: Oseltamivir as Phosphate……..75mg
	Diary No. Date of R& I & fee	Dy.No.26248;31-07-2018; Rs.20,000 (13-07-2018)
	Pharmacological Group	Antiviral
	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	Tamiflu 75mg capsules of M/s Roche (Reg. # 039619)
	GMP status	Last GMP inspection was conducted on 26-09-2018 and the report concludes of DML.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1163.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar, Haripur
	Brand Name +Dosage Form + Strength	Zafir tablet 10mg
	Composition	Each film- coated tablet contains: Zafirlukast……..…10mg
	Diary No. Date of R& I & fee	Dy.No.26249;31-07-2018; Rs.20,000 (13-07-2018)
	Pharmacological Group	Leukotriene Receptor Antagonists
	Type of Form	Form- 5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Zilesta 10mg Tablet of M/s Genix Pharma (Reg. # 055978)
	GMP status	Last GMP inspection was conducted on 26-09-2018 and the report concludes of DML.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1164.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar, Haripur
	Brand Name +Dosage Form + Strength	Zafir tablet 20mg
	Composition	Each film- coated tablet contains: Zafirlukast……..…20mg
	Diary No. Date of R& I & fee	Dy.No.26250;31-07-2018; Rs.20,000 (13-07-2018)
	Pharmacological Group	Leukotriene Receptor Antagonists
	Type of Form	Form- 5
	Finished product Specification	In-house
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Zilesta 20mg Tablet of M/s Genix Pharma (Reg. # 055979)
	GMP status	Last GMP inspection was conducted on 26-09-2018 and the report concludes of DML.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	

1165.	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	Zomix Tablet 5mg
	Composition	Each film-coated tablet contains: Zolmitriptan .....…….....5 mg
	Diary No. Date of R& I & fee	Dy. No 20087;04-06-2018, Rs.20,000 (04-06-2018)
	Pharmacological Group	Selective Serotonin Receptor Agonist
	Type of Form	Form-5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	3's, 5's & 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Zomip Tablets 5mg of M/s Feroza International Pharma (Reg. # 041661)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Approved	
1166.	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	Qufen-K Tablet 50 mg
	Composition	Each film-coated tablet contains: Diclofenac Potassium ….. 50mg
	Diary No. Date of R& I & fee	Dy.No.20069; 04-06-2018, Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	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	MHRA Approved
	Me-too status	Caflam Tablet of M/s Novartis Pharma (Reg.# 021528)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Approved	
1167.	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	Etorix tablet 60 mg
	Composition	Each film-coated tablet contains: Etoricoxib……..... 60mg
	Diary No. Date of R& I & fee	Dy.No.20071; 04-06-2018, Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	7's, 10's, 20's & 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Etoricox 60mg Tablet of M/s Kaizen Pharma (Reg. # 076226)

	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Approved as per innovators' specifications.	
1168.	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	Etorix tablet 120 mg
	Composition	Each film-coated tablet contains: Etoricoxib……..... 120mg
	Diary No. Date of R& I & fee	Dy.No.20072; 04-06-2018, Rs.50,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	7's, 10's, 20's & 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	**Could not be confirmed in the applied strength (60mg is available only)**
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Stability studies data of at least three batches at real and accelerated conditions is required against this strength of applied formulation. • Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.	
1169.	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	Coxibex tablet 100 mg
	Composition	Each tablet contains: Celecoxib .....…….100mg
	Diary No. Date of R& I & fee	Dy.No.20064; 04-06-2018, Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's,20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	**Could not be confirmed**
	Me-too status	Seleco tablet of M/s Wilshire Laboratories (Reg. # 028767)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• International availability for the applied **dosage form** could **not** be confirmed. • No USP or BP monograph is available for the applied formulation. • Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	

1170.	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	Coxibex tablet 200 mg
	Composition	Each tablet contains: Celecoxib .....……200mg
	Diary No. Date of R& I & fee	Dy.No.20067; 04-06-2018, Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's,20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	**Could not be confirmed**
	Me-too status	Seleco tablet of M/s Wilshire Laboratories (Reg. # 031991)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• International availability for the applied **dosage form** could **not** be confirmed. • No USP or BP monograph is available for the applied formulation. • Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1171.	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	Coxibex capsule 100mg
	Composition	Each capsule contains: Celecoxib ….....….100mg
	Diary No. Date of R& I & fee	Dy.No.20065; 04-06-2018, Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's,20's,30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 100mg capsule of M/s Pfizer Limited (MHRA Approved)
	Me-too status	Celexx 100mg Capsule of M/s Getz Pharma (Reg. # 028694)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation. • Firm has General Capsule Section as mentioned in the submitted GMP report.
	Decision: Approved as per innovators' specifications.	
1172.	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	Coxibex capsule 200mg
	Composition	Each capsule contains: Celecoxib ….....….200mg
	Diary No. Date of R& I & fee	Dy.No.20068; 04-06-2018; Rs.20,000 (01-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5

	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's,20's, 30's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Celebrex 200mg capsule of M/s Pfizer Limited (MHRA Approved)
	Me-too status	Celexx 200mg Capsule of M/s Getz Pharma (Reg. # 028693)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation. • Firm has General Capsule Section as mentioned in the submitted GMP report.
	Decision: Approved as per innovators' specifications.	
1173.	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	Swiflo capsule 4mg
	Composition	Each capsule contains: Silodosin ……4mg
	Diary No. Date of R& I & fee	Dy.No.20062; 04-06-2018; Rs.**50,000** (01-06-2018)
	Pharmacological Group	Alpha-1 adrenergic receptor antagonist
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30'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 on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• This molecule requires submission of **stability** studies data on at least three batches at real and accelerated conditions. • The applied formulation is non- pharmacopoeial. • Firm has General Capsule Section as mentioned in the submitted GMP report.
	Decision: Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board.	
1174.	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	Swiflo capsule 8mg
	Composition	Each capsule contains: Silodosin ……8mg
	Diary No. Date of R& I & fee	Dy.No.20070; 04-06-2018; Rs.**20,000** (01-06-2018)
	Pharmacological Group	Alpha-1 adrenergic receptor antagonist
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30'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 on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• This molecule requires submission of stability studies

		data on at least three batches at real and accelerated conditions. • The applied formulation is non- pharmacopoeial. • Differential fees need to be submitted as the applied molecule requires stability. • Firm has General Capsule Section as mentioned in the submitted GMP report.
	Decision: Registration Board deferred the case for submission of real time and accelerated stability study data of 3 batches as per the guidelines provided in 278th meeting of Registration Board. Moreover, differential fees need to be submitted.	
1175.	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	Concor tablet 5mg
	Composition	Each film- coated tablet contains: Bisoprolol Hemifumarate……...…5mg
	Diary No. Date of R& I & fee	Dy.No.20083;04-06-2018;Rs.20,000 (01-06-2018)
	Pharmacological Group	Beta- Blocker
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 28's & As per leader price
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Bisolol 5mg tablet of M/s Paramount Pharma (Reg. # 079558)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator XIII	• Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Approved with change of brand name	
1176.	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	Simitrex tablet 85mg/ 500mg
	Composition	Each film- coated tablet contains: Sumatriptan as Succinate……..…85mg Naproxen Sodium ……..…….500mg
	Diary No. Date of R& I & fee	Dy.No.20591;07-06-2018;Rs.20,000 (07-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2's, 5's, 10's & As per leader price
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Sumtan Plus Tablet of M/s Medisure (Reg. # 075904)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator XIII	• Firm has General Tablet Section as mentioned in the submitted GMP report.
	Decision: Approved as per innovators' specifications.	
1177.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot # 84/1, Block-A, Phase-V, Industrial estate, Hattar, KPK.
	Brand Name +Dosage Form + Strength	Cita 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.17914;15-05-2018; Rs.20,000 (15-05-2018)
	Pharmacological Group	Anti- hyperglycemic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Treviamet tablet 50mg/ 1000mg of M/s Getz Pharma (Reg. # 055444)
	GMP status	Last GMP inspection was conducted on 27-06-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for the applied formulation. • Firm has General tablet section as is mentioned in the submitted GMP report.
	Decision: Approved as per innovators' specifications.	
1178.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot # 84/1, Block-A, Phase-V, Industrial estate, Hattar, KPK.
	Brand Name +Dosage Form + Strength	Chico- Aul capsule 4mg
	Composition	Each capsule contains: Thiocolchicoside ……..…....4mg
	Diary No. Date of R& I & fee	D**y**.No.17915;15-05-2018;Rs.20,000(15-05-2018)
	Pharmacological Group	Skeletal muscle relaxant
	Type of Form	Form- 5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	20's & as per policy of MOH
	Approval status of product in Reference Regulatory Authorities	ANSM Approved
	Me-too status	Ezoside capsule 4mg of M/s Akhai Pharma (Reg. # 070427)
	GMP status	Last GMP inspection was conducted on 27-06-2019 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• No USP or BP monograph is available for applied formulation.
	Decision: Approved	
1179.	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	Cekalone 40mg/ 5ml Syrup
	Composition	Each 5ml contains: Simethicone ……..……..……40 mg
	Diary No. Date of R& I & fee	Dy.No.6462;21-02-2018;Rs.20,000 (19-02-2018)
	Pharmacological Group	Drugs For Functional Gastrointestinal Disorders
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml & 120ml & As per SRO
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed in the applied strength (Available strength is 40mg/ ml)
	Me-too status	Could not be confirmed in the applied strength (Available strength is 40mg/ ml)
	GMP status	Last GMP inspection was conducted on 04-09-2018 and compliance level of the firm was rated as good.

	Remarks of the Evaluator [XIII]	• No official monograph for the applied formulation is available in USP or BP. • Firm has Oral Liquid General Section as mentioned in the submitted GMP inspection report. • Me- too and international status could **not** be confirmed. • A letter was issued to the firm on **10th July, 2019** but still no reply has been received yet.
	Decision: Deferred for following reasons: • **Deferred for evidence of approval of applied formulation in reference regulatory authorities/ agencies which were declared/ approved by the Registration Board in its 275th meeting.** • **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.**	
1180.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Pvt. Ltd, Plot # 44 A & B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Telday Tablet 40 mg
	Composition	Each film- coated tablet contains: - Telmisartan…….40 mg
	Diary No. Date of R& I & fee	Dy.No.18303,18-05-2018, 20,000 (17-05-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 28's & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Telsarta 40 mg Tablet PharmEvo (Pvt.) Ltd., (Reg. # 061912)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1181.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Pvt. Ltd, Plot # 44 A & B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Telday Tablet 80 mg
	Composition	Each film- coated tablet contains: - Telmisartan…….80 mg
	Diary No. Date of R& I & fee	Dy.No.18306,18-05-2018, 20,000 (17-05-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 28's & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Telsartan tablets of M/s CCL Pharmaceuticals, (Pvt) Ltd; (Reg. # 045971)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1182.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Pvt. Ltd, Plot # 44 A & B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Flunext tablet 200mg/ 30 mg
	Composition	Each film-coated tablet contains: -

		Ibuprofen …….200 mg Pseudoephedrine HCl …....30 mg
	Diary No. Date of R& I & fee	Dy.No.18304,18-05-2018, 20,000 (17-05-2018)
	Pharmacological Group	NSAIDs/ Alpha adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Flurect Tablets of M/s Qintar Pharma (Reg. # 036476)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1183.	Name and address of manufacturer / Applicant	M/s Next Pharmaceutical Products Pvt. Ltd, Plot # 44 A & B, Sunder Industrial Estate, Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Flunext tablet 400mg/ 60 mg
	Composition	Each film-coated tablet contains: - Ibuprofen …….400 mg Pseudoephedrine HCl …....60 mg
	Diary No. Date of R& I & fee	Dy.No.18307,18-05-2018, 20,000 (17-05-2018)
	Pharmacological Group	NSAIDs/ Alpha adrenergic agonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's & as per policy of DRAP
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Fedrin Tablets 400mg/ 60 mg of M/s Davis Pharma (Reg.#024360)
	GMP status	Last GMP inspection was conducted on 22-02-2018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1184.	Name and address of manufacturer / Applicant	M/s Axis Pharmaceuticals 3-b, Valve Addition City, 1.5km, Khurrianwala- Sahianwala Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Solifare Tablet 10mg
	Composition	Each film- coated tablet contains: Solifenacin Succinate...…..10mg
	Diary No. Date of R& I & fee	Dy.No.20709; 08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- muscarinic Drug
	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	Approved in MHRA
	Me-too status	Solif-10mg tablets of M/s Global Pharma (Reg. # 066336)
	GMP status	Last GMP inspection was conducted on 03-10-2018 and the report concludes **fair** level of GMP compliance with grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • Firm has General tablet section as mentioned in the

		submitted inspection report.
	Decision: Approved	
1185.	Name and address of manufacturer / Applicant	M/s Axis Pharmaceuticals 3- B, Value Addition City, 1.5km, Khurrianwala- Sahianwala Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Solifare Tablet 5mg
	Composition	Each film- coated tablet contains: Solifenacin Succinate……...5mg
	Diary No. Date of R& I & fee	Dy.No.20707; 08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- muscarinic Drug
	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	Approved in MHRA
	Me-too status	Solif-5mg tablets of M/s Global Pharma (Reg. # 066335)
	GMP status	Last GMP inspection was conducted on 03-10-2018 and the report concludes **fair** level of GMP compliance with grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • Firm has General tablet section as mentioned in the submitted inspection report.
	Decision: Approved	
1186.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt. Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Sevelarnal tablets 400mg
	Composition	Each film-coated tablet contains: Sevelamer HCl……...….400mg
	Diary No. Date of R& I & fee	Dy.No.20077; 04-06-2018; Rs.20,000 (31-05-2018)
	Pharmacological Group	Drugs used in Hyper-kalemia and Hyper-phosphataemia
	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	USFDA Approved
	Me-too status	Sevela 400mg tablet of M/s Hilton Pharma (Reg. # 058394)
	GMP status	Last GMP inspection was conducted on 22-02-2019 and the report concludes: • The management has rectified almost all the observations from previous inspection and as of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. • Management is advised to develop a forward thinking progressive environment, adapting the recent trends.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report. • The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1187.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals, 124/A Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Linzogen tablet 600mg
	Composition	Each film-coated tablet contains: Linezolid ……..600 mg

	Diary No. Date of R& I & fee	Dy.No.20460; 06-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	5's, 6's, 10's, 12's, 14's, 20's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Linez 600mg Tablet of M/s Nexus Pharma (Reg. # 061309)
	GMP status	Last GMP inspection was conducted on 20-04-2018 and the report concludes renewal of DML except for the **tablet psychotropic section.**
	Remarks of the Evaluator [XIII]	The applied formulation is non-pharmacopoeial. The applied formulation is not psychotropic.
	Decision: Approved as per innovators' specifications.	
1188.	**Name and address of manufacturer / Applicant**	M/s Valor Pharmaceuticals, 124/A, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Vorizole Tablet 200mg
	Composition	Each film-coated tablet contains: Voriconazole……200mg
	Diary No. Date of R& I & fee	Dy.No.20463; 06-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Antimycotics for systemic use
	Type of Form	Form- 5
	Finished product Specification	JP specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Vorif tablets of M/s Ferozsons Laboratories (Reg. # 069765)
	GMP status	Last GMP inspection was conducted on 20-04-2018 and the report concludes renewal of DML except for the **tablet psychotropic section.**
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1189.	**Name and address of manufacturer / Applicant**	M/s Valor Pharmaceuticals, 124/A, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Sevelor Tablet 800mg
	Composition	Each film-coated tablet contains: Sevelamer Carbonate……..…800mg
	Diary No. Date of R& I & fee	Dy.No.26086; 30-07-2018;Rs.20,000 (30-07-2018)
	Pharmacological Group	Drugs used in the treatment of hyperkalaemia and hyperphosphataemia
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Sevela 800mg Tablet Hilton Pharma (Reg. # 058395)
	GMP status	Last GMP inspection was conducted on 20-04-2018 and the report concludes renewal of DML except for the **tablet psychotropic section.**
	Remarks of the Evaluator [XIII]	The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	

1190.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Naplis SR 750mg Tablet
	Composition	Each sustained-release tablet contains: Naproxen as Sodium… ……750mg
	Diary No. Date of R& I & fee	Dy.No.20689;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & Rs.100/- per tablet
	Approval status of product in Reference Regulatory Authorities	TGA, Australia Approved
	Me-too status	Dolonap S.R Tablets of M/s Platinum Pharma (Reg.No.029597)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	Firm has General tablet section.
	Decision: Approved	
1191.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Ibuprofen tablet 400mg
	Composition	Each film-coated tablet contains: Ibuprofen…….……400mg
	Diary No. Date of R& I & fee	Dy.No.20690;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	100's, 250's,500's & 30 Rs. per tablet
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Brufen tablet 400mg of M/s Boots Pharma (R.No. 001541)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	• Firm has claimed USP specifications while the official monograph for the applied formulation is available in BP and IP. • Firm has General tablet section.
	Decision: Approved	
1192.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Leviz Tablet 5mg
	Composition	Each film-coated tablet contains: Levocetirizine Dihydrochloride ……..……5mg
	Diary No. Date of R& I & fee	Dy.No.20693;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Antihistamines for systemic use (Piperazine derivatives)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's & Rs. 13/- per tablet
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Belair Tablets of M/s Bayer Pharma (Reg. # 044424)

	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	• Firm has General tablet section.
	Decision: Approved	
1193.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lacosa Tablet 50mg
	Composition	Each film- coated tablet contains: Lacosamide……..…50mg
	Diary No. Date of R& I & fee	Dy.No.20697;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	10's,14's & Rs. 100 per tablet
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Lacosbar 100mg tablet of M/s Barrett Hodgson (Reg. # 083224)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	Firm has General tablet section. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1194.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Flyzol 400mg Tablet
	Composition	Each film-coated tablet contains: Metronidazole ……400mg
	Diary No. Date of R& I & fee	Dy.No.20692;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Imidazole derivatives
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	20's, 100's, 150's, 200's,500's & Rs. 3/- per tablet
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Flagyl 400mg Tablet of M/s Rohne Poulenc Wah (Reg. No.000827)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	Firm has General tablet section.
	Decision: Approved	
1195.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lacosa Tablet 200mg
	Composition	Each film- coated tablet contains: Lacosamide……..…200mg
	Diary No. Date of R& I & fee	Dy.No.20691;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	10's,14's & Rs. 400 per tablet

	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Lacosbar 200mg tablet of M/s Barrett Hodgson (Reg. # 083226)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	Firm has General tablet section. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1196.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lacosa Tablet 100mg
	Composition	Each film- coated tablet contains: Lacosamide……..…100mg
	Diary No. Date of R& I & fee	Dy.No.20696;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form-5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	10's,14's & Rs. 200 per tablet
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Lacosbar 100mg tablet of M/s Barrett Hodgson (Reg. # 083223)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	Firm has General tablet section. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1197.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt. Ltd. 29-30/ 27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Piroxiget Tablet 20mg
	Composition	Each uncoated tablet contains: Piroxicam as Beta Cyclodextrin ……20mg
	Diary No. Date of R& I & fee	Dy.No.26268; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- inflammatory agents, Non- steroids
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	20's & Rs. 400/-
	Approval status of product in Reference Regulatory Authorities	ANSM, France Approved
	Me-too status	Piroxibet 20mg Tablets of M/s Lawari International (Reg. # 054939)
	GMP status	Last GMP inspection was conducted on 26-06-2018 and the report concludes **acceptable** level of GMP compliance.
	Remarks of the Evaluator [XIII]	Firm has General tablet section as mentioned in the submitted section approval letter. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	

1198.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Mirtazapine Tablets 30mg
	Composition	Each film- coated tablet contains: Mirtazapine…….30mg
	Diary No. Date of R& I & fee	Dy.No.20319; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- Depressant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Elaxine 30 mg Tablets of M/s Standpharm (Reg. # 041965)
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1199.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Eflo Cream 13.9%
	Composition	Each gram of tube contains: Eflornithine as HCl Monohydrate...139 mg **(**13.9%**)**
	Diary No. Date of R& I & fee	Dy.No.20586; 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- protozoal
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1's (15g) & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Depilus Cream 13.9% By Atco Laboratories Ltd (Reg. # 073869)
	GMP status	Last GMP inspection was conducted on 24-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	General Ointment/ Cream/ Gel Section is available in the firm as mentioned in the submitted GMP Certificate. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1200.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt. Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Sitevia tablet 25mg
	Composition	Each film-coated tablet contains: Sitagliptin Phosphate eq. to Sitagliptin…..…25mg
	Diary No. Date of R& I & fee	Dy.No.20589; 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Trevia Tablets 25mg of M/s Getz Pharma Pakistan Pvt. Ltd. (Reg. # 055435)
	GMP status	Last GMP inspection was conducted on 24-10-2018 and the report concludes grant of GMP certificate.

	Remarks of the Evaluator [XIII]	General Tablet Section is available in the firm as mentioned in the submitted GMP Certificate.
	Decision: Approved	
1201.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt. Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Sitevia tablet 50mg
	Composition	Each film-coated tablet contains: Sitagliptin Phosphate eq. to Sitagliptin…..…50mg
	Diary No. Date of R& I & fee	Dy.No.20588 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Trevia Tablets 25mg of M/s Getz Pharma Pakistan Pvt. Ltd. (Reg. # 055436)
	GMP status	Last GMP inspection was conducted on 24-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	General Tablet Section is available in the firm as mentioned in the submitted GMP Certificate.
	Decision: Approved	
1202.	Name and address of manufacturer / Applicant	M/s Global Pharmaceuticals Pvt. Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Sitevia tablet 100mg
	Composition	Each film-coated tablet contains: Sitagliptin Phosphate eq. to Sitagliptin…...100mg
	Diary No. Date of R& I & fee	Dy.No.20587; 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Trevia Tablets 100mg of M/s Getz Pharma Pakistan Pvt. Ltd. (Reg. # 055437)
	GMP status	Last GMP inspection was conducted on 24-10-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	General Tablet Section is available in the firm as mentioned in the submitted GMP Certificate.
	Decision: Approved	
1203.	Name and address of manufacturer / Applicant	M/s Well & Well Pharma Pvt. Limited, Plot 7, Street S-8, RCCI, National Industrial Zone, Rawat.
	Brand Name +Dosage Form + Strength	Vorcol Dry Suspension 200mg/ 5ml
	Composition	Each 5ml contains: Voriconazole ……..……...200mg
	Diary No. Date of R& I & fee	Dy.No.19397;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	Anti- fungal
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 75ml after reconstitution & Rs. 1683/-
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Vorif Dry Suspension of M/s Ferozsons Labs (R# 073330)

	GMP status	Last GMP inspection was conducted on 08-02-2018 and the report concludes **fair** level of GMP compliance.
	Remarks of the Evaluator [XIII]	General Dry Powder Suspension section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved	
1204.	Name and address of manufacturer / Applicant	M/s High-Q Pharmaceuticals, B-64, KDA, Scheme No. 1, Main Karsaz Road, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Itoper XR Tablet 150mg
	Composition	Each extended-release tablet contains: Itopride HCl……..……...…..150mg
	Diary No. Date of R & I & fee	Dy. No.20886; 11-06-2018;Rs.20,000 (11-06-2018)
	Pharmacological Group	Propulsive; drugs for GIT disorders
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's & As per leader price
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Ganaton OD Tablet of M/s Abbott Labs (Reg. # 058549)
	GMP status	Last GMP inspection was conducted on10-04-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has General Tablet Section as mentioned in the submitted GMP report. • International availability of the applied formulation could **not** be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1205.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K.
	Brand Name +Dosage Form + Strength	Aultolax 4mg Tablet
	Composition	Each **film- coated** tablet contains: Thiocolchicoside……...4mg
	Diary No. Date of R& I & fee	Dy.No.20318;05-06-2018;Rs.20,000 (05-06-2018)
	Pharmacological Group	Muscle Relaxant
	Type of Form	Form-5
	Finished product Specification	Innovators' specifications
	Pack size & Demanded Price	20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM (France) as uncoated tablet
	Me-too status	Wodnik 4mg tablet of M/s Martin Dow (Reg. # 081138)
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Approved in ANSM (France) as uncoated tablet. • Initially, firm had applied film- coated tablet. • Firm has revised the master formulation and outline of method of manufacture according to the reference with submission of requisite fees i.e. Rs. 5000/.
	Decision: Approved	
1206.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot No. 84/1, Block A, Phase V, Industrial Estate, Hattar, K.P.K
	Brand Name +Dosage Form + Strength	Dopin 10mg Tablet
	Composition	Each film- coated tablet contains: Domperidone……..10mg

	Diary No. Date of R& I & fee	Dy.No.20322; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Propulsives
	Type of Form	Form-5
	Finished product Specification	Innovator's
	Pack size & Demanded Price	50's & as per SRO
	Approval status of product in Reference Regulatory Authorities	TGA, Australia Approved
	Me-too status	Domi Tablets 10mg of M/s Heal Pharma (Reg. # 046130)
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1207.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot No. 84/1; Block A, Phase 5 Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Suxamethonium IV/ IM Injection 100mg
	Composition	Each 2ml contains: Suxamethonium Chloride …….. 100mg
	Diary No. Date of R& I & fee	Dy.No.20320; 05-06-2018; Rs.20,000(05-06-2018)
	Pharmacological Group	Muscle relaxant
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10's x 2ml glass ampoules & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Suxal Injection 100mg/ 2ml of M/s Global Pharma (Reg. # 026629)
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1208.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot No. 84/1; Block A, Phase 5 Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Clomipramine tablet 25mg
	Composition	Each **tablet** contains: Clomipramine HCl……25mg
	Diary No. Date of R& I & fee	Dy.No.20321;05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- Depressant
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved as film- coated
	Me-too status	Clonil Tablets of M/s Schazoo Laboratories (Reg. # 042800)
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• TGA; Australia Approved as **film- coated** while is applied as **uncoated** tablet. • Firm has submitted Rs. 5000/- requisite fees and changed the master formulation according to the reference.
	Decision: Approved	

1209.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot No. 84/1; Block A, Phase 5 Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Fusihyd Cream 15gm
	Composition	Each gram cream contains: Fusidic Acid……..…...…….….20mg Hydrocortisone Acetate……...…….….10mg
	Diary No. Date of R& I & fee	Dy.No.20323; 05-06-2018;Rs.20,000 (05-06-2018)
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	1's x 15gm & As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Husicort- H Cream of M/s Hisun Pharma (Reg. # 051062)
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1210.	Name and address of manufacturer / Applicant	M/s Aulton Pharmaceuticals, Plot No. 84/1, Block A, Phase 5 Industrial Estate, Hattar.
	Brand Name +Dosage Form + Strength	Soda Tablet 500mg
	Composition	Each **film- coated** tablet contains: Sodium Valproate……..500mg
	Diary No. Date of R& I & fee	Dy.No.20324;05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form-5
	Finished product Specification	BP
	Pack size & Demanded Price	10 x 10's & As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA and TGA, Australia as **enteric- coated** tablet
	Me-too status	Kontrol **CR** tablets of M/s Werrick Pharma (Reg. # 040654)
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Initially, firm had applied **film- coated** tablet while it is approved in MHRA and TGA, Australia as **enteric- coated** tablet. • Now, the firm has revised the applied formulation according to the reference with submission of requisite fees i.e. Rs. 5000/-. • Applied brand name may be changed.
	Decision: Approved as enteric coated tablet with change of brand name	
1211.	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 Novartis 059038
	GMP status	Last GMP inspection was conducted on 16-01-2018 and GMP certificate was granted.
	Remarks of the Evaluator [XIII]	• 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.**
	Decision: Deferred as the requisite fees i.e. Rs. 5000/- still needs to be submitted for revision of formulation.	
1212.	Name and address of manufacturer / Applicant	M/s Welmark Pharmaceuticals. Plot #122 Phase 5, Block B, Industrial Hattar, Haripur
	Brand Name +Dosage Form + Strength	Zafir tablet 10mg
	Composition	Each film- coated tablet contains: Zafirlukast……..…10mg
	Diary No. Date of R& I & fee	Dy.No.26249;31-07-2018; Rs.20,000 (13-07-2018)
	Pharmacological Group	Leukotriene Receptor Antagonists
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Zilesta 10mg Tablet of M/s Genix Pharma (Reg. # 055978)
	GMP status	Last GMP inspection was conducted on 26-09-2018 and the report concludes of DML.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1213.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Repride Tablet 10mg
	Composition	Each enteric-coated tablet contains: Rabeprazole Sodium……..10mg
	Diary No. Date of R& I & fee	Dy.No.20688;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's & Rs.40 per tablet
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rabezol Tablets 10mg of M/s Navegal Laboratories (Reg. # 043906)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	Firm has General tablet section. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1214.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Private limited, L-10-D, Block-21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Repride Tablet 20mg

	Composition	Each enteric-coated tablet contains: Rabeprazole Sodium……..20mg
	Diary No. Date of R& I & fee	Dy.No.20694;08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's & Rs.27 per tablet
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Paricon 20mg Tablets of M/s Barrett Hodgson Pakistan (Reg. No.036655)
	GMP status	Last GMP inspection was conducted on 24-04-2018 and the report concludes satisfactory level of GMP compliance. (Show cause notice was revoked on 27-04-2018).
	Remarks of the Evaluator [XIII]	Firm has General tablet section. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1215.	Name and address of manufacturer / Applicant	M/s Zafa Pharmaceutical Laboratories, Pvt. Limited, A- 46, SITE North Karachi.
	Brand Name +Dosage Form + Strength	Famila- Lact tablet 0.03mg
	Composition	Each sugar- coated tablet contains: Levonorgestrel ……..…0.03mg
	Diary No. Date of R& I & fee	Dy.No.15722;27-04-2018;Rs.20,000(27-04-2018)
	Pharmacological Group	Progestogen/ Contraceptive
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	28's &Rs. 30/- per pack of 28 tablets
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Could not be confirmed in the applied strength as 1.5mg and 0.75mg is available
	GMP status	Last GMP inspection was conducted on 07-02-2019 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• In 288th DRB meeting, Registration Board advised the firm to get approval from Licensing Division particularly for either Tablet (Steroidal Hormone) or Tablet (Non-steroidal Hormone) for further processing by Registration Board. • Me- too status in the applied strength 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.	
1216.	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	Pigomet Tablet 15/500mg
	Composition	Each film- coated tablet contains:- Pioglitazone…….....15mg Metformin HCl…….....500mg
	Diary No. Date of R& I & fee	Dy.No.20334; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	14's, 28's & as per SRO
	Approval status of product in Reference	USFDA Approved

	Regulatory Authorities	
	Me-too status	Diaset Plus 15mg/500mg Tablet Barrett Hodgson (Reg. # 076238)
	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. • The official monograph for the applied formulation is available in USP. • General tablet section is available in the firm as is mentioned in the submitted GMP inspection report.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1217.	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	Pigomet Tablet 15/ 850mg
	Composition	Each film- coated tablet contains:- Pioglitazone…….....15mg Metformin HCl…….....850mg
	Diary No. Date of R& I & fee	Dy.No.20335;05-06-2018;Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Muppet 15mg/ 850mg Tablet of M/s PPP (Reg. # 076217)
	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. • The official monograph for the applied formulation is available in USP. • General tablet section is available in the firm as is mentioned in the submitted GMP inspection report.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1218.	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	Pine Tablet 25mg
	Composition	Each film- coated tablet contains:- Quetiapine as fumarate……...25mg
	Diary No. Date of R& I & fee	Dy.No.20328; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti -psychotic

	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	Seroquel Tablets 25mg of M/s ICI Pharma (Reg. # 025269)
	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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1219.	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	Pine Tablet 100mg
	Composition	Each film- coated tablet contains:- Quetiapine as fumarate…...100mg
	Diary No. Date of R& I & fee	Dy.No.20329; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti -psychotic
	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	Seroquel Tablet 100mg of M/s ICI Pharma (Reg. # 025270)
	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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1220.	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	Escita Tablet 10mg
	Composition	Each film- coated tablet contains:- Escitalopram as Oxalate……10mg
	Diary No. Date of R& I & fee	Dy.No.20328; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- depressant

	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Flotella 10mg Tablets of M/s Candid Pharma (Reg. # 082033)
	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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1221.	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	Escita tablet 20mg
	Composition	Each film- coated tablet contains:- Escitalopram as Oxalate…...20mg
	Diary No. Date of R& I & fee	Dy.No.20331; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 28's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Escitaur Tablet 20mg of M/s Aurik Pharma (Reg. # 078050)
	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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1222.	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 50/500mg
	Composition	Each film- coated tablet contains:- Vildagliptin ……..……....50mg Metformin HCl……...500mg
	Diary No. Date of R& I & fee	Dy.No.20584; 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 50/ 500mg tablets of M/s Novartis Pharma (Reg. # 078106)
	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. • No official monograph is available for the applied formulation.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1223.	Name and address of manufacturer / Applicant	M/s Theramed Pharmaceutical Pvt. Ltd. 45-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Hypnomed Capsule 15mg
	Composition	Each capsule contains: Temazepam…….....15mg
	Diary No. Date of R& I & fee	Dy.No.20575; 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Hypnotic
	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	Calm 15mg capsule of M/s Wilshire Lab (Reg. # 065701)
	GMP status	GMP Inspection Certificate dated 10.10.2017. Panel recommended renewal of DML and additional section.
	Remarks of the Evaluator [XIII]	Psychotropic capsule section is available in the firm as is mentioned in the submitted section approval letter issued on 22nd February, 2018 by the Central Licensing Board.
	Decision: Approved	
1224.	Name and address of manufacturer / Applicant	M/s Theramed Pharmaceutical Pvt. Ltd. 45-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Hypnomed Capsule 30mg
	Composition	Each capsule contains: Temazepam…….....30mg
	Diary No. Date of R& I & fee	Dy.No.20572; 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Hypnotic
	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	Calm 30mg capsule of M/s Wilshire Labs. (R.#065707)

	GMP status	GMP Inspection Certificate dated 10.10.2017. Panel recommended renewal of DML and additional section.
	Remarks of the Evaluator [XIII]	Psychotropic capsule section is available in the firm as is mentioned in the submitted section approval letter issued on 22nd February, 2018 by the Central Licensing Board.
	Decision: Approved	
1225.	Name and address of manufacturer / Applicant	M/s Theramed Pharmaceutical Pvt. Ltd. 45-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Netra Tablet 5mg
	Composition	Each uncoated tablet contains: Nitrazepam……..5mg
	Diary No. Date of R& I & fee	Dy.No.20574; 07-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Sedative/ Hypnotic
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	50's & As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Nitpam-5 Tablets of M/s Glitz Pharma (Reg. # 081421)
	GMP status	GMP Inspection Certificate dated 10.10.2017. Panel recommended renewal of DML and additional section.
	Remarks of the Evaluator [XIII]	Psychotropic tablet section is available in the firm as is mentioned in the submitted section approval letter issued on 22nd February, 2018 by the Central Licensing Board.
	Decision: Approved	
1226.	Name and address of manufacturer / Applicant	M/s Theramed Pharmaceutical Pvt. Ltd. 45-km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Medate 10mg Tablet
	Composition	Each uncoated tablet contains: Methylphenidate as HCl……10mg
	Diary No. Date of R& I & fee	Dy.No.20573;07-06-2018;Rs.20,000(07-06-2018)
	Pharmacological Group	CNS Stimulant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	30's & As per DRAP policy
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Ritalin 10mg Tablet of M/s Novartis (Reg.# 004458)
	GMP status	GMP Inspection Certificate dated 10.10.2017. Panel recommended renewal of DML and additional section.
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1227.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Celtek capsule 100 mg
	Composition	Each capsule contains: Celecoxib…….100 mg
	Diary No. Date of R& I & fee	Dy.No.25937; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Non-steroidal Anti-inflammatory and Anti rheumatic drugs; NSAIDs
	Type of Form	Form -5
	Finished product Specification	Manufacturers

	Pack size & Demanded Price	10's, 20's, 30's ,50's,60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Celoxib 100mg capsule of M/s Schazoo Laboratories (Reg. # 030330)
	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	No official monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1228.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Celtek capsule 200 mg
	Composition	Each capsule contains: Celecoxib…….200 mg
	Diary No. Date of R& I & fee	Dy.No.25936; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Non-steroidal Anti-inflammatory and Anti rheumatic drugs; NSAIDs
	Type of Form	Form -5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10's, 20's, 30's ,50's,60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Celtac DS capsule of M/s Noa Hemis Pharma (Reg. # 061526)
	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	No official monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1229.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Gabin Capsule 100 mg
	Composition	Each capsule contains: Gabapentin …….100 mg
	Diary No. Date of R& I & fee	Dy.No.25938; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ,50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Gabagood 100 Capsules of M/s Goodman Lab (R# 052546)
	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	
	Decision: Approved	

1230.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Gabin Capsule 300 mg
	Composition	Each capsule contains: Gabapentin ……..300 mg
	Diary No. Date of R& I & fee	Dy.No.25941; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	14's, 10's, 20's, 30's ,50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Gabagood 300 Capsules of M/s Goodman Laboratories (Reg. # 052548)
	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1231.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Gabin Capsule 400mg
	Composition	Each capsule contains: Gabapentin ……...400mg
	Diary No. Date of R& I & fee	Dy.No.25940; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ,50's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Gabagood 100 Capsules of M/s Goodman Laboratories (Reg. # 052547)
	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1232.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Velfex tablet 37.5mg
	Composition	Each uncoated tablet contains: Venlafaxine as HCl ……..……37.5mg
	Diary No. Date of R& I & fee	Dy.No.26260; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Venlor-37.5 tablets of M/s Genome Pharma (Reg. # 053551)
	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]	• Tablet General Section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved	
1233.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Velfex tablet 50mg
	Composition	Each uncoated tablet contains: Venlafaxine as HCl ……..……...50mg
	Diary No. Date of R& I & fee	Dy.No.26261; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- depressant
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	2 x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	V- Fax 50mg uncoated tablet of M/s Sayyad Pharma (Reg. # 070374)
	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]	• Tablet General Section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved	
1234.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Floxen capsule 20mg
	Composition	Each capsule contains: Fluoxetine as HCl ……..20mg
	Diary No. Date of R& I & fee	Dy.No.26258; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	SSRI
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	2x 7's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Fluxine 20mg capsules of M/s Don Valley Pharma (Reg. # 020295)
	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]	Capsule General Section is available in the firm as mentioned in the submitted GMP certificate.
	Decision: Approved	
1235.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Metglip tablet 50mg/500mg
	Composition	Each film- coated tablet contains: Vildagliptin…….50mg Metformin Hydrochloride…….500mg
	Diary No. Date of R& I & fee	Dy.No.26264; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- Hyperglycemic
	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	TGA; Australia Approved
	Me-too status	Vildabar Plus Tablet of M/s Barrett Hodgson (Reg. # 085998)
	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]	Tablet General Section is available in the firm as mentioned in the submitted GMP certificate. No official monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1236.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Metglip tablet 50mg/ 850mg
	Composition	Each film- coated tablet contains: Vildagliptin…….50mg Metformin Hydrochloride……850mg
	Diary No. Date of R& I & fee	Dy.No.26265; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- Hyperglycemic
	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	MHRA Approved
	Me-too status	Vildabar Plus Tablet of M/s Barrett Hodgson (R# 085997)
	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]	Tablet General Section is available in the firm as mentioned in the submitted GMP certificate. No official monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1237.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Metglip tablet 50mg/ 1000mg
	Composition	Each film- coated tablet contains: Vildagliptin…….50mg Metformin Hydrochloride……..….1000mg
	Diary No. Date of R& I & fee	Dy.No.26266; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Anti- Hyperglycemic
	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	MHRA Approved
	Me-too status	Vildabar Plus Tablet of M/s Barrett Hodgson (Reg. # 085996)
	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]	Tablet General Section is available in the firm as mentioned in the submitted GMP certificate. No official monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1238.	Name and address of manufacturer / Applicant	M/s Magns Pharmaceuticals, Plot # 7-B, Value Addition City, Faisalabad.
	Brand Name +Dosage Form + Strength	Emflex 550mg Tablet
	Composition	Each film-coated tablet contains: Naproxen Sodium……550mg
	Diary No. Date of R& I & fee	Dy.No.26259; 31-07-2018; Rs.20,000 (31-07-2018)
	Pharmacological Group	Propionic Acid derivative (NSAID)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	2 x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Synflex 550mg tab of M/s Saitex (Reg. # 010197)
	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]	Tablet General Section is available in the firm as mentioned in the submitted GMP certificate. The official monograph for the applied formulation is available in USP.
	Decision: Approved with USP specifications.	
1239.	Name and address of manufacturer / Applicant	M/s Axis Pharmaceuticals 3-b, Valve Addition City, 1.5km, Khurrianwala- Sahianwala Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Transix Tablet 500mg
	Composition	Each film- coated tablet contains: Tranexamic Acid……..500mg
	Diary No. Date of R& I & fee	Dy.No.20706; 08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Anti- fibrinolytic
	Type of Form	Form- 5
	Finished product Specification	B.P.
	Pack size & Demanded Price	20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in MHRA
	Me-too status	Traumax Tablet 500mg of M/s Siza International (Reg. # 024787)
	GMP status	Last GMP inspection was conducted on 03-10-2018 and the report concludes **fair** level of GMP compliance with grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted inspection report.
	Decision: Approved	
1240.	Name and address of manufacturer / Applicant	M/s Axis Pharmaceuticals 3-b, Valve Addition City, 1.5km, Khurrianwala- Sahianwala Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Tames capsule 0.4mg
	Composition	Each capsule (sustained- release pellets) contains: Tamsulosin HCl……..….0.4mg
	Diary No. Date of R& I & fee	Dy.No.20708; 08-06-2018; Rs.20,000 (07-06-2018)
	Pharmacological Group	Alpha- adreno receptor Antagonist
	Type of Form	Form- 5

	Finished product Specification	USP
	Pack size & Demanded Price	10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Tamsolin capsule of M/s Getz Pharma (Reg. # 050392)
	GMP status	Last GMP inspection was conducted on 03-10-2018 and the report concludes **fair** level of GMP compliance with grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General capsule section as mentioned in the submitted inspection report. • Source of pellets is M/s Vision Pharma. • All the data related to pellets is submitted by the firm.
	Decision: Approved	
1241.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028, H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Calcidol 0.5mcg tablet
	Composition	Each uncoated tablet contains: Alfacalcidol……0.5mcg
	Diary No. Date of R& I & fee	Dy.No.20315; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Vitamin- D Analogue
	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	Could not be confirmed
	Me-too status	Alfacal tablet 0.5mcg of M/s Platinum Pharma (Reg. # 026683)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	• The applied formulation is non- pharmacopoeial. • General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • International availability could **not** be confirmed.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
1242.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028, H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Gabavant capsule 400mg
	Composition	Each capsule contains: Gabapentin……...400mg
	Diary No. Date of R& I & fee	Dy.No.20314; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- epileptic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Gerocin 400mg capsule of M/s KPL Pharma (Reg. # 073566)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good 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	
1243.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028, H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Defaxine 50mg SR Tablet
	Composition	Each extended- release film- coated tablet contains: Desvenlafaxine as Succicnate…….50mg
	Diary No. Date of R& I & fee	Dy.No.20313; 05-06-2018; Rs.20,000 (05-06-2018)
	Pharmacological Group	Anti- depressant
	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	USFDA Approved
	Me-too status	Desven XR 50mg Tablet of M/s Pharmevo (Reg. # 080283)
	GMP status	Last GMP inspection was conducted on 07-12-17 and the report concludes good GMP compliance.
	Remarks of the Evaluator [XIII]	• General tablet section is available in the firm as mentioned in the submitted GMP inspection report. • The applied formulation is non- pharmacopoeial.
	Decision: Approved	
1244.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt. Ltd. Plot no.9-B/1 & 2, Sector D-1,Old industrial Estate Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Diacran capsule 50mg
	Composition	Each capsule contains: Diacerein ……..……...50mg
	Diary No. Date of R& I & fee	Dy.No.20078;04-06-2018;Rs.20,000(31-05-2018)
	Pharmacological Group	NSAIDs
	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	Diacerein 50 mg hard capsule of M/s Biogaran (ANSM France Approved)
	Me-too status	Dibro 50mg capsules of M/s Winbrain Research Laboratories (Reg. # 071639)
	GMP status	Last GMP inspection was conducted on 22-02-2019 and the report concludes: • The management has rectified almost all the observations from previous inspection and as of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. • Management is advised to develop a forward thinking progressive environment, adapting the recent trends.
	Remarks of the Evaluator [XIII]	• Firm has General capsule section as mentioned in the submitted GMP inspection report. • The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1245.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products, Pvt. Limited, D- 122, Sindh Industrial Estate, Karachi.
	Brand Name +Dosage Form + Strength	Vicard tablet 12.5mg
	Composition	Each film- coated tablet contains: Carvedilol ……...12.5mg

	Diary No. Date of R& I & fee	Dy.No.26088;30-07-2018; Rs.20,000 (30-07-2018)
	Pharmacological Group	Alpha and beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & as per P.C.A
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Carveda tablets of M/s Ferozesons Labs (Reg. # 056263)
	GMP status	Last GMP inspection was conducted on 1-10-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General tablet section is available in the firm as is mentioned in the submitted GMP certificate.
	Decision: Approved	
1246.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products, Pvt. Limited, D- 122, Sindh Industrial Estate, Karachi.
	Brand Name +Dosage Form + Strength	Vicard tablet 25mg
	Composition	Each film- coated tablet contains: Carvedilol …….....25mg
	Diary No. Date of R& I & fee	Dy.No.26089;30-07-2018; Rs.20,000 (30-07-2018)
	Pharmacological Group	Alpha and beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & as per P.C.A
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Carveda tablets of M/s Ferozesons Labs (Reg. # 027714)
	GMP status	Last GMP inspection was conducted on 1-10-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General tablet section is available in the firm as is mentioned in the submitted GMP certificate.
	Decision: Approved	
1247.	Name and address of manufacturer / Applicant	M/s Pakistan Pharmaceutical Products, Pvt. Limited, D- 122, Sindh Industrial Estate, Karachi.
	Brand Name +Dosage Form + Strength	Vicard tablet 6.25mg
	Composition	Each film- coated tablet contains: Carvedilol ……...6.25mg
	Diary No. Date of R& I & fee	Dy.No.26087;30-07-2018; Rs.20,000 (30-07-2018)
	Pharmacological Group	Alpha and beta blocking agent
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10's & as per P.C.A
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Carveda tablets of M/s Ferozesons Labs (Reg. # 032569)
	GMP status	Last GMP inspection was conducted on 1-10-2018 and the report concludes good level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General tablet section is available in the firm as is mentioned in the submitted GMP certificate.
	Decision: Approved	

1248.	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	Roxaban Tablet 15mg
	Composition	Each film- coated tablet contains: Rivaroxaban……15mg
	Diary No. Date of R& I & fee	Dy.No.20887; 11-06-2018; Rs.20,000 (27-04-2018)
	Pharmacological Group	Anti- coagulant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & As per policy of MOH
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Rivaro Tablet of M/s Highnoon Laboratories (Reg. # 085872)
	GMP status	Last GMP inspection was conducted on 07-05-2019 with satisfactory GMP compliance.
	Remarks of the Evaluator [XIII]	Firm has General tablet section as mentioned in the submitted section approval letter. The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1249.	Name and address of manufacturer / Applicant	M/s Scotmann Pharmaceuticals, 5-D, I-10/ 3, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Diclosot K Tablets 50mg
	Composition	Each film- coated tablet contains: Diclofenac potassium…….50mg
	Diary No. Date of R& I & fee	Dy.No.20721; 08-06-2018; Rs.20,000 (08-06-2018)
	Pharmacological Group	Analgesic / NSAIDs
	Type of Form	Form- 5
	Finished product Specification	BP
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Clofenac Tablets of M/s Global Pharma (Reg. # 021636)
	GMP status	Last GMP inspection was conducted on 17-10-2018 and the report concludes good GMP compliance with grant of GMP certificate.
	Remarks of the Evaluator [XIII]	Firm has claimed BP specifications while its official monograph is in USP. Firm has General tablet section as mentioned in the submitted GMP inspection report.
	Decision: Approved	
1250.	Name and address of manufacturer / Applicant	M/s Novamed Pharmaceuticals (Pvt.) Ltd. 28- Km, Ferozepur Road, Lahore.
	Brand Name +Dosage Form + Strength	Supamol Tablet 500mg
	Composition	Each uncoated tablet contains: Paracetamol……..500mg
	Diary No. Date of R& I & fee	Dy.No.20889; 11-06-2018; Rs.20,000 (11-06-2018)
	Pharmacological Group	Analgesic / Antipyretic
	Type of Form	Form- 5
	Finished product Specification	Not claimed
	Pack size & Demanded Price	10x 10's, 10x 20's & as per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved

	Me-too status	Paracetamol Tablet of M/s S.Ejaz Ud Din (Reg. # 002554)
	GMP status	Last GMP inspection was conducted on 27-12-2017 and the report concludes issuance of GMP Certificate.
	Remarks of the Evaluator [XIII]	• The official monograph for the applied formulation is available in International Pharmacopoeia.
	Decision: Approved with International Pharmacopoeia.	
1251.	Name and address of manufacturer / Applicant	M/s Biomark Pharmaceuticals, Plot No. 527- Sunder Industrial Estate, Lahore.
	Brand Name + Dosage Form + Strength	X- ten tablet 60mg
	Composition	Each film- coated tablet contains: Dapoxetine as HCl……....……60mg
	Diary No. Date of R& I & fee	Dy.No.38682; 26-11-2018; Rs.20,000/- **DUPLICATE** (06-07-2017)
	Pharmacological Group	SSRI / Anti-depressant
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	1x 3 tablets & As per SRO (10% less than brand leader)
	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 16-08-2018 as a result of which the GMP Certificate was issued on 27-08-2018.
	Remarks of the Evaluator [XIII]	General Tablet section is available in the firm as mentioned in the submitted. **Me- too status could not be confirmed.** The applied formulation is non- pharmacopoeial.
	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.	
1252.	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	Gemiben tablet 320mg
	Composition	Each film-coated tablet contains:- Gemifloxacin as Mesylate……..……...320mg
	Diary No. Date of R& I & fee	Dy.No.19409;28-05-2018;Rs.20,000(28-05-2018)
	Pharmacological Group	Broad Spectrum Antibacterial (Fluoroquinolone)
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	7's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Genflox 320mg Tablet of M/s High- Q Pharmaceuticals (Reg. # 055998)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1253.	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	Rosiben Tablet 2mg/ 500mg
	Composition	Each film-coated tablet contains:- Rosiglitazone Maleate……..2mg Metformin HCl……..……...500mg
	Diary No. Date of R& I & fee	Dy.No.19410;28-05-2018;Rs.20,000(28-05-2018)
	Pharmacological Group	Anti- diabetic
	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	Discontinued in USFDA but not for safety reasons
	Me-too status	Roza- M Tablet of M/s Lexicon Pharma (Reg. # 055976)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted inspection report. • No official monograph for the applied formulation is available in USP and BP. • 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1254.	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	Rosiben Tablet 4mg/ 500mg
	Composition	Each film-coated tablet contains:- Rosiglitazone Maleate…….4mg Metformin HCl……...….500mg
	Diary No. Date of R& I & fee	Dy.No.19409;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	Anti- diabetic
	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	Discontinued in USFDA but not for safety reasons
	Me-too status	Rozicon-m Tablet of M/s Lexicon Pharma (Reg. # 057789)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted inspection report. • No official monograph for the applied formulation is available in USP and BP.

		• 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1255.	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	Rosiben Tablet 2mg/ 1000mg
	Composition	Each film-coated tablet contains:- Rosiglitazone Maleate…….2mg Metformin HCl……..….1000mg
	Diary No. Date of R& I & fee	Dy.No.19405;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	Anti- diabetic
	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	Discontinued in USFDA but not for safety reasons
	Me-too status	Ritazone Plus 2mg Tablets of M/s Standpharm Pakistan (Reg. # 046355)
	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted inspection report. • No official monograph for the applied formulation is available in USP and BP. • 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1256.	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	Rosiben Tablet 4mg/ 1000mg
	Composition	Each film-coated tablet contains:- Rosiglitazone Maleate…….4mg Metformin HCl……..….1000mg
	Diary No. Date of R& I & fee	Dy.No.19408;28-05-2018; Rs.20,000 (28-05-2018)
	Pharmacological Group	Anti- diabetic
	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	Discontinued in USFDA but not for safety reasons
	Me-too status	Diaglu Tablets of M/s Global Pharma (Reg. # 054595)

	GMP status	Last GMP inspection was conducted on 13-11-2018 and the report concludes grant of DML.
	Remarks of the Evaluator [XIII]	• Tablet section (General) is available in the firm as mentioned in the submitted inspection report. • No official monograph for the applied formulation is available in USP and BP. • 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.
	Decision: Deferred for clarification as DML of the firm at Plot No. 119, Street # 8, I-10/3, Industrial Area, Islamabad is not valid.	
1257.	Name and address of manufacturer / Applicant	M/s Gallop Water Sciences, Plot # 404, Sunder Indusrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Gee-sol DS I/V Infusion 5g +0.9g/ 100ml
	Composition	Each 100ml contains: Dextrose Anhydrous…….……....5g Sodium Chloride……0.9g
	Diary No. Date of R& I & fee	Dy.No.18170; 17-05-2018; Rs.20,000 (16-05-2018)
	Pharmacological Group	Caloric & Electrolyte Solution
	Type of Form	Form- 5
	Finished product Specification	**BP**
	Pack size & Demanded Price	500ml & Rs. 40/-
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Medisol- S of M/s MediPak Limited (Reg. # 084878)
	GMP status	Last GMP inspection was conducted on 16-02-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has claimed both Manufacturers and BP specifications while the official monograph for applied formulation is available in **USP**. • Letter was issued on **1st August, 2019** for applied specifications but still no reply has been received yet. • Firm has Large Volume Parenteral (LVP) section as mentioned in the submitted GMP certificate.
	Decision: Approved with USP specifications.	
1258.	Name and address of manufacturer / Applicant	M/s Gallop Water Sciences, Plot # 404, Sunder Indusrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Gee- Sol RLD I/V Infusion 5g + 0.9g/ 100ml
	Composition	Each 100ml contains: Sodium Chloride……...0.60g Sodium Lactate……...….0.31g Potassium Chloride…….……..….0.03g Calcium Chloride Dihydrate……..…..0.02g Dextrose Anhydrous.……..…...5g
	Diary No. Date of R& I & fee	Dy.No.18169; 17-05-2018; Rs.20,000 (16-05-2018)
	Pharmacological Group	Caloric & Electrolyte Solution
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1000ml & Rs. 84/-per 1000ml pack
	Approval status of product in Reference	USFDA Approved

	Regulatory Authorities	
	Me-too status	Ringolact- D I/V Infusion of M/s Otsuka (Reg. # 011224)
	GMP status	Last GMP inspection was conducted on 16-02-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	Firm has Large Volume Parenteral (LVP) section as mentioned in the submitted GMP certificate.
	Decision: Approved	
1259.	Name and address of manufacturer / Applicant	M/s Gallop Water Sciences, Plot # 404, Sunder Indusrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Gee Haem AC+ BC I/V Infusion
	Composition	**Portion A:** 1 Litre contains: Sodium Chloride……...210.69g Potassium Chloride……...5.22g Glacial Acetic Acid……..….6.31g Calcium Chloride Dihydrate…….6.43g Magnesium Chloride hexahydrate...…..…3.56g Dextrose……....38.5g **Portion B:** Sodium Bicarbonate
	Diary No. Date of R& I & fee	Dy.No.18171; 17-05-2018; Rs.20,000 (16-05-2018)
	Pharmacological Group	Haemodialysis Solutions
	Type of Form	Form- 5
	Finished product Specification	Both Manufacturers and BP specifications
	Pack size & Demanded Price	4 litre & Rs. 350/- per 4 litre pack
	Approval status of product in Reference Regulatory Authorities	Could not be confirmed
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 16-02-2018 and the report concludes grant of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has claimed both Manufacturers and BP specifications. • Me- too status could not be verified. • International Reference could not be verified. • Firm has Large Volume Parenteral (LVP) section as mentioned in the submitted GMP certificate. • Letter was issued on **1st August, 2019** for applied specifications but still no reply has been received yet.
	Decision: Deferred for following reasons: • **Firm has claimed both Manufacturers and BP specifications.** • **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.**	
1260.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals, 124/A, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Alendrogen tablet 70mg
	Composition	Each film- coated tablet contains: Alendronate (As Sodium) ……...70 mg
	Diary No. Date of R& I & fee	Dy.No.20461;06-06-2018;Rs.20,000 (05-06-2018)
	Pharmacological Group	Bisphosphonate, for the treatment of bone diseases
	Type of Form	Form- 5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	4's, 10's & As per SRO

	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Bonfit 70mg tablets of M/s Searle Pak (Reg. # 045429)
	GMP status	Last GMP inspection was conducted on 20-04-2018 and the report concludes renewal of DML except for the **tablet psychotropic section.**
	Remarks of the Evaluator [XIII]	• Alendronate as Sodium **Trihydrate** should be applied. • Letter was issued on **1st August, 2019** but still no reply has been received by the firm yet.
	Decision: Deferred as the salt is applied as Alendronate as Sodium which is not complete because Alendronate as Sodium "Tri-hydrate" should be applied.	
1261.	Name and address of manufacturer / Applicant	M/s Valor Pharmaceuticals, 124/A, Industrial Triangle, Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Alendrogen Plus Tablet
	Composition	Each **film-coated** tablet contains: Alendronate (As Sodium) ……..…..……..70 mg Cholecalciferol……..…..…70mcg
	Diary No. Date of R& I & fee	Dy.No.20462;06-06-2018;Rs.20,000 (05-06-2018)
	Pharmacological Group	Drugs for treatment of bone diseases (Bisphosphonates)
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	4's, 7's, 10's: As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved as **uncoated**
	Me-too status	Alendron- C tablets of M/s Bosch Pharma (Reg. # 048508)
	GMP status	Last GMP inspection was conducted on 20-04-2018 and the report concludes renewal of DML except for the **tablet psychotropic section.**
	Remarks of the Evaluator [XIII]	• The formulation in the applied strength is approved in reference as **uncoated** tablet while the firm has applied the tablet **as film- coated**. • Alendronate as Sodium **Trihydrate** should be applied. • Letter was issued on **1st August, 2019** but still no reply has been received by the firm yet.
	Decision: Deferred due to following reasons: • **The salt is applied as Alendronate as Sodium which is not complete because Alendronate as Sodium "Tri-hydrate" should be applied.** • **The formulation in the applied strength is approved in reference regulatory authorities as uncoated tablet while the firm has applied the tablet as film- coated.**	
1262.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	AVH Tablet 10mg/ 160mg/ 12.5mg
	Composition	Each tablet contains: Amlodipine as Besylate …..…..……..…10mg Valsartan …..……..…..160mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R& I & fee	Dy. No.26095;30-07-2018; Rs.20,000 (16-07-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 28's, 50's ,100's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge- HCT 10/160/12.5mg film- coated tablets of M/s

		Novartis Pharma (Reg. # 069550)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report. • Film- coating was not mentioned in the master formulation nor was the outline of method of manufacture submitted. • Now, the firm has revised its master formulation as film- coated tablet and outline of method of manufacture is also submitted with submission of requisite fees Rs. 5000/-.
	Decision: Approved	
1263.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	AVH Tablet 10mg/ 160mg/ 25mg
	Composition	Each tablet contains: Amlodipine as Besylate ……..……..…10mg Valsartan …..……...…….…..…..160mg Hydrochlorothiazide……25mg
	Diary No. Date of R& I & fee	Dy. No.26096;30-07-2018; Rs.20,000 (16-07-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 28's, 50's ,100's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge- HCT 10/160/25mg film- coated tablets of M/s Novartis Pharma (Reg. # 069551)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report. • Film- coating was not mentioned in the master formulation nor was the outline of method of manufacture submitted. • Now, the firm has revised its master formulation as film- coated tablet and outline of method of manufacture is also submitted with submission of requisite fees Rs. 5000/-.
	Decision: Approved.	
1264.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	AVH Tablet 10mg/ 320mg/ 25mg
	Composition	Each tablet contains: Amlodipine as Besylate ……..……..…10mg Valsartan ……..……..…..320mg Hydrochlorothiazide……25mg
	Diary No. Date of R& I & fee	Dy. No.26097;30-07-2018; Rs.20,000 (16-07-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 28's, 50's ,100's & as per SRO

	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge- HCT 10/320/25mg film- coated tablets of M/s Novartis Pharma (Reg. # 069552)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report. • Film- coating was not mentioned in the master formulation nor was the outline of method of manufacture submitted. • Now, the firm has revised its master formulation as film- coated tablet and outline of method of manufacture is also submitted with submission of requisite fees Rs. 5000/-.
	Decision: Approved	
1265.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	AVH Tablet 5mg/ 160mg/ 12.5mg
	Composition	Each tablet contains: Amlodipine as Besylate ……..……..…5mg Valsartan …..……..…..160mg Hydrochlorothiazide……..12.5mg
	Diary No. Date of R& I & fee	Dy.No.26093;30-07-2018;Rs.20,000(16-07-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10’s, 14’s, 20’s, 30’s, 28’s, 50’s ,100’s & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge-HCT 5/160/12.5mg film- coated tablets of M/s Novartis Pharma(Reg. # 069548)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report. • Film- coating was not mentioned in the master formulation nor was the outline of method of manufacture submitted. • Now, the firm has revised its master formulation as film- coated tablet and outline of method of manufacture is also submitted with submission of requisite fees Rs. 5000/-.
	Decision: Approved	
1266.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	AVH Tablet 5mg/ 160mg/ 25mg
	Composition	Each tablet contains: Amlodipine as Besylate ……..……..…5mg Valsartan …..……..…..160mg Hydrochlorothiazide……25mg
	Diary No. Date of R& I & fee	Dy. No.26094;30-07-2018; Rs.20,000 (16-07-2018)
	Pharmacological Group	Anti- hypertensive
	Type of Form	Form-5

	Finished product Specification	USP
	Pack size & Demanded Price	10's, 14's, 20's, 30's, 28's, 50's ,100's & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Exforge- HCT 5/160/25mg film- coated tablets of M/s Novartis Pharma (Reg. # 069549)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report. • Film- coating was not mentioned in the master formulation nor was the outline of method of manufacture submitted. • Now, the firm has revised its master formulation as film-coated tablet and outline of method of manufacture is also submitted with submission of requisite fees Rs. 5000/-.
	Decision: Approved	
1267.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name + Dosage Form + Strength	Galanta- H Tablet 4mg
	Composition	Each film- coated tablet contains: Galantamine as Hydrobromide ……4mg
	Diary No. Date of R& I & fee	Dy. No.26090; 30-07-2018;Rs.20,000 (16-07-2018)
	Pharmacological Group	Anti- cholinesterase (Anti- Dementia Drug)
	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	Reminyl 4mg tablets of M/s Johnson & Johnson Pakistan (Reg. # 039801)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report.
	Decision: Approved	
1268.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Galanta- H Tablet 8mg
	Composition	Each film- coated tablet contains: Galantamine as Hydrobromide ……..…..……8mg
	Diary No. Date of R& I & fee	Dy. No.26091; 30-07-2018;Rs.20,000 (16-07-2018)
	Pharmacological Group	Anti- cholinesterase (Anti- Dementia Drug)
	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	Reminyl 8mg tablets of M/s Johnson & Johnson Pakistan (Reg. # 039802)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report.
	Decision: Approved.	

1269.	Name and address of manufacturer / Applicant	M/s Glitz Pharma Plot # 265, Industrial Triangle, Kahuta Road, Islamabad
	Brand Name +Dosage Form + Strength	Galanta- H Tablet 12mg
	Composition	Each film- coated tablet contains: Galantamine as Hydrobromide ……..…12mg
	Diary No. Date of R& I & fee	Dy. No.26092; 30-07-2018;Rs.20,000 (16-07-2018)
	Pharmacological Group	Anti- cholinesterase (Anti- Dementia Drug)
	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	Reminyl 12mg tablets of M/s Johnson & Johnson Pakistan (Reg. # 039803)
	GMP status	Last GMP inspection was conducted on 16-01-2019 and the report concludes issuance of GMP certificate.
	Remarks of the Evaluator [XIII]	• Firm has General tablet section as mentioned in the submitted GMP inspection report.
	Decision: Approved	
1270.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Fibry capsule 67 mg
	Composition	Each capsule contains: Fenofibrate micronized ……..67mg
	Diary No. Date of R& I & fee	Dy.No.25934; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ,50's,60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Fenoget 67mg micronized capsules of M/s Getz Pharma (Reg. # 047197)
	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	
	Decision: Approved.	
1271.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Fibry capsule 134 mg
	Composition	Each capsule contains: Fenofibrate (micronized **)**……...134mg
	Diary No. Date of R& I & fee	Dy.No.25939; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ,50's,60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Fenoget 134mg micronized capsules of M/s Getz Pharma (Reg. # 055692)

	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1272.	Name and address of manufacturer / Applicant	M/s Innvotek Pharmaceuticals Plot- 35 Industrial Triangle Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	Fibry capsule 200 mg
	Composition	Each capsule contains: Fenofibrate (micronized **)**……..……...200mg
	Diary No. Date of R& I & fee	Dy.No.25935; 27-07-2018; Rs.20,000 (27-07-2018)
	Pharmacological Group	Lipid modifying agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10's, 20's, 30's ,50's,60's & As per SRO
	Approval status of product in Reference Regulatory Authorities	TGA; Australia Approved
	Me-too status	Fenoget 200mg micronized capsules of M/s Getz Pharma (Reg. # 047198)
	GMP status	Last GMP inspection was conducted on 30-11-2017 and the panel recommends renewal of DML and recommends the amendment changes in existing sections: Tablet section Gen (Revised) and Capsule section (revised).
	Remarks of the Evaluator [XIII]	
	Decision: Approved	
1273.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M-028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Zolmitan tablet 2.5mg
	Composition	Each film- coated tablet contains: Zolmitriptan……..…..2.5mg
	Diary No. Date of R& I & fee	Dy.No.27057; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- migraine
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 3's & as per SRO
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Migzor 2.5mg tablet of M/s Hilton Pharma (Reg. # 055144)
	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 GMP inspection report.
	Decision: Approved	
1274.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Cloza tablet 100mg
	Composition	Each uncoated tablet contains: Clozapine……100mg
	Diary No. Date of R& I & fee	Dy.No.27056; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- psychotic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO & as per SRO

	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Clozcare tablets of M/s Dr. Raza Pharma (Reg. # 084243)
	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 GMP inspection report.
	Decision: Approved	
1275.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Citavant tablet 50mg/ 500 mg
	Composition	Each film- coated tablet contains: Sitagliptin as Phosphate Monohydrate…...….50mg Metformin Hydrochloride……..500mg
	Diary No. Date of R& I & fee	Dy.No.27066; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti-diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Sita Plus 50/500 tablet of M/s PharmEvo (Reg. # 055477)
	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 GMP inspection report. • No USP or BP monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1276.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Citavant tablet 50/1000 mg
	Composition	Each film- coated tablet contains: Sitagliptin as Phosphate Monohydrate...…….50mg Metformin Hydrochloride……..……..1000mg
	Diary No. Date of R& I & fee	Dy.No.27067; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- diabetic
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & as per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Sita Plus 50/1000 tablet of M/s Pharm Evo (Reg. # 055486)
	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 GMP inspection report. • No USP or BP monograph is available for the applied formulation.
	Decision: Approved as per innovators' specifications.	
1277.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Avecip tablet 500mg

	Composition	Each film- coated tablet contains: Ciprofloxacin as Hydrochloride……...500mg
	Diary No. Date of R& I & fee	Dy.No.27059; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- bacterial
	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	Wincip 500 mg tablet of M/s Winthrox (Reg. # 074926)
	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 GMP inspection report.
	Decision: Approved	
1278.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Bandro tablet 150mg
	Composition	Each film- coated tablet contains: Ibandronate as Sodium Monohydrate……...150mg
	Diary No. Date of R& I & fee	Dy.No.27063; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Bisphosphonate
	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	Franjic 150mg film- coated tablet of M/s Martin Dow (Reg. # 081130)
	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 GMP inspection report. • The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1279.	Name and address of manufacturer / Applicant	M/s Avant Pharmaceuticals, M- 028 H.I.T.E, Lasbela, Balochistan.
	Brand Name +Dosage Form + Strength	Irofic tablet 100mg/0.35 mg
	Composition	Each chewable tablet contains: Iron (III) Hydroxide Polymaltose Complex eq. to Iron……...100mg Folic Acid……0.35mg
	Diary No. Date of R& I & fee	Dy.No.27061; 07-08-2018; Rs.20,000 (07-08-2018)
	Pharmacological Group	Anti- Anaemic
	Type of Form	Form- 5
	Finished product Specification	In- house
	Pack size & Demanded Price	2x 10's & as per SRO
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Planka FA tablet 100mg/ 0.35 mg of M/s Macter International (Reg. # 057760)
	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 GMP inspection report. • The applied formulation is non- pharmacopoeial.
	Decision: Approved as per innovators' specifications.	
1280.	Name and address of manufacturer / Applicant	M/s Caraway Pharmaceuticals, Plot # 12, Street N-3, National industrial Zone, Rawat, Islamabad.
	Brand Name +Dosage Form + Strength	Rold Injection 1mcg
	Composition	Each ampoule contains: Calcitriol……..…1mcg
	Diary No. Date of R& I & fee	Dy.No.20698; 08-06-2018; Rs.20,000 (08-06-2018)
	Pharmacological Group	Vitamin- D Analogue
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1's glass ampoule & As per SRO
	Approval status of product in Reference Regulatory Authorities	USFDA Approved
	Me-too status	Bonky Injection 1mcg of M/s Pharmatec (Reg. # 081083)
	GMP status	Last GMP inspection was conducted 26-02-2019 and the report concludes the firm to be GMP compliant.
	Remarks of the Evaluator [XIII]	• Firm has Liquid ampoule Injectable section as is mentioned in the submitted section approval letter.
	Decision: Approved	
1281.	Name and address of manufacturer / Applicant	M/s Getz Pharma Pvt Ltd. 29-30/ 27, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Saltra DPI 50mcg + 100mcg Powder for Inhalation
	Composition	Each capsule contains: Salmeterol as Xinafoate (Micronised)..…50mcg Fluticasone Propionate (Micronised)…...100mcg
	Diary No. Date of R& I & fee	Dy.No.26267;31-07-2018;Rs.20,000(31-07-2018)
	Pharmacological Group	Adrenergics in combination with Corticosteroids
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	60's & Rs.1000/-
	Approval status of product in Reference Regulatory Authorities	Approved in USFDA as plastic inhaler containing a foil blister strip
	Me-too status	Seretide Diskus 50/100mcg Powder for Inhalation of M/s Glaxosmithkline (Reg. # 074726)
	GMP status	Last GMP inspection was conducted on 26-06-2018 and the report concludes acceptable level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Firm has metered dose Inhalers (MDIs) General/ Steroidal section as mentioned in the submitted section approval letter. • Approved in USFDA as plastic inhaler containing a foil blister strip. Letter was issued to the firm on 31st July, 2019 with the following short- coming: "The international reference which you have submitted as ADVAIR DISKUS is a plastic inhaler containing a foil blister strip. Each blister on the strip contains a powder mix of micronized fluticasone propionate and micronized salmeterol xinafoate. After the inhaler is activated, the powder is dispersed into the airstream created by the patient inhaling through the mouthpiece. While you have applied as capsules having micronized powder. Justify

		the applied drug delivery system." The firm replied: *This is to bring to your kind attention that DRAP has already approved Salmeterol + Fluticasone propionate DPI 50mcg + 100mcg in hard capsule in its 275th DRP meeting for M/s Macter international Ltd, Karachi with the brand name of Salmicort DPI (Salmeterol + Fluticasone propionate) Capsules 50mcg + 100mcg (extract attached).* *In order to confirm the compatibility of applied formulation with hard capsules, this is to inform you that HMPC based capsule shell is inert in nature and has no impact on formulation. Also, the primary packaging of our applied product and reference product is same i.e., Blister foil.* *The Capsule contain micronized APIs. When capsule get punctured in the DPI device, the powder is dispersed into the airstream created by the patient inhaling through the mouth piece of DPI device.*
	Decision: Approved.	
1282.	Name and address of manufacturer / Applicant	M/s Asian Continental Pvt. Limited, Continental House, D-133, Tipu Sultan Road, KDA Scheme- I, Karachi.
	Brand Name +Dosage Form + Strength	AC- Tidal SR tablet 100mg
	Composition	Each Sustained- release tablet contains: Tramadol HCl……...…….100mg
	Diary No. Date of R& I & fee	Dy.No.98;01-01-2018; Rs.20,000/- (01-01-2018)
	Pharmacological Group	Analgesic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 10's, 3x 10's & as per latest decision taken by PRC
	Approval status of product in Reference Regulatory Authorities	MHRA Approved
	Me-too status	Tramitt SR 100mg Tablets of M/s Lowitt Pharma (R#068417)
	GMP status	Last GMP inspection was conducted on 25-06-2019 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 GMP inspection report.
	Decision: Approved	

a. Deferred cases:

1283.	Name and address of manufacturer / Applicant	M/s Nabi Qasim Industries (Pvt) Ltd; 17/24, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lusidone Tablet 20mg
	Composition	Each film-coated tablet contains: Lurasidone as Hydrochloride ……...20mg
	Diary No. Date of R& I & fee	Dy. No.435; 30-03-2015; Rs.20,000/- (21-02-2015)
	Pharmacological Group	Anti-psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	10's, 14's, 30's; as per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status	Not available

	GMP status	Last GMP inspection was conducted on 03-08-2017 which concludes an acceptable level of GMP compliance.
	Previous remarks of the Evaluator	• Submission on Form-5D. • Submission of differential fees. • Submission of stability data according to 251st DRB meeting.
	Previous decision	**Deferred in 275th DRB meeting for:** • Clarification from QA & LT Division regarding GMP status of the firm in the light of observations made by the panel of inspection for the product SOVIR-C 400mg tablet and those recorded by area FID in inspection report dated 03-08-2017. • Confirmation of generic/ me-too status of applied formulation.
	Evaluation by PEC	• Firm has submitted its latest GMP inspection report; dated: 02-08-2018 and the report concludes satisfactory level of GMP compliance. • Firm has submitted me- too reference as: **"**Lurasidone HCl 20mg strength with brand name Lusidon 20mg tablet has been approved to M/s Hilton Pharma in the DRB 281st Meeting." • *The applied formulation requires submission of stability data along with protocols and testing methods of three batches at real and accelerated conditions.* • *The firm wants to get the registration on Form- 5 and undertakes that the stability data will be submitted after import of API.*
	Decision: Deferred as the applied formulation requires submission of stability data along with protocols and testing methods of three batches at real and accelerated conditions. Differential fees i.e. Rs. 30,000/- needs to be submitted as well.	
1284.	Name and address of manufacturer / Applicant	M/s Nabi Qasim Industries (Pvt) Ltd; 17/24, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lusidone Tablet 40mg
	Composition	Each film-coated tablet contains: Lurasidone as Hydrochloride ……....40mg
	Diary No. Date of R& I & fee	Dy. No.436; 30-03-2015; Rs.20,000/- (21-02-2015) (Duplicate Dossier)
	Pharmacological Group	Anti-psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	10's, 14's, 30's; as per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status	Not available
	GMP status	Last GMP inspection was conducted on 03-08-2017 which concludes an acceptable level of GMP compliance.
	Previous remarks of the Evaluator	• Submission on Form-5D. • Submission of differential fees. • Submission of stability data according to 251st DRB meeting. • As the dossier is duplicate so fee-challan needs verification. • The proposed shelf-life is 4 years.

		• Original sign on form and application**.**
	Previous decision	**Deferred in 275th DRB meeting for:** • Clarification from QA & LT Division regarding GMP status of the firm in the light of observations made by the panel of inspection for the product SOVIR-C 400mg tablet and those recorded by area FID in inspection report dated 03-08-2017. • Confirmation of generic / me-too status of applied formulation.
	Evaluation by PEC	• Firm has submitted its latest GMP inspection report; dated: 02-08-2018 and the report concludes satisfactory level of GMP compliance. • Firm has submitted me- too status as: *Lurisa 40mg tablets of M/s Helix Pharma (Reg. # 089358).* • *The applied formulation requires submission of stability data along with protocols and testing methods of three batches at real and accelerated conditions.* • *The firm wants to get the registration on Form- 5 and undertakes that the stability data will be submitted after import of API.*
	Decision: Deferred as the applied formulation requires submission of stability data along with protocols and testing methods of three batches at real and accelerated conditions. Differential fees i.e. Rs. 30,000/- needs to be submitted as well.	
1285.	Name and address of manufacturer / Applicant	M/s Nabi Qasim Industries (Pvt) Ltd; 17/24, Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Lusidone Tablet 80mg
	Composition	Each film-coated tablet contains: Lurasidone as Hydrochloride ……....80mg
	Diary No. Date of R& I & fee	Dy. No.608; 20-04-2015; Rs.20,000/- (21-02-2015) (Duplicate Dossier)
	Pharmacological Group	Anti-psychotic
	Type of Form	Form- 5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	10's, 14's, 30's; as per PRC
	Approval status of product in Reference Regulatory Authorities	Approved by TGA of Australia
	Me-too status	Not available
	GMP status	Last GMP inspection was conducted on 03-08-2017 which concludes acceptable level of GMP compliance.
	Previous remarks of the Evaluator	• Submission on Form-5D. • Submission of differential fees. • Submission of stability data according to 251st DRB meeting. • As the dossier is duplicate so fee-challan needs verification. • The proposed shelf-life is 4 years. • Original sign on form and application**.**
	Previous decision	Deferred in 275th DRB meeting for: • Clarification from QA & LT Division regarding GMP status of the firm in the light of observations made by the panel of inspection for the product

		SOVIR-C 400mg tablet and those recorded by area FID in inspection report dated 03-08-2017. • Confirmation of generic / me-too status of applied formulation.
	Evaluation by PEC	• Firm has submitted its latest GMP inspection report; dated: 02-08-2018 and the report concludes satisfactory level of GMP compliance. • Firm has submitted me- too status as: *Lurisa 80mg tablets of M/s Helix Pharma (Reg. # 089359).* • *The applied formulation requires submission of stability data along with protocols and testing methods of three batches at real and accelerated conditions.* • *The firm wants to get the registration on Form- 5 and undertakes that the stability data will be submitted after import of API.*
	Decision: Deferred as the applied formulation requires submission of stability data along with protocols and testing methods of three batches at real and accelerated conditions. Differential fees i.e. Rs. 30,000/- needs to be submitted as well.	
1286.	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.	
	Decision: Deferred for submission of fee for change in contract manufacturer.	
1287.	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.	
	Decision: Deferred for submission of fee for change of contract manufacturer.	
1288.	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.	
	Decision: Deferred for submissionof fee for change of contract manufacturer.	
1289.	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.	
	Decision: Deferred for submission of fee for change of contract manufacturer.	
1290.	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.	
	Decision: Deferred for submission of fee for change of contract manufacturer.	
1291.	Name and address of manufacturer / Applicant	M/s Jinnah Pharmaceuticals, 13- Km, Lahore.
	Brand Name +Dosage Form + Strength	Dewcal Sachet
	Composition	Each sachet contains: Calcium Lactate Gluconate……1000mg Vitamin C ……...500mg Calcium Carbonate…….……..327mg
	Diary No. Date of R& I & fee	Dy. No. 9046, 28-09-2016;Rs.20,000 (28-09-2016)
	Pharmacological Group	Calcium Supplement with high potency Vitamin C
	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.	Not provided
	Me-too status	ZF-C 1000 Sachet of M/s Zafa, Karachi (Reg. # 070744)
	GMP status	Not provided
	Previous remarks of the Evaluator	• The applied formulation is not available in the reference regulatory authorities as sachet. Instead tablet dosage form is approved in MHRA.

		• The latest GMP inspection report is not provided by the firm. • Letter was issued to the firm on 3rd May, 2018 and reminder has been issued on 10th July, 2018.
	Previous decision	Deferred in 284th DRB meeting for further deliberation.
	Evaluation by PEC	• The applied formulation is non- pharmacopoeial. • Firm has General Sachet section as mentioned in the submitted section approval letter. • Firm has submitted its latest GMP inspection report dated 03-05-2019 and concludes renewal of DML. • The applied formulation is **not** available in the reference regulatory authorities as sachet. Instead **tablet** dosage form is approved in MHRA.
	Decision: Deferred as the applied formulation is not available in the reference regulatory authorities as sachet. Instead tablet dosage form is approved in MHRA.	
1292.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Rozic 20mg/5ml Syrup
	Composition	Each 5ml contains: Zinc Sulphate monohydrate eq. to Elemental Zinc ……..…… 20mg
	Diary No. Date of R& I & fee	Dy.No.41131;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Zinc Supplement
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	60ml, 120ml &Rs. As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Osiris 20mg/5ml of M/s Sami (Reg. # 066902)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Previous remarks of the Evaluator	• The international availability of the applied formulation could not be confirmed.
	Previous decision	Deferred in 289 DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.
	Evaluation by PEC	The applied formulation is available in International Pharmacopoeia
	Decision: Approved with International Pharmacopoeia specifications.	
1293.	Name and address of manufacturer / Applicant	M/s Rotex Pharma (Pvt) Ltd. Plot No. 206 & 207, Industrial Triangle Kahuta Road Islamabad.
	Brand Name +Dosage Form + Strength	Katif 1mg/ 5ml Liquid Syrup
	Composition	Each 5ml contains: Ketotifen (as hydrogen fumarate) ……..… 1mg
	Diary No. Date of R& I & fee	Dy.No.41105;06-12-2018;Rs.20,000 (06-12-2018)
	Pharmacological Group	Antihistamine
	Type of Form	Form 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zaditen 1mg/5ml oral solution by M/s Sigma Tau, ANSM approved
	Me-too status	Tifien Syrup of M/s Hicon Pharma (Reg. # 041474)
	GMP status	New Sections (Inspection Date: 19th Sep. 2018)
	Previous remarks of the Evaluator	• No USP or BP monograph is available for the

		applied formulation.
	Previous decision	Deferred in 289 DRB meeting for evidence of approval of applied formulation in reference agencies as applied formulation is Ketotifen (as hydrogen fumarate) 1mg/5ml syrup, which is different from quoted reference i.e. ketotifen (as fumarate) 1mg/5ml syrup.
	Evaluation by PEC	Firm has submitted reference of an already registered drug named Kestox 1mg **tablet** in 286th DRB meeting while the applied formulation is a **liquid syrup.**
	Decision: Deferred for revision of formulation as per reference product along with submission of fee for revision of formulation.	
1294.	Name and address of manufacturer / Applicant	M/s Saffron Pharmaceuticals (Pvt.) Limited, 19 km, Sheikhupura Road, Faisalabad.
	Brand Name +Dosage Form + Strength	Enew 400mg soft gelatin capsule
	Composition	Each soft gelatin capsule contains: Vitamin E……400mg
	Diary No. Date of R& I & fee	Dy.No.38945;27-11-2018; Rs.20,000 (26-11-2018)
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	30's & 100's Rs. 300 & Rs. 600
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Evion 400mg Cap of M/s Ad Marker (Reg. # 008754)
	GMP status	Last GMP inspection was conducted on 13.10.2018 and report concludes good compliance with grant of GMP certificate.
	Previous remarks of the Evaluator	• The official monograph for the applied formulation is available in USP. • Firm has soft gelatin capsule section as mentioned in the submitted GMP inspection report and section approval letter. • The applied strength could not be confirmed internationally.
	Previous decision	Deferred in 288th DRB meeting for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.
	Evaluation by PEC	Following reference has been verified from Austrian Agency for Health and Food Safety: Evit 600 I.E kapseln. The qualitative composition of said product declares following equivalency: 1 capsule contains: 400 mg = 600 I.U. alpha- tocopherol https://aspregister.basg.gv.at/aspregister/faces/aspregister.jspx?_afrLoop=53559007139362908&_afrWindowMode=0&_adf.ctrl-state=11ajcl0qd9_4
	Decision: Deferred for confirmation of equivalency as recorded above	
1295.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals, 14 Km, Adyala Road, Post Office Dahgal, Rawalpindi.
	Brand Name +Dosage Form + Strength	Moyotec SR tablets 2.6mg
	Composition	Each SR tablet contains: Nitroglycerine …….130mg (2% dispersion eq. to 2.6mg Nitroglycerine)

	Diary No. Date of R& I & fee	Dy.No.2131;27-05-2016; Rs.20,000/- (27-05-2016)
	Pharmacological Group	Nitrate
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	3 Blisters of 3x 10 Tablets/ Pack & Rs. 175/-
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Nitroscot SR tablet 2.6mg of M/s Scotmann Pharma (Reg. # 031070)
	GMP status	Last GMP inspection was conducted on 14-12-2017 and the report concludes the firm to be GMP compliant.
	Previous remarks of the Evaluator	• The official monograph for the applied formulation is available in USP. • General tablet section is available in the firm as mentioned in the submitted GMP certificate.
	Previous decision	Deferred in 290th DRB meeting for correction of applied label claim and equivalency of applied drug.
	Evaluation by PEC	Now, the firm has corrected the applied label claim and equivalency as: Each SR tablet contains: 2% dispersion of nitroglycerin, 130mg equivalent to nitroglycerin……2.6mg
	Decision: Approved with USP specifications.	
1296.	Name and address of manufacturer / Applicant	M/s Horizon Health Care Pvt Ltd, Plot 35 A, Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Vinocare Injection 500mg
	Composition	Each Vial Contains: Vancomycin as Hydrochloride (lyophilized ready-to-fill Powder)…….500mg
	Diary No. Date of R& I & fee	Dy. No. 24744; 17-07-2018; Rs.20,000/- (13-07-2018)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1 x 1's Vial As per SRO
	Approval status of product in Reference Regulatory Authorities.	APPROVED by MHRA
	Me-too status	Hisun 500mg Injection by Biocare Pharma (Reg.# 052214)
	GMP status	Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II.
	Previous remarks of the Evaluator	General Dry powder Vial section is available in the firm as mentioned in the GMP inspection report.
	Previous decision	Deferred in 288th DRB meeting for **the confirmation of details of already considered products as priority for new section.**
	Evaluation by PEC: 11 products were applied against 08 molecules in previous meetings.	
	Decision: Approved	
1297.	Name and address of manufacturer / Applicant	M/s Horizon Health Care Pvt Ltd. Plot 35 A, Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Vinocare Injection 1000mg
	Composition	Each Vial Contains: Vancomycin as Hydrochloride (lyophilized ready-to-fill

		Powder)……1000mg
	Diary No. Date of R& I & fee	Dy. No. 24742; 17-07-2018; Rs.20,000/- (13-07-2018)
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished product Specification	USP Specifications
	Pack size & Demanded Price	1 x 1's Vial As per SRO
	Approval status of product in Reference Regulatory Authorities.	APPROVED by MHRA
	Me-too status	Vancocin 1g Injection by Biolab Laboratories
	GMP status	Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II.
	Previous remarks of the Evaluator	General Dry powder Vial section is available in the firm as mentioned in the GMP inspection report.
	Previous decision	Deferred in 288th DRB meeting for the confirmation of details of already considered products as priority for new section.
	Evaluation by PEC: 11 products were applied against 08 molecules in previous meetings.	
	Decision: Approved	
1298.	Name and address of manufacturer / Applicant	M/s Horizon Health Care Pvt Ltd. Plot 35 A, Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Erynate Injection 30mg
	Composition	Each Vial Contains: Artesunate…….30mg
	Diary No. Date of R& I & fee	Dy. No. 24741; 17-07-2018; Rs.20,000/- (13-07-2018)
	Pharmacological Group	Anti- malarial
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	1 x 1's Vial As per SRO
	Approval status of product in Reference Regulatory Authorities.	APPROVED by WHO
	Me-too status	Gen M Injection by M/s Genix PHarma
	GMP status	Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II.
	Previous remarks of the Evaluator	The official monograph for the applied formulation is available in International Pharmacopoeia. General Dry powder Vial section is available in the firm.
	Previous decision	Deferred in 288th DRB meeting for the confirmation of details of already considered products as priority for new section.
	Evaluation by PEC: 11 products were applied against 08 molecules in previous meetings.	
	Decision: Approved	
1299.	Name and address of manufacturer / Applicant	M/s Horizon Health Care Pvt Ltd. Plot 35 A, Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Erynate Injection 60mg
	Composition	Each vial contains: Artesunate…….……60mg
	Diary No. Date of R& I & fee	Dy. No. 24743; 17-07-2018; Rs.20,000/- (13-07-2018)
	Pharmacological Group	Anti- malarial

	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	1 x 1's Vial As per SRO
	Approval status of product in Reference Regulatory Authorities.	APPROVED by WHO
	Me-too status	Misonate 60mg Injection by M/s Tabros Pharma
	GMP status	Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II.
	Previous remarks of the Evaluator	The official monograph for the applied formulation is available in International Pharmacopoeia. General Dry powder Vial section is available in the firm.
	Previous decision	Deferred in 288th DRB meeting for the confirmation of details of already considered products as priority for new section.
	Evaluation by PEC: 11 products were applied against 08 molecules in previous meetings.	
	Decision: Approved	
1300.	Name and address of manufacturer / Applicant	M/s Horizon Health Care Pvt Ltd, Plot 35 A, Small Industrial Estate, Taxila.
	Brand Name +Dosage Form + Strength	Erynate Injection 120mg
	Composition	Each vial contains: Artesunate…….120mg
	Diary No. Date of R& I & fee	Dy. No. 24745; 17-07-2018; Rs.20,000/- (13-07-2018)
	Pharmacological Group	Anti- malarial
	Type of Form	Form 5
	Finished product Specification	Innovator's Specifications
	Pack size & Demanded Price	1 x 1's Vial As per SRO
	Approval status of product in Reference Regulatory Authorities.	APPROVED by WHO
	Me-too status	Gen M Injection by M/s Genix PHarma
	GMP status	Last GMP inspection was conducted on 25-06-2018 and the report concludes that company has shown good response and rectified the problems and has shown good compliance as per schedule B-II.
	Previous remarks of the Evaluator	• The official monograph for the applied formulation is available in International Pharmacopoeia. • General Dry powder Vial section is available in the firm.
	Previous decision	Deferred in 288th DRB meeting for the confirmation of details of already considered products as priority for new section.
	Evaluation by PEC: 11 products were applied against 08 molecules in previous meetings.	
	Decision: Approved	

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

a. New Cases

1301.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutical Pvt. Ltd, Plot No. 5, Pharmacity, 30-Km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Tilmicopri oral liquid
	Composition	Each ml contains: Tilmicosin Phosphate……..……..... 250mg
	Diary No. Date of R& I & fee	Dy.No.16001;30-04-2018; Rs.20,000 (30-04-2018)
	Pharmacological Group	Macrolides antibiotics /Anti-bacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers' specifications
	Pack size & Demanded Price	100 ml , 500 ml & 1000 ml & De-Controlled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Tilmofas Oral Liquid Intervac Pvt. Ltd., Lahore (Reg. # 046644)
	GMP status	Last GMP inspection was conducted on 11-12-2018 and the report concludes renewal of DML.
	Remarks of the Evaluator [XIII]	Oral Liquid Section (Veterinary) is available in the firm as mentioned in the submitted section approval letter.
	Decision: Approved as per innovators' specifications.	
1302.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutical Pvt. Ltd, Plot No. 5, Pharmacity, 30-Km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri-Cyanofos Injection
	Composition	Each ml Injection contains: Toldimphos Sodium…….. 200mg Cyanocobalamin (Vitamin B_{12})…… 0.05mg
	Diary No. Date of R& I & fee	Dy.No.16002;30-04-2018; Rs.20,000 (30-04-2018)
	Pharmacological Group	Mineral (Phosphorous)/ Vitamins
	Type of Form	Form 5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	100 ml glass vials & De-Controlled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Pri- Cyanofos Injection of M/s Prix Pharma (Reg. # 080742)
	GMP status	Last GMP inspection was conducted on 11-12-2018 and the report concludes renewal of DML.
	Remarks of the Evaluator [XIII]	• Firm has General Injectable Liquid (Veterinary) section. • The same application has already been registered in the name of applicant with 50ml volume of injection.
	Decision: Approved as per innovators' specifications.	
1303.	Name and address of manufacturer / Applicant	M/s Prix Pharmaceutical Pvt. Ltd, Plot No. 5, Pharmacity, 30-Km Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Pri- Buquone Injection
	Composition	Each ml Injection contains: Buparvaquone……...50 mg
	Diary No. Date of R& I & fee	Dy.No.16003;30-04-2018; Rs.20,000 (30-04-2018)
	Pharmacological Group	Anti- protozoal
	Type of Form	Form-5
	Finished product Specification	Manufacturer Specifications
	Pack size & Demanded Price	100 ml & De-Controlled

	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Pri- Buquone Injection of M/s Prix Pharma (Reg. # 080755)
	GMP status	Last GMP inspection was conducted on 11-12-2018 and the report concludes renewal of DML.
	Remarks of the Evaluator [XIII]	• Firm has General Injectable Liquid (Veterinary) section. • The same application has already been registered in the name of applicant with 50ml volume of injection.
	Decision: Approved as per innovators' specifications.	
1304.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt. Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Linco Premix Powder
	Composition	Each 100 gm contains: Lincomycin HCl ……. 4.4gm
	Diary No. Date of R& I & fee	Dy.No.15738; 27-04-2018; Rs.20,000 (24-04-2018)
	Pharmacological Group	Penicillin (Antibiotic)
	Type of Form	Form-5
	Finished product Specification	BP (Vet Specifications)
	Pack size & Demanded Price	1kg, 2.5kg, 5kg, 10kg, 25kg & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Lincos- P Powder of M/s A & K Pharma (Reg. No. 049667)
	GMP status	Last GMP inspection was conducted on 16-10-2018 and the report concludes grant of renewal of DML.
	Remarks of the Evaluator [XIII]	• Firm has Veterinary Oral powder section as mentioned in the GMP inspection report.
	Decision: Approved	
1305.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt. Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Linco Forte Premix Powder
	Composition	Each kg contains: Lincomycin HCl ……...11gm
	Diary No. Date of R& I & fee	Dy.No.15739; 27-04-2018; Rs.20,000 (24-04-2018)
	Pharmacological Group	Lincosamide Antibiotic
	Type of Form	Form-5
	Finished product Specification	BP (Vet Specifications)
	Pack size & Demanded Price	1kg, 2.5kg, 5kg, 10kg, 25kg & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Linco Premix 1100 of M/s Attabak Pharma (Reg. # 075703)
	GMP status	Last GMP inspection was conducted on 16-10-2018 and the report concludes grant of renewal of DML.
	Remarks of the Evaluator [XIII]	• Firm has Veterinary Oral powder section as mentioned in the GMP inspection report.
	Decision: Approved	
1306.	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	MB COL Liquid
	Composition	Each 1000ml contains: Colistin Sulphate……...2000,000,000 IU
	Diary No. Date of R& I & fee	Dy.No.18450;21-05-2018;Rs.20,000(18-05-2018)
	Pharmacological Group	Anti- bacterial/ Anti- infective

	Type of Form	Form- 5
	Finished product Specification	In-house
	Pack size & Demanded Price	50ml, 100ml, 200ml, 250ml, 500ml, 1 litre, 2.5 litre, 5 litre, 10 litre, 15 litre, 20 litre, 25litre & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Colibar Oral Liquid of M/s Baariq Pharma (Reg. # 075784)
	GMP status	Last GMP inspection was conducted on 16-03-2017 and the report concludes good GMP compliance with advice to increase light in the Veterinary Liquid section.
	Remarks of the Evaluator [XIII]	• Firm has Veterinary Oral Liquid Section as mentioned in the submitted GMP report.
	Decision: Approved with label warning not for lactating animals and as per innovators' specifications.	
1307.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt. Ltd. 36-Km, Multan Road, Lahore.
	Brand Name +Dosage Form + Strength	Iverlon Liquid Injection 50ml
	Composition	Each ml contains: Ivermectin…….20mg Clorsulon……...10mg
	Diary No. Date of R& I & fee	Dy.No.15742; 27-04-2018; Rs.20,000 (24-04-2018)
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	50ml & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Ivoclor Super Injection of M/s Nawal Pharma (Reg. # 078244)
	GMP status	Last GMP inspection was conducted on 16-10-2018 and the report concludes grant of renewal of DML.
	Remarks of the Evaluator [XIII]	• Firm has liquid injectable section as mentioned in the submitted GMP inspection report.
	Decision: Approved	
1308.	Name and address of manufacturer / Applicant	M/s Wimits Pharmaceuticals Pvt Ltd. Plot 129 Sunder Industrial Estate Raiwind, Lahore.
	Brand Name +Dosage Form + Strength	Hepawim Solution for Injection I/M
	Composition	Each 100 ml contains: Phenoxy-2-methyl-2-Propionic Acid …….10g
	Diary No. Date of R& I & fee	Dy.No.18967;24-05-2018; Rs.20,000 (24-05-2018)
	Pharmacological Group	Drugs used in Liver Therapy
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50ml glass vial & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Hepagen Injection of M/s Prix Pharma (Reg. # 012896)
	GMP status	Last GMP inspection was conducted on 03-11-2017 and the report concludes satisfactory GMP compliance.
	Remarks of the Evaluator [XIII]	Veterinary Liquid Injection Section (General) is available in the firm as mentioned in the submitted GMP inspection report. **Vial** manufacturing facility needs confirmation.
	Decision: Approved as per innovators' specifications.	

1309.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries, Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Actimox 70% Powder
	Composition	Each 100gm powder contains: Amoxicillin Trihydrate…….80mg (Eq. to 70mg of Amoxicillin Base)
	Diary No. Date of R& I & fee	Dy. No.24438; 13-07-2018;Rs.20,000 (13-07-2018)
	Pharmacological Group	Anti- bacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100g, 500g, 1kg, 2.5kg, 5kg, 10kg & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Bio-Amoxyllin 70% Water Soluble Powder of M/s Bio Labs (Reg. # 079850)
	GMP status	Last GMP inspection was conducted on 14-02-19 and the report concludes: "Keeping in view the fact that production was not seen either due to schedule or the fact that the oral liquid (gen) and liquid injection (general) were under maintenance, the GMP in the production areas could not be rated as subsequent visit is required upon completion of repair/maintenance work.
	Remarks of the Evaluator [XIII]	• Oral powder section (Veterinary) is available in the firm as mentioned in the submitted GMP inspection report. • GMP status of the applicant could **not** be confirmed.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1310.	Name and address of manufacturer / Applicant	M/s Inshal Pharmaceutical Industries. Plot No. 2, Street SS 2, National Industrial Zone, Rawat, Islamabad
	Brand Name +Dosage Form + Strength	Bromothol Liquid
	Composition	Each 100ml contains: Bromhexine HCl……..…….2gm Menthol……..4gm
	Diary No. Date of R& I & fee	Dy. No.24437; 13-07-2018; Rs.20,000(13-07-2018)
	Pharmacological Group	Mucolytic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	100ml,250ml,500ml,1 litre,2.5 litre & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	BROMAN Liquid D-Maarson Pharma 073994
	GMP status	Last GMP inspection was conducted on 14-02-19 and the report concludes: "Keeping in view the fact that production was not seen either due to schedule or the fact that the oral liquid (gen) and liquid injection (general) were under maintenance, the GMP in the production areas could not be rated as subsequent visit is required upon completion of repair/maintenance work.
	Remarks of the Evaluator [XIII]	• Oral Liquid section (Veterinary) is available in the firm as mentioned in the submitted GMP inspection report. • GMP status of the applicant could **not** be confirmed.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	

1311.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt Ltd. 36- Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Vital Plus Powder
	Composition	Each kg contains: Vitamin-A……10 MIU Vitamin-D3……3 MIU Vitamin-E……5000 MIU Vitamin-K3……3000 MIU Vitamin-C……30,000 MIU
	Diary No. Date of R& I & fee	Dy. No.25079; 19-07-2018; Rs.20,000(19-07-2018)
	Pharmacological Group	Multi- Vitamin
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	500g, 1kg, 2.5kg & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Advet Plus Water Soluble Powder of M/s Medicure Labs (Reg. # 019929)
	GMP status	Last GMP inspection was conducted on 16-10-2018 and the report concludes grant of renewal of DML.
	Remarks of the Evaluator [XIII]	Veterinary Oral powder is available in the firm as is mentioned in the submitted GMP inspection report.
	Decision: Deferred for clarification regarding solubility of vitamins as formulation has both water soluble and fat soluble vitamins.	
1312.	Name and address of manufacturer / Applicant	M/s Selmore Pharmaceuticals Pvt. Ltd. 36- Km, Multan Road Lahore.
	Brand Name +Dosage Form + Strength	Actimec Forte Injection
	Composition	Each ml contains: Ivermectin……10mg Vitamin A……25000 IU Vitamin D……3750 IU Vitamin E……25mg
	Diary No. Date of R& I & fee	Dy.No.15741;27-04-2018; Rs.20,000 (24-04-2018)
	Pharmacological Group	Anti- parasite with Vitamins
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	50ml/ vial & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Could not be confirmed
	GMP status	Last GMP inspection was conducted on 16-10-2018 and the report concludes grant of renewal of DML.
	Remarks of the Evaluator [XIII]	• Me- too status could **not** be confirmed. • General Liquid Injectable section is available in the firm as mentioned in the submitted GMP inspection report.
	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.	
1313.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories Pvt. Ltd. 136 sector 15 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Toximac- Plus Aerosol Spray
	Composition	Each gm contains: Oxytetracycline HCl……40mg Gentian violet……4mg Permethrin……10mg

		Citronella oil……20mg
	Diary No. Date of R& I & fee	Dy. No.24006; 11-07-2018;Rs.20,000 (10-07-2018)
	Pharmacological Group	Antibiotic
	Type of Form	Form- 5
	Finished product Specification	In-house
	Pack size & Demanded Price	150ml, 300ml & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Teragen Plus Aerosol Spray of M/s Star Laboratories (Reg. # 063623)
	GMP status	Last GMP inspection report was conducted on 30-04-018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Availability of Aerosol spray section/ manufacturing facility in the firm needs to be confirmed.
	Decision: Deferred for evidence of Aerosol spray section/ manufacturing facility in the firm.	
1314.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories Pvt. Ltd. 136 sector 15 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Doxywan- 50% Oral Powder
	Composition	Each gram contains: Doxycycline Hyclate……500mg
	Diary No. Date of R& I & fee	Dy. No.24005; 11-07-2018;Rs.20,000 (10-07-2018)
	Pharmacological Group	Anti- microbial/ Anti- infective
	Type of Form	Form- 5
	Finished product Specification	In-house
	Pack size & Demanded Price	1 kg jar & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Seldox Powder of M/s Selmore Pharma (Reg. # 058717)
	GMP status	Last GMP inspection report was conducted on 30-04-018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	General Veterinary Oral Dry powder sachet/ bag section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved as per innovators' specifications.	
1315.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories Pvt. Ltd. 136 sector 15 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Cefanil IMM injector (Intramammary suspension)
	Composition	Each 8gm syringe contains: Cefquinome as Sulfate……75mg
	Diary No. Date of R& I & fee	Dy. No.24004; 11-07-2018;Rs.20,000 (10-07-2018)
	Pharmacological Group	Anti- bacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	As per SRO & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Cobac 7.5 % LA Injection of M/s Mylab (Pvt) Ltd. (Reg. # 073911)
	GMP status	Last GMP inspection report was conducted on 30-04-018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• Liquid Injectable Veterinary (Cephalosporin) section is available in the firm.
	Decision: Deferred for confirmation of manufacturing facility of PFS.	

1316.	Name and address of manufacturer / Applicant	M/s Nawan Laboratories Pvt. Ltd. 136 sector 15 Korangi Industrial Area, Karachi.
	Brand Name +Dosage Form + Strength	Micowan-300 Injection (300mg/ ml)
	Composition	Each ml contains: Tilmicosin as Tilmicosin Phosphate……300mg
	Diary No. Date of R& I & fee	Dy. No.24003; 11-07-2018;Rs.20,000 (10-07-2018)
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form- 5
	Finished product Specification	In-house
	Pack size & Demanded Price	50ml & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Mico Sol Injection of M/s Elko 300mg/ ml Organization (Pvt.) Ltd (Reg. # 080150)
	GMP status	Last GMP inspection report was conducted on 30-04-018 and the report concludes satisfactory level of GMP compliance.
	Remarks of the Evaluator [XIII]	• General Veterinary Sterile Liquid Injection Section is available in the firm as mentioned in the submitted GMP inspection report.
	Decision: Approved as per innovators' specifications.	
1317.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot # 11- A Small Industrial Estate Taxilla, Rawalpindi.
	Brand Name +Dosage Form + Strength	Vitawal Liquid Injection
	Composition	Each ml contains: Vitamin-A……80,000 IU Vitamin- D3……..40,000 IU Vitamin- E……..20mg
	Diary No. Date of R& I & fee	Dy.No.25274; 20-07-2018; Rs.20,000 (19-07-2018)
	Pharmacological Group	Vitamin supplement
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	10ml, 50ml, 100ml, 500ml glass vials & Decontrolled
	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Vital-3 Injection of M/s Selmore Pharmaceuticals (Pvt) Ltd., Lahore. (Reg. # 049635)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes the firm to be GMP compliant with the need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [XIII]	Liquid Injection Section (Veterinary) is available in the firm as mentioned in the submitted inspection report.
	Decision: Approved as per innovators' specifications.	
1318.	Name and address of manufacturer / Applicant	M/s Nawal Pharmaceuticals, Plot # 11- A Small Industrial Estate Taxilla, Rawalpindi.
	Brand Name +Dosage Form + Strength	Ivoclor Liquid Injection 10ml
	Composition	Each ml contains: Ivermectin……...20mg Clorsulon……..…10mg
	Diary No. Date of R& I & fee	Dy.No.25273; 20-07-2018; Rs.20,000 (19-07-2018)
	Pharmacological Group	Anthelmintic
	Type of Form	Form- 5
	Finished product Specification	USP
	Pack size & Demanded Price	10ml & Decontrolled

	Approval status of product in Reference Regulatory Authorities	N/A
	Me-too status	Ivobak Super Injection of M/s Attabak Pharma (Reg. # 063825)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concludes the firm to be GMP compliant with the need of some improvements which have been discussed and agreed with the management.
	Remarks of the Evaluator [XIII]	• Liquid Injection Section (Veterinary) is available in the firm as mentioned in the submitted inspection report.
	Decision: Approved with label warning.	

Evaluator PEC-XIV

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

a. New cases

1319.	Name and address of manufacturer / Applicant	M/s McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Contract manufactured from M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad
	Brand Name +Dosage Form + Strength	Ronem 500mg Injection I.V
	Composition	Each vial contains: Meropenem as trihydrate…….500mg
	Diary No. Date of R& I & fee	Duplicate; 15-04-2013, 50,000/-, 15-04-2013
	Pharmacological Group	Carbapenem
	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.	Meronem IV 500 mg by Pfizer Limited (MHRA Approved)
	Me-too status	Merem 500mg injection by Global Pharma
	GMP status	GMP inspection of M/s Nicholas Pharmaceuticals, Rawat dated 03-08-2018 recommends for the grant of Drug Manufacturing License by way of formulation. GMP inspection of M/s McOlson Research Laboratories (Pvt.) Ltd., Sheikhupura dated 03-08-2018 recommends for the grant of Drug Manufacturing License by way of formulation.
	Remarks of the Evaluator.	The firm had initially applied for contract manufacturing with M/s English pharmaceuticals, Multan Road, Lahore. Now the firm has requested to change the contract manufacturing to M/s Nicholas Pharma. However, request for such change is made after 7th March, 2019. The submitted master formulation contains 1gm of Meropenem while applied strength of Meropenem is 500mg. M/s Nicholas Pharma, Rawat has provided Dry Powder injectable section (Carbapenems).
	Decision: Registration Board deferred the case and directed the firm to submit application on Form-5F.	
1320.	Name and address of manufacturer / Applicant	M/s McColson Research Laboratories, 26km Lahore Sheikhupura Road, Sheikhupura Contract manufactured from: M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National Industrial Zone Rawat

	Brand Name +Dosage Form + Strength	Ronem 1g Injection I.V
	Composition	Each vial contains: Meropenem as trihydrate…….1g
	Diary No. Date of R& I & fee	Duplicate; 15-04-2013, 50,000/-, 15-04-2013
	Pharmacological Group	Carbapenem
	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.	Meronem IV 1g by Pfizer Limited (MHRA Approved)
	Me-too status	Merem 1g injection by Global Pharma
	GMP status	GMP inspection of M/s Nicholas Pharmaceuticals, Rawat dated 03-08-2018 recommends for the grant of Drug Manufacturing License by way of formulation. GMP inspection of M/s McOlson Research Laboratories (Pvt.) Ltd., Sheikhupura dated 03-08-2018 recommends for grant of Drug Manufacturing License by way of formulation.
	Remarks of the Evaluator.	The firm had initially applied for contract manufacturing with M/s English pharmaceuticals, Multan Road, Lahore. Now the firm has requested to change the contract manufacturing to M/s Nicholas Pharma. However, request for such change is made after 7th March, 2019. The submitted master formulation contains 1gm of Meropenem while applied strength of Meropenem is 500mg. M/s Nicholas Pharma, Rawat has provided Dry Powder injectable section (Carbapenems).
	Decision: Registration Board deferred the case and directed the firm to submit application on Form-5F.	
1321.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt.) Ltd. 23-Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	ROCETRAX-50 I.V
	Composition	Each vial contains: Ceftriaxone as sodium……..500mg
	Diary No. Date of R& I & fee	4158, 02-02-2018, 20,000/-, 18-01-2018
	Pharmacological Group	Antibiotic (Third Generation Cephalosporine)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Rezone 500mg Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031982)
	GMP status	GMP inspection conducted on 05-10-2018 & 12-11-2018 concluded that the firm was considered to be operating at a satisfactory level of GMP compliance at the time of inspection except for Human Liquid injectable section and Human injectable section (Psychotropic).
	Remarks of the Evaluator.	The firm has provided Dry Powder injectable (vial) Cephalosporine section
	Decision: Approved.	
1322.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt.) Ltd. 23-Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	ROCETRAX-100 I.M

	Composition	Each vial contains: Ceftriaxone as sodium……..1000mg
	Diary No. Date of R& I & fee	4156, 02-02-2018, 20,000/-, 18-01-2018
	Pharmacological Group	Antibiotic (Third Generation Cephalosporine)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Rezone 1gm Injection IV by M/s Well Care Pharmaceuticals, Islamabad. (Reg.#031980)
	GMP status	GMP inspection conducted on 05-10-2018 & 12-11-2018 concluded that the firm was considered to be operating at a satisfactory level of GMP compliance at the time of inspection except for Human Liquid injectable section and Human injectable section (Psychotropic).
	Remarks of the Evaluator.	The firm has provided Dry Powder injectable (vial) Cephalosporine section. The firm has requested to change the route of administration from I.V to I.M with submission of Rs. 5,000/- (Deposit slip # 1961262) dated 10-08-2019.
	Decision: Approved.	
1323.	Name and address of manufacturer / Applicant	M/s Star Laboratories (Pvt.) Ltd. 23-Km, Multan Road, Lahore
	Brand Name +Dosage Form + Strength	ROCETRAX-25 I.V
	Composition	Each vial contains: Ceftriaxone as sodium……..250mg
	Diary No. Date of R& I & fee	4155, 02-02-2018, 20,000/-, 18-01-2018
	Pharmacological Group	Antibiotic (Third Generation Cephalosporine)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Wincef 250 mg IV Injection of M/s Wel Wink Pharmaceuticals (Reg.# 078096)
	GMP status	GMP inspection conducted on 05-10-2018 & 12-11-2018 concluded that the firm was considered to be operating at a satisfactory level of GMP compliance at the time of inspection except for Human Liquid injectable section and Human injectable section (Psychotropic).
	Remarks of the Evaluator.	The firm has provided Dry Powder injectable (vial) Cephalosporine section.
	Decision: Approved.	
1324.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Glu VID-500mg / 50mg Tablet
	Composition	Each film coated tablet contains: Metformin hydrochloride…….500mg Vildagliptin……..50mg
	Diary No. Date of R& I & fee	26745, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Biguanide / DPP-4 inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house

	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/500 film coated tablet by M/s Novartis Pharma Ltd. Approved in TGA Australia.
	Me-too status	Galvus Met 50/500mg Tablets of M/s Novartis (Reg#078106)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	The firm has submitted revised master formulation and manufacturing outline without submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
1325.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	Glu VID-1000mg / 50mg Tablet
	Composition	Each film coated tablet contains: Metformin hydrochloride…….1000mg Vildagliptin……..50mg
	Diary No. Date of R& I & fee	26757, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Biguanide / DPP-4 inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	GALVUMET 50/1000 film coated tablet by M/s Novartis Pharma Ltd. Approved in TGA Australia.
	Me-too status	Galvus Met 50/1000mg Tablets of M/s Novartis. (Reg#066107)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	The firm has submitted revised master formulation and manufacturing outline without submission of fee.
	Decision: Deferred for submission of fee for revision of formulation.	
1326.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	METHODAR FORT TABLET
	Composition	Each Tablet contains: Artemether……80mg Lumefantrine…….480mg
	Diary No. Date of R& I & fee	26758, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Anti-malarial
	Type of Form	Form-5
	Finished product Specification	IP
	Pack size & Demanded Price	6's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Artem-DS Plus Tablets 80/480 of M/s Hilton Pharma, Karachi (Reg.# 066843)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	
	Decision: Approved.	

1327.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	EsiBer-20mg Tablet
	Composition	Each film coated tablet contains: Escitalopram as oxalate……..20mg
	Diary No. Date of R& I & fee	26721, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Escitalopram 20 mg Of (MHRA Approved)
	Me-too status	Gentle 20mg Tablet Of M/S Wilson's Pharmaceuticals,
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	
	Decision: Approved.	
1328.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	EsiBer-10mg Tablet
	Composition	Each film coated tablet contains: Escitalopram as oxalate……..10mg
	Diary No. Date of R& I & fee	26724, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Selective serotonin reuptake inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Escitalopram 10 mg Of (MHRA Approved)
	Me-too status	Gentle 10mg Tablet Of M/S Wilson's Pharmaceuticals,
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	
	Decision: Approved.	
1329.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerNIM TABLET 100mg
	Composition	Each film coated tablet contains: Nimesulide……..100mg
	Diary No. Date of R& I & fee	26750, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	2 × 10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMA approved
	Me-too status	Amsolide by Amson
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	Keeping in view the approval status of Nimesulide 100mg tablet in EMA, the Registration Board in its 269th approved

		the formulation of Nimesulide Tablets 100mg with a pack size of 15 tablets as per recommendations of EMA only for the following clinical indications as a second line choice. Treatment of acute pain Primary dysmenorrhea
	Decision: Deferred for confirmation of approval of applied formulation in reference regulatory authority as film coated or uncoated tablet.	
1330.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerOGREL Plus TABLET 75/81mg
	Composition	Each film coated Tablet contains: Clopidogrel as Bisulfate……75mg Aspirin ……..81mg
	Diary No. Date of R& I & fee	26754, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Antiplatelet
	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.	Not confirmed
	Me-too status	Not confirmed
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authority could not be verified. • Evidence of applied formulation already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Decision: Deferred for following: • **Evidence of approval of applied formulation in reference regulatory authority adopted by Registration Board in 275th meeting.** • **Evidence of applied formulation already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1331.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	EFFIBer TABLET 10mg
	Composition	Each film coated tablet contains: Prasugrel……..……10mg
	Diary No. Date of R& I & fee	26755, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Platelet aggregation inhibitor
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Effient (USFDA approved)
	Me-too status	Effin 10mg tablet of M/s Macter International, Karachi
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	Correction of salt form is required.
	Decision: Deferred for correction of salt form of applied formulation alongwith requisite fee.	

1332.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerVASTATIN-20mg TABLET
	Composition	Each film coated Tablet contains: Atorvastatin as Calcium……20mg
	Diary No. Date of R& I & fee	26756, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Lipid Lowering Agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status	Lipitor of M/s Pfizer
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	
	Decision: Approved.	
1333.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerVASTATIN-10mg TABLET
	Composition	Each film coated Tablet contains: Atorvastatin as Calcium……10mg
	Diary No. Date of R& I & fee	26737, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Lipid Lowering Agent
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Lipitor tablets by Pfizer (MHRA Approved)
	Me-too status	Lipitor of M/s Pfizer
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1334.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerBAC-10mg TABLET
	Composition	Each film coated Tablet contains: Bambuterol hydrochloride……10mg
	Diary No. Date of R& I & fee	26747, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Selective β2 agonist
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	2×15's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bambec Tablet by Astrazaneca (MHRA Approved)
	Me-too status	Bambuscot tablet by scotmann
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	

1335.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	VESI-Ber TABLET 10mg
	Composition	Each film coated tablet contains: Solifenacin succinate……..10mg
	Diary No. Date of R& I & fee	26718, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	2×15's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Solfin Tablet 10mg of Regal Pharmaceuticals
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1336.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerNOIN-20 CAPSULE
	Composition	Each capsule contains: Isotretinoin……..20mg
	Diary No. Date of R& I & fee	26741, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Vitamin A derivative
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	30's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Absorica 10mg capsules of (USFDA approved)
	Me-too status	Iret 10mg Capsule of M/s Baxter
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	• For hard gelatin Submit the complete data of isotretionine as per 250th meeting (Each capsule contains isotretinoin, stearoyl macrogolglycerides, soybean oil, sorbitan monooleate and propyl gallate. Gelatin capsules contain the following dye systems: 10 mg – iron oxide (yellow) and titanium dioxide.)
	Decision: Deferred for submission of stability study data as per the requirements of 278th meeting of Registration Board.	
1337.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerACE-5mg TABLET
	Composition	Each film coated Tablet contains: Lisinopril as dihydrate……..5mg
	Diary No. Date of R& I & fee	26740, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	ACE Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 ×14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA

	Me-too status	Zestril tablet 10 mg by ICL Pharma
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1338.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerLEXIN TABLET 500mg
	Composition	Each film coated Tablet contains: Naproxen as sodium……500mg
	Diary No. Date of R& I & fee	26738, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	NSAIDs
	Type of Form	Form-5
	Finished product Specification	USP specs
	Pack size & Demanded Price	2 ×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Naproxen 500mg Tablet of Mylan (USFDA approved)
	Me-too status	Flexin 500mg Tablet of Abbott, Karachi
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1339.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	OMJET-40 CAPSULE
	Composition	Each capsule contains: Omeprazole (as enteric coated pellets)……..40mg
	Diary No. Date of R& I & fee	26744, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	USP specs
	Pack size & Demanded Price	2 ×7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA
	Me-too status	Acizole Capsule 40mg by M/s Cirin Pharmaceuticals, (Reg# 034369)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets is required to be submitted.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
1340.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerCLOPRINE TABLET
	Composition	Each film coated tablet contains: Clopidogrel as Bisulfate……75mg
	Diary No. Date of R& I & fee	26727, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Platelet aggregation inhibitor
	Type of Form	Form-5

	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 ×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cadix 75mg of (MHRA approved)
	Me-too status	Clorel 75mg tablet of M/s Mission
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1341.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerVALDIPINE-5/80mg TABLET
	Composition	Each film coated tablet contains: Valsartan……...80mg Amlodipine as besylate…….5mg
	Diary No. Date of R& I & fee	26749, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Angiotensin-II antagonists/ Calcium antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2 ×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Exforge Tablet of M/s Novartis Pharma (Reg.#047569)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1342.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerVALDIPINE-5/160mg TABLET
	Composition	Each film coated tablet contains: Valsartan……...160mg Amlodipine as besylate…….5mg
	Diary No. Date of R& I & fee	26722, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Angiotensin-II antagonists/ Calcium antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Exforge of M/s Novartis Pharma (Reg. # 047571)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1343.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	EFFIBer TABLET 5mg
	Composition	Each film coated Tablet contains: Prasugrel……5mg
	Diary No. Date of R& I & fee	26720, 29-12-2017, 20,000/-, 27-12-2017

	Pharmacological Group	Antiplatelet
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Eficlot Tablet 5mg of CCL Pharma (Reg#067765)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	Correction of salt form is required.
	Decision: Deferred for correction of salt form of applied formulation alongwith requisite fee.	
1344.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerZOLE TABLET 400mg
	Composition	Each film coated Tablet contains: Metronidazole……400mg
	Diary No. Date of R& I & fee	26728, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Nitromidazole
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	10×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Flagyl 400mg Tablets by M/s Aventis Pharma Limited (MHRA Approved)
	Me-too status	Flagyl 400mg Tablet by M/s Sanofi Aventis (Reg#000827)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1345.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	ROSU-Ber TABLET 10mg
	Composition	Each film coated Tablet contains: Rosuvastatin as calcium ……10mg
	Diary No. Date of R& I & fee	26739, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 10mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved)
	Me-too status	Loster 10mg Tablets by M/s Helix Pharma, (Reg#045334)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1346.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	ROSU-Ber TABLET 20mg
	Composition	Each film coated Tablet contains: Rosuvastatin as calcium ……20mg
	Diary No. Date of R& I & fee	26719, 29-12-2017, 20,000/-, 26-12-2017

	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form-5
	Finished product Specification	Manufacturer specifications
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Crestor 20mg film-coated tablets by M/s AstraZeneca UK Ltd (MHRA Approved)
	Me-too status	Loster 20mg Tablets by M/s Helix Pharma, (Reg#045335)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1347.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerZINE TABLET 10mg
	Composition	Each film coated Tablet contains: Cetirizine Dihydrochloride……10mg
	Diary No. Date of R& I & fee	26729, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Antihistamines
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cetec 10 mg film-coated tablets by M/s Bristol Laboratories Ltd (MHRA Approved)
	Me-too status	RIGIX 10mg TABLET by M/s GLAXO (Reg#011248)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	• The firm has submitted revised Form-5 with correct label claim.
	Decision: Deferred for submission of fee for revision of formulation.	
1348.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	PARABERATE TABLET
	Composition	Each Tablet contains: Paracetamol……..650mg Orphenadrine citrate…….50mg
	Diary No. Date of R& I & fee	26734, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Central anticholinergic (skeletal muscle relaxant)
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Nuberol Forte tablet of M/s Searle
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	• Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting is required to be submitted.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting.	

1349.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	S-Cid 300mg TABLET
	Composition	Each film coated Tablet contains: Ranitidine as hydrochloride……300mg
	Diary No. Date of R& I & fee	26746, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Ranidol Tablets 300mg of Fedro (Reg # 079258)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1350.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerBASTIN TABLET 10mg
	Composition	Each film coated Tablet contains: Ebastine…….10mg
	Diary No. Date of R& I & fee	26735, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Antihistamine
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	ANSM Approved
	Me-too status	Sebastin of M/s Vision Pharmaceuticals (Reg. # 041730)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1351.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerTONEL TABLET 35mg
	Composition	Each film coated tablet contains: Risedronate sodium……35mg
	Diary No. Date of R& I & fee	26733, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Bisphosphonate
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	2×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Risedronate Sodium Tablets by M/s TEVA UK, Ltd (MHRA Approved)
	Me-too status	Atconate 35mg Tablet by M/s Atco Laboratories
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	

1352.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	MEDIFEN-50 CAPSULE
	Composition	Each Capsule Contains: Diclofenac sodium (as enteric coated pellets)……50mg
	Diary No. Date of R& I & fee	26725, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by HPRA of Ireland
	Me-too status	Phlogin 50mg capsules of M/s Brookes pharma
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets is required to be submitted.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
1353.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerPEP TABLET 50mg
	Composition	Each film coated Tablet Contains: Itopride hydrochloride……..50mg
	Diary No. Date of R& I & fee	26753, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ganaton Tablet of M/s Abbott Laboratories (PMDA)
	Me-too status	Itop 50mg Tablet by M/s Nexus.
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1354.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	VESI-Ber TABLET 5mg
	Composition	Each film coated tablet contains: Solifenacin succinate…….5mg
	Diary No. Date of R& I & fee	26730, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Muscarinic receptor antagonist
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2×15's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vesicare (Approved in USFDA)
	Me-too status	Solfin Tablet 5 mg of Regal Pharmaceuticals
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug

		Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1355.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	TAZ-250 TABLET
	Composition	Each Tablet contains: Terbinafine as hydrochloride……250mg
	Diary No. Date of R& I & fee	26731, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2×5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Neoterbin Tablets 250mg by M/s Neomedix (Reg# 081411)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1356.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerACE-10mg TABLET
	Composition	Each film coated tablet contains: Lisinopril as dihydrate…….10mg
	Diary No. Date of R& I & fee	26732, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	ACE Inhibitor
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	2×5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Zestril tablet 10 mg by ICL Pharma
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1357.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerBAC-20mg TABLET
	Composition	Each film coated tablet contains: Bambuterol hydrochloride…….20mg
	Diary No. Date of R& I & fee	26748, 29-12-2017, 20,000/-, 26-12-2017
	Pharmacological Group	Selective β2 agonist
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	2× 15's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bambec Tablet by Astrazaneca (MHRA Approved)
	Me-too status	Bambuscot Tablet by Scotmann (Reg#029928)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of

		the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1358.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	LOZID TABLET
	Composition	Each film coated tablet contains: Losartan Potassium…….50mg Hydrochlorothiazide…….12.5mg
	Diary No. Date of R& I & fee	26743, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Angiotensin –II receptor antagonist/Thiazide diuretics
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	14's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Losartan Potassium / Hydrochlorothiazide 50 mg/12.5 mg Film-coated Tablets by M/s Sandoz (MHRA Approved)
	Me-too status	Sartan –H Tablets by M/s Barrett Hodgson Pakistan (Pvt) Ltd (Reg#024252)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved.	
1359.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerZOX TABLET 500mg
	Composition	Each film coated tablet contains: Nitazoxanide……..500mg
	Diary No. Date of R& I & fee	26742, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Antiprotozoal agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	2 ×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Izato tablet of M/s Sami Pharmaceuticals (Reg. # 076308)
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Approved with innovator's specifications.	
1360.	Name and address of manufacturer / Applicant	M/s 3S Pharmaceuticals (Pvt) Limited, 5-Km off Raiwind Road, Manga Road, Lahore
	Brand Name +Dosage Form + Strength	BerPEP TABLET 25mg
	Composition	Each film coated tablet contains: Itopride HCl……..25mg
	Diary No. Date of R& I & fee	26752, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1×10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.

	Me-too status	Could not be confirmed.
	GMP status	The panel inspection dated 01-03-2019 and 13-05-2019 is of the opinion to recommend the grant of renewal of Drug Manufacturing License.
	Remarks of the Evaluator.	•
	Decision: Registration Board rejected the application as applied formulation is not approved by any reference regulatory authority and firm has not submitted safety and efficacy data.	
1361.	Name and address of manufacturer / Applicant	M/s. Welwrd Pharmaceuticals, Plot 3, Block A, phase I-II, industrial Estate Hattar-Pakistan
	Brand Name +Dosage Form + Strength	Weldine 2mg Tablet
	Composition	Each tablet contains: Tizanidine as HCl……..2mg
	Diary No. Date of R& I & fee	5168, 28-07-2017, 20,000/-, 28-07-2017
	Pharmacological Group	Skeletal muscle relaxant
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Ronelin 2mg tablet of M/s Rock Pharma (Reg # 077305)
	GMP status	Last GMP inspection conducted on 14-06-2017 and the report concludes that overall the firm is GMP compliant.
	Remarks of the Evaluator.	The dossier was received from section vide letter No.F.16-4/2013-Reg-IV as duplicate with a stance of the firm that they had applied for registration of this product but could not be discussed in any meeting of Registration Board.
	Decision: Approved. Fee shall be verified as per procedure adopted in 285th meeting.	
1362.	Name and address of manufacturer / Applicant	M/s GT Pharma private Limited. Plot no. 713, Sundar industrial Estate, Lahore
	Brand Name +Dosage Form + Strength	G-TANT POWDER FOR SUSPENSION
	Composition	Each Sachet after reconstitution gives: Aprepitant ……..125mg / 5ml
	Diary No. Date of R& I & fee	14750, 20-04-2018, 20,000/-, 20-04-2018
	Pharmacological Group	Antiemetics and anti-nauseants
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	EMENED SUSPENSION of MERCK & Co, USA
	Me-too status	EMEND of Merck
	GMP status	Keeping in view the observations made on the day of inspection and after going through the documentation and overall operations, the panel of inspectors dated 08-08 2017 was of the opinion that the firm M/s GT Pharma Lahore had maintained conformance to GMP compliance in the manufacturing and quality control operations.
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory could not be confirmed. Evidence of applied formulation already approved by DRAP/ DCO is required.
	Decision: Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.	

1363.	Name and address of manufacturer / Applicant	M/s Albert Pharmaceuticals (Pvt.) Ltd., Plot # 127, Sundar Industrial Estate, Raiwind , Lahore
	Brand Name +Dosage Form + Strength	DELOAD Dry Suspension
	Composition	Each 5ml (when reconstituted) contains: Nitazoxanide……100mg
	Diary No. Date of R& I & fee	19412, 30-10-2017, 20,000/-, 23-10-2017
	Pharmacological Group	Antiprotozoal
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	30ml & 60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alinia by Romark (USFDA Approved)
	Me-too status	Diatazox 100mg/5ml Dry Suspension of M/s S.J & G
	GMP status	GMP status could not be verified.
	Remarks of the Evaluator.	The firm has provided oral dry powder suspension (General) section.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1364.	Name and address of manufacturer / Applicant	M/s Care Pharmaceuticals, 8-km, Thokar Raiwind road, Lahore.
	Brand Name +Dosage Form + Strength	HYDRAMIN SYRUP
	Composition	Each 5ml contains: Aminophylline…….32mg Diphenhydramine……8mg Ammonium chloride……30mg Menthol…….0.98mg
	Diary No. Date of R& I & fee	Duplicate, 23-02-2011, 8,000/-, (Photocopy attached), 30-06-2013, 12,000/-, (Photocopy attached)
	Pharmacological Group	Cough preparation
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	60ml & 120ml; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Hydryllin Syrup by M/s Searle, Pakistan
	GMP status	Panel inspection conducted on 13th March, 2019 recommends renewal of DML.
	Remarks of the Evaluator.	RRA status 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.

1365.	Name and address of manufacturer / Applicant	M/s Welwink Pharmaceuticals, Factory G.T. Road, industrial Estate, Gujranwala cantt contract manufactured from M/s Weather Folds Pharmaceuticals, Plot No.69/2, Phase II, Industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	DYDROGEN 10mg TABLET
	Composition	Each film coated tablet contains: Dydrogesterone……..10mg
	Diary No. Date of R& I & fee	17165, 05-10-2017, 50,000/-, 04-10-2017
	Pharmacological Group	Progestogen
	Type of Form	Form-5
	Finished product Specification	USP

	Pack size & Demanded Price	As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Duphaston by BGP Products (Swissmedic Approved)
	Me-too status	Duphaston by Abbott (Reg. No. 006654)
	GMP status	Last GMP inspection (M/s Welwink Pharma) dated 20-12-2017 and the panel concluded that the firm was operating at a satisfactory level of GMP compliance for all sections except Liquid injectable section.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for deliberation upon Cis / Trans isomer of Dydrogesterone (M-284).
	Evaluation by PEC	The firm has submitted that we will use the Trans isomer in production of our tablets. The firm has provided Tablet section (steroidal hormone).
	Decision: Approved.	
1366.	Name and address of manufacturer / Applicant	M/s Hudson Pharma (Pvt) Ltd, Plot No.D-93, North Western Industrial Zone, Port Qasim, Karachi
	Brand Name +Dosage Form + Strength	SYMBIVENT 400mcg +12mcg Rotacaps
	Composition	Each Rotacap contains: Budesonide ……400mcg Formoterol fumarate …….12mcg
	Diary No. Date of R& I & fee	Diary No:42060, 07/12/2018, Rs: 20,000/-, 07/12/2018
	Pharmacological Group	Adrenergics, Inhalants (Adrenergics in combination with corticosteroids or other drugs, excl. anticholinergics)
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30's/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Symbicort 400/12 Inhalation Powder of M/s Astrazeneca, UK (MHRA approved)
	Me-too status	Venticort 400mcg+12mcg Rotacaps of Highnoon Labs (Reg#089365)
	GMP status	19-01-2018 Panel recommends grant of additional sections
	Previous remarks of the Evaluator.	The submitted me-too reference could not be verified.
	Previous decision(s)	Deferred for further deliberation upon required manufacturing facility for applied formulation (M-287).
	Evaluation by PEC	The firm has submitted 6 months accelerated and 6 months ambient stability studies data for three trial batches.
	Decision: Deferred for following reasons: **Confirmation of manufacturing facility for applied formulation.** **Scientific justification for using ambient conditions in submitted stability studies data.**	
1367.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd.Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dyac (Clindamycin) 1 % Lotion
	Composition	Each gm contains: Clindamycin phosphate …… 1 % w/w
	Diary No. Date of R& I & fee	Dy. No 5577 dated 07-2-2019 Rs.20,000/- Dated 7- 2-2019
	Pharmacological Group	Bacteroistatic
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	30ml; as per DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Austaclin T Lotion by Bloom Pharma (Reg # 063077)

	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Previous remarks of the Evaluator.	Salt factor is incorrect. Firm has Lotion Section (general)
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation (M-288).
	Evaluation by PEC	The firm has specified the formulation as w/w and the composition is same as reference product alongwith submission of fee challan of Rs 5000/- (deposit slip # 1901018) dated 22-07-2019.
	Decision: Approved.	
1368.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd. Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dynovate (Betamethasone Valerate) 0.1 % cream
	Composition	Each gm contains: Betamethasone Valerate USP …….....0.1 % w/w
	Diary No. Date of R& I & fee	Dy. No 4848 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	10gm; as per DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Betvonate Cream 0.1 % by M/s GSK Pakistan.
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Previous remarks of the Evaluator.	Salt factor is incorrect Firm has Cream Section (Steroid)
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation (M-288).
	Evaluation by PEC	The firm has specified that the formulation is w/w and the composition is same as reference product. The firm has submitted fee challan of Rs. 5000/- (deposit slip#1901017) dated 22-07-2019.
	Decision: Approved.	
1369.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd.Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dytasone 0.1% Lotion
	Composition	Each gram contains: Mometasone Furoate….0.1% w/w
	Diary No. Date of R& I & fee	Dy. No 5579 dated 08-2-2019 Rs.20,000/- Dated 7-2-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	20ml; as per DPC
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Hivate Cream by Saffron Pharma reg # 46432
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Previous remarks of the Evaluator.	Firm did not specify whether the formulation is w/w or w/v. The pack size in USFDA approved product is 30ml whereas firm has applied in 20ml. Firm has Lotion Section (general)

	Previous decision(s)	Deferred for the clarification whether the applied formulation is w/w or w/v (M-288).
	Evaluation by PEC	The firm has specified that the formulation is w/w. The firm has submitted fee challan of Rs. 5000/- (deposit slip#1901020) dated 22-07-2019.
	Decision: Approved.	
1370.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd.Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Dynovate N (Betamethasone Valerate + Neomycin) 1.22mg + 5mg cream
	Composition	"Each gm contains: Betamethasone Valerate USP …….....1.22mg Neomycin Sulphate USP ……5mg"
	Diary No. Date of R& I & fee	Dy. No 4847 dated 04-2-2019 Rs.20,000/- Dated 1- 2-2019
	Pharmacological Group	Corticosteroid
	Type of Form	Form 5
	Finished product Specification	In-House
	Pack size & Demanded Price	10gm, 15gm & 20gm; As per DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Betnovate-N Cream "Each gm contains: Betamethasone Valerate USP …….....1.22mg Neomycin Sulphate USP ……5mg" by M/s GSK Pakistan.
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Previous remarks of the Evaluator.	On Fee challan Neomycin is written10mg instead of 5mg.
	Previous decision(s)	Deferred for submission of relevant fee challan (M-288).
	Evaluation by PEC	The firm has submitted fresh fee challan of Rs. 20,000/- (Deposit slip # 1901016) dated 22-07-2019.
	Decision: Approved with innovator's specifications.	
1371.	Name and address of manufacturer / Applicant	"Dynatis Pakistan Pvt Ltd.Plot No.710, Sundar Industrial Estate, Raiwind Road, Lahore"
	Brand Name +Dosage Form + Strength	Scabnil (Permethrin) 5% Lotion
	Composition	"Each gm contains: Permethrin ……5%"
	Diary No. Date of R& I & fee	Dy. No 5578 dated 07-2-2019 Rs.20,000/- Dated 7- 2-2019
	Pharmacological Group	Synthetic Pyrethyroid/ scabicide
	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	60ml, 120ml; as per DPC
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Permilot Lotion 5% by M/S Semos reg # 076033
	GMP status	Inspection dated 04-12-2018 recommends grant of DML.
	Previous remarks of the Evaluator.	Firm has Lotion Section (general) Firm did not specify whether the formulation is w/w or w/v.
	Previous decision(s)	Deferred for the clarification whether the applied formulation is w/w or w/v (M-288).
	Evaluation by PEC	The firm has submitted fresh fee challan of Rs. 5,000/- (deposit slip # 1901019) dated 22-07-2019.
	Decision: Approved with innovator's specifications and change of brand name.	

1372.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, Hattar
	Brand Name +Dosage Form + Strength	Defrx 250mg tablet
	Composition	Each dispersible tablet contains: Deferasirox……..250mg
	Diary No. Date of R& I & fee	Dy. No.979; 25-01-2018; Rs.20,000/- (24-1-2018)
	Pharmacological Group	Oral Iron Chelator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1x10's, 3x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Obsarox 250mg dispersible tablet Reg # 081465
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	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-281).
	Evaluation by PEC	
	Decision: Approved with innovator's specifications.	
1373.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, Hattar
	Brand Name +Dosage Form + Strength	Defrx 500mg tablet
	Composition	Each dispersible tablet contains: Deferasirox……..500mg
	Diary No. Date of R& I & fee	Dy. No.978; 25-01-2018; Rs.20,000/- (24-1-2018)
	Pharmacological Group	Oral Iron Chelator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1x10's, 3x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	ODEROX -500 DISPERSIBLE TABLET Reg # 078116
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	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-281).
	Evaluation by PEC	
	Decision: Approved with innovator's specifications.	
1374.	Name and address of manufacturer / Applicant	M/s Navegal Laboratories, Hattar
	Brand Name +Dosage Form + Strength	Navepro 500mg tablets
	Composition	Each film coated tablet contains: Deferiprone……500mg
	Diary No. Date of R& I & fee	Dy. No.980; 25-01-2018; Rs.20,000/- (24-1-2018)
	Pharmacological Group	Oral Iron Chelator
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1x10's, 3x10's, 5x10's, 10x10's, As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Defcap Tablet Reg # 048031
	GMP status	Last inspection report 11-3-2017 The GMP was satisfactory
	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-281).
	Evaluation by PEC	
	Decision: Approved with innovator's specifications.	
1375.	Name and address of manufacturer / Applicant	M/s Lisko Pakistan Pvt Ltd. L-10-D, Block 21, Shaheed Rashid Minhas Road, F.B. Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Fulliron 800mg/15ml Dry Suspension
	Composition	Form-5 Dy.No 3586 dated 29-01-2018 Rs. 20,000 Dated 17-01-2018
	Diary No. Date of R& I & fee	Each 15ml Contains: Iron Protein Succinylate…800mg
	Pharmacological Group	Anti-Anemic
	Type of Form	Form-5
	Finished product Specification	Innovator's Specs.
	Pack size & Demanded Price	30ml: 80 Rupees, 60ml:160 rupees, 90ml:220 rupees, 100ml:250 rupees, 120ml: 300 rupees.
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Follinemic suspension by Epharm Labs (Reg # 044349)
	GMP status	Latest inspection dated 24-04-2018 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)"
	Previous remarks of the Evaluator.	Firm has requested to change the formulation to Liquid Each 15ml contains: Iron Protein Succinylate 800mg equivalent to elemental Iron … 40mg Firm has also submitted fee PKR 5,000/- (Chalan No. 0747452) for change in formulation
	Previous decision(s)	Deferred for submission of differential fee of Rs. 15,000/- fee for revision of dosage form (M-288).
	Evaluation by PEC	The firm has submitted fee challan of Rs. 15,000/- (Deposit slip # 0849350) dated 02-05-2019.
	Decision: Approved.	
1376.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited, 1st F-319 SITE, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	XORISAR 250mg Tablet
	Composition	Each dispersible tablet contains: Deferasirox…….250mg
	Diary No. Date of R& I & fee	30572, 11-09-2018, 20,000/-, 05-09-2018
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per DPC; As per DPC
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	Obsarox 250mg tablet of M/s OBS Pakistan Karachi (Reg # 081465)
	GMP status	GMP certificate valid upto 05-2019, issued by Additional Director, DRAP, Karachi has been submitted.
	Previous remarks of the Evaluator.	The firm has submitted revised Form-5 and master

		formulation from plain tablet to dispersible tablet as per reference product.
	Previous decision(s)	Deferred for submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted fee challan of Rs.5000/- (Deposit slip # 1943083) dated 28-06-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
1377.	Name and address of manufacturer / Applicant	M/s The Searle Company Limited, 1st F-319 SITE, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	XORISAR 500mg Tablet
	Composition	Each dispersible tablet contains: Deferasirox…….500mg
	Diary No. Date of R& I & fee	30573, 11-09-2018, 20,000/-, 05-09-2018
	Pharmacological Group	Iron chelating agent
	Type of Form	Form-5
	Finished product Specification	Firm has claimed in-house specifications
	Pack size & Demanded Price	As per DPC; As per DPC
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved
	Me-too status	ODEROX -500 DISPERSIBLE TABLET (Reg#078116)
	GMP status	GMP certificate valid upto 05-2019, issued by Additional Director, DRAP, Karachi has been submitted.
	Previous remarks of the Evaluator.	The firm has submitted revised Form-5 and master formulation from plain tablet to dispersible tablet as per reference product.
	Previous decision(s)	Deferred for submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted fee challan of Rs.5000/- (Deposit slip # 1943084) dated 28-06-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
1378.	Name and address of manufacturer / Applicant	M/s English Pharmaceutical Industries, Link Kattar Bund Road , Thokar Niaz baig, Multan Road, lahore
	Brand Name +Dosage Form + Strength	Evorit 25mg Tablet
	Composition	Each tablet contains:- Levosulpiride…….25mg
	Diary No. Date of R& I & fee	Dy No. 7816, 08-10-2012, 20,000/- 8.10.2012
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by **AIFA , Italy**
	Me-too status	Levopraid 25mg tab by Pacific Pharma
	GMP status	Certificate of last, GMP Inspection dated 16-01-18 with cGMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Rejected as per decision of 250th DRB meeting as the formulation is not approved by reference drug regulatory agencies **(M-265).** Registration Board deliberated the matter in detail and decided to advise the firm to submit fresh application for

		consideration on priority basis **(M-282)**.
	Evaluation by PEC	The firm has submitted fresh application on Form-5 dated 02-03-2019 alongwith fee challan of Rs. 20,000/- (Deposit slip # 0601865) dated 25-02-2019.
	Decision: Approved with innovator's specifications.	
1379.	Name and address of manufacturer / Applicant	M/s English Pharmaceutical Industries, Link Kattar Bund Road , Thokar Niaz baig, Multan Road, lahore
	Brand Name +Dosage Form + Strength	Evorit 50mg Tablet
	Composition	Each tablet contains:- Levosulpiride…….50mg
	Diary No. Date of R& I & fee	Dy No. 7812, 08-10-2012, 20,000/- 8.10.2012
	Pharmacological Group	Antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	2x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by **AIFA , Italy**
	Me-too status	Levopraid 50mg tab by Pacific Pharma
	GMP status	Certificate of last, GMP Inspection dated 16-01-18 with cGMP compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Rejected as per decision of 250th DRB meeting as the formulation is not approved by reference drug regulatory agencies **(M-265).** Registration Board deliberated the matter in detail and decided to advise the firm to submit fresh application for consideration on priority basis **(M-282)**.
	Evaluation by PEC	The firm has submitted fresh application on Form-5 dated 02-03-2019 alongwith fee challan of Rs. 20,000/- (Deposit slip # 0601866) dated 25-02-2019.
	Decision: Approved with innovator's specifications.	
1380.	Name and address of manufacturer / Applicant	M/s Reko Pharmacal Limited, 13km, Multan road, Lahore
	Brand Name +Dosage Form + Strength	Irofol Tablets
	Composition	Each film coated tablet contains: Folic Acid……35mg Iron Polymaltose…..10mg
	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	Manfacturer'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	**Could not be confirmed**
	GMP status	GMP inspection dated 30-3-2016, firm was operating at satisfactory level of compliance with GMP guidelines.
	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.
	Evaluation by PEC	The firm has submitted that by your clerical mistake, composition was written as below; Each film coated tablet contains: Iron Polymaltose……..100mg Folic Acid……0.35mg Formulation containing same formulation as per me-too reference: Bisleri F Tablet of M/s Sami Pharma Ferosoft FA tablet of M/s Hilton Pharma
	Decision: Deferred for confirmation of formulation as applied by the firm.	
1381.	Name and address of manufacturer / Applicant	M/s Inventor Pharma, Plot No. K/196, S.I.T.E, (SHW) Phase-II, Karachi
	Brand Name +Dosage Form + Strength	In-ORS Solution 500ml
	Composition	Each 500 ml contains: Sodium Chloride ……1.75gm Trisodium Citrate Trihydrate ……..1.45gm Potassium Chloride ……..0.75gm Glucose Anhydrous ……..10gm
	Diary No. Date of R& I & fee	Diary No: 13910, 30/08/2017, Rs: 20,000/-
	Pharmacological Group	Electrolyte
	Type of Form	Form 5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	1'sx500ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Standard ORS formulation
	Me-too status	Pedinex Oral Rehydration Solution by M/s Nexus Pharma (Pvt) Ltd (Reg#057883)
	GMP status	**10-06-2017** New License
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for confirmation whether applied formulation is preservative free or not. **(M-277)** Deferred for confirmation of terminal sterilization method for applied formulation. **(M-286)** Deferred for confirmation of capacity of autoclave for terminal sterilization. **(M-289)**
	Evaluation by PEC	• The firm has submitted that we have removed "Sodium benzoate" from our formulation and our new formulation for this product is free from preservative. • The firm has submitted fee challan of Rs.5000/-, (Deposit slip#0808315) dated 05-11-2018 for revision of formulation. • The liquid is filled under the area of laminar flow hood in polypropylene bottle immediately sealed. • Bottle are sterilized in autoclave with steam upto 100oC for 3 hours and pressure 1 to 2 bars. • GMP inspection conducted on 06th February, 2019 concluded that keeping in view the stated conditions and attitude of the firm towards better compliance, their current GMP is rated as GOOD. • The firm has submitted that the capacity of autoclave for terminal sterilization is 50 pounds and chamber capacity is

		300 liters. The firm has provided invoice for the purchase of autoclave from friends engineering works with these dimensions.
	Decision: Approved with innovator's specifications.	
1382.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd, Plot # 9-B/1&2, Old Industrial Estate, Sector D 1, Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Leflomide 10 tablet
	Composition	Each film coated tablet contains: Leflunamide…….10mg
	Diary No. Date of R& I & fee	Dy.No.23079, 04-07-2018, Rs. 20,000/-
	Pharmacological Group	Anti-rheumatic (DMARD-Immunosupressant)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arabloc leflunomide 10mg tablet (TGA approved)
	Me-too status	Lefanor of Macter international
	GMP status	Last inspection of Akson Pharmaceuticals was conducted on 16-6-17 & 25-07-2017 for renewal of DML and panel recommend renewal of DML
	Previous remarks of the Evaluator.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-285)**.
	Evaluation by PEC	Copy of inspection report dated 22-02-2019 concludes that *"Keeping in view the above stated facts based upon the areas visited, records reviewed and people met, it may be concluded that the management has rectified almost all the observations from the previous inspection and as of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. As, the GMP is a continual process of improvement, hence updating the procedures shall always remain a task; the management is advised to develop a forward thinking progressive environment, adapting the recent trends."*
	Decision: Approved.	
1383.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd, Plot # 9-B/1&2, Old Industrial Estate, Sector D 1, Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Leflomide 20 tablet
	Composition	Each film coated tablet contains: Leflunamide…….20mg
	Diary No. Date of R& I & fee	Dy.No.23080, 04-07-2018, Rs. 20,000/-
	Pharmacological Group	Anti-rheumatic (DMARD-Immunosupressant)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arabloc leflunomide 20mg tablet (TGA approved)
	Me-too status	AIDRA 20 mg tablets of WILSHIRE
	GMP status	Last inspection of Akson Pharmaceuticals was conducted on 16-6-17 & 25-07-2017 for renewal of DML and panel recommend renewal of DML
	Previous remarks of the Evaluator.	

	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-285)**.
	Evaluation by PEC	GMP inspection report as recorded above.
	Decision: Approved.	
1384.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd, Plot # 9-B/1&2, Old Industrial Estate, Sector D 1, Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Leflomide 100 tablet
	Composition	Each film coated tablet contains: Leflunamide…….100mg
	Diary No. Date of R& I & fee	Dy.No.23081, 04-07-2018, Rs. 20,000/-
	Pharmacological Group	Anti-rheumatic (DMARD-Immunosupressant)
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	3x10's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Arabloc leflunomide 100mg tablet (TGA approved)
	Me-too status	AIDRA 100 mg tablets of WILSHIRE
	GMP status	Last inspection of Akson Pharmaceuticals was conducted on 16-6-17 & 25-07-2017 for renewal of DML and panel recommend renewal of DML
	Previous remarks of the Evaluator.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-285)**.
	Evaluation by PEC	GMP inspection report as recorded above.
	Decision: Approved.	
1385.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd, Plot # 9-B/1&2, Old Industrial Estate, Sector D 1, Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	Ketosterim Tablet
	Composition	Each film coated tablet contains:- Histidine…..……..38mg Isoleucine……..67mg Leucine……..…101mg Lysine……..…105mg Methionine…….59mg Phenylalanine……..….68mg Threonine…….53mg Tryptophan…….23mg Tyrosine……...….30mg Valine……..…..86mg
	Diary No. Date of R& I & fee	24-09-2013 vide diary # 6137 R&I Rs.20,000.
	Pharmacological Group	Amino-Acids
	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.	KETOSTERIL by Fresenius Kabi, Germany.(Bfarm approved)
	Me-too status	Ketoalfa Tablets M/s Genome Pharmaceuticals
	GMP status	Last inspection of Akson Pharmaceuticals was conducted on 16-6-17 & 25-07-2017 for renewal of DML and panel recommend renewal of DML
	Previous remarks of the Evaluator.	Approval status in Pakistan and reference countries is not provided.

	Previous decision(s)	Deferred for the confirmation of approval status in Pakistan and by reference regulatory authorities **(M-259)**.
	Evaluation by PEC	GMP inspection report as recorded above.
	Decision: Approved with innovator's specifications.	
1386.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd, Plot # 9-B/1&2, Old Industrial Estate, Sector D 1, Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	R-Zole 10 Tablets
	Composition	Each tablet contains:- Rabeprazole Sodium……..10mg
	Diary No. Date of R& I & fee	Dy.No.3370, 13-05-2015, Rs.8000/-, Rs.12,000/-,13-05-2015
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's; Rs.325.00
	Approval status of product in Reference Regulatory Authorities.	Rabeprazole 10mg gastro-resistant tablet of Accord healthcare Ltd, (MHRA approved)
	Me-too status	Pariet Tablets 10mg by M/s Hilton (Reg#027399)
	GMP status	Last inspection report 5-11-2016 GMP status not clear.
	Previous remarks of the Evaluator.	Internationally available as delayed release/ Gastro resistant tablet
	Previous decision(s)	Deferred for confirmation of GMP status from QA division **(M-265)**.
	Evaluation by PEC	Copy of inspection report dated 22-02-2019 concludes that *"Keeping in view the above stated facts based upon the areas visited, records reviewed and people met, it may be concluded that the management has rectified almost all the observations from the previous inspection and as of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. As, the GMP is a continual process of improvement, hence updating the procedures shall always remain a task; the management is advised to develop a forward thinking progressive environment, adapting the recent trends."*
	Decision: Deferred for revision of formulation as per reference product.	
1387.	Name and address of manufacturer / Applicant	M/s Akson Pharmaceuticals Pvt Ltd, Plot # 9-B/1&2, Old Industrial Estate, Sector D 1, Mirpur Azad Kashmir
	Brand Name +Dosage Form + Strength	R-Zole 20 Tablets
	Composition	Each tablet contains:- Rabeprazole Sodium…….20mg
	Diary No. Date of R& I & fee	Dy.No.3371, 13-05-2015, Rs.8000/-, Rs.12,000/-, 13-05-2015
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's; Rs.595.00
	Approval status of product in Reference Regulatory Authorities.	Rabeprazole 20mg GR tablets of M/s Actavis , UK (MHRA Approved)
	Me-too status	Rabecid tablets 20mg of M/s Highnoon (Reg # 028360)
	GMP status	Last inspection report 5-11-2016 GMP status not clear.
	Previous remarks of the Evaluator.	Internationally available as delayed release/ Gastro resistant tablet
	Previous decision(s)	Deferred for confirmation of GMP status from QA division **(M-265)**.

	Evaluation by PEC	Copy of inspection report dated 22-02-2019 concludes that *"Keeping in view the above stated facts based upon the areas visited, records reviewed and people met, it may be concluded that the management has rectified almost all the observations from the previous inspection and as of today the firm's facility is suitable to carry out manufacturing and testing of pharmaceuticals. As, the GMP is a continual process of improvement, hence updating the procedures shall always remain a task; the management is advised to develop a forward thinking progressive environment, adapting the recent trends."*
	Decision: Deferred for revision of formulation as per reference product.	
1388.	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	Lite 600mg Tablets
	Composition	Each film-coated tablet contains: Linezolid …….……...600mg
	Diary No. Date of R& I & fee	Dy. No.2994; 19-12-2016; Rs.20,000/- (15-12-2016)
	Pharmacological Group	Oxazolidinone , Antibiotics
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Zyvox of M/s Pharmacia, Ramsgate Road, Sandwich , Kent (UK)/ Zyvox by Pharmacia (**USFDA** Approved)
	Me-too status	Nezocin of M/s Brookes Pharmaceuticals/ Volinza by Wilshire
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1389.	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	Lite Dry suspension 100mg/5ml
	Composition	After reconstitution each 5ml contains: Linezolid ……100mg
	Diary No. Date of R& I & fee	Dy. No.2993; 19-12-2016; Rs.20,000/- (16-12-2016)
	Pharmacological Group	Antibacterial Agent Of Oxazolidinone Class
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)

	Approval status of product in Reference Regulatory Authorities.	Zyvox of M/s Pharmacia limited (UK)
	Me-too status	Nezocin of M/s Brookes Pharmaceuticals
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1390.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore contract manufactured by M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	PATHOCEF 500mg INJECTION I.V
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone……500mg
	Diary No. Date of R& I & fee	19490, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Rocephin powder for solution for injection by Roche (MHRA Approved)
	Me-too status	Rocephin 500mg IV of Roche , Karachi
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad **(M-287).**
	Evaluation by PEC	
	Decision: Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	
1391.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore contract manufactured by M/s Bio-Labs (pvt) Ltd, Plot# 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	BIMEP 40MG INJECTION IV
	Composition	Each vial contains: Omeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19491, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5

	Finished product Specification	USP
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Omeprazole 40mg powder for solution for injection of Sandoz, UK **(MHRA)**
	Me-too status	Zegrid-40 Injection of Shaigan Pharma
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad **(M-287).**
	Evaluation by PEC	
	Decision: Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	
1392.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore contract manufactured by M/s Bio-Labs (pvt) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	NULOC 40MG INJECTION IV
	Composition	Each vial contains: Esomeprazole (as sodium)……..40mg
	Diary No. Date of R& I & fee	19492, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Proton pump inhibitor
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1's vial; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Nexium IV 40mg powder for solution for injection of AstraZeneca, UK **(MHRA)**
	Me-too status	Somezol Injection of Bosch, Karachi
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad **(M-287).**
	Evaluation by PEC	
	Decision: Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	
1393.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore contract manufactured by M/s Bio-Labs (pvt) Ltd, Plot# 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	ONDAN 8mg/4ml INJECTION
	Composition	Each 4ml ampoule contains: Ondansetron as hydrochloride dihydrate……8mg
	Diary No. Date of R& I & fee	19499, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Selective serotonin 5-HT3 receptor antagonist
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1 × 5's ; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 2 mg/ml Solution for Injection of Generics, (MHRA)
	Me-too status	Zofran Injection 8mg/4ml of Glaxo Wellcome, Karachi
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017.

	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad **(M-287).**
	Evaluation by PEC	The firm has submitted revised formulation for salt form of API as per reference product along with submission of Rs. 5,000/- (Deposit Slip # 0849964) dated 27/06/2019).
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
1394.	Name and address of manufacturer / Applicant	M/s Bio-Mark Pharmaceuticals, 527 Sundar Industrial Estate, Lahore contract manufactured by M/s Bio-Labs (pvt) Ltd, Plot# 145, Industrial Triangle, Kahuta Road, Islamabad.
	Brand Name +Dosage Form + Strength	RP-XIME SUSPENSION 100mg/5ml
	Composition	Each 5ml contains: Cefixime as Trihydrate……100mg
	Diary No. Date of R& I & fee	19503, 30-10-2107, 50,000/-, 28-10-2017
	Pharmacological Group	Third generation cephalosporin antibiotic
	Type of Form	Form-5
	Finished product Specification	USPs
	Pack size & Demanded Price	30ml ; As recommended by the PRC
	Approval status of product in Reference Regulatory Authorities.	Suprax of Sanofi Aventis, **USFDA**
	Me-too status	Cef-OD by CCL Pharma
	GMP status	The firm M/s Biolabs was granted GMP certificate based on inspection conducted on 5th & 06th December, 2017
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred due to capacity constraint in "Dry Vial (Cephalosporin) Injection of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad **(M-287).**
	Evaluation by PEC	
	Decision: Deferred due to capacity constraint in "Dry Powder suspension (Cephalosporin) of M/s Bio-Labs (Pvt.) Ltd, Plot # 145, Industrial Triangle, Kahuta Road, Islamabad	
1395.	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	Pain-Go 8mg Tablet
	Composition	Each film-coated tablet contains: Lornoxicam……..8mg
	Diary No. Date of R& I & fee	Dy. No.2992; 19-12-2016; Rs.20,000/- (16-12-2016)
	Pharmacological Group	Oxicams
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Xefo, ANSM, France Approved
	Me-too status	Xoni-fast by M/s Macter International
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not

		conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1396.	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	Tromser-P Tablets 37.5/325mg
	Composition	Each film-coated tablet contains: Tramadol HCl……..……..37.5mg Acetaminophen ……325mg
	Diary No. Date of R& I & fee	Dy. No.2991; 19-12-2016; Rs.20,000/- (16-12-2016)
	Pharmacological Group	NSAIDs, Opioid Analgesic
	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.	Ultracet of M/s Janssen Pharmaceuticals (USA)
	Me-too status	Distalgesic of M/s Atco Pharmaceuticals
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1397.	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 5/160mg
	Composition	Each film-coated tablet contains: Amlodipine Besylate eq.to Amlodipine ……..…….....5mg Valsartan……160mg
	Diary No. Date of R& I & fee	Dy. No.2990; 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	Exforge of M/s Novartis Pharmaceuticals (UK) MHRA

	Reference Regulatory Authorities.	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1398.	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	

1399.	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	Qutec XR Tablets 300mg
	Composition	Each Extended-Release tablet contains: Quetiapine as Fumarate eq.to Quetiapine …….....300mg
	Diary No. Date of R& I & fee	Dy. No.4343; 30-12-2016; Rs.20,000/- (29-12-2016)
	Pharmacological Group	Atypical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Seroquel of M/s Astra Zeneca (Belgium)
	Me-too status	Evokalm of M/s Pharm Evo Pharmaceuticals
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1400.	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	Qutec 25mg Tablets
	Composition	Each film-coated tablet contains: Quetiapine as Fumarate eq.to Quetiapine ……..……...25mg
	Diary No. Date of R& I & fee	Dy. No.4344; 30-12-2016; Rs.20,000/- (27-12-2016)
	Pharmacological Group	A typical antipsychotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Seroquel of M/s Astra Zeneca (Belgium)/ Quetiapine Fumarate 25 mg film-coated tablet by M/s Teva (USFDA)
	Me-too status	Evokalm 25 mg film-coated tablet of M/s Pharm Evo Pharmaceuticals
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**.

		Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1401.	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	Sitamet Tablets 50/500mg
	Composition	Each film-coated tablet contains: Sitagliptin Phosphate Monohydrate eq.to Sitagliptin……50mg Metformin HCl……..500mg
	Diary No. Date of R& I & fee	Dy. No.4026; 02-12-2016; Rs.20,000/- (27-12-2016)
	Pharmacological Group	Hypoglycemic agents
	Type of Form	Form-5
	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO& as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Janumet of M/s Merck Sharp & Dohme (UK)/USFDA Approved
	Me-too status	Treviamet tablet 50/500mg of M/s Getz Pharmaceuticals
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1402.	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	Sitamet Plus Tablet 50/1000mg
	Composition	Each film-coated tablet contains: Sitagliptin Phosphate Monohydrate eq.to Sitagliptin……50mg Metformin HCl……..1000mg
	Diary No. Date of R& I & fee	Dy. No.4020; 02-12-2016; Rs.20,000/- (27-12-2016)
	Pharmacological Group	Hypoglycemic agents
	Type of Form	Form-5

	Finished product Specification	Manufacturer's
	Pack size & Demanded Price	As per SRO & as recommended by the PRC (MOH)
	Approval status of product in Reference Regulatory Authorities.	Janumet of M/s Merck Sharp & Dohme MHRA Approved
	Me-too status	Treviamet of M/s Getz Pharmaceuticals
	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.	
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority **(M-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1403.	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-277)**. Deferred for updated status of GMP of the firm form QA & LT division as inspection report submitted by firm does not conclude GMP compliant status **(M-284)**.
	Evaluation by PEC	Based on inspection conducted on 27-02-2018, it is concluded that the firm is complying cGMP as of today. However, compliance of the observations is advised to be submitted along with an action plan at an earliest. 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.	
1404.	Name and address of manufacturer / Applicant	M/s Care Pharmaceuticals, 8-km, Thokar Raiwind road, Lahore.
	Brand Name +Dosage Form + Strength	Zincar Syrup
	Composition	Each 5ml contains:- Zinc Sulphate Monohydrate as elemental Zinc……..20mg
	Diary No. Date of R& I & fee	Dy No. 1063 dated 24-05- 2011 Rs.8000 & Rs.12,000 dated 30-07-2013
	Pharmacological Group	Mineral supplement
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Rs. 80/60ml
	Approval status of product in Reference Regulatory Authorities.	WHO recommended formulation
	Me-too status	Diazinc syrup by M/s Searle
	GMP status	Panel inspection conducted on 13th March, 2019 recommends renewal of DML.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for comments/opinion from WHO Pakistan (M-257)
	Evaluation by PEC	The applied formulation is approved by WHO and is available in international pharmacopoeia
	Decision: Approved.	
1405.	Name and address of manufacturer / Applicant	M/s Care Pharmaceuticals, 8-km, Thokar Raiwind road, Lahore.
	Brand Name +Dosage Form + Strength	Fusidcare Cream
	Composition	Each gm contains: Fusidic Acid (2%)…….20mg
	Diary No. Date of R& I & fee	Dy.No.4033, 30-09-2010, Rs.8000/-, 15-05-2013, Rs.12,000/-
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs.65/5gm, Rs.165/15gm
	Approval status of product in Reference Regulatory Authorities.	Fucidin 20 mg/g Cream by M/s LEO Laboratories Limited (MHRA Approved)
	Me-too status	Fusiway Cream 2% by M/s Caraway (Reg#050021)
	GMP status	Panel inspection conducted on 13th March, 2019 recommends renewal of DML.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Last reminder will be issued to the firm for rectification of shortcomings **(M-246)**.
	Evaluation by PEC	
	Decision: Approved.	
1406.	Name and address of manufacturer / Applicant	M/s Care Pharmaceuticals, 8-km, Thokar Raiwind road, Lahore.
	Brand Name +Dosage Form + Strength	Clomezole Cream
	Composition	Each gm contains: Clotrimazole……..10mg
	Diary No. Date of R& I & fee	Dy.No.4029, 30-09-2010, Rs.8000/-, 15-05-2013, Rs.12,000/-

	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	Rs.41/10gm, Rs.70/20gm
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Benestine Cream 1% by M/s Searle IV Solutions (Pvt.) Ltd, Karachi (Reg#078619)
	GMP status	Panel inspection conducted on 13th March, 2019 recommends renewal of DML.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Last reminder will be issued to the firm for rectification of shortcomings **(M-246)**.
	Evaluation by PEC	
	Decision: Approved.	
1407.	Name and address of manufacturer / Applicant	M/s Ophth Pharma (Pvt) Ltd, Plot No. 241, Sector-24, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	NEPO (Nepafenac 0.1%) Sterile Ophthalmic suspension
	Composition	Each ml contains: Nepafenac …….1mg
	Diary No. Date of R& I & fee	16965, 04-10-2017, 20,000/-, 27-09-2017
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per PRC As per PRC
	Approval status of product in Reference Regulatory Authorities.	AVANEP sterile ophthalmic suspension of ALCON Labs , USA
	Me-too status	NEPATEK 0.1% Sterile Ophthalmic suspension
	GMP status	GMP certificate issued based on the inspection report dated 12-04-2018
	Previous remarks of the Evaluator.	The firm has submitted revised Form-5 with correct strength of applied formulation.
	Previous decision(s)	Deferred for submission of fee for revision of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted fee challans of Rs. 5000/- (deposit slip # 0830741) dated 05-04-2019 and Rs. 15000/- (deposit slip # 23-08-2019) dated 23-08-2019 for revision of formulation.
	Decision: Approved with innovator's specifications.	
1408.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories, 28 km, Ferozpur Road Lahore contract manufactured from M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad
	Brand Name +Dosage Form + Strength	DYPENEM 500mg Injection
	Composition	Each vial contains: Meropenem trihydrate eq. to Meropenem……500mg
	Diary No. Date of R& I & fee	Dy no: 2411 dated 15-04-2013, 50,000/-, dated 15-04-13
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in	Meronem IV 500 mg by Pfizer Limited (MHRA Approved)

	Reference Regulatory Authorities.	
	Me-too status	Merem 500mg injection by Global Pharma
	GMP status	GMP inspection of M/s Nicholas Pharmaceuticals, Rawat dated 03-08-2018 recommends for the grant of Drug Manufacturing License by way of formulation. GMP inspection of M/s Dyson Research laboratories, lahore dated 11-01-2019 concluded that the firm has maintained satisfactory conformance to cGMP compliance in the manufacturing and Quality Control operations on the day of inspection.
	Previous remarks of the Evaluator.	Deferred for following: **(M-246)** 1. Evidence of approval of manufacturing facility for applied product needs to be submitted 2. Latest GMP Inspection report of M/s English Pharma is required.
	Previous decision(s)	
	Evaluation by PEC	The firm had initially applied for contract manufacturing with M/s English pharmaceuticals, Multan Road, Lahore. Now the firm has requested to change the contract manufacturing to M/s Nicholas Pharma. However, request for such change has been made after 7th March, 2019. M/s Nicholas Pharma, Rawat has provided Dry Powder injectable section (Carbapenems).
	Decision: Registration Board deferred the case and directed the firm to submit application on Form-5F.	
1409.	Name and address of manufacturer / Applicant	M/s Dyson Research Laboratories, 28 km, Ferozpur Road Lahore contract manufactured from M/s Nicholas Pharmaceuticals, plot # 34, St # SS-02 National industrial Zone Rawat Islamabad
	Brand Name +Dosage Form + Strength	DYPENEM 1g Injection
	Composition	Each vial contains: Meropenem trihydrate eq. to Meropenem……1g
	Diary No. Date of R& I & fee	Dy no: 2412 dated 15-04-2013, 50,000/-, dated 15-04-13
	Pharmacological Group	Carbapenems
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meronem IV 1g by Pfizer Limited (MHRA Approved)
	Me-too status	Merem 1g injection by Global Pharma
	GMP status	GMP inspection of M/s Nicholas Pharmaceuticals, Rawat dated 03-08-2018 recommends for the grant of Drug Manufacturing License by way of formulation. GMP inspection of M/s Dyson Research laboratories, lahore dated 11-01-2019 concluded that the firm has maintained satisfactory conformance to cGMP compliance in the manufacturing and Quality Control operations on the day of inspection.
	Previous remarks of the Evaluator.	Deferred for following: **(M-246)** 1. Evidence of approval of manufacturing facility for applied product needs to be submitted 2. Latest GMP Inspection report of M/s English Pharma is required.
	Previous decision(s)	

	Evaluation by PEC	The firm had initially applied for contract manufacturing with M/s English pharmaceuticals, Multan Road, Lahore. Now the firm has requested to change the contract manufacturing to M/s Nicholas Pharma. However, request for such change has been made after 7th March, 2019. M/s Nicholas Pharma, Rawat has provided Dry Powder injectable section (Carbapenems).
	Decision: Registration Board deferred the case and directed the firm to submit application on Form-5F.	
1410.	Name and address of manufacturer / Applicant	M/s KANEL PHARMACEUTICALS**.** Plot#6-road SS-3.National Indust. Zone. Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	MASALAKANE 800mg Tablet
	Composition	Each enteric coated Tablet contains: Mesalamine……. 800mg
	Diary No. Date of R& I & fee	Dy: 23193, 05-12-2017; Fee in PKR: 20,000/-, 28-11-2017.
	Pharmacological Group	Aminosalicylate anti-inflammatory
	Type of Form	Form-5
	Finished product Specification	In-house Specifications
	Pack size & Demanded Price	1 x 10's, 3 x 10's / As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	MESALAMINE TABLET, DELAYED RELEASE; ORAL ZYDUS PHARMS USA INC USFDA Approved.
	Me-too status	MASACOL 800mg Tablet of GETZ Pharma (Reg#061348)
	GMP status	GMP certificate issued and valid till: 20-12-2018. On the basis of inspection conducted on: 20-12-2017.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for followings: (M-286) i. Submission of relevant details of enclosures as per Form 5 of Schedule-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976 ii. Master formulation describing quantities of actives and in-actives not in accordance with the testing specifications, clarification is required. iii. Outline of method of manufacturing do not contains all particulars for subject products. iv. Finished product specification is submitted for film coated tablet while you have applied for "enteric coated tablet" justification/clarification is required in this regard. (In case of revision of formulation submit the requisite fee, as applicable). v. Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm, not submitted.
	Evaluation by PEC	The firm has submitted revised Form-5, master formulation and finished product specifications alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1934307) dated 28-06-2019.
	Decision: Approved with innovator's specifications.	
1411.	Name and address of manufacturer / Applicant	M/s KANEL PHARMACEUTICALS**.** Plot#6-road SS-3.National Indust. Zone. Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	ORKAN 120mg Capsule
	Composition	Each Hard Gelatin capsule contains: Orlistat pellets……120mg
	Diary No. Date of R& I & fee	Dy: 23186, 05-12-2017; Fee in PKR: 20,000/- 28-11-2017.
	Pharmacological Group	Lipase Inhibitor

	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 10's, 3x 10's, / As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	Xenical, orlistat120mg, capsule;oral, USFDA Approved.
	Me-too status	Trimzak 120mg Capsule BY Schazoo Zaka (Pvt) Ltd, Lahore. (Reg.# 071105)
	GMP status	GMP certificate issued and valid till: 20-12-2018. On the basis of inspection conducted on: 20-12-2017.
	Previous remarks of the Evaluator.	• You have not applied on prescribed application format as per Schedule A of Drugs (Licensing, Registering, and Advertising) Rules, 1976. • Packaging material of the applied drug is not correctly mentioned in form-5. • It is claimed in form-5(18.b) that the production capacity per shift is 150,000 capsules while the equipment mentioned in form-5(18.a) have the max. Capacity of 80,000-100,000 cap./ per shift, clarification is required in this regard. • Master formulation describing quantities of actives and in-actives not in accordance with the testing specifications, clarification is required. • Outline of method of manufacturing do not contain steps for subject products as per approved product. • The applied drug has been approved as "orlistat pellets" while you have applied the drug "orlistat powder", justification/clarification is required in this regard (in case of revision of formulation submit the requisite fee, as applicable). Confirmation for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.
	Previous decision(s)	Deferred for following: (M-286) • Submission of revised Form 5 with label claim as per reference product declaring the salt form & equivalency of Solifenacin with requisite fee. • For the clarification of remarks mentioned above.
	Evaluation by PEC	The firm has submitted revised Form-5, master formulation and finished product specifications alongwith submission of fee challan of Rs. 5,000/- (Deposit slip # 1934311) dated 28-06-2019. Source of Pellets: M/s Vision Pharma, Islamabad.
	Decision: Deferred for source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
1412.	Name and address of manufacturer / Applicant	M/s KANEL PHARMACEUTICALS**.** Plot#6-road SS-3.National Indust. Zone. Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	OLMEKAN 20mg Tablet
	Composition	Each film coated Tablet contains: Olmesartan medoxomil…… 20mg
	Diary No. Date of R& I & fee	Dy: 23196, 05-12-2017; Fee in PKR: 20,000/- 28-11-2017.
	Pharmacological Group	Angiotensin II Receptor Antagonist
	Type of Form	Form-5
	Finished product Specification	Kanel Specifications
	Pack size & Demanded Price	1 x 10's, / As per policy of DRAP.

	Approval status of product in Reference Regulatory Authorities.	Olmesartan Medoxomil Tablet Teva Pharms USA, US-FDA Approved. (film coated Tablet)
	Me-too status	Olesta Searle karachi. (Reg.# 050736)
	GMP status	GMP certificate issued and valid till 20-12-2018. On the basis of inspection conducted on: 20-12-2017.
	Previous remarks of the Evaluator.	• You have not applied on prescribed application format as per Schedule-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976. • Master formulation describing quantities of actives and in-actives not in accordance with the testing specifications, clarification is required. • Outline of method of manufacturing do not contains all particulars for subject products. • The applied drug has been approved as "film coated" while you have applied the drug without film coating, justification/clarification is required in this regard (In case of revision of formulation submit the requisite fee, as applicable).
	Previous decision(s)	Deferred for following: **(M-286)** • Submission of relevant details of enclosures as per Form 5 of Schedule-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976 • For the submission of master formulation in accordance with the testing specifications, clarification is required. • For the clarification/justification of outline of method of manufacturing that does not contains all particulars for subject product.
	Evaluation by PEC	The firm has submitted revised Form-5, master formulation and finished product specifications alongwith submission of fee challan of Rs. 5,000/- (Deposit slip # 1934309) dated 28-06-2019.
	Decision: Approved with innovator's specifications.	
1413.	Name and address of manufacturer / Applicant	M/s KANEL PHARMACEUTICALS**.** Plot#6-road SS-3.National Indust. Zone. Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	SOLIFKAN 10mg Tablets
	Composition	Each film coated Tablet contains: Solifenacin Succinate……..….10mg
	Diary No. Date of R& I & fee	Dy: 23195, 05-12-2017; Fee in PKR: 20,000/- 28-11-2017.
	Pharmacological Group	Antimuscarinic
	Type of Form	Form-5
	Finished product Specification	Kanel Specifications
	Pack size & Demanded Price	1 x 10's, / As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	Giraxine 10mg (film coated Tablet) MHRA Approved.
	Me-too status	FENASO Highnoon Laboratories, Lahore. (Reg.# 069313)
	GMP status	GMP certificate issued and valid till: 20-12-2018. On the basis of inspection conducted on: 20-12-2017.
	Previous remarks of the Evaluator.	• The applied product submitted with incorrect label claim i.e., Solifenacin Succinate, while the correct label claim is "Solifenacin Succinate equivalent to Solifenacin". Accordingly you are advised to submit the requisite documents with correct label claim along with applicable fee. • Master formulation describing quantities of actives and

		in-actives not in accordance with the testing specifications, clarification is required. • Outline of method of manufacturing do not contains all particulars for subject products. • You have not applied on prescribed application format as per Schedule-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976. • The applied drug has been approved as "film coated" while you have applied the drug without film coating, justification/clarification is required in this regard (In case of revision of formulation submit the requisite fee, as applicable).
	Previous decision(s)	Deferred for following: **(M-286)** • Submission of revised Form 5 with label claim as per reference product declaring the salt form & equivalency of Solifenacin with requisite fee. • Master formulation describing quantities of actives and in-actives not in accordance with the testing specifications, clarification is required. • Outline of method of manufacturing do not contains all particulars for subject products. • The applied drug has been approved as "film coated" while you have applied the drug without film coating, justification/clarition is required in this regard (In case of revision of formulation submit the requisite fee, as applicable).
	Evaluation by PEC	The firm has submitted revised Form-5, master formulation and finished product specifications alongwith submission of fee challan of Rs. 5,000/- (Deposit slip # 1934310) dated 28-06-2019.
	Decision: Approved with innovator's specifications.	
1414.	Name and address of manufacturer / Applicant	M/s KANEL PHARMACEUTICALS**.** Plot#6-road SS-3.National Indust. Zone. Rawat, Rawalpindi.
	Brand Name +Dosage Form + Strength	SOLIFKAN 5mg Tablets
	Composition	Each film coated Tablet contains: Solifenacin Succinate…….5 mg
	Diary No. Date of R& I & fee	Dy: 23194, 05-12-2017; Fee in PKR: 20,000/- 28-11-2017.
	Pharmacological Group	Antimuscarinic
	Type of Form	Form-5
	Finished product Specification	Kanel Specifications
	Pack size & Demanded Price	1 x 10's, / As per policy of DRAP.
	Approval status of product in Reference Regulatory Authorities.	Giraxine 5mg (film coated Tablet) MHRA Approved.
	Me-too status	FENASO Highnoon Laboratories, Lahore. (Reg.# 069314)
	GMP status	GMP certificate issued and valid till: **20-12-2018.** On the basis of inspection conducted on: **20-12-2017.**
	Previous remarks of the Evaluator.	• The applied product submitted with incorrect label claim i.e., Solifenacin Succinate, while the correct label claim is "Solifenacin Succinate equivalent to Solifenacin". Accordingly you are advised to submit the requisite documents with correct label claim along with applicable fee. • Master formulation describing quantities of actives and in-actives not in accordance with the testing

		specifications, clarification is required. • Outline of method of manufacturing do not contains all particulars for subject products. • You have not applied on prescribed application format as per Schedule-A of Drugs (Licensing, Registering, and Advertising) Rules, 1976. • The applied drug has been approved as "film coated" while you have applied the drug without film coating, justification/clarification is required in this regard (In case of revision of formulation submit the requisite fee, as applicable).
	Previous decision(s)	Deferred for following: **(M-286)** • Submission of revised Form 5 with label claim as per reference product declaring the salt form & equivalency of Solifenacin with requisite fee. • Master formulation describing quantities of actives and in-actives not in accordance with the testing specifications, clarification is required. • Outline of method of manufacturing do not contains all particulars for subject products. • The applied drug has been approved as "film coated" while you have applied the drug without film coating, justification/clarition is required in this regard (In case of revision of formulation submit the requisite fee, as applicable).
	Evaluation by PEC	The firm has submitted revised Form-5, master formulation and finished product specifications alongwith submission of fee challan of Rs. 5,000/- (Deposit slip # 1934308) dated 28-06-2019.
	Decision: Approved with innovator's specifications.	
1415.	Name and address of manufacturer / Applicant	M/s Hiranis Pharmaceuticals (Pvt.) Ltd. Plot No. E-145 to E-149, North Western Industrial Zone, Port Qasim, Karachi.
	Brand Name +Dosage Form + Strength	Zareka 100mg/5ml Suspension
	Composition	Each 5ml Contains: Linezolid……100mg
	Diary No. Date of R& I & fee	Dy. No. 4015, 01-02-2018, Rs. 20,000/- 31-01-2018
	Pharmacological Group	Other antibacterials
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	60ml; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyvox Dry Suspension by Pharmacia (USFDA Approved)
	Me-too status	Nezolid 100mg Suspension by Searle (Reg# 050326)
	GMP status	GMP inspection conducted on 07-09-2017 concluded that the firm was considered to be operating at satisfactory compliance with GMP guideline
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the Registration Board in its 275th meeting as reference product is as dry suspension **(M-288)**.
	Evaluation by PEC	The firm has submitted that we have applied above formulation as Dry Suspension" dosage form in our registration dossier. Copies of Form-5 Application /

		covering letter & Master formulation is herewith attached for ready reference where we mentioned in dosage form as well as in brand name as Dry suspension, further our submitted master formulation confirmed that it is Dry suspension.
	Decision: Approved with innovator's specifications.	
1416.	Name and address of manufacturer / Applicant	M/s MKB Pharmaceuticals (Pvt) Ltd. 66 – Hayatabad Industrial Estate, Peshawar, KPK.
	Brand Name +Dosage Form + Strength	Dicloflex-P 75 mg Tablets
	Composition	Each film coated tablet contains; Diclofenac Potassium……75 mg
	Diary No. Date of R& I & fee	Dy. No.591, 2-06-2012, Rs.8,000/- dated 27-06-2012), Rs.12,000/- dated 28-01-2015
	Pharmacological Group	NSAID
	Type of Form	Form 5
	Finished product Specification	USP Specs
	Pack size & Demanded Price	20's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Not Provided
	Me-too status	Artimov-K 75 mg Tablet Barrett Hodgson Pakistan
	GMP status	Inspection report dated 26-12-2016 Firm was advised to conduct self-GMP inspection, The management agreed to rectify at their earliest
	Previous remarks of the Evaluator.	Dossier was received through registration section letter No.F.16-4/2013-Reg-IV(Vol-I) International availability in reference regulatory authorities cannot be confirmed
	Previous decision(s)	Deferred for Evidence of approval status of applied formulation in reference regulatory authorities (M-272).
	Evaluation by PEC	The firm has revised the strength of formulation as below: Each film coated tablet contains; Diclofenac Potassium……50mg The firm has deposited fee challan of Rs. 5,000/- (deposit slip#1901164) dated 15-07-2019.
	Decision: Deferred for submission of remaining fee of Rs. 15000/- for revision of formulation.	
1417.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Irosoft syrup
	Composition	Each 5ml Contains: Iron III Hydroxide Polymaltose Complex equivalent to Elemental Iron…50mg Folic Acid …0.35mg
	Diary No. Date of R& I & fee	Diary No:6027, 13/06/2017, Rs: 20,000/-
	Pharmacological Group	Haematinic
	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.	N/A
	Me-too status	Ferosoft-FA Syrup by M/s Hilton Pharma (Reg#045110)
	GMP status	Last inspection report dated 25-04-2017, the panel recommended the grant of New DML
	Previous remarks of the Evaluator.	GMP inspection older than 1 year. Shortcoming letter issued on 4th June, 2018.

	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of firm on priority **(M-284)**.
	Evaluation by PEC	The firm has submitted copy of inspection report dated 24-05-2019 which concluded that the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Decision: Registration Board approved the case with innovator's specification, since iron preparations are not considered as drug by various reference regulatory authorities.	
1418.	Name and address of manufacturer / Applicant	M/s Briell Pharmaceuticals (Pvt.) Ltd. 538-C, Sundar Industrial Estate, Lahore.
	Brand Name +Dosage Form + Strength	Beldene 20mg Capsule
	Composition	Each Capsules Contains: Piroxicam…….20mg
	Diary No. Date of R& I & fee	Diary No:5959, 13/06/2017, Rs: 20,000/-
	Pharmacological Group	Anti-inflammatory and antirheumatic products, non-steroid (Oxicams)
	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.	Piroxicam 20 mg capsules, hard by M/s Generics [UK] Ltd t/a Mylan (MHRA Approved)
	Me-too status	Felden by Pfizer
	GMP status	Last inspection report dated 25-04-2017, the panel recommended the grant of New DML
	Previous remarks of the Evaluator.	GMP inspection older than 1 year. Shortcoming letter issued on 4th June, 2018.
	Previous decision(s)	Registration Board referred the case to QA & LT Division to conduct GMP inspection of firm on priority **(M-284)**.
	Evaluation by PEC	The firm has submitted copy of inspection report dated 24-05-2019 which concluded that the firm was found to be operating at a satisfactory level of cGMP compliance at the time of inspection.
	Decision: Approved with change of brand name.	
1419.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	SAIFLOX 750mg tablet
	Composition	Each film coated tablet contains: Levofloxacin (as hemihydrate)……750mg
	Diary No. Date of R& I & fee	Dy. No.432; 21-03-2016; Rs.20,000/- (18-03-2016)
	Pharmacological Group	Antibacterial
	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.	Approved by USFDA
	Me-too status	Tevoflox Tablets 750 mg of M/s Pearl Pharmaceuticals (068560)
	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.
	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.	
1420.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Dulotin 60mg capsule
	Composition	Each capsule contains: Duloxetine(as hydrochloride) enteric coated pellets……60mg
	Diary No. Date of R& I & fee	Dy. No.429; 21-03-2016; Rs.20,000/- (18-03-2016)
	Pharmacological Group	Serotonin & nor adrenalin reuptake inhibitors
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	1 x 7's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Dulan capsules of M/s Hilton Pharma (Pvt.) Limited Karachi (Reg.# 055448)
	GMP status	Last GMP inspection report dated 02-01-2017 confirms good compliance to GMP
	Previous remarks of the Evaluator.	• Source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets shall be submitted.
	Previous decision(s)	Deferred for submission of source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets (M-274).
	Evaluation by PEC	The firm has submitted documents of Dexlansoprazole pellets.
	Decision: Deferred for submission of source of pellets, along with stability studies data, GMP certificate of supplier and differential fee in case of import of pellets.	
1421.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	RIBAN 10mg tablets
	Composition	Each film coated tablet contains: Rivaroxaban…….10mg
	Diary No. Date of R& I & fee	Dy. No.303; 16-03-2016; Rs.20,000/- (15-03-2016)
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Xarelto of M/s Bayer Health Care (Reg.# 059057)
	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.	

1422.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	RIBAN 15mg tablets
	Composition	Each film coated tablet contains: Rivaroxaban…….15mg
	Diary No. Date of R& I & fee	Dy. No.304; 16-03-2016; Rs.20,000/- (15-03-2016)
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Xarelto of M/s Bayer Health Care (Reg.# 072549)
	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.	
1423.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	RIBAN 20mg tablets
	Composition	Each film coated tablet contains: Rivaroxaban…….20mg
	Diary No. Date of R& I & fee	Dy. No.305; 16-03-2016; Rs.20,000/- (15-03-2016)
	Pharmacological Group	Anticoagulant
	Type of Form	Form 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 x 14's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Xarelto of M/s Bayer Health Care (Reg.# 072550)
	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.	
1424.	Name and address of manufacturer / Applicant	M/s Saibins Pharmaceuticals, Plot 316, Industrial Triangle Kahuta Road Islamabad
	Brand Name +Dosage Form + Strength	Azitabin 500mg capsules
	Composition	Each capsule contains:

		Azithromycin (as dihydrate)……..500mg
	Diary No. Date of R& I & fee	Dy. No.3813; 08-06-2015; Rs.20,000/- (08-06-2015)
	Pharmacological Group	Antibacterial
	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 provided
	Me-too status	Zygrel 500mg capsules of M/s Searle Pakistan Pvt. Ltd.
	GMP status	Last inspection report dated 02-01-2017 confirms good compliance to GMP.
	Previous remarks of the Evaluator.	➢ **Shortcomings** • Evidence of approval of applied formulation in reference regulatory authorities/agencies • Product specific outline of method of manufacturing (method of manufacturing for Tiotropium bromide capsules is provided instead of azithromycin capsules).
	Previous decision(s)	Deferred for following: **(M-274)** • Evidence of approval of applied formulation in reference regulatory authorities/agencies. • Product specific outline of method of manufacturing.
	Evaluation by PEC	
	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.** **Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.**	
1425.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories, 20KM, Lahore-Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	ZUKAST 10mg Tablet
	Composition	Each tablet contains: Zafirlukast……10mg
	Diary No. Date of R& I & fee	26796, 29-12-2017, 20,000/-, 20-12-2017
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1 × 4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Accolate 10mg film-coated tablets of M/s Astra Zeneca Pharmaceuticals (USFDA Approved)
	Me-too status	Zilesta 10mg tablet of M/s Genix Pharma
	GMP status	Last inspection as per cGMP audit proforma dated 23-02-2018 & 26-02-2018 confirms satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	Clarification is required regarding dosage form since reference product is film coated while applied formulation is uncoated tablet.
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted revised master formulation without coating alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1952984) dated 31-05-2019.
	Decision: Approved with innovator's specifications.	

1426.	Name and address of manufacturer / Applicant	M/s DeMont Research Laboratories, 20KM, Lahore-Sharikpur Road, Sheikhupura
	Brand Name +Dosage Form + Strength	ZUKAST 20mg Tablet
	Composition	Each Film coated tablet contains: Zafirlukast……20mg
	Diary No. Date of R& I & fee	26797, 29-12-2017, 20,000/-, 27-12-2017
	Pharmacological Group	Anti-asthmatic
	Type of Form	Form-5
	Finished product Specification	In-house
	Pack size & Demanded Price	1 × 4's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Accolate 20mg tablet (USFDA Approved)
	Me-too status	Zilesta 20mg tablet of M/s Genix Pharma
	GMP status	Last inspection as per cGMP audit proforma dated 23-02-2018 & 26-02-2018 confirms satisfactory level of GMP compliance.
	Previous remarks of the Evaluator.	• Clarification is required regarding dosage form since reference product is film coated while applied formulation is uncoated tablet.
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has submitted revised master formulation without coating alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1952985) dated 31-05-2019.
	Decision: Approved with innovator's specifications.	
1427.	Name and address of manufacturer / Applicant	M/s Trigon Pharmaceuticals, (Pvt.) Limited, 8-km Thoker Raiwind Road, Lahore.
	Brand Name +Dosage Form + Strength	Linzot 100mg/ 5ml Dry suspension
	Composition	Each 5ml after reconstitution contains: Linezolid ……...…..100mg
	Diary No. Date of R& I & fee	Dy.No.26631; 29-12-2017;Rs.20,000/-(29-12-2017)
	Pharmacological Group	Antibacterial
	Type of Form	Form- 5
	Finished product Specification	Manufacturers
	Pack size & Demanded Price	60ml & Rs.367.50 per pack
	Approval status of product in Reference Regulatory Authorities.	USFDA / MHRA and TGA (Australia) Approved as Dry suspension.
	Me-too status	Nezocin 100mg/ 5ml suspension of M/s Brookes Pharma (Reg. # 055003)
	GMP status	Last GMP inspection was conducted on 14-02-2018 and the report concludes satisfactory level of GMP compliance with some recommendations.
	Previous remarks of the Evaluator.	• Liquid suspension is applied while in reference regulatory authorities, it is approved as dry powder suspension. • No USP or BP monograph is available for the applied formulation. • Firm has general dry powder suspension section as mentioned in the GMP inspection report.
	Previous decision(s)	Deferred for revision of formulation as per reference product along with submission of requisite fee for change of formulation **(M-287)**.
	Evaluation by PEC	The firm has revised relevant annexures of Form-5 to Dry

		Powder suspension with submission of fee challan of Rs. 20,000/- (Deposit slip # 1952810) dated 24-06-2019.
	Decision: Approved with innovator's specifications.	
1428.	Name and address of manufacturer / Applicant	M/s. Bajwa Pharmaceuticals (Pvt) Ltd, 36-Km G.T. Road, Khori Mureedke
	Brand Name +Dosage Form + Strength	Lignox-AD Injection B.P 2% Injection for IM
	Composition	DUPLICATE DOSSIER PKR 20,000/-, 21-05-2014
	Diary No. Date of R& I & fee	Each ml injection contains Lignocaine Hydrochloride……..2% w/v Adrenaline…….……0.001%
	Pharmacological Group	Local anesthetic
	Type of Form	Form 5
	Finished product Specification	BP Specs
	Pack size & Demanded Price	1ml x 50's: As per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed.
	Me-too status	Lignocaine with Adrenaline Injection of Elite Pharma (Reg#026235)
	GMP status	Last inspection report dated 13-03-2017 and 24-03-2017, the panel recommended the firm for production resumption
	Previous remarks of the Evaluator.	Letter of shortcoming was issued on 18th April 2017 and the reply received is still deficient for following • Evidence of approval of applied formulation in reference regulatory authorities • Me-too status, as the provided reference contains different strength of adrenaline
	Previous decision(s)	Deferred for submissions of following documents: (M-271) • Evidence of approval status of applied formulation in reference regulatory authorities. • Evidence of me-too status.
	Evaluation by PEC	Evidence of approval of applied formulation in reference regulatory authority could not be verified.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authorities / agencies which were adopted by the Registration Board in its 275th meeting.	
1429.	Name and address of manufacturer / Applicant	M/s Roryan Pharmaceuticals Pvt Ltd. 85/B-Hayatabad Industrial Estate, Peshawar, kpk, Pakistan
	Brand Name +Dosage Form + Strength	Pirocin 2% w/w Topical Ointment
	Composition	Form-5 Dy.No 39870 dated 04-12-2018 Rs.20,000/- Dated 04-12-2018
	Diary No. Date of R& I & fee	Each Gram Topical Ointment Contains: Mupirocin as calcium……..…20mg (2% w/w)
	Pharmacological Group	Other antibiotics for topical use
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	15g / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Bactroban 2% Ointment by M/s GlaxoSmithKline (MHRA Approved)
	Me-too status	Mucin 20mg Ointment of M/s Alza Pharma (Reg#079996)
	GMP status	19-09-2018 ad 03-10-2018 Grant of Additional sections and cGMP certificate Panel recommends Grant of Additional sections and cGMP

		certificate
	Previous remarks of the Evaluator.	• Firm has applied as Mupirocin Calcium…20mg where as approved formulation in MHRA, AIFA (Italy) is Mupirocin …20mg.
	Previous decision(s)	Deferred for submission of correct composition with salt form as per Reference product along with correction fee (M-288).
	Evaluation by PEC	The firm has submitted revised master formulation with correct salt form alongwith fee challan of Rs. 5000/- (Deposit slip # 0815756) dated 21-06-2019.
	Decision: Approved.	
1430.	Name and address of manufacturer / Applicant	M/s Medicraft Pharmaceuticals (Pvt) Ltd, 126-B, Industrial Estate, Hayatabad, Peshawar.
	Brand Name +Dosage Form + Strength	Vit.D 5mg/ml Injection
	Composition	Each 1ml ampoule contains: Cholecalciferol (200,000I.U).....5mg
	Diary No. Date of R& I & fee	Rs. 40,000/- (Duplicate Dossier)
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specification	BP Spec's
	Pack size & Demanded Price	1ml x 5's
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 Good 200,000IU / 1 ml solution for injection of (ANSM France approved)
	Me-too status	Calciferol Injection M/s Global Pharmaceuticals
	GMP status	Last GMP inspection conducted on 30-01-2018 and report concludes that firm may be considered to be operative in Good level of cGMP Compliance.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for following: **(M-282)** a. Revised Form-5 is submitted with following label claim: Each ml contains: Cholecalciferol……..5mg eq. to 250000 IU b. Clarification is required regarding calculation of 5mg eq. to 250000IU. c. Quantity of API submitted in master formulation is not rational with label claim. d. Reference of calcitrol (1mcg/ml) injection is given under evidence of availability in reference agencies and Pakistan. Deferred for submission of differential fee for revision of formulation (**M-289).**
	Evaluation by PEC	The firm has submitted revised Form-5 with fee challan of Rs. 5,000/- (Deposit slip#0802855) dated 09-01-2019. The firm has deposited remaining fee of Rs. 15,000/- (Deposit slip#0785703) dated 02-07-2019.
	Decision: Approved.	
1431.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Irofer 500mg /10ml injection
	Composition	Each ampoule of 10ml contains: Iron as ferric carboxymaltose…….500mg
	Diary No. Date of R& I & fee	14901, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Haematinic
	Type of Form	Form-5
	Finished product Specification	In-house

	Pack size & Demanded Price	10ml × 1's; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Ferinject Injectable 10ml vial of M/s M/s. RG Pharmaceutica (Pvt.) Ltd., (Reg.# 072548)
	GMP status	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: Liquid ampoule (General) section
	Previous remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Previous decision(s)	Registration Board deferred the case for justification of 3% overage in master formulation (M-289).
	Evaluation by PEC	The firm has submitted master formulation without overage.
	Decision: Approved with innovator's specifications. Regsitration letter will be issued after comments of Legal affairs divison, about patent issue of applied formulation.	
1432.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Acobal 1ml injection
	Composition	Each 1ml injection contains: Mecobalamin…….500mcg
	Diary No. Date of R& I & fee	14934, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specification	In-house specifications
	Pack size & Demanded Price	1ml; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	PMDA approved
	Me-too status	Wycomin 500 mcg Injection by Wnsfeild Pharmaceutical
	GMP status	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: Liquid ampoule (General) section
	Previous remarks of the Evaluator.	R & I date mentioned is 07-09-2019 and date mentioned on fee challan is 07-06-2019. Brand name mentioned on fee challan is Acobalamin while that mentioned on Form-5 is Acobal 1ml Injection. Pharmacological group is not written on Form-5. 3% Overage is mentioned in master formulation.
	Previous decision(s)	Registration Board deferred the case for justification of 3% overage in master formulation (M-289).
	Evaluation by PEC	The firm has submitted master formulation without overage.
	Decision: Approved with innovator's specifications and change of brand name.	
1433.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Kitax Injection 1ml
	Composition	Each 1ml amber glass ampoule contain: Ketorolac Tromethamine…….30mg / ml
	Diary No. Date of R& I & fee	16516, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	NSAID
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1ml × 5's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Toradol Injection of Atnahs Pharma, UK (MHRA Approved)

	Me-too status	Toralac Injection 30mg/ml by M/s Vision (Reg#050290)
	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: Liquid ampoule (General) section
	Previous remarks of the Evaluator.	
	Previous decision(s)	Registration Board deferred the case for justification of 3% overage in master formulation (M-289).
	Evaluation by PEC	The firm has submitted master formulation without overage.
	Decision: Approved with change of brand name.	
1434.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	AT-D Injection 1ml
	Composition	Each 1ml amber glass ampoule contain: Cholecalciferol……..5mg
	Diary No. Date of R& I & fee	16531, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Vitamin D analogue
	Type of Form	Form-5
	Finished product Specification	In-house specification
	Pack size & Demanded Price	1ml × 1's; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 BON of Bouchara, ANSM Approved
	Me-too status	GET-D of GETZ Pharma Pakistan
	GMP status	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: Liquid ampoule (General) section
	Previous remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Previous decision(s)	Registration Board deferred the case for justification of 3% overage in master formulation (M-289).
	Evaluation by PEC	The firm has submitted master formulation without overage.
	Decision: Approved with innovator's specifications and change of brand name.	
1435.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Ondansetron Injection 8mg/4ml
	Composition	Each 4ml amber glass ampoule contain: Ondansetron as hydrochloride dihydrate……8mg
	Diary No. Date of R& I & fee	16498, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antiemetic
	Type of Form	Form-5
	Finished product Specification	USP Specification
	Pack size & Demanded Price	4ml ×5's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ondansetron 8mg/4ml solution for injection (MHRA approved)
	Me-too status	Zofran 8mg/4ml injection of M/s GSK
	GMP status	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: Liquid ampoule (General) section
	Previous remarks of the Evaluator.	3% Overage is mentioned in master formulation.
	Previous decision(s)	Registration Board deferred the case for justification of 3% overage in master formulation (M-289).
	Evaluation by PEC	The firm has submitted master formulation without overage.
	Decision: Approved.	

1436.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Fusihyd Cream 15g
	Composition	Each gram cream contains: Fusidic Acid ……..20mg (2%) Hydrocortisone acetate……10mg (1%)
	Diary No. Date of R& I & fee	16497, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Fucidin H Cream (UK MHRA Approved)
	Me-too status	Melas H Cream of M/s Atco Laboratories
	GMP status	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: Cream/Ointment (General) section
	Previous remarks of the Evaluator.	Salt form of Hydrocortisone is not mentioned in Form-5. Revision of Form-5 with applicable fee is required.
	Previous decision(s)	Deferred for revision of formulation as per reference product alongwith requisite fee (M-289).
	Evaluation by PEC	The firm has revised Form-5 with correct salt form with submission of fee of Rs. 5,000/- (Deposit slip#1914383) dated 18-07-2019.
	Decision: Approved with innovator's specifications.	
1437.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	CITA 50/1000mg Tablet
	Composition	Each film coated Tablet contains: Sitagliptin as phosphate…….50 mg Metformin hydrochloride……1000 mg
	Diary No. Date of R& I & fee	16499, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	ARTG ID: 149023; JANUMET 50mg/1000mg film-coated tablet by M/s Merck Sharp & Dohme (Australia) Pty Ltd (**Approved in TGA).**
	Me-too status	Neoglip 50/1000mg Tablets of M/s Atco Laboratories Ltd **(Reg#053100)**
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Previous remarks of the Evaluator.	Salt forms of sitagliptin and metformin are not mentioned. Revision of Form-5 with requisite fee is required. Brand name mentioned in master formulation is CITAWEL which is different from that mentioned in Form-5. Clarification is required. Brand name mentioned in specification part is CITAWEL. Clarification is required.
	Previous decision(s)	Deferred for following: **(M-289)**

		• Revision of formulation as per reference product alongwith requisite fee. • Clarification of brand name of applied formulation.
	Evaluation by PEC	The firm has submitted revised Form-5 with correct salt form alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914381) dated 18-07-2019.
	Decision: Approved with innovator's specifications.	
1438.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	CITA 50/500mg Tablets
	Composition	Each film coated Tablet contains: Sitagliptin as phosphate…….50 mg Metformin hydrochloride……500 mg
	Diary No. Date of R& I & fee	16510, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-diabetic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	JANUMET™ (sitagliptin/metformin HCl) tablets USFDA Approved
	Me-too status	S-Gliptin Plus Tablets of M/s Barrett Hodgson
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Previous remarks of the Evaluator.	Salt forms of sitagliptin and metformin are not mentioned. Revision of Form-5 with requisite fee is required. Brand name mentioned in master formulation is CITAWEL which is different from that mentioned in Form-5. Clarification is required. Product name mentioned in finished product specification part is CITAWEL Tablet. Clarification is required.
	Previous decision(s)	Deferred for following: **(M-289)** • Revision of formulation as per reference product alongwith requisite fee. • Clarification of brand name of applied formulation.
	Evaluation by PEC	The firm has submitted revised Form-5 with correct salt form alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914380) dated 18-07-2019.
	Decision: Approved with innovator's specifications.	
1439.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultolax 4 mg Tablets
	Composition	Each tablet contains; Thiocolchicoside……..…....4 mg
	Diary No. Date of R& I & fee	14932, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Innovator specification
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in ANSM (France) as uncoated tablet
	Me-too status	Wodnik 4mg tablet of M/s Martin Dow (Reg. # 081138)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has

		considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Previous remarks of the Evaluator.	Approved in ANSM (France) as uncoated tablet while it is applied as film-coated. Fee challan mentions capsule dosage form while submitted Form-5 suggests tablet dosage form.
	Previous decision(s)	Deferred for following: **(M-289)** • Revision of formulation as per reference product alongwith requisite fee. • Clarification of dosage form in Form-5.
	Evaluation by PEC	The firm has submitted revised Form-5 From film coated to uncoated tablet alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914382) dated 18-07-2019.
	Decision: Approved.	
1440.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Aultazole 50mg / 5ml Suspension
	Composition	Each ml dry Powder contains: Fluconazole……..10mg
	Diary No. Date of R& I & fee	14927, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished product Specification	BP specifications
	Pack size & Demanded Price	30ml; As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Zefung Dry Powder Suspension of Nexus Pharma
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Oral Powder suspension (General) section
	Previous remarks of the Evaluator.	Fee challan does not specify brand name, strength and dosage form of applied product. Only API is written as "Fluconazole". Label claim and master formulation does not suggest Dry powder suspension. Revision of Form-5 is required.
	Previous decision(s)	Deferred for revision of formulation as per reference product alongwith submission of applicable fee. (M-289)
	Evaluation by PEC	The firm has submitted revised Form-5 from liquid suspension to Dry powder suspension alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914386) dated 18-07-2019. Remaining fee is required.
	Decision: Deferred for submission of remaining fee of Rs. 15,000/- for revision of formulation.	
1441.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Atro 10/40mg Tablet
	Composition	Each film coated tablet contains; Ezetimibe……...10 mg Atorvastatin as calcium trihydrate……..40 mg
	Diary No. Date of R& I & fee	16525, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	HMG-CoA reductase inhibitor and other lipid modifying agents

	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved.
	Me-too status	Atozet 10/40 tablet of M/s Hilton Pharma
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Previous remarks of the Evaluator.	Salt form of atorvastatin is not mentioned. Revision of Form-5 with requisite fee is required. You have claimed BP and innovator's specifications simultaneously for your finished product. Clarification is required.
	Previous decision(s)	Decision: Deferred for following: (M-289) • Revision of formulation as per reference product along with submission of requisite fee. • Clarification of finished product specifications of applied formulation.
	Evaluation by PEC	The firm has submitted revised Form-5 with correct salt for alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914377) dated 18-07-2019.
	Decision: Approved.	
1442.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Atro 10/20mg Tablet
	Composition	Each film coated tablet contains; Ezetimibe…….....10mg Atorvastatin as calcium trihydrate…….....20mg
	Diary No. Date of R& I & fee	16545, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Lipid lowering Agent
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Atozet 10/20 tablet of M/s Hilton Pharma (Reg#061223)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Previous remarks of the Evaluator.	Salt form of atorvastatin is not mentioned. Revision of Form-5 with requisite fee is required. You have claimed BP and innovator's specifications simultaneously for your finished product. Clarification is required.
	Previous decision(s)	Decision: Deferred for following: (M-289) • Revision of formulation as per reference product along with submission of requisite fee. • Clarification of finished product specifications of applied formulation.
	Evaluation by PEC	The firm has submitted revised Form-5 with correct salt for alongwith submission of fee challan of Rs. 5000/- (deposit

		slip # 1914378) dated 18-07-2019.
	Decision: Approved with innovator's specifications.	
1443.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Dyclin Gel 50gm
	Composition	Each tube contains: Diclofenac Diethylamine…….1.16%
	Diary No. Date of R& I & fee	16547, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Analgesic
	Type of Form	Form-5
	Finished product Specification	BP specification
	Pack size & Demanded Price	15g & 30g; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA (Voltarol 1.16% Emulgel) 10grams / 20grams)
	Me-too status	Voltral emulgel of M/s GSK (Pvt.) Ltd. (Reg.# 083991)
	GMP status	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: Cream/Ointment (General) section
	Previous remarks of the Evaluator.	Label claim of applied formulation is not as per reference product. Revision of Form-5 with applicable fee is required.
	Previous decision(s)	Deferred for following: (M-289) Revision of formulation as per reference formulation alongwith requisite fee. Clarification regarding required manufacturing facility since section is of cream/ointment while applied formulation is gel.
	Evaluation by PEC	The firm has submitted fee challan of Rs. 5000/- (deposit slip # 1914385) dated 18-07-2019. However, firm has not revised Form-5 as per reference product.
	Decision: Registration Board referred the case to Licensing Division for clarification whether Gel formulation can be manufactured in Cream/Ointment (General) section.	
1444.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Azithromycin 250mg Dry Suspension
	Composition	Each 5ml contains: Azithromycin ……..250mg
	Diary No. Date of R& I & fee	14926, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Macrolide antibiotic
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	60ml; As recommended by PRC
	Approval status of product in Reference Regulatory Authorities.	Zithromax 200mg/ 5ml powder for oral suspension of M/s Pfizer Limited (MHRA Approved)
	Me-too status	Azomax 200mg oral suspension of M/s Novartis Pharma, Pakistan (Reg. # 022201)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Oral Powder suspension (General) section
	Previous remarks of the Evaluator.	You have applied Azithromycin 250mg Dry Suspension while reference formulation is 200mg Dry Suspension. Clarification / Revision of Form-5 with requisite fee is

		required.
	Previous decision(s)	Deferred for revision of formulation as per reference product alongwith requisite fee. (M-289)
	Evaluation by PEC	The firm has submitted fee challan of Rs. 5000/- (Deposit slip # 1914387) dated 18-07-2019. However, firm has not revised Form-5 and its enclosures.
	Decision: Deferred for revision of formulation as per reference product.	
1445.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	Adyzil 400mg Tablet
	Composition	Each film coated tablet contains; Linezolid……..……..400mg
	Diary No. Date of R& I & fee	16504, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Oxazolidinone antibiotic
	Type of Form	Form-5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zyvox 400 mg film-coated tablets by Pharmacia Limited (USFDA Approved and discontinued but for reasons other than safety and efficacy as per USFDA website)
	Me-too status	Linzor 400mg Tablets by Hilton Pharma
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Previous remarks of the Evaluator.	Master formulation does not contain ingredients for film coating. Correction is required.
	Previous decision(s)	Deferred for revision of master formulation as per reference formulation alongwith requisite fee. (M-289)
	Evaluation by PEC	The firm has revised master formulation with film coating composition alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914379) dated 18-07-2019.
	Decision: Approved with innovator's specifications.	
1446.	Name and address of manufacturer / Applicant	M/s. Athan Pharmaceuticals Plot No 84/1, block B, Phase V industrial Estate, Hattar
	Brand Name +Dosage Form + Strength	M-Cobo 500 mcg/ Tablet
	Composition	Each film coated tablet contains; Mecobalamin …….500 mcg
	Diary No. Date of R& I & fee	16527, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Vitamin B12
	Type of Form	Form-5
	Finished product Specification	JP specifications
	Pack size & Demanded Price	2 × 10's; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Approved by PMDA of Japan
	Me-too status	Mecomed 500mcg by Global Pharma (Reg. No. 041670)
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Tablet General section
	Previous remarks of the Evaluator.	In contrary to reference product approved by PMDA of Japan, which is available as sugar coated tablet, firm has applied for film coated tablet.
	Previous decision(s)	Deferred for revision of master formulation as per reference

		formulation alongwith requisite fee. (M-289)
	Evaluation by PEC	The firm has revised Form-5 with sugar coating composition alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914384) dated 18-07-2019.
	Decision: Approved.	
1447.	Name and address of manufacturer / Applicant	M/s Hoover Pharmaceuticals, Lahore
	Brand Name +Dosage Form + Strength	Erythrotel granules for Suspension
	Composition	Each 5ml contains: Erthromycin Ethyl Succinate eq to Erythromycin……...200mg
	Diary No. Date of R& I & fee	Dy. No.4622; 1-06-2017; Rs.20,000/- (1-06-2017)
	Pharmacological Group	Macrolide
	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.	Eryped granules for oral suspension of Abror Pharms (USFDA approved)
	Me-too status	Wotez oral granules for suspension by Martin Dow (Reg#079758)
	GMP status	Last inspection report 20-01-2017. Panel recommended the grant of additional section.
	Previous remarks of the Evaluator.	• Product monograph is present in USP • International availability in RRA could not be confirmed.
	Previous decision(s)	Deferred for clarification as Reference Regulatory Authority product is present as granules for oral suspension (M-274).
	Evaluation by PEC	The approval status of applied formulation has been confirmed in USFDA.
	Decision: Approved with innovator's specifications.	
1448.	Name and address of manufacturer / Applicant	M/s Surge Laboratories (Pvt) Ltd., 10 KM, Faisalabad Road Bikhi, District Sheikhupura
	Brand Name +Dosage Form + Strength	Iprasol Nebuliser Solution 250mcg/1ml
	Composition	Each 1ml contains:- Ipratropium Bromide…….250mcg
	Diary No. Date of R& I & fee	Diary #614 dated 24-10-2013, 20,000/- (photocopy attached), 06-11-2013
	Pharmacological Group	Anticholinergic
	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.	Ipratropium bromide 250 mcg/1ml Nebuliser solution (MHRA approved)
	Me-too status	Tropium inhalation solution of Atco labs (Reg#053356)
	GMP status	The firm was granted GMP certificate based on inspection conducted on 09-11-2017 & 22-02-2018.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred in **254th** meeting for followings: • The firm has applied the product as priority as new section, however, in the letter issued from licensing it seems that this is the amendment, not new section. • Clarification from licensing division is required • Firm has applied on Form 5 only accelerated stability data is attached without any supporting documents like

		• Chromatograms, raw data etc. • International availability is required to be provided. Internationally, in UK this Product is presented in the form of plastic bottles. Deferred for confirmation of required manufacturing facility for filling of applied formulation in LDPE container closure system. **(M-284)**
	Evaluation by PEC	The firm has provided General Liquid Injectable (including blow fill seal area).
	Decision: Approved with innovator's specifications. Fee shall be verified as per procedure adopted in 285th meeting.	
1449.	Name and address of manufacturer / Applicant	M/s Surge Laboratories (Pvt) Ltd., 10 KM, Faisalabad Road Bikhi, District Sheikhupura
	Brand Name +Dosage Form + Strength	Iprasol Nebuliser Solution 500mcg/1ml
	Composition	Each 1ml contains:- Ipratropium Bromide…….500mcg
	Diary No. Date of R& I & fee	Diary #615 dated 24-10-2013, 20,000/- (photocopy attached), 06-11-2013
	Pharmacological Group	Anticholinergic
	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.	Ipratropium bromide 500 mcg/1ml Nebuliser solution (MHRA approved)
	Me-too status	Atem nebuliser solution of Atco labs (Reg#053356)
	GMP status	The firm was granted GMP certificate based on inspection conducted on 09-11-2017 & 22-02-2018.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred in **254th** meeting for followings: • The firm has applied the product as priority as new section, however, in the letter issued from licensing it seems that this is the amendment, not new section. • Clarification from licensing division is required • Firm has applied on Form 5 only accelerated stability data is attached without any supporting documents like • Chromatograms, raw data etc. • International availability is required to be provided. Internationally, in UK this Product is presented in the form of plastic bottles. Deferred for confirmation of required manufacturing facility for filling of applied formulation in LDPE container closure system. **(M-284)**
	Evaluation by PEC	The firm has provided General Liquid Injectable (including blow fill seal area).
	Decision: Approved with innovator's specifications. Fee shall be verified as per procedure adopted in 285th meeting.	
1450.	Name and address of manufacturer / Applicant	M/s Scilife Pharma Private Limited, Plot # FD-57/58-A2, Korangi Creek Industrial Park, Karachi **Contract Manufacturer from** M/s Opal Laboratories (Pvt) limited, Plot # LC-41, T.E., Landhi, Karachi.
	Brand Name +Dosage Form + Strength	Scifix Tablet 200mg
	Composition	Each film-coated tablet contains: Cefixime (as Trihydrate)……200mg
	Diary No. Date of R& I & fee	Dy. No.3911; 27-12-2016; **Rs.50,000/-** (27-12-2016)

	Pharmacological Group	Antibacterial (Cephalosporin)
	Type of Form	Form-5
	Finished product Specification	U.S.P.
	Pack size & Demanded Price	1x10's & as per PRC policy 2015
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Cefiget tablet 200mg of M/s Getz Pharma
	GMP status	Last GMP inspection of M/s Scilife was conducted on 14-06-2017 with satisfactory remarks of GMP compliance. Last GMP inspection of M/s Opal was conducted on 08-12-2016 and the date of signature mentioned on the same report is 05-04-2017 and the report concludes: "To keep an eye on momentum of progress towards committed compliance, annual surveillance inspection after 12 months is recommended."
	Previous remarks of the Evaluator.	Letter of intent is submitted. Agreement between both the firms has also been submitted. Manufacturer firm has relevant section i.e. tablet (Cephalosporin) section. Applicant has five approved sections and their no drug is already registered on contract basis. Submitted Opals' inspection report seems to be incomplete as the date of inspection and date of signature of the concerned area FID are different. Moreover, annual inspection after 12 months is recommended in the conclusion of the submitted report.
	Previous decision(s)	Deferred for confirmation by QA&LT Division regarding latest GMP inspection report conducted within a period of last 1 year by DRAP (M-278).
	Evaluation by PEC	GMP inspection dated ……of M/s Opal laboratories, Karachi concluded that the firm is operating at fair level of compliance.
	Decision: Approved.	
1451.	Name and address of manufacturer / Applicant	M/s Rotex Pharma Pvt Ltd., Islamabad
	Brand Name +Dosage Form + Strength	Staglin E2 1mg Tablets
	Composition	Each uncoated tablet contains: Cinitapride (as acid tartrate)……1 mg
	Diary No. Date of R& I & fee	2355, 05-05-2011, Rs.8000/-, Rs.12,000/-, 08-12-2014
	Pharmacological Group	Gastroprokinetic agent
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	10's, 50's; As Per PRC
	Approval status of product in Reference Regulatory Authorities.	Cidine 1 mg Tablets by M/ ALMIRALL, S.A. (Spanish Agency of Medicines and Health Products Approved)
	Me-too status	Cidine Tablets 1mg by M/s Highnoon (Reg#052940)
	GMP status	Last Inspection report 17-03-2017 concluded that the panel concluded that the company is following GMP guidelines.
	Previous remarks of the Evaluator.	
	Previous decision(s)	Deferred for evidence of approval status in Reference Regulatory Authorities (M-263).
	Evaluation by PEC	The firm has submitted revised Form-5, master formulation from film coated to uncoated formulation alongwith submission of fee challan of Rs. 5000/- (deposit slip #

		1930993) dated 27-06-2019.
	Decision: Approved with innovator's specifications.	
1452.	Name and address of manufacturer / Applicant	M/s Maxitech Pharma Pvt. Ltd. Plot No. E/178, Phase-II, SITE Super Highway, Karachi.
	Brand Name +Dosage Form + Strength	C-Flox Dry Powder Suspension 250mg/5ml
	Composition	Each 5 ml after reconstitution contains: Ciprofloxacin……250mg
	Diary No. Date of R& I & fee	Diary No:1091, 24/11/2016, Rs: 20,000/-
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Ciproxin 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved.
	Me-too status	Hiflox Dry suspension 250mg/5ml by M/s Hilton (Reg#067499)
	GMP status	22-11-2017; Routine GMP Inspection Current GMP compliance level is rated as good
	Previous remarks of the Evaluator.	-
	Previous decision(s)	264th Meeting of Registration Board held on 27-28th April, 2017. Deferred for revision of formulation as per Innovator according to decision of 250th RB meeting.
	Evaluation by PEC	Firm has submitted revised formulation as per Innovator for consideration by the board. Fee challan of Rs. 5000/- (deposit slip # 0781237) dated 26-11-2018 has been submitted. Source of granules: M/s Vision pharmaceuticals, Islamabad
	Decision: Approved with diluent as per innovator's specifications.	
1453.	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	Calamine G Lotion
	Composition	Each 100ml Contains: Calamine……15gm Zinc Oxide…….5gm
	Diary No. Date of R& I & fee	Dy.No 30859-E dated 13-09-2018 Rs.20,000/- dated 13-09-2018
	Pharmacological Group	Antipuritic
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	Rs.16/120 ml
	Approval status of product in Reference Regulatory Authorities.	Calamine Lotion BP of Boots company (MHRA approved)
	Me-too status	Calamine Lotion BP of M/s Prime labs (Reg#028621)
	GMP status	16-10-2018 Firm was operating at the fair level of GMP Compliance.
	Previous remarks of the Evaluator.	Evidence in RRA
	Previous decision(s)	Deferred for following: • Clarification from Licensing Division for details of dosage forms which could be manufactured in the approved section of "External preparations/ Application/Aerosol Section for Human" • Evidence of approval of applied formulation in reference regulatory authorities/agencies which were adopted by the

		Registration Board in its 275th meeting. • Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.
	Evaluation by PEC	The firm has submitted that inadvertently excipients are mentioned in applied formulation. Otherwise calamine and zinc oxide are APIs as specified in reference formulation MHRA and me-too reference. Following are considered as excipients: **Excipients** Bentonite…3gm Sodium Citrate…0.5gm Menthol…50mg Glycerin…5gm The firm has submitted fee challan of Rs. 5000/- (deposit slip # 1960852) dated 26-08-2019. Licensing division vide letter No. F.1-14/2002-Lic (Vol-I) dated 04th July, 2019 has forwarded the copy of inspection report of M/s International Pharma Labs. Lahore, conducted for inspection of "External preparations/ Application/Aerosol Section." The List of Machinery attached as Annex-XI of the above cited inspection report includes following machinery: 13. Bottle blowing machine 14. Batch manufacturing tank SS 5001 15. Storage tank SS 500L 16. Spray Bottle filling machine 17. Filteration assembly. 18. Bottle filling machine. 19. Table S.S 20. Packing Hall table. 21. Scope set for manufacturing area. 22. S.S pellets. 23. Liquid filling machine. 24. Weighing balance.
	Decision: Approved with BP specifications.	

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)

Ophthalmic (General) Drop Section (10 molecules/ 12 products)		
1454.	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	DORZITAMOL Eye Drop
	Composition	One ml of solution contains: Olopatadine HCl eq. to Olopatadine……..1.0mg
	Diary No. Date of R& I & fee	16653, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Allergic conjunctivitis
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml , LDPE bottle with LDPE dropper and HDPE cap; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Olopatadine 1mg/ml eye drops, solution by Generics [UK] Limited t/a Mylan (MHRA Approved)
	Me-too status	Patanol 0.1% by AGP Reg. # 041187
	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	The firm has submitted revised Form-5 with change in fill volume from 15ml to 5ml alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914389) dated 25-07-2019. Upon communication, the firm has clarified that applied formulation is solution.
	Decision: Approved.	
1455.	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	OLOP Eye Drop 5ml
	Composition	Each Drop Tainer Dispenser contains: Olopatadine hydrochloride 2.326 mg/ml eq. to Olopatadine…..2mg/ml
	Diary No. Date of R& I & fee	16655, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-histamine, Anti-allergy
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml Drop tainer Dispenser; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	USFDA approved
	Me-too status	Olopat DS Eye Drops by M/s Vega Pharmaceuticals, Lahore (Reg.# 069169)
	GMP status	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	The firm has clarified that the applied formulation is solution alongwith submission of fee of Rs. 5000/- (deposit slip # 1914390) dated 25-07-2019.
	Decision: Approved.	
1456.	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	Dimat Eye Drop 5ml
	Composition	One ml of solution contains: Dorzolamide HCl eq. to Dorzolamide……20mg

		Timolol maleate eq. to Timolol……..5mg
	Diary No. Date of R& I & fee	16536, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Antiglaucoma drugs
	Type of Form	Form-5
	Finished product Specification	USP specifications
	Pack size & Demanded Price	1×5ml , LDPE bottle with LDPE dropper and HDPE cap; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Approved in USFDA
	Me-too status	Dorlol Dye Drops of Genix Karachi
	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	
	Decision: Approved.	
1457.	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	TOP-PRED 0.5 / 0.3% w/v Eye Drops
	Composition	Each Drop-Tainer Dispenser Contains: LOTEPREDNOL……..0.5% TOBRAMYCIN ……..0.3%
	Diary No. Date of R& I & fee	14917, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Topical anti-inflammatory corticosteroid; Aminoglycosider antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5ml Drop Tainer Dispenser ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zylet of (USFDA approved)
	Me-too status	Lotepred-T of M/s Elko
	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	Salt form of Loteprednol eye drop is missing. Correction is required with requisite fee is required.
	Decision: Deferred for correction of salt form of Loteprednol in applied formulation alongwith requisite fee.	
1458.	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	TIMO Eye Drops
	Composition	Each ml contains: Timolol as maleate…….2.5mg
	Diary No. Date of R& I & fee	16546, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Beta adrenergic blocking agent
	Type of Form	Form-5
	Finished product Specification	Firm has claimed USP specifications
	Pack size & Demanded Price	5ml HDPE dropper bottle
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Blotim 0.25% Eye Drops of Remington Pharma
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by

		way of formulation with following section: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	Evidence of approval of applied formulation in reference regulatory authority could not be confirmed. Evidence of applied formulation already approved by DRAP/DCO is required.
	Decision: Deferred for evidence of approval of applied formulation in reference regulatory authority adopted by Registration Board in 275th meeting.	
1459.	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	Nefnac eye drop 5ml
	Composition	One ml of suspension contains: Nepafenac…….0.001mg
	Diary No. Date of R& I & fee	16496, 07-03-2019, 20,000/-, 06-03-2019
	Pharmacological Group	Non-steroidal anti-inflammatory drug
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	1 × 5ml; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	AVANEP sterile ophthalmic suspension of ALCON Labs USA
	Me-too status	NEPATEK 0.1% Sterile Ophthalmic suspension.
	GMP status	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	The strength of applied formulation is not as per reference formulation. Revision of Form-5 with requisite fee is required. The firm has submitted fee challan of Rs. 5,000/- (Deposit slip # 1914392) dated 25-07-2019.
	Decision: Deferred for revision of formulation as per reference product.	
1460.	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	CHLOROTAN EYE DROPS
	Composition	Each ml contains: Chloramphenicol……..0.5% w/v
	Diary No. Date of R& I & fee	14933, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml HDPE Dropper bottle
	Approval status of product in Reference Regulatory Authorities.	Martindale Pharma (not confirmed)
	Me-too status	Optachlor 0.5% Eye Drops of Remington Pharma
	GMP status	CLB in its 269th meeting held on 26th February, 2019 has considered and approved the grant of DML (#000900) by way of formulation with following section: Ophthalmic (General) Drop Section
	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 authority adopted by Registration Board in 275th meeting.	

1461.	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	Hypertonic 5% eye drops
	Composition	Each ml contains: Sodium chloride……..5%
	Diary No. Date of R& I & fee	14930, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Irrigation solution
	Type of Form	Form-5
	Finished product Specification	Firm has claimed USP specifications
	Pack size & Demanded Price	5ml HDPE bottle dropper; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Not confirmed
	Me-too status	Sodium Chloride 5% Ophthalmic Solution of Opal (Reg#048483)
	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: Ophthalmic (General) Drop Section
	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 authority adopted by Registration Board in 275th meeting.	
1462.	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	MOXI 5mg Eye Drops
	Composition	Each ml solution contains: Moxifloxacin HCl……..5mg
	Diary No. Date of R& I & fee	14897, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml; As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	MHRA approved
	Me-too status	Eyemox Eye Drops 0.5%. by M/s Vega Pharmaceuticals,
	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	The firm has clarified that the applied formulation is solution with submission of fee of Rs. 5000/- (deposit slip # 1914393) dated 25-07-2019.
	Decision: Approved.	
1463.	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	Allfresh eye drop 15ml
	Composition	One ml of suspension contains: Polyethylene glycol……..4.00mg Propylene glycol……..3.00mg
	Diary No. Date of R& I & fee	16488, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Eye Lubricant
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	15ml; As fixed by Govt.

	Approval status of product in Reference Regulatory Authorities.	Approved by MHRA of UK
	Me-too status	Systane Lubricant Eye Drops M/s Ali Gohar, Company (Pvt) Ltd., Karachi (Reg # 0448340)
	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	The firm has corrected the fill volume from 5ml to 15ml alongwith submission of fee challan of Rs. 5000/- (deposit slip #1914394) dated 25-07-2019.
	Decision: Approved with innovator's specifications.	
1464.	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	TOBDEX Eye Drops
	Composition	Each Drop Tainer Dispenser contains: Dexamethasone ……0.1% Tobramycin…….0.3%
	Diary No. Date of R& I & fee	14921, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Corticosteroids, Aminoglycoside antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	5ml Drop Tainer Dispenser, As fixed by Govt
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Bracin D Sterile Ophthalmic Suspension (Reg. 30904) of Atco.
	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: Ophthalmic (General) Drop Section
	Remarks of the Evaluator.	The firm has clarified that applied formulation is in solution form alongwith submission of fee challan of Rs. 5000/- (deposit slip # 1914395) dated 25-07-2019.
	Decision: Approved.	
1465.	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	Dorzitamol 0.1% w/v Eye Drops
	Composition	Each Drop Tainer Dispenser contains: Olopatadine hydrochloride 2.326 mg/ml eq. to Olopatadine…..1mg/ml
	Diary No. Date of R& I & fee	16522, 07-03-2019, 20,000/-, 07-03-2019
	Pharmacological Group	Anti-histamine, Anti-allergy
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	1×5ml , LDPE bottle with LDPE dropper and HDPE cap; As fixed by Govt.
	Approval status of product in Reference Regulatory Authorities.	Olopatadine 1mg/ml eye drops, solution by Generics [UK] Limited t/a Mylan (MHRA Approved)
	Me-too status	Patanol 0.1% by AGP Reg. # 041187
	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: Ophthalmic (General) Drop Section

	Remarks of the Evaluator.	Same formulation with same brand name has already been applied in the same section. Label claim of applied formulation is not correct. Revision of Form-5 is required. Clarification shall be submitted whether applied formulation is in solution form or suspension form. Revision of Form-5 with applicable fee is required
	Decision: Registration Board rejected the application as already considered at serial number 1455.	

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

a. New Cases

1466.	Name and address of manufacturer / Applicant	M/s Star Laboratories (pvt.) Ltd. 23 km, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Ceriflox 2.5% Oral Liquid
	Composition	Each ml contains: Enrofloxacin…….25mg
	Diary No. Date of R& I & fee	4157, 02-02-2018, 20,000/-, 10-01-2018
	Pharmacological Group	Fluoroquinolone
	Type of Form	Form-5
	Finished Product Specification	In-house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Enrotin oral liquid of M/s Epla Lab (Reg#025789)
	GMP status	GMP inspection conducted on 05-10-2018 & 12-11-2018 concluded that the firm was considered to be operating at a satisfactory level of GMP compliance at the time of inspection except for Human Liquid injectable section and Human injectable section (Psychotropic).
	Remarks of the Evaluator.	The submitted me-too reference is of different strength.
	Decision: Deferred for confirmation of me-too status since applied formulation is of different strength.	
1467.	Name and address of manufacturer / Applicant	M/s Star Laboratories (pvt.) Ltd. 23 km, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	TILMISIN 30% Injection
	Composition	Each ml contains: Tilmicosin as phosphate…….300mg
	Diary No. Date of R& I & fee	4163, 02-02-2018, 20,000/-, 10-01-2018
	Pharmacological Group	Anti-Parasitic agent
	Type of Form	Form-5
	Finished Product Specification	In-house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Micobak injection of Attabak Pharma (Reg#062148)
	GMP status	GMP inspection conducted on 05-10-2018 & 12-11-2018 concluded that the firm was considered to be operating at a satisfactory level of GMP compliance at the time of inspection except for Human Liquid injectable section and Human injectable section (Psychotropic).
	Remarks of the Evaluator.	
	Decision: Approved with USP specifications.	

1468.	Name and address of manufacturer / Applicant	M/s Star Laboratories (pvt.) Ltd. 23 km, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	FLORFENIC 20% Oral Solution
	Composition	Each ml contains: Florfenicol…….200mg
	Diary No. Date of R& I & fee	4161, 02-02-2018, 20,000/-, 18-01-2018
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished Product Specification	In-house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Flurotin Liquid of Elegance Pharma (Reg#075751)
	GMP status	GMP inspection conducted on 05-10-2018 & 12-11-2018 concluded that the firm was considered to be operating at a satisfactory level of GMP compliance at the time of inspection except for Human Liquid injectable section and Human injectable section (Psychotropic).
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1469.	Name and address of manufacturer / Applicant	M/s Star Laboratories (pvt.) Ltd. 23 km, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	VITAFON Injection
	Composition	Each ml contains:- Butaphosphan …..….100mg Cyanocobalamin …...50mcg Taurine ……..…. 37.3mg Nicotinamide ……. 23mg DL-Methionine ……..18.7mg
	Diary No. Date of R& I & fee	4159, 02-02-2018, 20,000/-, 18-01-2018
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished Product Specification	In-house specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Carasil Injection of Selmore agencies (Reg#058816)
	GMP status	GMP inspection conducted on 05-10-2018 & 12-11-2018 concluded that the firm was considered to be operating at a satisfactory level of GMP compliance at the time of inspection except for Human Liquid injectable section and Human injectable section (Psychotropic).
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications.	
1470.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	ALBENTIC GRANULES
	Composition	Each 100gm contains: Albendazole……..21gm
	Diary No. Date of R& I & fee	851, 08-08-2016, 20,000/-, 01-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack size & Demanded Price	10gm, 20gm, 50gm, 100gm, 500gm; Decontrolled

	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	IALBENZOLE GRANULES of M/s international Pharma labs (Reg#063616)
	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.	
1471.	Name and address of manufacturer / Applicant	M/s Intervac (Pvt.) Limited., 18-km, Lahore Sheikhupura Road, Sheikhupura, Pakistan
	Brand Name +Dosage Form + Strength	VERMIFAS BOLUS
	Composition	Tetramisol hydrochloride……2gm
	Diary No. Date of R& I & fee	845, 08-08-2016, 20,000/-, 01-08-2016
	Pharmacological Group	Anthelmintic
	Type of Form	Form-5
	Finished Product Specification	In-house specifications
	Pack size & Demanded Price	1×5 bolus = 50 bolus packing; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	VERMISOL Bolus of Star Laboratories (Reg#007369)
	GMP status	Panel inspection dated 28-05-2019 & 19-06-2019 decided to recommend the renewal of DML.
	Remarks of the Evaluator.	
	Decision: Deferred for clarification of composition of applied formulation.	

b. Deferred Cases

1472.	Name and address of manufacturer / Applicant	M/s Grand Pharma (Pvt) Ltd., Plot No. 5 A, Street No. N-5, National Industrial zone, RCCI, Rawat Islamabad
	Brand Name +Dosage Form + Strength	NONA VIT Oral Liquid
	Composition	Dy No. 1793, 21-11-2014 PKR 20,000/-, 24-09-2014
	Diary No. Date of R& I & fee	Each 1000ml contains Vitamin A……..20,000,000 IU Vitamin E……5000mg Vitamin B1……740mg Vitamin B2……700mg Vitamin B6……..500mg Vitamin D3……..2,00,000 IU Vitamin C……..2,000 mg Vitamin H (Biotin)…...10mg Vitamin B12 ……5mg
	Pharmacological Group	Vitamins
	Type of Form	Form 5
	Finished product Specification	In-house
	Pack size & Demanded Price	1 Liter, 2.5 Liter, 5 Liter, 10 Liter Plastic bottles
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Biatox Liquid-E by Leads Pharma
	GMP status	Last inspection report dated 12-05-2017 confirms compliance to GMP
	Previous remarks of the Evaluator.	Withdrawl period: Zero days Firm has claimed in house specs without providing data as required in 267th RB meeting.

	Previous decision	Deferred for followings: **(M-271)** Clarification/rationale regarding the stability of formulation since the formulation contains both water and oil soluble vitamins. Specifications of the finished product. Deferred for confirmation of solubility of fat soluble vitamins (vitamin E) in propylene glycol as literature evidence suggests solubility of water soluble vitamins in propylene glycol. **(M-276)** Deferred for justification of compatibility of Ethanol with other formulation ingredients. **(M-287)**
	Evaluation by PEC	Firm has submitted stability study data sheet for accelerated stability data conducted at 40 ±2°C and 75± 5% RH. Now the firm has submitted that we are replacing propylene glycol with Ethanol in the formulation. Master formulation alongwith method of manufacturing has been revised accordingly. The firm has submitted that Ethanol used in this formulation as solvent, and its quantity is 0.2% v/v in the formulation which is very low. The firm has given reference of USP that vitamin E is soluble in Ethanol.
	Decision: Deferred for clarification regarding rationale/indication of applied formulation.	
1473.	Name and address of manufacturer / Applicant	M/s. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat
	Brand Name +Dosage Form + Strength	NSP PLUS Water Soluble Powder
	Composition	Each Kg contains: Neomycin sulphate……10gm Streptomycin sulphate……36gm Procaine penicillin……12gm Zinc Bacitracin 10%..... 52gm
	Diary No. Date of R& I & fee	21-10-2016, Dy. No.2112, Rs.20,000/-, 19-10-2016
	Pharmacological Group	Antibacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	50g, 100g, 500g, 1kg, 5Kg, 10Kg,20Kg; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Pro SB-Plus of M/s. NoaHemis Pharma
	GMP status	QA Division vide letter No.F.8-6/2018-QA dated 18th September, 2018 concluded that the firm M/s. Decent Pharma, Rawat is allowed to resume production in oral dosage forms. However, production in sterile area shall remain suspended till the installation of distillation assembly, verification by the panel of experts and subsequent approval for resumption of production.
	Previous remarks of the Evaluator.	The submitted me-too reference could not be verified.
	Previous decision	Deferred for evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm (M-286).
	Evaluation by PEC	The firm has submitted me-too reference PSB Excel Oral Powder of M/s Nawan lab (Reg#082489) confirmed from relevant section.
	Decision: Approved with innovator's specifications.	

1474.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtain Chowk Defence Road, 1Km Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	I-ADEC Oral Solution
	Composition	Each ml contains: Vitamin A……52500IU Vitamin E……..52.5mg Vitamin D3……5250IU Vitamin C……105mg
	Diary No. Date of R& I & fee	Dy. No: 254 dated 03-01-11, 8000/- dated 03-01-11 12000/- dated 30-07-13
	Pharmacological Group	Vitamins
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Decontrolled/- pack of 50ml, 100ml, 250ml, 500ml, 1000ml, 5000ml
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	DECA SOL LIQUID of Sanna Labs (Reg#025749)
	GMP status	GMP inspection dated 16-10-2018 concludes that firm was operating at fair level of GMP Compliance.
	Previous remarks of the Evaluator.	
	Previous decision	Deferred for confirmation of me-too status. If product is not me-too, firm shall submit application on Form-5-D with relevant fee **(M-248)**.
	Evaluation by PEC	The firm has submitted me-too reference which has been verified.
	Decision: Deferred for clarification/rationale regarding the stability of formulation since the formulation contains both water and oil soluble vitamins.	
1475.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtain Chowk Defence Road, 1Km Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	Dairy Supplement Granules Powder
	Composition	Each kg contains:- Calcium…….....155gm Phosphorus……...135gm Magnesium…….....55gm Sodium…….45gm Iron……1gm Zinc……..……..…..3gm Manganese…….....2gm Copper……..0.6gm Cobalt……..…0.01gm Iodine……0.04gm selenium……0.003gm
	Diary No. Date of R& I & fee	Dy.No 202 dated 27-8-2015 Rs. 20,000 dated 26-8-2015
	Pharmacological Group	Minerals
	Type of Form	Form-5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	5gm,10gm, 20gm, 50gm, 100gm, 200gm, 250gm, 500gm, 1000gm, 5000gm, 10000gm, 20000gm, 25000gm; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	L.S.MINERALS POWDER NAWAN LABS KARACHI (Could not be confirmed)

	GMP status	GMP inspection dated 16-10-2018 concludes that firm was operating at fair level of GMP Compliance.
	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-285)**.
	Evaluation by PEC	The firm has submitted following me-too reference which has been verified. SP MINERALS GRANULES of M/s Selmore Pharma (Reg#088154)
	Decision: Deferred for confirmation of source of minerals of applied formulation.	
1476.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtian Chowk Defence Road, 1Km Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	I-Salline Injection 100ml
	Composition	Each ml contains: Amoxicillin trihydrate eq to base amoxicillin……200mg
	Diary No. Date of R& I & fee	Dy.No 36 dated 9-7-2015 Rs. 20,000 Dated 9-7-2015
	Pharmacological Group	Pencillin
	Type of Form	Form-5
	Finished product Specification	In-House
	Pack size & Demanded Price	100ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	NAOMOX LA INJECTION of VET CURE PHARMA, LAHORE. (Could not be confirmed)
	GMP status	GMP inspection dated 16-10-2018 concludes that firm was operating at fair level of GMP Compliance
	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-285)**.
	Evaluation by PEC	The firm has submitted me-too reference VETY MOXIL-LA 200 INJECTION of Vety care (Reg#031464) which has been verified.
	Decision: Approved with USP specifications.	
1477.	Name and address of manufacturer / Applicant	M/s International Pharma Labs, Raiwind Road, Bobhtian Chowk Defence Road, 1Km Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	AJA-Foren Injection
	Composition	Each ml contains:- Estradiol Dipropionate……..…..1mg
	Diary No. Date of R& I & fee	48, 09-08-12, Rs. 8000/- (Photocopy attached), Rs.12000/-, (Photocopy attached) 25-06-2014
	Pharmacological Group	Hormones
	Type of Form	Form-5
	Finished product Specification	In-house Specs;
	Pack size & Demanded Price	2ml; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	N/A
	Me-too status	Agofollin Injection of Ghazi Brothers (Reg # 028587)
	GMP status	Panel inspection dated 19-12-2017 & 02-03-2018 unanimously recommends for renewal of DML.

	Previous remarks of the Evaluator.	The firm has provided Veterinary Hormone Injectable section.
	Previous decision	Deferred for confirmation of source of Estradiol Dipropionate whether natural or synthetic origin. **(M-285)**.
	Evaluation by PEC	The firm has submitted source of Estradiol dipropionate as synthetic.
	Decision: Approved with innovator's specifications.	
1478.	Name and address of manufacturer / Applicant	M/s International Pharma Labs. Raiwind Road, Bhobtian Chowk, defence Road, 1-KM Towards Kahna, Lahore
	Brand Name +Dosage Form + Strength	I-Mocolis Powder
	Composition	Each 100gm Contains: Amoxicillin as Trihydrate…15% Colistin Sulphate…50 MIU
	Diary No. Date of R& I & fee	Dy.No 31031-J dated 14-09-2018 Rs.20,000/- Dated 14-09-2018
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	Manufacturer
	Pack size & Demanded Price	100gm, 250 gm, 500 gm, 1 kg, 2.5 kg, 5 kg, 10 kg, 25 kg ; Decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	NA (074033) Each Gm Contains:- Amoxycillin Base (As Trihydrate) 600mg
	GMP status	Last GMP Inspection Conducted on December 19,2017 August 2018 with conclusive remarks of good compliance
	Previous remarks of the Evaluator.	Me too not available
	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-287)**.
	Evaluation by PEC	The firm has revised the strength of Colistin Sulphate as per me-too reference alongwith submission of fee challan of Rs. 5,000/- (deposit slip # 1960851) dated 26-08-2019.
	Decision: Deferred for submission of remaining fee PKR 15,000/-.	

Case No. 04: Registration Applications of Import Cases.

a. New Cases (Human)

1479.	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:** M/S Rottendorf pharma, GmbH ostenfelder dstraBe 51-6159320,enigerloh Germany **QC testing:** M/s Medinova AG, eggbuhlstr 28 8050 zurich Switzerland **Microbial testing:** M/s Labor Zollinger AG scarenmoostr 105 8050 zurich Switzerland 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.
	Decision: Deferred for clarification regarding details of marketing authorization holder of applied formulation.	
1480.	Name and address of Applicant	M/s Mehran international, 498-C Feroz Shah Mehta Road, Karachi
	Detail of Drug Sale License	**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. Address: Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone, Jining , Shangdong, China. **Exporting agent for Pakistan:** M/s Ninhua Group Ltd PVT, 21 Jiangxia street, Ningbo, P.R. China
	Name and address of marketing authorization holder (Product license holder)	M/s Cisen Pharmaceutical Co., Ltd. Address: Tongji Tech Industry Garden, Jining High & New Technology Industrial Development Zone, Jining , Shangdong, China.
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.875 Dated 21-03-2017
	Fee including differential fee	Rs. 100,000/- Dated 14-03-2017
	Brand Name +Dosage Form + Strength	Metronidazole infusion 0.5g 100ml
	Composition	Each bottle (100ml PP bottle) contains: Metronidazole……..500mg
	Finished Product Specification	BP specifications
	Pharmacological Group	Fluoroquinolone antibacterial
	Shelf life	3 years
	Demanded Price	As per brand leader
	Pack size	100ml
	International availability	Metronidazole 500 mg / 100 ml Intravenous Infusion of Baxter Healthcare Ltd, (MHRA approved)
	Me-too status	Metrida I.V Infusion of Zafa labs (Reg#026232)
	Detail of certificates attached	Certificate of pharmaceutical products (COPP): **Certificate No**: P151100B0/47080 **Certifying Authority**: Jining Food and Drug Administration, China Original, legalized COPP submitted by the firm confirm GMP and free sale status of the product in the country of origin.

		Date of issue: 08-09-2018 Validity = 2 years Sole agency agreement submitted by the firm confirm that the agent Mehran International will enable the pharmaceuticals enter into the market of Pakistan. The agreement is valid to May 9, 2022.
	Remarks of the Evaluator.	The firm has submitted 6 months accelerated and 36 months long term stability study data of following 3 batches Batch No. 090103 Batch No. 090104 Batch No. 090105. The firm has submitted copy of fee deposited in the District Health officer, Karachi for renewal of Drug sale license.
	Decision: Approved as per policy for inspection of manufacturer abroad.	
1481.	Name and address of Applicant	M/s Mehran international, 498-C Feroz Shah Mehta Road, Karachi
	Detail of Drug Sale License	**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 Zhejiang Hisun Pharmaceutical Co., Ltd. 1 Haizheng Avenue, Jiaojong District Taizhou City, Zhejiang province 318000, P.R. China
	Name and address of marketing authorization holder (Product license holder)	M/s Zhejiang Hisun Pharmaceutical Co., Ltd. 1 Haizheng Avenue, Jiaojong District Taizhou City, Zhejiang province 318000, P.R. China
	Name of exporting country	China
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No.31410 Dated 18-09-2018
	Fee including differential fee	Rs. 100,000/- Dated 18-09-2018
	Brand Name +Dosage Form + Strength	Letrozole Tablet
	Composition	Each film coated tablet contains: Letrozole…….2.5mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Aromatase inhibitor
	Shelf life	3 years
	Demanded Price	As per brand leader
	Pack size	1 × 100 tablets
	International availability	Femara 2.5mg Tablet of Novartsi Pharma (MHRA approved)
	Me-too status	Femara 2.5mg Tablet of Novartis Pharma
	Detail of certificates attached	<u>Certificate of pharmaceutical products (COPP):</u> **Certificate No**: 181100B0/014096 **Certifying Authority**: Zhejiang Food and Drug Administration, China Original, legalized COPP submitted by the firm confirm GMP and free sale status of the product in the country of origin. The certificate will remain valid 12-03-2022. Sole agency agreement submitted by the firm confirm that the agent Mehran International will enable the pharmaceuticals enter into the market of Pakistan. The agreement is valid to 31 October, 2022.
	Remarks of the Evaluator.	The firm has submitted 12 months accelerated and 12 months long term stability study data of following 3 batches Batch No. 21801031

		Batch No. 21801032 Batch No. 21801041 The firm has submitted copy of fee deposited in the District Health officer, Karachi for renewal of Drug sale license.
	Decision: Approved as per policy for inspection of manufacturer abroad.	

b. New Cases (Veterinary)

1482.	Name and address of Applicant	M/s Mehran international, 498-C Feroz Shah Mehta Road, Karachi
	Detail of Drug Sale License	**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 Hebei New Century Pharmaceutical Co., Ltd. No.189 Taihang Street Hi-tech Zone Shijiazhuang City, Hebei China. **Exporting agent for Pakistan:** M/s Ninhua Group Ltd PVT, 21 Jiangxia street, Ningbo, P.R. China
	Name and address of marketing authorization holder (Product license 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.1107 Dated 19-10-2016
	Fee including differential fee	Rs. 100,000/- Dated 19-10-2016
	Brand Name +Dosage Form + Strength	Ivermectin 1% + Clorsulon 10% Injection
	Composition	Each ml contains: Ivermectin ……..10mg Clorsulon……..100mg
	Finished Product Specification	USP specifications
	Pharmacological Group	Anthelmintic drug
	Shelf life	3 years
	Demanded Price	Decontrolled
	Pack size	100ml
	International availability	Ivomec® plus Injection of Merial Inc. USFDA
	Me-too status	Elvomec super injection of Elko organization, Karachi.
	Detail of certificates attached	Certificate of pharmaceutical products (COPP): **Certificate No**: 2016030515 **Certifying Authority**: Shijiazhuang Animal husbandry Aquatic Product Bureau Zhonghua South Street no.253, China Original, legalized COPP submitted by the firm confirm GMP and free sale status of the product in the country of origin. The certificate will remain valid 04-03-2021. Sole agency agreement submitted by the firm confirm that the agent Mehran International will enable the pharmaceuticals enter into the market of Pakistan. The agreement is valid till 4 March, 2020.
	Remarks of the Evaluator.	The firm has submitted 6 months accelerated and 36 months long term stability study data of 3 batches as per Zone IV-A. Batch No. 12502701 Batch No. 12502702 Batch No. 12502703 The firm has submitted copy of fee deposited in the District Health officer, Karachi for renewal of Drug sale license.
	Decision: Approved as per policy for inspection of manufacturer abroad.	

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
1483.	M/s. Cirin Pharmaceuticals Pvt. Ltd 32/2-A, Phase-III, Industrial Estate Hattar, District Haripur, KPK,	Dorinem 500mg Injection Each vial contains: Doripenem (as monohydrate) …500mg (Carbapenem antibiotic) Japanese pharmacopeia	Form 5-D Duplicate dossier Dairy No. 66, Dated 09.03.2016. Rs.20,000/-, Dated 09.03.2016.(Duplicate) Rs.30,000/-, Dated 21.04..2016. (Duplicate) 1's/ As per SRO	0.5g for Finibax IV (doripenem for injection), M/s Shionogi & Co., Ltd. (PMDA Approved) The Firm has submitted copy of last inspection conducted on 07-05-2018 and report concludes good level of cGMP compliance.

STABILITY STUDY DATA

Drug	Dorinem 500mg Injection		
Name of Manufacturer	M/s. Cirin Pharmaceuticals Pvt. Ltd 32/2-A, Phase-III, Industrial Estate Hattar, District Haripur, KPK,		
Manufacturer of API	M/s Kopran Research Laboratories Limited, K-4/4, Additional MIDC. At/Post: Birwadi, Tal: Mahad, Dist: Raigad, Pin 402302, Maharashtra- India.		
API Lot No.	DPIV/P1703001 1KG DPIV/P1703002 1KG DPIV/P1703003 1KG		
Description of Pack (Container closure system)	Glass vial with flip off seal. Pack in unit carton		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 26 weeks Real Time: 26 weeks		
Frequency	Accelerated: 0,1,2,3,4,6,8,12,16,20,24,26 (weeks) Real Time: 0,1,2,3,4,6,8,12,16,20,24,26 (weeks)		
Batch No.	T-01 (NPD801) API Batch# DPIV/P1703001	T-02 (NPD801) API Batch# DPIV/P1703002	T-03 (NPD801) API Batch# DPIV/P1703003
Batch Size	1912 vials	1916 vials	1920 vials
Manufacturing Date	Jan 2018	Jan 2018	Jan 2018
Date of Initiation	18-01-2018	01-02-2018	12-02-2018
No. of Batches	03		
Date of Submission	07-01-2019 (Dy. No. 746)		

Decision in previous meeting of Registration Board:
Registration Board in its 258th Meeting held on 25-26th April, 2016. decided:
Deferred for submission of Form 5D and stability studies as per 251st RB meeting

<table>
<tr><th colspan="3">DOCUMENTS / DATA PROVIDED BY THE APPLICANT</th></tr>
<tr><th>Sr.#</th><th>Documents to Be Provided</th><th>Status</th></tr>
<tr><td>1.</td><td>COA of API</td><td>Copy of COA for Doripenem (as monohydrate from M/s Kopran Research Labopratories Limited, India. Has been submitted for batch no. DPIV/P1703001, DPIV/P1703002 and DPIV/P1703003.</td></tr>
<tr><td>2.</td><td>Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Firm has submitted copy of certificate of GMP issued by FDA Maharashtra. Certificate# NEW-WHO-GMP/CERT/KD/59163/2017/11/21723
Document confirms that the firm is GMP compliant.
Document is valid till 05/12/2019.</td></tr>
<tr><td>3.</td><td>Protocols followed for conduction of stability study and details of tests.</td><td>Yes</td></tr>
<tr><td>4.</td><td>Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.</td><td>Yes</td></tr>
<tr><td>5.</td><td>Documents confirming import of API etc.</td><td>Firm has submitted copy of ADC attested invoice dated 22-09-2017. Firm has imported Doripenem from M/s Kopran Research Laboratories Limited
<table>
<tr><td>Batch#</td><td>Quantity</td></tr>
<tr><td>DPIV/P1703001</td><td>1KG</td></tr>
<tr><td>DPIV/P1703002</td><td>1KG</td></tr>
<tr><td>DPIV/P1703003</td><td>1KG</td></tr>
</table></td></tr>
<tr><td>6.</td><td>All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.</td><td>Yes</td></tr>
<tr><td>7.</td><td>Commitment to continue real time stability study till assigned shelf life of the product.</td><td>Yes</td></tr>
<tr><td>8.</td><td>Commitment to follow Drug Specification Rules, 1978.</td><td>Yes</td></tr>
<tr><th colspan="3">REMARKS OF EVALUATOR</th></tr>
<tr><td colspan="3"><u>QUESTIONNAIRE FOR VERIFICATION OF AUTHENTICITY OF STABILITY DATA REGARDING DORINEM INJECTION 500MG</u>

Firm Name & Address: M/s Cirin Pharmaceuticals (Pvt.) Limited Hattar
Date of inspection: 24-07-2019

<u>Panel members</u>
1. Prof. Dr. Jamshed Ali Khan, Member Central Licensing Board.
2. Dr. Khalid Javed, Director Drug Testing Laboratory, Peshawar.
3. Mr. Atiq Ul Bari, FID/`Assistant Director, DRAP Peshawar</td></tr>
</table>

S.No	Questions	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	Doripenem Monohydrate sterile API has been imported from M/s Kopran Research Laboratories India vide proper approval from DRAP– Peshawar. Three lots of API have been used in the manufacturing of stability batches with details as below. Lot No. DPIV/P1703001 Lot No. DPIV/P1703002 Lot No. DPIV/P1703003 Date ofImport: 29-09-2017 Invoice No.: BEXP-1718-193 Quantity Imported: 3kg (1kg each) **DRAP Clearance No.: F 10-72/2017-DRAP CPS/2830** **(22-09-2017)** Lot No. DPIV/P1703001 has been used in manufacturing of the NPD801(T-01), Lot No. DPIV/P1703002used in NPD801(T02)and Lot No. DPIV/P1703003)has been used in NPD801(T03) of the product.
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	The rationale for selection of the API manufacturer is the vendor qualification criteria including GMP Certificate, DMF, Site master file, MSDS, Client List,Stability data etc.
Q.No.3	Do you have documents confirming the import of API, reference standard & impurity standard?	Yes, the firm has documents confirming the import of API and Working standard along with COA from M/s Kopran, India. Working Standard received with the Sample is having batch number WS/DRM/16/01. The secondary working standard (Batch No. DPIV/P1601002) has been used as reference for the analysis of three lots for stability studies. Currently the secondary working standard (DPIV/P1703003) is in use.
Q.No.4	Do you have certificate of analysis of the API, reference standard & impurity standard?	Yes, the firm has certificates of Analysis for API andWorking Standard. According to the firm there is no known impurity of the molecule , so no impurity standard has been used and observed.
Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes, the firm has copy of GMP Certificate of M/s Kopran, India issued by competent authority and valid up to5th Dec, 2019.
Q.No.6	Do you use API manufacturer method of testing for testing API?	Yes, the firm has used manufacturer's method for API testing.
Q.No.7	Do you have stability studies report on API?	Yes, the firm has stability study data on Doripenem Monohydrate Sterile.
Q.No.8	If yes, whether the stability testing has been performed as per SIM method & degradation products have been quantified?	No degradation product has been quantified as there is no detectable degradation product of the API.
Q.No.9	Do you have method for quantifying the impurities in the API?	Yes, the firm has method for quantifying the unknown impurities in the API.

<table>
<tr><td>Q.No.10</td><td>Do you have some remaining quantities of the API, its reference standard & impurities standard?</td><td>The firm has some remaining quantities of API & Working Standard.
API
<table><tr><th>Lot No.</th><th>Remaining Qty.</th></tr><tr><td>DPIV/P1703001</td><td>70.5gm</td></tr><tr><td>DPIV/P1703002</td><td>40gm</td></tr><tr><td>DPIV/P1703003</td><td>111.1gm</td></tr></table>Working Standard: 1.87gm (remaining Qty)</td></tr>
<tr><td>Q.No.11</td><td>Have you used pharmaceuticals grade excipients?</td><td>Since Doripenem Monohydrate sterile is a ready to fill powder, and doesn't involve further processing, hence firm has not used any excipient.</td></tr>
<tr><td>Q.No.12</td><td>Do you have documents confirming the import of the used excipients?</td><td>As above</td></tr>
<tr><td>Q.No.13</td><td>Do you have test reports & other records on the excipients used?</td><td>As above</td></tr>
<tr><td>Q.No.14</td><td>Do you have written & authorized protocols for the development of applied product?</td><td>Yes, the firm has written and authorized protocols for the development of Doripenem Injection.</td></tr>
<tr><td>Q.No.15</td><td>Have you performed Drug-excipient compatibility studies?</td><td>Not Applicable</td></tr>
<tr><td>Q.No.16</td><td>Have you performed comparative dissolution studies?</td><td>Not Applicable</td></tr>
<tr><td>Q.No.17</td><td>Do you have product development (R&D) section?</td><td>Yes, the firm has product development (PD) Section for tablet. However the development of the concerned product has been carried out in main routine dedicated sterile manufacturing area of Carbapenem and routine quality control lab due to specialized requirements.</td></tr>
<tr><td>Q.No.18</td><td>Do you have necessary equipment available in product development section for development of applied product?</td><td>Refer to Point 17</td></tr>
<tr><td>Q.No.19</td><td>Are the equipment in product development section qualified?</td><td>Refer to Point 17</td></tr>
<tr><td>Q.No.20</td><td>Do you have proper maintenance /calibration/ re –qualification program for the equipment used in product development?</td><td>PD section equipment has not been used for the development for this product.</td></tr>
<tr><td>Q.No.21</td><td>Do you have qualified staff in product development section with proper knowledge & training in the product development?</td><td>Yes, the firm has qualified & experienced pharmacists for product development assisted by the staff of manufacturing and quality control.</td></tr>
<tr><td>Q.No.22</td><td>Have you manufactured three stability batches for the stability studies for applied product as required?</td><td>Yes, the firm has manufactured three stability batches for the stability studies of Doripenem Injection as below.

Batch No. Batch Size
NPD801 (T-01) 1912vials
NPD801 (T-02) 1916 vials
NPD801 (T-03) 1920 vials</td></tr>
</table>

<table>
<tr><td>Q.No.23</td><td>Do you have any criteria for fixing the batch size of stability batches?</td><td>Yes, the minimum workable batch size for filling machine is taken into consideration. Also the firm has manufactured 10% of their planned commercial batch size i.e., 20,000 vials</td></tr>
<tr><td>Q.No.24</td><td>Do you have complete record of production of stability batches?</td><td>Yes, the firm has complete record of production of stability batches.</td></tr>
<tr><td>Q.No.25</td><td>Do you have protocols for stability testing of stability batches?</td><td>Yes, the firm has developed protocols for stability testing of stability batches.</td></tr>
<tr><td>Q.No.26</td><td>Do you have developed & validated the method for testing of stability batches?</td><td>The firm has adopted manufacturer’s method and validated the same for testing of stability batches of Doripenem Injection.</td></tr>
<tr><td>Q.No.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 method being used by the firm is validated.</td></tr>
<tr><td>Q.No.28</td><td>Do you have documents confirming the qualification of equipment /instruments being used in the test & analysis for applied API & finished drug?</td><td>Yes, the firm has proper documents confirming the qualification of equipment/instruments being used in the test and analysis of Doripenem API and finished product</td></tr>
<tr><td>Q.No.29</td><td>Is your method of analysis stability indicating?</td><td>Yes, the firm has used stability indicating method shared by the manufacturer.</td></tr>
<tr><td>Q.No.30</td><td>Is your HPLC software 21CFR compliant?
(Detail of model, software, description /version (i.e., software validation report for CFR part II compliance including audit trail, password protection, date& time lock & user authorization shall also be reported.))</td><td>Shimadzu HPLC (Japan)
The HPLC (UFLC) Software Lab Solution (Version 6.82) is 21 CFR compliant.
Detector
Model: SPD-M20A 230V
Serial No.: L20155517984 CD
Pump
Model: LC-20AT
Serial No.: L20115532439 AE
Auto-sampler
Model: SIL-20AHT
Serial No.: L20345504474 AE
Column Oven
Model: CTO-20A
Serial No.: L20205517625 CD
Degasser
Model: DGU-20A5R
Serial No.: L20705515788 IX
Reservoir Tray
Model: Reservoir Tray
Serial No.: L20305562903 SL</td></tr>
<tr><td>Q.No.31</td><td>Can you show audit trail reports on stability studies testing?</td><td>Audit trail reports on testing of finished product are available.</td></tr>
<tr><td>Q.No.32</td><td>Do you have some remaining quantities of degradation products & stability batches?</td><td>The firm has following remaining quantities (approx.) of stability batches only.
Stability Batches<table><tr><th>Batch No.</th><th>Remaining Qty (vials)</th></tr><tr><td>NPD801 (T-01)</td><td>1468</td></tr><tr><td>NPD801 (T-02)</td><td>1533</td></tr><tr><td>NPD801 (T-03)</td><td>1403</td></tr></table></td></tr>
<tr><td>Q.No.33</td><td>Do you have stability batches kept on</td><td>Yes, the firm has three stability batches kept on real</td></tr>
</table>

	stability testing?	time stability testing, currently 12 months studies is completed.
Q.No.34	Do you have valid calibration status for the equipment used in production &analysis?	Yes, the firm has valid calibration status for the equipment used in Doripenem Injection production and analysis.
Q.No.35	Do proper & continuous monitoring & controlled are available for stability chamber? (number& utilized /available capacity of stability chamber shell also be reported.)	Adequate monitoring and controls are available for stability chambers, both for accelerated and long term stability studies.
Q.No.36	Do related manufacturing area, equipment, personals & utilities be rated c GMP compliant?	Related manufacturing area, equipment, personnel and utilities are GMP complaint.

Conclusion:- The panel unanimously verifies the authenticity of stability data regarding Dorinem Injection 500mg manufactured by M/s Cirin Pharmaceuticals (Pvt.) Limited Hattar as per above provided questionnaire.

Decision: Registration Board decided to approve registration of Dorinem 500mg Injection by M/s. Cirin Pharmaceuticals Pvt. Ltd 32/2-A, Phase-III, Industrial Estate Hattar, District Haripur, KPK. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

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
1484.	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	DAPLOS 5mg Tablet Each Film coated tablet contains: Dapagliflozin as propanediol monohydrate….5mg Anti-diabetic In-house specifications	Form 5-D Duplicate dossier required As per P.R.C	Farxiga Tablets by Astrazaneca **USFDA** GMP inspection dated 23-02-2018 showed that the firm was considered to be operating at an acceptable level of compliance with GMP standards.

STABILITY STUDY DATA

Drug	DAPLOS 5mg Tablet
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China
API Lot No.	DGF-201804001
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-2389-05-T	18PD-2390-06-T	18PD-2391-07-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	08-2018	08-2018	09-2018
Date of Initiation	28-08-2018	28-08-2018	28-08-2018
No. of Batches	03		
Date of Submission	4155 (22/04/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # DGF-201804001) from M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China issued by China Food and Drug Administration. The certificate is valid till 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Dapagliflozin propanediol monohydrate (700 g) attested by ADC DRAP, Karachi dated 26-06-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Shortcomings communicated	Response of the firm
Justify the dissolution specifications NLT 75% in 30 min since the dissolution specifications of FDA approved product (**FARXIGA Tablet)** is NLT Q in 15 min. (The value of Q has been defined by FDA as well as USP general chapter is 75% to 80%).	The firm has submitted that after thoroughly reviewing literature we found that Dapagliflozin product is in BCS Class 1 so we have revised our current specifications as NLT 85% in 15 min. We have performed 9 months stability sample kept for long term stability on this revised specification and dissolution results showed more than 85% in 15 minutes. The firm has submitted revised specifications with method of analysis and 9 months dissolution test report.

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
1485.	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	DAPLOS 10mg Tablet Each Film coated tablet contains: Dapagliflozin as propanediol monohydrate…….10mg Anti-diabetic In-house specifications	Form 5-D Duplicate dossier required Rs. 50,000/- dated 14-07-2015 As per P.R.C	Farxiga Tablets by Astrazaneca **USFDA** GMP inspection dated 23-02-2018 showed that the firm was considered to be operating at an acceptable level of compliance with GMP standards.

STABILITY STUDY DATA

Drug	DAPLOS 10mg Tablet		
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China		
API Lot No.	DGF-201804001		
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-2409-06-T	18PD-2410-07-T	18PD-2411-08-T
Batch Size	2500 Tablet	2500 Tablet	2500 Tablet
Manufacturing Date	09-2018	09-2018	09-2018
Date of Initiation	27-09-2018	27-09-2018	27-09-2018
No. of Batches	03		
Date of Submission	4993 (02/05/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	Copy of COA (Batch # DGF-201804001) from M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China issued by China Food and Drug Administration. The certificate is valid till 03-03-2021.

3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Dapagliflozin propanediol monohydrate (700 g) attested by ADC DRAP, Karachi dated 26-06-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Shortcomings communicated	Response of the firm
Justify the dissolution specifications NLT 75% in 30 min since the dissolution specifications of FDA approved product (**FARXIGA Tablet)** is NLT Q in 15 min. (The value of Q has been defined by FDA as well as USP general chapter is 75% to 80%).	The firm has submitted that after thoroughly reviewing literature we found that Dapagliflozin product is in BCS Class 1 so we have revised our current specifications as NLT 85% in 15 min. We have performed 9 months stability sample kept for long term stability on this revised specification and dissolution results showed more than 85% in 15 minutes. The firm has submitted revised specifications with method of analysis and 9 months dissolution test report.

Decision: Deferred for following:

- **Scientific justification how the stability study data at 9th month conducted as per revised dissolution specification [i.e. NLT 85% (Q=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 75% after 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
1486.	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	EMPAL 10mg Tablet Each Film coated tablet contains: Empagliflozin….10mg Sodium Glucose Co-Transporter 2 Inhibitor In-house specifications	Form 5-D Dy. No. 638 dated 19-10-2015 Rs. 50,000/- dated 19-10-2015 As per P.R.C	Jardiance 10mg Tablet by Boehinger Ingelheim, **(USFDA approved)** Emazin 10mg Tablet of Atco GMP inspection dated 23-02-2018 showed that the firm was considered to be

				operating at an acceptable level of compliance with GMP standards.

STABILITY STUDY DATA			
Drug	EMPAL 10mg Tablet		
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China		
API Lot No.	EPG-201807001		
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-2441-05-T	18PD-2442-06-T	18PD-2443-07-T
Batch Size	2500	2500	2500
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	31-12-2018	31-12-2018	31-12-2018
No. of Batches	03		
Date of Submission	433 (19/04/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA (Batch # EPG-201807001) from M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China issued by China Food and Drug Administration. The certificate is valid till 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Empagliflozin (1.2 Kg) attested by ADC DRAP, Karachi dated 10-09-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes

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

REMARKS OF EVALUATOR

The firm has submitted 6 months 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
1487.	M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	EMPAL 25mg Tablet Each Film coated tablet contains: Empagliflozin….25mg Sodium Glucose Co-Transporter 2 Inhibitor In-house specifications	Form 5-D Dy. No. 638 dated 19-10-2015 Rs. 50,000/- dated 19-10-2015 As per P.R.C	Jardiance 25mg Tablet by Boehinger Ingelheim, **(USFDA approved)** Emazin 25mg Tablet of Atco GMP inspection dated 23-02-2018 showed that the firm was considered to be operating at an acceptable level of compliance with GMP standards.

STABILITY STUDY DATA

Drug	EMPAL 25mg Tablet		
Name of Manufacturer	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.		
Manufacturer of API	M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China		
API Lot No.	EPG-201807001		
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-2444-05-T	18PD-2445-06-T	18PD-2446-07-T
Batch Size	2500	2500	2500
Manufacturing Date	10-2018	10-2018	10-2018
Date of Initiation	31-12-2018	31-12-2018	31-12-2018
No. of Batches	03		
Date of Submission	4581 (21/04/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA (Batch # EPG-201807001) from M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate of M/s Jiangsu Yongan Pharmaceutical Co, Ltd, China issued by China Food and Drug Administration. The certificate is valid till 03-03-2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Empagliflozin (1.2 Kg) attested by ADC DRAP, Karachi dated 10-09-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Empal (Empagliflozin) 10mg and 25mg Tablets by M/S. PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No: F.13-11/2017-PEC (Vol-1) dated 26th June, 2019.

Investigation Date and Time: 02nd August, 2019.

Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Background:

Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29,North Western Industrial Zone, Port Qasim , Karachi for registration of Empal (Empagliflozin) 10mg & 25mg Tablets and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

1. Director, CDL, DRAP, Karachi.
2. Prof. Dr. Ghulam Sarwar, Member Registration Board, DRAP
3. Dr.Krishan, Assistant Director, DRAP, Karachi.

Scope of investigation:

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

Tools for Investigation:

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

Q. No	Question	Observation by panel
1.	Do you have documents confirming the import of Empagliflozin API including approval from DRAP?	The firm has imported Empagliflozin 1.2Kg vide Invoice No.ZY18082901G/W dated 29/08/2018 from M/S Suzhou Zhi Yu Biotechnology Co. Ltd. Manufactured by M/s Jiangsu Youngan Pharm Co. Ltd. for the manufacturing of lab scale batches of Empagliflozin 10 & 25 mg Tablet. The firm has proper approval for the import of the API from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Vendor Evaluation procedure which include the GMP status of the firm, DMF source and capability to provide API
3.	Do you have documents confirming the import of Empagliflozin, reference standard and impurity standards?	Firm has documents confirming the import of Empagliflozin working standard as well as the impurities (02 major process related impurities) which were imported at the time of import of the API
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, Working standards of the API and impurities standards.
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate of the API manufacturer issued by the Jiangsu Food and Drug Administration, China
6.	Do you use API manufacturer method of testing for testing API?	The firm has used API manufacturer method for testing the API.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and no degradation products are reported by the manufacturer. However process related impurities have been quantified during stability studies.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has some quantities of the API, working standard as well as impurities.
11.	Have you used pharmaceutical grade excipients?	The firm has used pharmaceutical grade excipients and include microcrystalline cellulose PH.101, Lactose Monohydrate, Hydroxypropyl Cellulose, Cross Carmellose Sodium, Colloidal Silicon di oxide, Opadry white and iron oxide yellow used in
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipients.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipients used.

14.	Do you have written and authorized protocols for the development of Empagliflozin10mg and 25mg Tablets?	The firm has written and authorized protocols for the development of Empagliflozin10mg and 25mg Tablets.
15.	Have you performed Drug-excipient Compatibility studies?	The firm has not performed Drug-excipient Compatibility studies as the composition of their tablets is similar to that of the innovator product (JARDIANCE Tablets).
16.	Have you performed comparative Dissolution studies?	The firm has performed comparative dissolution profile in three recommended dissolution medium. Reference products used for comparative studies are Jardiance 10 mg Tablet, Lot no. 844058 and Jardiance 25 mg Tablet, Lot no. 844064. The firm's tablets have comparable dissolution profile with that of the innovator tablets.
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities.
18.	Do you have necessary equipment Available in product development section for development of Empagliflozin10mg&25mg Tablets?	The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Empagliflozin10mg and 25 mg Tablets. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product Development section qualified?	All the equipment used in product development are qualified.
20.	Do you have proper maintenance /calibration/ re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration programme. Re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 07 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product development. 02 QC Analysts are dedicated for New products testing.
22.	Have you manufactured three stability Batches for the stability studies of Empagliflozin 10 mg and 25 mg Tablet Tablets as required?	The firm has manufactured three stability batches for the stability studies of: **EMPAL 10 mg TABLET** Batch no. 18PD-2441-05-T Batch no. 18PD-2442-06-T Batch no. 18PD-2443-07-T **EMPAL 25 mg TABLET** Batch no. 18PD-2444-05-T Batch no. 18PD-2445-06-T Batch no. 18PD-2446-07-T
23.	Do you have any criteria for fixing the batch size of stability batches?	As per DRAP guideline (2500 tablets/Batch)
24.	Do you have complete record of Production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.

26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation and method
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?	Method transfer is not applicable as the method has been developed in-house.
28.	Do you have documents confirming the qualification of equipment/ instruments being used in the test and analysis of Empagliflozin and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment/ instruments being used in the analysis of Empagliflozin and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation.
30.	Do your HPLC software21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit trail reports on Empagliflozin testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches kept on long term stability.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Currently, 6 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Empagliflozin 10mg&25mg tablets production and analysis?	The firm has valid calibration status for the equipment used in Empagliflozin 10 and 25mg tablets production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has14 stability chambers, 02 for accelerated and 12 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring. The data of data loggers is reviewed every 15th day.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of Empal (Empagliflozin) 10mg and 25 mg Tablets is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of Empal (Emapgliflozin) 10mg and 25mg Tablets.

Recommendations: The firm may kindly be granted necessary registration of Empal (Empagliflozin) 10mg and 25mg Tablets.

Decision: Registration Board decided to approve registration of Empal (Empagliflozin) 10mg and 25mg Tablets by M/s. PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
1488.	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	Memura SR 14mg Capsule Each Capsule contains: Memantine Hydrochoride SR pellets eq. to Memantine HCl.....…14mg Anti-Alzheimer Manufacturer's specifications	Form 5-D Duplicate 12-03-2011, 15,000/- (attested photocopy) dated 12-03-2011 35,000/- dated 19-11-2014 7's; Rs. 350.00/pack 14's Rs. 630.00/pack 28's Rs. 1170.00/pack	Namenda XR capsule 14mg of Forest Laboratories **(USFDA approved)** .

STABILITY STUDY DATA

Drug	Memura SR 14mg 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	Accelerated : 0 , 3, 6 (months) Real Time: 0 , 3, 6 (Months)		
Batch No.	18PD-2255-01-T	18PD-2256-02-T	18PD-2257-03-T
Batch Size	2500	2500	2500
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	27-04-2018	27-04-2018	27-04-2018
No. of Batches	03		
Date of Submission	4034 (19/04/2019)		

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 13-01-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months 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
1489.	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	Memura SR 21mg Capsule Each Capsule contains: Memantine Hydrochoride SR pellets eq. to Memantine HCl.....21mg Anti-Alzheimer Manufacturer's specifications	Form 5-D Duplicate 12-03-2011, 15,000/- (attested photocopy) dated 12-03-2011 35,000/- 19-11-2014 7's; Rs. 350.00/pack 14's Rs. 630.00/pack 28's Rs. 1170.00/pack	Namenda XR capsule 21mg of Forest Laboratories **(USFDA approved)** .

STABILITY STUDY DATA

Drug	Memura SR 21mg 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	Accelerated : 0 , 3, 6 (months)	Real Time: 0 , 3, 6 (Months)	
Batch No.	18PD-2258-01-T	18PD-2259-02-T	18PD-2260-03-T

Batch Size	2500	2500	2500
Manufacturing Date	03-2018	03-2018	03-2018
Date of Initiation	27-04-2018	27-04-2018	27-04-2018
No. of Batches	03		
Date of Submission	4153 (22/04/2019)		

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 13-1-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has submitted 6 months 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
1490.	M/s PharmEvo (Pvt) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.	Memura SR 28mg Capsule Each Capsule contains: Memantine Hydrochoride SR pellets eq. to Memantine HCl.....…28mg Anti-Alzheimer	Form 5-D Duplicate 12-03-2011, 15,000/- (attested photocopy) dated 12-03-2011 35,000/- dated 19-11-2014	Namenda XR capsule 28mg of Forest Laboratories **(USFDA approved)** Evidence of fee challans not submitted

		Manufacturer's specifications	7's; Rs. 350.00/pack 14's Rs. 630.00/pack 28's Rs. 1170.00/pack	.

STABILITY STUDY DATA			
Drug	Memura SR 28mg 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	Accelerated : 0 , 3, 6 (months) Real Time: 0 , 3, 6 (Months)		
Batch No.	18PD-2222-01-T	18PD-2223-02-T	18PD-2224-03-T
Batch Size	2500	2500	2500
Manufacturing Date	02-2018	02-2018	02-2018
Date of Initiation	26-04-2018	26-04-2018	26-04-2018
No. of Batches	03		
Date of Submission	4152 (22/04/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**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 13-01-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes

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

REMARKS OF EVALUATOR

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

Report on Investigation of Authenticity / Genuineness of data submitted for registration of Memura (Memantine HCl) SR 14mg, 21mg and 28mgCAPSULE by M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim , Karachi.

Reference No: F.13-11/2017-PEC (Vol-1) dated 26th June, 2019.

Investigation Date and Time: 02nd August, 2019.

Investigation Site: Factory premises of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi.

Background:

Chairman Registration Board considered the applications of M/s PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, Karachi for registration of Memura (Memantine HCl) SR 14mg, 21mg and 28mg Capsules and constituted a three member panel to investigate the authenticity / genuineness of data (import of raw material and stability data). Panel was advised to conduct inspection of the firm and to submit report for further consideration.

Composition of Panel:

1. Director, CDL, DRAP, Karachi.
2. Prof. Dr Ghulam Sarwar, Member Registration Board, DRAP
3. Dr Krishan, Assistant Director, DRAP, Karachi.

Scope of investigation:

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

Tools for Investigation:

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

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of Memantine API including approval from DRAP?	The firm has imported Memantine 7Kg vide Invoice No.061/2016-17 dated 28/12/2016 from Alphamed Formulations (Pvt) Ltd/.for the manufacturing of lab scale batches of Memantine SR Capsules 14mg, 21mg and 28mg.. The firm has proper approval for the import of the API from DRAP, Karachi.
2.	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the particular source of API is the laid down criteria of the firm in their Vendor Evaluation procedure which include the GMP status of the firm, DMF source and capability to provide API reference standard and impurity standard.

3.	Do you have documents confirming the import of Memantine, reference standard and impurity standards?	The firm has imported Memantine impurity 25mg vide Invoice No. SYN/PYD/113-1920 dated 16/05/2019 from SYNPURE LABS. Firm has documents attested from DRAP, Karachi.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificates of analysis for API, Working standards of the API and impurities standards.
5.	Do you have GMP certificate of API Manufacturer issued by regulatory Authority of country of origin?	Firm has GMP certificate issued by the Drug Control Administration, Govt. of Telangana.
6.	Do you use API manufacturer method of testing for testing API?	Firm has developed in-house testing method for the testing of API.
7.	Do you have stability studies reports on API?	The firm has stability studies reports on API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and however no degradation products are reported by the manufacturer.
9.	Do you have method for quantifying the impurities in the API?	The firm has API manufacturer method for quantifying the impurities in the API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Firm has some quantities of the API, working standard as well as impurities.
11.	Have you used pharmaceutical grade excipients?	No excipient used in finished product. Composition consist of 10% ready to fill pellets only.
12.	Do you have documents confirming the import of the used excipients?	No excipient used in the formulation.
13.	Do you have test reports and other records on the excipients used?	No excipient used in the formulation.
14.	Do you have written and authorized protocols for the development of Memantine SR Capsules 14mg, 21mg and 28mg?	The firm has written and authorized protocols for the development of Memantine SR 14mg, 21mg and 28mg CAPSULE.
15.	Have you performed Drug-excipient Compatibility studies?	No excipient used in the formulation.

16.	Have you performed comparative Dissolution studies?	The firm has not performed comparative dissolution profiles studies with innovator capsules due to their limited availability only in US market, however, conducted dissolution profile studies on the pellets and their all strengths of capsule formulations in three different media i.e. pH 1.2, 4.5 and 6.8 as required by WHO and FDA guidelines. Furthermore the firm has a copy of the dissolution studies of the capsule formulation conducted by the pellets manufacturer (Alphamed, India) in comparison to that of the innovator product (Forest Pharmaceutical Inc., USA) having comparable dissolution profiles. The pellets and their capsules manufactured by the firm show acceptable dissolution profiles in all the three discriminating media, with no significant effect of capsule shell, hence the conducted dissolution profile studies can be accepted on the risk based assessment. The firm will conduct comparative dissolution profiles with innovator products before commercial manufacturing.
17.	Do you have product development (R&D) section?	The firm has dedicated R&D section with reasonable facilities of equipment, human resource and utilities.
18.	Do you have necessary equipment Available in product development section for development of Memantine SR Capsules 14mg, 21mg and 28mg?	The firm has all necessary equipment related to manufacturing available in R&D section for manufacturing of Memantine SR 14mg, 21mg and 28mg Capsule. The quality control related to development work has been done in the routine quality control laboratory; however, there are dedicated HPLCs and Human Resource for this purpose.
19.	Are the equipment in product Development section qualified?	All the equipment used in product development are qualified.
20.	Do you have proper maintenance/calibration /re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration programme. Re-qualification program for the equipment used in PD section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm has 07 pharmacists and 01 chemist in manufacturing section of product development section currently with suitable knowledge and training in product. 02 QC Analysts are dedicated for New products testing.

22.	Have you manufactured three stability batches for the stability studies of Memantine SR Capsules 14mg, 21mg and 28mg as required?	The firm has manufactured three stability batches for the stability studies of: **Memantine SR 14mg Capsule** Batch no. 18PD-2255-01-T Batch no. 18PD-2256-02-T Batch no. 18PD-2257-03-T **Memantine SR 21mg Capsule** Batch no. 18PD-2258-01-T Batch no. 18PD-2259-02-T Batch no. 18PD-2260-03-T **Memantine SR 28mg Capsule** Batch no. 18PD-2222-01-T Batch no. 18PD-2223-02-T Batch no. 18PD-2224-03-T
23.	Do you have any criteria for fixing the batch size of stability batches?	As per DRAP guideline (2500 Capsules/Batch)
24.	Do you have complete record of Production of stability batches?	The firm has complete record of production of stability batches.
25.	Do you have protocols for stability testing of stability batches?	The firm has detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm has developed and validated stability indicating method for testing of their finished product supported by forced degradation.
27.	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	Method transfer is not applicable as the method has been developed in-house.
28.	Do you have documents confirming the qualification of equipments/ instruments being used in the test and analysis of Memantine and the finished drug?	The firm has documents confirming the installation and operational qualification of the equipment/ instruments being used in the test and analysis of Memantine and the finished drug.
29.	Do your method of analysis stability indicating?	The firm's method of testing is stability indicating as supported by forced degradation.
30.	Do your HPLC software 21CFR Compliant?	The HPLC software is 21CFR Compliant as per record available with the firm.
31.	Can you show Audit trail reports on Memantine testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of the stability batches.
33.	Do you have stability batches kept on stability testing?	The firm has kept all the three batches on real time and accelerated stability testing. Currently, 12 months studies have been completed with satisfactory results.
34.	Do you have valid calibration status for the Equipment used in Memantine SR Capsule 14mg, 21mg and 28mg production and analysis?	The firm has valid calibration status for the equipment used in Memantine Capsule production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	The firm has 14 stability chambers, 02 for accelerated and 12 for real time stability testing. All the chambers are properly qualified. All the chambers are provided with continuous power supply and data loggers for continuous monitoring. The data of data loggers is reviewed every 15th day.

36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has manufacturing area provided with necessary qualified equipment and utilities. The manufacturing personnel are suitable in number and qualification to run the manufacturing processes as per GMP requirements. The environmental conditions and their controls are also proper. The overall GMP conditions can be rated as compliant.

Conclusions:

1. On the basis of risk-based approach the genuineness / authenticity of stability data submitted by the firm for registration of MEMURA (MEMANTINE HCl) SR 14mg, 21mg and 28mg CAPSULE is verifiable to satisfactory level.
2. The related manufacturing area, equipment, personnel and utilities are GMP compliant and well suited for the manufacturing of MEMURA (MEMANTINE HCl) SR 14mg, 21mg and 28mg CAPSULES

Recommendations:

The firm may kindly be granted necessary registration of Memura (Memantine HCl) SR 14mg, 21mg and 28mg Capsules.

Decision: Registration Board decided to approve registration of MEMURA (MEMANTINE HCl) SR 14mg, 21mg and 28mg CAPSULES by M/s. PharmEvo (Pvt.) Limited, A-29, North Western Industrial Zone, Port Qasim, 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.

1491.	Name and address of manufacturer / Applicant	M/s Welmark pharmaceuticals, Plot # 122, Block-B, Phase-V, Industrial Estate, Hattar, Pakistan
	Brand Name +Dosage Form + Strength	SOFOMARK TABLETS 400mg
	Composition	Each film coated tablet contains: Sofosbuvir……..…400mg
	Diary No. Date of R& I & fee	15-07-2014, Rs. 50,000/- Rs. 85,000/ tablet
	Pharmacological Group	Antiviral
	Type of Form	Form 5 D
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	Blister Pack Alu Alu 10's
	Approval status of product in Reference Regulatory Authorities.	Sovaldi Tablets of M/s Gilead Sciences **(USFDA approved)**
	Me-too status	Sofiget Tablet 400mg of M/s GETZ pharma
	GMP status	Last inspection report dated 12-07-2017 concluded that overall cGMP was satisfactory as per DRAP Guidelines.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	As per decision of 248th & 249th meeting of Registration Board, Lab scale scientifically rationale stability is required **(M-251)**. Mr. Muhammad Muneer, Quality Control Manager presented the data before Registration Board. The Board observed that the stability data provided by the firm is not in accordance with the guidelines approved by the Board in 251st meeting as firm has not provided approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin, protocols followed for conduction of stability study and details of tests, data of 03 batches along with attested respective documents like chromatograms, laboratory reports, data sheets and Commitment to continue real time stability study till assigned shelf life of the product. Therefore, **the case was deferred** till the applicant

		completes the requisite information in respect of stability studies. **(M-253)**
	Evaluation by PEC	• Following Stability study data have been submitted.
	Decision:	

STABILITY STUDY DATA			
Drug	SOFOMARK TABLETS 400mg		
Name of Manufacturer	M/s Welmark pharmaceuticals, Plot # 122, Block-B, Phase-V, Industrial Estate, Hattar, Pakistan		
Manufacturer of API	M/s Zhejiang Warrant Pharmaceutical Co., Ltd, Zhejiang Province, China		
API Lot No.	SF-20160101		
Description of Pack (Container closure system)	28 Tablets contained in Blister packs		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 24 (Weeks) Real Time: 39 (Weeks		
Frequency	Accelerated: 1, 2, 3, 4, 6, 8, 12, 16, 20, 24 (Weeks) Real Time: 1, 2, 3, 4, 6, 8, 12, 16, 20, 24, 26, 39 (Weeks)		
Batch No.	T001	T002	T003
Batch Size	1800 Tablets	1800 Tablets	1800 Tablets
Manufacturing Date	01-18	01-18	01-18
Date of Initiation	22-01-2018	22-01-2018	22-01-2018
No. of Batches	3		
Date of Submission	11-12-2018 (Dy. No. 42379)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA from M/s Zhejiang Warrant 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.	The firm has submitted copy of GMP certificate of M/s Zhejiang Warrant Pharmaceutical Co., Ltd, China (Certificate No. ZJ20160046) issued by China 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.	The firm has submitted copy of commercial invoice (Invoice#20160110L-3) for the import of Sofosbuvir (2.5Kg) attested by ADC DRAP, Peshawar dated 08-03-2016.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has provided 24 Weeks Accelerated and 39 Weeks Real Time Stability Data for 03 Batches.

Scope of Inspection: Verification of authenticity of stability data
Letter No. F.13-11/2017-PEC(Pt) dated 29-01-2019

Inspection date 01-07-2019

S.No	Questions	Remarks
1	Do you have documents confirming the import of Sofosbuvir API?	Yes, ADC attested invoice , Shipment documents available.
2	What was the rationale behind selecting the particular manufacturer of API?	GMP compliant
3	Do you have documents confirming the import of Sofosbuvir 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, Have GMP Certificate of API Manufacturer, Wujiang Xiee Pharmaceuticals. Subsidiary of Zeiging Warrant pharmaceutical.
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 available for already approved products.
12	Do you have documents confirming the import of the used excipients?	Yes.
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 Sofosbuvir Tablets?	Yes, records seen of written and authorized protocols for the development of Sofosbuvir Tablets
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 Sofiget tablets 400mg.
17	Do you have product development (R&D) section	No
18	Do you have necessary equipments available in product development section for development of Sofosbuvir 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 the stability studies of Sofosbuvir Tablets as required.	Yes, as T001, T002, and T003

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 frequency and number of testing Frequencies are attached.
24	Do you have complete record of production of stability batches?	Yes, BMR availblae.
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 Sofosbuvir 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
31	Can you show Audit Trail reports on Sofosbuvir testing?	Yes
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 Sofosbuvir Tablets production in analysis?	Yes
35	Do proper and continuous monitoring and control are available for stability chamber?	Yes, Manual records maintained.
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes

Conclusion:

On risk based approach the genuineness /authenticity of stability data submitted by the firm for registration of **sofomark 400mg tablets** is verifiable to satisfactory level.

Decision: Registration Board decided to approve registration of SOFOMARK 400MG Tablets by M/s Welmark pharmaceuticals, Plot # 122, Block-B, Phase-V, Industrial Estate, Hattar, Pakistan. 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
1492.	M/s Welwink Pharmaceuticals, Factory G.T. Road, Industrial Estate, Gujranwala Cantt.	Dexzol Capsule 30mg Each capsule contains: Dexlansoprazole as Enteric coated Granules (22.5% pellets)……..30mg	Form 5-D Dairy No. 2912 dated 25-1-2019.	DEXILANT by M/s Takeda Pharms, USFDA.

		(Proton Pump Inhibitor) Manufacturer's specifications	Rs.20,000/- dated 21-1-2019 (Challan#0810253)	Panel inspection dated 20-12-2017 concluded that the firm was operating at satisfactory level of GMP compliance for all sections except liquid injectable section.

STABILITY STUDY DATA			
Drug	Dexilans 30mg capsule		
Name of Manufacturer	M/s Welwink Pharmaceuticals, Factory G.T. Road, Industrial Estate, Gujranwala Cantt.		
Manufacturer of API	**Dexlansoprazole:** M/s Vision Pharmaceuticals Plot #22-23, Industrial triangle, kahuta road, Islamabad.		
API Lot No.	**Dexlansoprazole** DLP360		
Description of Pack (Container closure system)	Alu Alu Blister pack		
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5% RH Accelerated: 40˚C ± 2˚C/ 75% ± 5% RH		
Time Period	Real time: 6 months Accelerated:6 months		
Frequency	Accelerated : 0 , 1 , 2 , 3, 4, 6 (months) Real Time: 0 , 3, 6 (Months)		
Batch No.	701	702	703
Batch Size	1500	1500	1500
Manufacturing Date	07-2018	07-2018	07-2018
Date of Initiation	20-07-2018	20-07-2018	20-07-2018
No. of Batches	03		
Date of Submission	5927 (11/2/19)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (No. F8-1/2016-DDG (E&M)) of M/s Vision Pharmaceuticals, Islamabad issued on 26-01-2018. The certificate is valid till 21-01-2019.
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.	Dexlansoprazole DDR pellets 17.0% were Purchased from M/s Vision pharmaceuticals Islamabad.
6.	All provided documents will be attested (name,	Yes

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

REMARKS OF EVALUATOR

The firm has submitted 6 months accelerated and 6 months real time stability study data for 3 batches.
The firm has applied Dexlansoprazole enteric coated pellets while reference formulation contains dual delayed release 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
1493.	M/s Welwink Pharmaceuticals, Factory G.T. Road, Industrial Estate, Gujranwala Cantt.	Dexzol Capsule 60mg Each capsule contains: double delayed release coated pellets 22.5% eq. to Dexlansoprazole ……..60mg (Proton Pump Inhibitor)	Form 5-D Dairy No. 2913 Dated 22-1-2019. Rs.20,000/- dated 21-1-2019 (Challan#0810254)	DEXILANT by M/s Takeda Pharms, USFDA. Last inspection report 8-20-Dec-2017 with satisfactory GMP

STABILITY STUDY DATA

Drug	Dexilans 60mg capsule		
Name of Manufacturer	M/s Welwink Pharmaceuticals, Factory G.T. Road, Industrial Estate, Gujranwala Cantt.		
Manufacturer of API	**Dexlansoprazole:** M/s Vision Pharmaceuticals Plot #22-23, Industrial triangle, kahuta road, Islamabad.		
API Lot No.	**Dexlansoprazole:** DLP360		
Description of Pack (Container closure system)	Alu/Alu blister Bi colored (white & green) double delayed release pellets (22.50%w/w) are filled in empty hard gelatin capsules size # 2 and 10 capsules are packed in a blister made up of unprinted 894luminium foil and Alu Alu silver film. Such 3 blisters packed in a 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 , 1 , 2 , 3, 4, 6 (months) Real Time: 0 , 3, 6 (Months)		
Batch No.	704	705	706
Batch Size	1500	1500	1500
Manufacturing Date	07-2018	07-2018	07-2018
Date of Initiation	20-07-2018	20-07-2018	20-07-2018

No. of Batches	704
Date of Submission	5927 (11/2/19)

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	The firm has submitted copy of GMP certificate (No. F8-1/2016-DDG (E&M)) of M/s Vision Pharmaceuticals, Islamabad issued on 26-01-2018. The certificate is valid till 21-01-2019.
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.	Dexlansoprazole DDR pellets 17.0% were Purchased from M/s Vision pharmaceuticals 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 6 months accelerated and 6 months real time stability study data for 3 batches.
The firm has applied Dexlansoprazole enteric coated pellets while reference formulation contains dual delayed release pellets.

Verification of Authenticity of Stability Data

1. General Information:

Name of Manufacturer	M/s Welwink Pharmaceuticals
Physical address	G.T. Road Industrial Estate, Gujranwala.
Drug Manufacturing License No. and validity	DML by way of formulation, No: 000751
Contact address	Mr. Arshad Mehmood, Managing Director Tel: +92 3215008415
Date of inspection	20th August 2019
Purpose of inspection	Panel inspection for verification of authenticity of stability data with reference to registration of Dexzol Capsule 30 & 60 mg.
Name of Inspector (s)	i. Mr. Shaheen Iqbal, Director, DTL, Lahore. ii. Mr. Ajmal Sohail Asif, FID (F), Lahore. iii. Ms. Maham Misbah, AD DRAP, Lahore.
Name of firm's representative (s)	i. Mr. Qayyum Nawaz, Production Manager ii. Mr. Aftab Alam, Quality Control Manager

2. Observations:

S. No	Question	Observations
1	Whether the firm has documents confirming import of API?	Not Applicable. Firm had locally purchased Dexlansoprazole DDR pellets from M/s. Vision Pharmaceuticals vide invoice No. 402775 dated 02.07.2018
2	What was the rationale behind selecting the particular manufacturer of API?	The rationale behind selecting the manufacturer was the cGMP status of M/s Vision Pharmaceuticals, availability of Drug Master File (open part) and adequate sample for initial testing for prequalification, as informed by the firm's management.
3	Whether documents confirm the import of API reference standard and impurity standards?	Not applicable. Firm has not imported Reference standard rather was using working standard provided by API manufacturer free of cost.
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 and working standards.
5	Whether the firm has any approval of API or GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm had cGMP compliance certificate of M/s Vision Pharmaceuticals issued by DRAP. (No.F.8-1/2016-DDG(E&M) valid till 25.01.2019).
6	Whether firm use API manufacturer method of testing?	Yes.
7	Whether firm has 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, firm has not conducted analysis for degradation products.
9	Whether firm has method for quantifying the impurities in the API?	Yes, as provided by the manufacturer of API, but firm has not performed analysis for impurities.
10	Whether firm has some remaining quantities of the API, its reference standard and impurities standards?	Firm had remaining quantities of API (approx. 100g as retained sample) and working standards (less than 1gram).
11	Whether firm has used pharmaceutical grade excipients?	No excipients used in the process. Firm is only filling the pellets (as purchased) in capsules.
12	Whether firm has documents confirming the import of the used excipients?	Not applicable.
13	Whether firm has test reports and other records on the excipients used?	Not applicable.
14	Whether firm has written and authorized protocols for the development of tablets?	Firm had written protocols for product development. However, the protocols were not signed and required improvement.
15	Whether firm has performed Drug-excipient compatibility studies?	Not applicable.
16	Whether firm has performed comparative dissolution studies?	No. Firm had not procured innovator's product.
17	Whether firm has product development (R&D) section?	No. Capsules were filled with pellets using semi-automatic capsule filling machine installed in the commercial production area.
18	Whether firm has necessary equipment available in product development section for development of finished product?	No.

19	Are the equipment in product development section qualified?	Equipment of commercial production was used. The equipment was qualified.
20	Whether firm has proper maintenance / calibration/re-qualification program for the equipment used in PD section?	Firm did not have any PD section.
21	Whether firm has qualified staff in product development section with proper knowledge and training in product development?	No. Separate staff for product development was not available.
22	Whether firm has manufactured three stability batches for the stability studies of finished product tablets as required?	Firm had manufactured three stability batches each for the stability studies of finished products Dexlansoprazole 30mg and Dexlansoprazole 60mg. Dexlansoprazole 30mg (Batch Nos. 701, 702 & 703) and Dexlansoprazole 60mg (Batch Nos. 704, 705 & 706)
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 available quantity of API and DRAP guidelines for stability testing.
24	Whether firm has complete record of production of stability batches?	Firm had BMRs of all relevant stability batches.
25	Whether firm has protocols for stability testing of stability batches?	Yes. However, the protocols required improvement. Stability Chamber with 200 Liter capacity having ID No. CN/WP/CAL/017 was used for accelerated stability studies & stability chamber with 450 Liter capacity having ID No. CN/WP/CAL/018 was used for real time stability studies.
26	Whether firm has developed and validated the method for testing of stability batches?	Protocols for testing method validation were incomplete. Method validation report was not satisfactory.
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?	No.
30	Whether firm has HPLC software 21CFR compliant?	No, HPLC was not 21CFR compliant. Firm had used HPLC of Waters, model LC Module I plus.
31	Whether firm could show Audit Trail reports?	No
32	Whether firm has some remaining quantities of degradation products and stability batches?	Firm had remaining quantities of stability batches. Degradation products had not been isolated.
33	Whether firm has stability batches kept on stability testing?	Yes.
34	Whether firm has valid calibration status for the equipment used in production and	Yes.

	analysis?	
35	Do proper and continuous monitoring and control are available for stability chamber?	No, only manual monitoring was performed on log books. Firm was advised to install data loggers with alarm system in the stability chambers in order to monitor and control excursions.
36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	GMP compliance of capsule section was satisfactory.

3. Remarks:

In addition to above mentioned checklist panel also verified the parameter regarding dissolution testing of dual delayed released pellets before filling in capsules as required. It was noted that the firm has conducted dissolution testing on pellets when procured before filling in capsules. The firm did not possess product development section, the firm neither performed tests for impurities nor for degradation products. The firm also did not conduct comparative dissolution studies with innovator product.

However, the panel noted that the firm has conducted the stability study of Dexzole 30 mg and 60 mg capsules for 6 months at accelerated and real time conditions on the basis of document provided at the time of inspection.

Decision: Registration Board decided to approve registration of Dexzole (Dexlansoprazole) 30mg, 60mg CAPSULES by M/s Welwink Pharmaceuticals, Factory G.T. Road, Industrial Estate, Gujranwala Cantt. 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
1494.	M/s Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar-Pakistan	EMPAA 25mg Tablet Each film coated Tablet contains: Empagliflozin…..25mg Sodium Glucose Co-Transporter 2 Inhibitor Innovator's specification	Form-5 Dy. No.2431, 18-01-2019 Rs.20,000/-, dated 16-01-2018, As per SRO As per SRO	Jardiance 25mg Tablet by Boehinger Ingelheim, **(USFDA approved)** Emazin 25mg Tablet of Atco

STABILITY STUDY DATA			
Drug	EMPAA 25mg Tablet		
Name of Manufacturer	M/s Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar-Pakistan		
Manufacturer of API	M/s Zhejiang Hongyuan Pharmaceutical Co., Ltd, China		
API Lot No.	20170929		
Description of Pack (Container closure system)	Alu Alu Blister packed 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: 06 Months Real Time: 06 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	1200 Tablets	1200 Tablets	1200 Tablets
Manufacturing Date	09-04-2018	09-04-2018	09-04-2018

Date of Initiation	10-04-2018	10-04-2018	10-04-2018
No. of Batches	3		
Date of Submission	18-01-2019 (Dy. No. 2431)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.	Documents To Be Provided	Status
1.	COA of API	Copy of COA from M/s Zhejiang Hongyuan 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.	The firm has submitted copy of GMP certificate (Certificate No: TZDA170032) issued by TAIZHOU DRUG ADMINISTRATION, China. The certificate is valid until 21-09-2022.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice (Invoice#WC20181586-1) dated 15-03-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Batches.
ADC attested commercial invoice is required to be submitted.

Inspection of the firm M/s Weatherfolds Pharmaceuticals, Plot No. 69 Phase II, Industrial Estate, Hattar is conducted today on 10.05.2019 in compliance to PEC letter No. F.13-11/2017-PEC (Vol-I) dated 25.04.2019 for the verification o authenticity of stability data for the registration of following products.

Empaa-M XR 12.5/1000mg Tablets
Empaa 25 mg Tablet

The following panel conducted inspection of the firm

I. Prof. Dr. Jamshed Ali Khan, Member, CLB
II. Dr. Muhammad Khalid Javed, Director, DTL , Peshawar
III. Ch. Zeeshan Nazir, Deputy Director (QA), DRAP, Islamabad

S.No	Question	Observation by Panel
Q.No.1	Do you have documents confirming the import of API including approval from DRAP?	Import documents including internal record is available. However Goods Declaration and Commercial Invoice of Metformin Hcl is also available.
Q.No.2	What was the rationale behind selecting the particular manufacturer of API?	GMP compliant
Q.No.3	Do you have documents confirming the import of reference standard and impurity standards?	Working standards provided by the manufacture.
Q.No.4	Do you have certificate of Analysis of the API, reference standards and impurity standards?	YES

Q.No.5	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Yes
Q.No.6	Do you use API manufacturer method of testing for testing API?	Yes
Q.No.7	Do you have stability studies reports on API?	Yes
Q.No.8	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	Yes
Q.No.9	Do you have method for quantifying the impurities in the API?	No
Q.No.10	Do you have some remaining quantities of the API, its reference standard and impurities standards?	Yes only of API
Q.No.11	Have you used pharmaceutical grade excipients?	Yes
Q.No.12	Do you have documents confirming the import of the used excipients?	No
Q.No.13	Do you have test reports and other records on the excipients used?	Yes
Q.No.14	Do you have written and authorized protocols for the development of applied product?	Yes
Q.No.15	Have you performed Drug-excipients compatibility studies?	Brand Formulation is taken as standard
Q.No.16	Have you performed comparative dissolution studies?	Yes
Q.No.17	Do you have product development (R&D) section	No
Q.No.18	Do you have necessary equipments available in product development section for development of applied product?	No
Q.No.19	Are the equipments in product development section qualified?	N/A
Q.No.20	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	N/A
Q.No.21	Do you have qualified staff in product development section with proper knowledge and training in product development?	N/A
Q.No.22	Have you manufactured three stability batches for the stability studies of applied product as required?	Yes

Q.No.23	Do you have any criteria for fixing the batch size of stability batches?	Yes
Q.No.24	Do you have complete record of production of stability batches?	Yes
Q.No.25	Do you have protocols for stability testing of stability batches?	Yes
Q.No.26	Do you have developed and validated the method for testing of stability batches?	Yes
Q.No.27	Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?	N/A
Q.No.28	Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of API and the finished drug?	Yes
Q.No.29	Is your method of analysis stability indicating?	Yes
Q.No.30	Is your HPLC software is 21CFR compliant? (Details of Model, software, description/version (i.e. software validation report for 21 CFR Part 11 compliance including audit trail, password protection, date & time lock and user authorizations shall also be reported.)	Yes 21 CFR, Water's 600 pump, 486 Detector with Empower software.
Q.No.31	Can you show Audit Trail reports on stability studies testing?	Yes
Q.No.32	Do you have some remaining quantities of degradation products and stability batches?	Yes
Q.No.33	Do you have stability batches kept on stability testing?	Yes
Q.No.34	Do you have valid calibration status for the equipments used in production and analysis?	Yes
Q.No.35	Do proper and continuous monitoring and control are available for stability chamber? (Number and utilized/available capacity of stability chambers shall also be reported.)	Two stability chambers are provided. Each is having capacity of 600 litres with manual record keeping.
Q.No.36	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Yes

The panel goes through the record of the raw material of Metformin Hcl. The firm's representative provided the In-gate pass, Good Receiving Note, Goods Declaration, Commercial Invoice, Form-3, Form-7 and testing record of the imported raw material. However the firm fails to provide the attested invoice by the Assistant Director (I &E). Provided record shows that the firm imported Metformin Hcl from the firm M/s The Moleculez, Mumbai, India.

The firm is using manual coating technique for the coating of Empagliflozin on the core of Metformin HCL. The firm uses 5 kg coating pan for the R&D purpose. The record of testing of the finish product is scrutinized and found satisfactory.

Technical staff provided testing record of the finish product. The technical staff stated that the coating of Empagliflozin was done with 100 %, 102 %, 105 % and 110 %. The testing record show that 105 % of Empagliflozin provided 100 % results on finish testing. The firm after trial decided to use overage of 5 % of Empagliflozin.

Technical staff stated that during test trial of finish product, they have developed a placebo for the adjustment of excipients as well as EMPA. The UV method does not interfere with ingredients of formulation and Empagliflozin.

Stability data of the above mentioned products is also verified through manual record and directory of HPLC. The HPLC provided is 21 CFR compliant, Water's 600 pump, 486 Detector with Empower software. Manual record of above mentioned products is also verified and found satisfactory.

Keeping in view the above mentioned facts, the panel unanimously verified the authenticity of stability data of below mentioned products.

Empaa-M XR 12.5/1000mg Tablets
Empaa 25 mg Tablet

Decision: Registration Board decided to approve registration of Empaa (Empagliflozin) 25mg Tablet by M/s Weather Folds Pharmaceuticals, Plot # 69, Phase-II, Industrial Estate, Hattar-Pakistan. 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.

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
1495.	M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore	Valpas 400/100 tablets Each Film Coated Tablet contains: Sofosbuvir……400mg Velpatasvir…..100 mg Anti-viral drug	Form 5D Dy. No. 2009 (Duplicate dossier) 13/01/2017 Fee 50000/- (Challan # 0568772) Duplicate Pack Size 14's tablets Price /- per pack	Epclusa400mg/100mg Tablet (Canada) Last inspection report Dated **27/09/2018** is attached which confirms the good level of GMP compliance.

STABILITY STUDY DATA	
Drug	Valpas 400/100 tablets
Name of Manufacturer	M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore
Manufacturer of API	**Sofosbuvir (**Optimus Drugs Pvt Ltd, India**)** **Velpatasvir (**Optrix Laboratories Pvt Ltd**)**
API Lot No.	**Sofosbuvir** (OP-GLD/10/17/073) **Velpatasvir (**OT-VCP/002/79)
Description of Pack (Container closure system)	Alu – Alu blister
Stability Storage Condition	**Real Time:** 30'C ± 2'C / 65% ± 5%RH

	Accelerated:40'C ±2'C / 75% ± 5%RH		
Time Period	**Real Time:** 6 Months **Accelerated:** 6 Months		
Frequency	**Real Time:**0,3,6,9, 12, 18, 24 (Months) **Accelerated:** 0,3 & 6 (Months)		
Batch No.	**RD 18123**	**RD 18124**	**RD 18125**
Batch Size	900 tablets	900 tablets	900 tablets
Manufacturing Date	06-2018	06-2018	06-2018
Date of Initiation	06-2018	06-2018	06-2018
No. of Batches	**03 batches**		
Date of Submission	5-3-2019 (Dy. No.11568)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API	Copy of COA from: **Sofosbuvir:** Optimus Drugs Pvt Ltd, 1-2-11/1, Above SBI bank st no.2,Kakatiya Nagar, Habsiguda Hyderabad-500007, Telangana India **Velpatasvir:** Optrix Laboratories Pvt Ltd, Survey no 147,Ramalingampally (V), Bommalaramaram (M), Yadadri Bhuvanagirl (D)-508126, Telangana India
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate: **Sofosbuvir:** (#2021/A3/2018) issued to Optimus Drugs Pvt Ltd, 1-2-11/1, Above SBI bank st no.2,Kakatiya Nagar, Habsiguda Hyderabad-500007, Telangana India issued by drug control administration Gov of telangana valid till 21-5-2020. **Velpatasvir:** (#5109/A3/2018) issued to Optrix Laboratories Pvt Ltd, Survey no 147,Ramalingampally (V), Bommalaramaram (M), Yadadri Bhuvanagirl(D)-508126, Telangana India drug control administration Gov of telangana valid till 4-9-2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of commercial invoice has been submitted issued by ADC, DRAP. **Sofosbuvir:** Import quantity: 250 kg **Reference standard:** NA **Impurities:** Not provided **Velpatasvir:** Import quantity: 2 kg **Reference standard:** NA **Impurities:** Not provided

6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes
REMARKS OF EVALUATOR		
Data for exemption from On-site investigation of submitted stability data		
Administrative Portion		
1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Last onsite inspection conducted on 1st January, 2019 for following products • Nebvax (Nebivolo + Valsartan) 5/80mg Tablet • Daplozmet 5/850mg Tablet • Daplozmet 5/1000mg Tablet According to the report following important points were confirmed 1. HPLC is 21 CFR compliant 2. Audit trails of the test reports were available. 3. Related manufacturing area equipment's personals and utilities were found GMP compliant.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Sofosbuvir:** The firm has submitted photocopies of ADC (Lahore) attested, dated 31-10-2017, Commercial Invoice for 250 Kg via Invoice # 293/EXP dated: 24-10-2017 Lot No. OP-GLD/10/17/071 from M/s. Optimus Drugs (Pvt) Ltd., India Survey No. 239 & 240, Dothigudem (V), Pochampally (M), Yadadri – Bhuvanagiri (D), 508284, Telangana, India. vide proper approval from DRAP Office, Lahore. **Velpatasvir:** The firm has submitted photocopies of ADC (Lahore) attested, dated 21-02-2018, Commercial Invoice for 2Kg via Invoice # OT069/EXP dated: 25-01-2018 Lot No. OT-VCP/002/79 from M/s. Optrix Laboratories (Pvt) Ltd., India, Survey No. 147, Ramalingampally (V), Bommalaramaram (M), Yadadri – Bhuvanagiri (D), Telangana, India vide proper approval from DRAP Office, Lahore.
3.	Documents for the procurement of reference standard and impurity standards.	The reference standards were received free of cost with API Sofosbuvir & Velpatasvir. Therefore, no separate procuring documents available.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sofosbuvir** copy of GMP Certificate issued on 02 January, 2017 by Drugs Control Administration, Government of Telangana, India. **Velpatasvir** copy of GMP Certificate issued on 12th July, 2017 by Drugs Control Administration, Government of Telangana, India.
5.	Mechanism for Vendor pre-qualification	Firm has submitted Vendor Qualification Flow Chart.

<table>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Sofosbuvir API:
Photocopy of COA of Batch No. OP-GLD/10/17/073 issued by M/s Optimus Drugs Pvt Ltd, India is submitted.
1. Reference standards:
The firm has submitted the copy of Reference Standards (Sofosbuvir) Batch No. OP-SFS/RS1402, provided by the API Manufacturer - M/s Optimus Drugs Pvt Ltd, India
• Velpatasvir API:
Photocopy of COA of Batch No. OT-VCP/002/79 issued by M/s Optrix Laboratories Pvt Ltd, India is submitted.
2. Reference standards:
The firm has submitted the copy of Reference Standards (Velpatasvir) Batch No. OT-VCP/S1/003/01, provided by the API Manufacturer - M/s Optrix Laboratories Pvt Ltd, India</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted documents for procurement of excipients used in product development.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted list of 06 qualified person working in R&D section</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted copy of generalized SOP with the title ‘Product Design & Development’.
Effective Date: 10th April, 2017</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>Firm has provided complete batch manufacturing record of all the three batches
SOFOSBUVIR - VELPATASVIR 400-100MG TABLET
<table><tr><th>BATCH NO.</th><th>BATCH SIZE</th><th>MFG. STARTED</th><th>MFG. COMPLETED</th></tr><tr><td>RD-18123</td><td>900 Tabs</td><td>06-06-2018</td><td>06-06-2018</td></tr><tr><td>RD-18124</td><td>900 Tabs</td><td>06-06-2018</td><td>06-06-2018</td></tr><tr><td>RD-18125</td><td>900 Tabs</td><td>06-06-2018</td><td>06-06-2018</td></tr></table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Firm has submitted following remaining quantities:
Sofosbuvir-Velpatasvir 400-100mg Tablet; Stability Pack Size : 4 x 7’s)
• RD-18123: Batch Size : 900 Tablets
23 Packs placed on stability (Accelerated: 06 Packs, Real Time: 17 Packs), out of which 02 pack are remaining Accelerated and 13 Packs remaining Real Time.
• RD-18124: Batch Size : 900 Tablets
23 Packs placed on stability (Accelerated: 06 Packs, Real Time: 17 Packs), out of which 02 pack are remaining Accelerated and 13 Packs remaining Real Time.
• RD-18125: Batch Size : 900 Tablets
23 Packs placed on stability (Accelerated: 06 Packs, Real Time : 17 Packs), out of which 02 pack are remaining Accelerated and 13 Packs remaining</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Real Time.</td></tr>
<tr><td colspan="3">QA/QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted record of digital data logger for temperature and humidity monitoring control for the complete stability period.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>Firm has provided the method used for analysis of API along with its certificate of analysis</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>Firm has provided method used for analysis of FPP and complete record of testing of stability batches including chromatograms, lab reports and raw data sheets are submitted with 06 months Accelerated stability data and 06 months Real Time Stability Data.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Sofosbuvir: The firm has submitted copy of Long Term 24 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches of Sofosbuvir from M/s Optimus Drugs (Pvt) Ltd., India.
Velpatasvir: The firm has submitted copy of Accelerated 03 Months (40°C ± 2°C & 75±5%RH) and Long Term 03 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches of Velpatasvir from M/s Optrix Laboratories (Pvt) Ltd., India.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted Drug-excipients compatibility studies</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>Firm has submitted comparative dissolution profile with the reference product Epclusa™ 400mg/100mg Tablet, Patheon Inc. Mississauga, ON L5N 7K9 Canada.
<table>
<tr><th>FEATURE</th><th>REFERENCE PRODUCT</th><th>PRODUCT OF HI</th></tr>
<tr><td>BRAND NAME</td><td>Epclusa™ 400/100mg Tablet</td><td>Sofosbuvir–Velp 400/100mg Tabl</td></tr>
<tr><td>BATCH NO.</td><td>YPPGD3</td><td>RD-18124</td></tr>
<tr><td>MFG. / EXPIRY DATE</td><td>Mfg. Date: 07-2017
Exp. Date: 07-2020</td><td>Mfg. Date: 06-20
Exp. Date: 06-20</td></tr>
</table>
Test was performed at:
i. 1.2N Hydrochloric Acid Solution
ii. pH 4.5 Acetate buffer solution.
iii. pH 7.4 phosphate buffer solution.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>Firm has submitted compliance record of HPLC software 21 CFR & audit trail reports.</td></tr>
</table>

Evaluation by PEC:

S #	Short comings	Response of Firm
1.	COA of impurity standards are required	The related substance in API and FPP are evaluated by the validated method provided by API manufacturer (Optimus drug pvt Ltd). In this method the related substance (RP isomers) are calculated by area normalization method which does not required impurity standard. For identification of known impurity (RP isomer) the relative retention time of the impurity are used. The relative retention time of impurity is

		about 0.95 with reference to sofosbuvir retention time.
2.	Valid GMP certificate is required as Photocopy of GMP Certificate Sofosbuvir: (# 11980/A3/2016) issued to Optimus Drugs Pvt Ltd, was valid up to 1-2019.	Valid GMP certificate of Sofosbuvir: (# 2021/A3/2018) issued to Optimus Drugs Pvt Ltd, valid up to 21-5-2020 is provided.
3.	Valid GMP certificate is required as Photocopy of GMP Certificate Velpatasvir: (#8340/A3/2017) issued by Optrix Laboratories Pvt Ltd, was valid up to 7-2018.	Valid GMP certificate of Velpatasvir: (#5109/A3/2018) issued to Optimus Drugs Pvt Ltd, valid up to 4-9-2020 is provided.
4.	The innovators finish product testing including tests for microbial contents. Justify the exemption of these tests	The microbiological testing is not performed on trial batches the first three commercial validation batches will be subject to microbiology testing and subsequently every 5th commercial batch of solid dosage form will be tested
5.	Stability studies reports on conditions of Zone IV-A for API conducted by API manufacturer is required.	**For API:** The firm has submitted copy Long Term 03 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches On **query** they submitted that according to WHO technical report series Regarding real time stability study storage conditions for long term stability study is 25°C ± 2°C / 60% ± 5% RH or 30°C ± 2°C / 65% ± 5% RH "which is determined by the climatic condition under which API is intended to be stored". ICH guideline also supported that statement that "*therefore the climatic conditions for long term stability study can be selected based on the intended storage conditions of the API*. Manufacturer recommended the storage of valpatesvir API at 25°C ± 2°C / 60% ± 5% RH and at highnoon the raw material store is maintained at 25°C ± 2°C / 60% ± 5% RH therefore we request you to accept the stability at 25°C ± 2°C / 60% ± 5% RH

Previous Decision: Registration Board decided to defer the case for submission of complete stability studies for three batches of API either as per zone IV-A conditions as only copy of Long Term 03 Months (25°C ± 2°C & 60±5%RH) stability study reports of 03 batches are submitted OR Justification on scientific basis that wheather an API with stability studies at (25^0C ±2^0C & 60 ±5% RH.) be used to prepare a FPP which has to be stored at zone IV-A conditions (M-288).

Evaluation by PEC:

The firm has submitted following:

Clarification on the requirement of the storage conditions for the API Stability and FPP Stability for submission of the stability data.

Review of the Recent WHO Guidelines titled "***Stability testing of Active Pharmaceutical Ingredients (API) and Finished Pharmaceutical Products (FPP) - WHO Technical Report Series, No. 1010, 2018, Annex 10"*** to determine / establish the requirement of the storage conditions for the API Stability and FPP Stability for submission of the stability data based on the intended storage condition for API and climatic zone in which the FPP is intended to be Marketed.

According to the WHO Guidelines:

QUOTE:

- ***for API stability study the storage conditions are (See pages 316-317 of TRS # 1010, 2018, Annex – 10):***

Study	**Storage condition**	**Minimum time period covered by data at submission**

Long-terma	25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH or 30°C ± 2°C/75% RH ± 5% RH	12 months or 6 months as described in point 2.1.7
Intermediateb	30°C ± 2°C/65% RH ± 5% RH	6 months
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months

a Whether long-term stability studies are performed at 25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH or 30°C ± 2°C/75% RH ± 5% RH is ***determined by the climatic condition under which the API is intended to be stored*** (see "Long-term stability testing conditions as identified by WHO Member States"). Testing at a more severe long-term condition can be an alternative to testing condition, i.e. 25°C/60% RH or 30°C/65% RH for zone II.

b If 30°C ± 2°C/65% RH ± 5% RH or 30°C ± 2°C/75% RH ± 5% RH is the long-term condition there is no intermediate condition**.**

- ***And for Finished Pharmaceutical Products (FPP) the storage conditions and the length s of studies chosen should be sufficient to cover storage, shipment and subsequent use with due regard to climatic conditions in which the product is intended to be marketed (See pages 325-326 of TRS # 1010, 2018 Annex - 10).***

Study	**Storage condition**	**Minimum time period covered by data at submission**
Long-term a	25°C ± 2°C/60% RH ± 5% RH or 30°C ± 2°C/65% RH ± 5% RH or 30°C ± 2°C/75% RH ± 5% RH	12 months or 6 months as described in point 2.2.7
Intermediate b	30°C ± 2°C/65% RH ± 5% RH	6 months
Accelerated	40°C ± 2°C/75% RH ± 5% RH	6 months

a Whether long-term stability studies are performed at 25°C ± 2°C/60% RH ± 5% RH or 30 °C ± 2 °C/65% RH ± 5% RH or 30 °C ± 2°C/75% RH ± 5% RH is determined by the ***climatic zone in which the FPP is intended to be marketed***. Testing at a more severe long-term condition can be an alternative to storage at 25°C/60% RH or 30 °C/65% RH.

b If 30°C ± 2°C/65% RH ± 5% RH or 30°C ± 2°C/75% RH ± 5% RH is the long-term condition, there is no intermediate condition. **UNQUOTE**

WHO guidelines state that there are different criteria for selection of stability study storage conditions for API and Finished product. Storage condition for API is determined by the climatic condition where API is **intended to be stored**. Therefore, stability study conducted at 25°C ± 2°C/60% RH ± 5% RH is equally acceptable for Zone IVA if the API is ensured to be stored at these condition till it is converted in to Finished Product.

DRAP has a system to verify temperature and humidity of raw material store to be maintained through appropriate HVAC system, and there is an appropriate back up system installed to ensure that the storage conditions are maintained.

On the other hand WHO guidelines recommend the stability study storage condition for Finished Product to be determined according to the Climatic Zone where the product is **intended to be marketed**. Therefore for finished product, it is mandatory to conduct stability study at 30°C ± 2°C/65% RH ± 5% RH (Climatic Conditions for Zone IVA).

Based on this WHO Guidelines (TRS No. 1010, 2018, Annex 10), if the manufacturer of the FPP submit FPP stability for Climatic Zone IVA, i.e. 30°C ± 2°C/65% RH ± 5% RH and API Stability study for climatic condition of 25°C ± 2°C/60% RH ± 5% RH and confirm that the API intended storage condition is 25ºC then the data should be acceptable.

Previous Decision: Registration Board decided as follows: (M-290)

- The firm shall submit the record of data logger for the storage conditions throughout the transportation.

• Firm shall submit long term stability studies data of the product for 1 year along with degradation studies in the finished pharmaceutical product.
The firm has submitted 12 months long term stability data conducted at 30ºC±2 ºC/65%±5%RH for Velpatasvir: Copovidone (1:1) API for 03 batches. The results of values for batch numbers OT-VCP/002/15 and OT-VCP/002/16 were same as submitted previously for 3 months.
Decision: Registration Board decided to approve registration of Valpas (Sofoabuvir/velpatasvir) 400mg/100mg Tablet with submission of undertaking by M/s Highnoon Laboratories, 17.5km, Multan Road, Lahore that all responsibility lies with the firm in case of any safety, efficacy or quality related issues related to the product in the market. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

c. Exemption from onsite verification of stability data

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
1496.	M/s Aspin Pharma (pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi	DAGLI Tablet 5mg Each film coated tablet contains: Dapagliflozin as propanediol monohydrate…….5mg Anti-diabetic Manufacturer's specs	Form 5 Dairy No. 37592 dated 13-11-2018 Rs.20,000/- dated 17-10-2018 As per latest DPC	FARXIGA film coated tablets 5mg by M/s Astrazeneca AB (USFDA approved) Inspection dated 20-02-2-2018 concluded that M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012.	The Firm has claimed Manufacturer's Specifications.
1497.	M/s Aspin Pharma (pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi	DAGLI Tablet 10mg Each film coated tablet contains: Dapagliflozin as propanediol monohydrate…….10mg Antidiabetic Manufacturer's specs	Form 5 Dairy No. 37593 dated 13-11-2018 Rs.20,000/- dated 17-10-2018 As per latest DPC	FARXIGA film coated tablets 10mg by M/s Astrazeneca AB (USFDA approved) Inspection dated 20-02-2-2018 concluded that M/s Aspin Pharma is considered to be operating at satisfactory level of compliance with respect to cGMP guidelines as per Drug Act 1976 and DRAP Act 2012.	The Firm has claimed Manufacturer's Specifications.

STABILITY STUDY DATA				
Drug	DAGLI Tablet 10mg			
Name of Manufacturer	M/s Aspin Pharma (pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi			
Manufacturer of API	M/s MSN Laboratories Private limited, Telangana, India			
API Lot No.	DQ0010217			
Description of Pack (Container closure system)	Alu /Alu Blister of 1 × 7's × 2 packed 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: 06 Months Real Time: 06 Months			
Frequency	Accelerated: 0,3,6 (Month) Real Time: 0,3,6,9 (Month)			
Products	Batch No.	Bach size	Manufacturing Date	Date of initiation
Dagli Tablet 5mg	044DS01	2500	17-05-2017	June-2017
	044DS02	2500	17-05-2017	June-2017
	044DS03	2500	17-05-2017	June-2017
Dagli Tablet 10mg	045DS01	2500	19-07-2017	August-2017
	045DS02	2500	19-07-2017	August-2017
	045DS03	2500	20-07-2017	August-2017
No. of Batches	03			
Date of Submission	21-06-2019 (Dy. No. 9158)			

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr.#	**Documents To Be Provided**	**Status**
1.	COA of API	Copy of COA of Dapagliflozain propanediol (B#DQ0010217) from M/s MSN Laboratories Private 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.	Copy of GMP Certificate for Pharmaceutical Products issued by Drugs Control Administration, Government of Telangana, India is submitted.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the purchase of Dapagliflozin propanediol monohydrate (0.5Kg) attested by ADC DRAP, Karachi dated 29-03-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes

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

PREVIOUS REMARKS OF EVALUATOR[1]

The firm has submitted 6months accelerated and 6 months real stability study data of 3 batches developed by M/s OBS Pakistan Pvt. Ltd, Karachi.

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: 21-06-2019 vide diary no. 9158

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection report of their products "Jantovia XR 50mg/500mg, 50mg/1000mg & 100mg/1000mg", which was presented in 285th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Aspin Pharma., Karachi. **Date of inspection**: 29-08-2018 According to inspection report, following points were confirmed. • The software of the HPLC used upto 03 months studies is not 21CFR compliant whereas , the 02 other software of HPLCs used for 06 months studies and scheduled to be used for further studies are 21 CFR compliant. • Audit trail on the testing reports can be made for 06 month studies and onward.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted commercial invoice for the purchase of Dapagliflozin propanediol monohydrate (0.5Kg) attested by ADC DRAP, Karachi dated 29-03-2017.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted following working standards & impurity Standards Dapagliflozin Propandiol Working standard (DQWS1501) Bromo Compound Acetyl impurity Bromo Lactone Impurity Methoxy impurity
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP Certificate for Pharmaceutical Products issued by Drugs Control Administration, Government of Telangana, India is submitted.
5.	Mechanism for Vendor pre-qualification	The firm has submitted mechanism for vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	The firm has submitted copy of COA of Dapagliflozain propanediol (B#DQ0010217) from M/s MSN Laboratories Private limited, Telangana, India. The firm has submitted COAs of working standard and impurity standards
7.	Documents for the procurement of excipients used in product development?	The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product
8.	List of qualified staff involved in product	The firm has submitted List of qualified staff involved in

<table>
<tr><td></td><td>development with relevant experience.</td><td>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 Tablet range”.</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 from OBS Pakistan (Pvt) Limited:
Dagli Tablet 5mg
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>044DS01</td><td>2500 Tablets</td><td>17-05-2017</td></tr>
<tr><td>044DS02</td><td>2500 Tablets</td><td>17-05-2017</td></tr>
<tr><td>044DS03</td><td>2500 Tablets</td><td>17-05-2017</td></tr>
</table>
Dagli Tablet 10mg
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>045DS01</td><td>2500 Tablets</td><td>19-07-2017</td></tr>
<tr><td>045DS02</td><td>2500 Tablets</td><td>19-07-2017</td></tr>
<tr><td>045DS03</td><td>2500 Tablets</td><td>20-07-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>Dagli Tablet 5mg
<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>044DS01</td><td>20 packs (2×10’s)</td><td>10 packs (2×10’s)</td><td>10 packs</td></tr>
<tr><td>044DS02</td><td>20 packs (2×10’s)</td><td>10 packs (2×10’s)</td><td>10 packs</td></tr>
<tr><td>044DS03</td><td>20 packs (2×10’s)</td><td>10 packs (2×10’s)</td><td>10 packs</td></tr>
</table>
Dagli Tablet 10mg
<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>045DS01</td><td>29 packs (2×7’s)</td><td>15 packs (2×7’s)</td><td>14 packs</td></tr>
<tr><td>045DS02</td><td>29 packs (2×7’s)</td><td>15 packs (2×7’s)</td><td>14 packs</td></tr>
<tr><td>045DS03</td><td>29 packs (2×7’s)</td><td>15 packs (2×7’s)</td><td>14 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 30-05-2017 to 29-11-2017.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Dapagliflozin.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP &</td><td>The firm has submitted photocopy of Finished Product</td></tr>
</table>

	complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	Testing Procedure for "Dapagliflozin 5mg & 10mg Tablets" along with Stability Study Reports.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s MSN Laboratories Private Limited, India. The storage conditions under which long term stability studies were conducted are 25ºC±2ºC/60±5%RH.
16.	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has submitted we used all the ingredients same as used in innovator product.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution of two different brands of Dapagliflozin tablet i.e., Dapagliflozin (5mg & 10mg) Tablet & Forxiga (5mg & 10mg) Tablet" and concludes that both, reference product and test product shows comparable dissolution profile in three recommended mediums at pH 1.2, pH 4.5, pH 6.8. However f2 factor has not been calculated.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail log for complete stability studies.

Justify the dissolution specifications NLT 85% in 30 min since the dissolution specifications of FDA approved product (**FARXIGA Tablet)** is NLT Q in 15 min.
(The value of Q defined by FDA as well as USP general chapter is 75% to 80%).
Audit trail reports do not cover all the time points of HPLC software. Submission of audit reports at all the time points as well as reports of comparative dissolution study is required.
The storage conditions under which long term stability studies of API were conducted are 25ºC±2ºC/60±5%RH. Justification is required.

Observations communicated	Response of the applicant
Justify the dissolution specifications NLT 85% in 30 min since the dissolution specifications of FDA approved product (**FARXIGA Tablet)** is NLT Q in 15 min. (The value of Q defined by FDA as well as USP general chapter is 75% to 80%).	Our established specifications for dissolution NLT 85% (Q+5) in 30 min is justified with FDA as well as with USP as the value of Q defined by FDA . USP general chapter is 75% to 80% (Q greater than 80% not generally used). The time of 30 min was established for FDA site for dissolution Method. The CDP reports also reflect that all dissolution results are greater than 85% in 15min so the product complies with FDA approved specifications.
Audit trail reports do not cover all the time points of HPLC software. Submission of audit reports at all the time points as well as reports of comparative dissolution study is required.	The firm has submitted audit trail log for complete stability studies
The storage conditions under which long term stability studies of API were conducted are 25ºC±2ºC/60±5%RH. Justification is required	The provided stability data for API at storage condition 25ºC/60% RH is justified as this material is stored in same storage condition which is also recommended for product storage (As the product storage for Farxiga is 15ºC to 25ºC).

The firm has submitted 6months accelerated and 6 months real stability study data of 3 batches developed at M/s OBS Pakistan Pvt. Ltd, Karachi.

Decision: Registration Board deferred the cases for following:

- **Clarification and scientific justification for conducting the API stability data conducted at storage conditions of 25ºC±2 ºC/60%±5% RH which are not as per Zone IV-A.**

- **Scientific justification for selecting dissolution specifications [i.e. NLT 85% (Q=80%) in 30 minutes] which are different from dissolution specifications of innovator product [i.e. NLT 85% in 15 minutes]. Moreover, how CDP results can be representative of whole 6 months accelerated and real time stability study storage conditions.**
- **Scientific justification for performance of stability study data at M/s OBS Pakistan Pvt. Ltd, Karachi while applicant firm is M/s Aspin Pharma (pvt.) Ltd., Plot No. 10 & 25, Sector 20, Korangi Industrial Area, Karachi.**

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
1498.	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.	Dapaduo XR Tablets 10/500mg Each film coated tablet contains: Dapagliflozin (as propanediol monohydrate) (immediate release)…..10mg Metformin hydrochloride (Extended release)….500mg (Anti-diabetic)	Form 5-D Dy No. 16127 07-03-2019 PKR 50,000/- 05-03-2019 As per SRO	XIGDUO XR Tablet (**USFDA** Approved) GMP Inspection conducted on 10-10-2018 & 17-10-2018 concluded that the panel unanimously recommended for the grant of cGMP certificate.

STABILITY STUDY DATA

Drug	Dapaduo XR Tablets 10/500mg		
Name of Manufacturer	M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad.		
Manufacturer of API	**Dapagliflozin:** Hangzhou Huadong Medicine group Zhejiang Huayi Pharmaceutical Co. Ltd.		
	Metformin: Abhilasha Pharma Pvt. Ltd. Plot No. 1408,1409 GIDC Ankleshwar Gujrat India		
API Lot No.	**Dapagliflozin:** C017-51710001		
	Metformin: MET123/17		
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 (months)		
Batch No.	T #01	T #02	T #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	08-2018	08-2018	08-2018
Date of Initiation	13-08-2018	13-08-2018	13-08-2018
No. of Batches	03		
Date of Submission	16127 (07-03-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate (No. ZJ20170047) issued by CFDA, valid till 02-07-2022.
		Metformin: Copy of GMP certificate (No. 1706138) issued by Food and Drugs Control Administration Gujrat state India, valid till 01-06-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Dapagliflozin:** ADC attested invoice dated 16-3-2018 specifying import of 300g dapagliflozin propanediol monohydrate.
		Metformin: ADC attested invoice dated 6-09-2017 specifying import of 1000g metformin hydrochloride.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Registration Board decided to approve registration of "DASCOT 30 mg Tablets (Daclatasvir 30 mg)" & "DASCOT 60 mg Tablets (Daclatasvir 60 mg)" as well as VELSCOT 400mg/100mg Tablet by M/s Scotmann Pharmaceuticals, 5-D, I-10/3, Industrial Area, Islamabad. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelerated studies for six months. Date of Inspection: 26-01-2018. • The HPLC software is 21 CFR compliant. • The firm has demonstrated all audit trail reports for DASCOT 30 & 60mg tablet.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Dapagliflozin:** ADC attested invoice dated 16-03-2018 specifying import of 300g dapagliflozin propanediol monohydrate.
		Metformin: ADC attested invoice dated 6-09-2017 specifying import of 1000Kg metformin hydrochloride.

3.	Documents for the procurement of reference standard and impurity standards.	Firm has submitted documents for procurement of working and impurity standards.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Dapagliflozin:** Firm has submitted copy of GMP certificate (No. ZJ20170047) issued by CFDA, valid till 02-07-2022.
		Metformin: Copy of GMP certificate (No. 1706138) issued by Food and Drugs Control Administration Gujarat state India, valid till 01-06-2019.
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	Firm has submitted certificate of analysis of API, working standard and impurity standard.
7.	Documents for the procurement of excipients used in product development?	The firm has submitted copy of Commercial invoices/COAs of all the excipients used in the formulation of applied product
8.	List of qualified staff involved in product development with relevant experience.	The firm has submitted List of qualified staff involved in R&D department.
Production Data		
9.	Authorized Protocols/SOP for the development & stability testing of trial batches.	The firm has submitted copy of protocols for product development for applied product.
10.	Complete batch manufacturing record of three stability batches.	The firm has submitted copy of Batch Manufacturing Records of three Batches
11.	Record of remaining quantities of stability batches.	Firm has submitted record of remaining quantities of the stability batches as: T#01: 196 tablets T#02: 196 tablets T#03: 196 tablets
QA / QC DATA		
12.	Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)	Firm has submitted copies of data logger record for stability chambers with real time and accelerated stability testing
13.	Method used for analysis of API along with COA.	The firm has submitted method used for analysis of API along with COA.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted Finished Product Testing method for the finished product
15.	Reports of stability studies of API from manufacturer.	The firm has submitted data sheets for real time and accelerated stability study data for both API as per the conditions of Zone IV-A.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has submitted the compatibility profile of all excipients used in their formulation through various literature sources including handbook of pharmaceutical excipients and FDA NDA product chemistry review.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 buffers against reference product. The firm has calculated f2 values and their results are within acceptance criteria.

19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	Firm has submitted audit trail reports for the testing of their product.

Remarks of the evaluator:
Firm's dissolution specification for Dapagliflozin layer was NLT 85% in 30 and 45 minutes, the dissolution for the FDA approved reference product is performed at 30 minutes. The results of dissolution were above 85% at 30 minutes.

Decision: Registration Board decided to approve registration of Dapaduo XR Tablets 10/500mg by M/s. Scotmann Pharmaceuticals, 5D, I-10/3, Industrial Area, Islamabad. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

1499. Application on CTD format

MODULE 1: ADMINISTRATIVE

Section	Sub-Section	Heading
1.1		Covering Letter and Fee Deposit Slip Submitted Dy. No. 3942 dated 29-01-2019, PKR: 100,000/- dated 15-01-2019
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 AGP Limited, B-23-C, S.I.T.E., Karachi**
	1.3.2	Name, address and contact details of Manufacturing site. M/s Mylan Laboratories Limited, Plot No. 20 & 21, Pharmez, Sarkhej-Bavla natonal Highway no. 8-A, Near Village – Matoda, Tal-Sanand, Dist. – Ahmedabad -382 213, India.
	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. Drug sale license by way of whole sale Validity: 21-09-22019 Address: M/s AGP Limited, B-23-C, S.I.T.E., Karachi
	1.3.5	Evidence of approval of manufacturing facility / Approved Section from Licensing Authority The firm has provided Parenteral (SVP) Sex hormone section as evident from GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India
	1.3.6	List of already approved registered drugs in this section Submitted
	1.3.7	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance Provided
	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) □ **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. Medroxyprogesterone injectable suspension USP 150mg/ml
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit 150mg /ml
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance. DIMPLE
	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 pack [One vial in a carton] 25's pack [25 vial in a carton] 100's pack [100 vial in a carton] PKR 519.91/- for 1 vial of 1ml PKR 12997.75/- for 25 vials of 1ml PKR 51991.00/- for 100 vials of 1ml
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API) Progestogens, ATC code: G03AC06
	1.5.6	Pharmacopoeial reference / Status of applied formulation USP
	1.5.7	Route of administration Intramuscular route of administration
	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. Depo Provera Injection of M/s Pfizer laboratories (Reg#000607) Megesteron of OBS Healthcare (Pvt.) Ltd (Reg#025226)
	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. USFDA approved.
	1.5.10	Dosage form of applied drug Sterile injectable Suspension
	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
	1.5.13	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).
	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: 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.
	COPP Original, legalized CoPP issued by Food and Drug Control Administration confirm GMP status of the firm and free sale status of product in country of origin. The certificate is valid till 24/07/2019. **Letter of Authorization** Original legalized letter of authorization between Mylan and AGP made on 19th September, 2018 declare that the products shall be distributed in the territory by the AGP.	

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

2.3 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 Submitted	
2.6	Non-Clinical Written and Tabulated Summaries (Normally not required for generics) Not applicable	
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***
	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** ***Not submitted***
	3.2.S.2.3	**Control of Materials** ***Not submitted***
	3.2.S.2.5	**Process Validation and/or Evaluation** ***Submitted***
	The firm has referred to WHO PQ number : WHOAPI-210 for description of manufacturing process and process controls and control of materials. The firm has procured API from M/s FARMABIOS S.p.A, ITALY.	
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** 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***
	The firm has referred to WHO PQ number : WHOAPI-210 for stability data. The firm has submitted document of WHO namely "Confirmation of active pharmaceutical ingredient Prequalification (CPQ)" which confirms that API is prequalified by WHO.	

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 ***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***
	The firm has submitted dissolution test as per USFDA recommended method. However comparative dissolution profile with innovator formulation was not performed.	
3.2.P.3	**MANUFACTURE**	
	3.2.P.3.1	**Manufacturer(s)** ***Submitted*** 2. Name and full address(es) of the facility(ies) 3. 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*** 2. Testing specifications (including identification and characterization) 3. 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** ***Submitted*** (if using Pharmacopoeial procedure, must provide verification of Pharmacopoeial procedure)
	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** ***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
3.2.P.8	**STABILITY**	
	3.2.P.8.1	**Stability summary and conclusion (Finished Dosage Form)** ***Submitted***
		2. Stability protocol submitted 3. Expiration dating period for marketed packaging 4. Expiration dating period for bulk packaging (if applicable)
		Comments
	3.2.P.8.2	**Post-approval Stability Protocol and Stability Commitment** ***Not applicable***
		Comments
	3.2.P.8.3	**Stability** ***Submitted***
		The firm has submitted 6 month accelerated stability study data and 24 months long term stability study data for three batches. Batch # 6475A001 Batch # 6475A002 Batch # 6475A003
Decision: Approved as per policy for inspection of manufacturer abroad.		

Case No.1: Request For Change In Registration Status of Product(s) From M/s. GlaxoSmithKline Pakistan Ltd, Karachi to M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd, Karachi.

M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd [Formerly M/s GSK OTC (Pvt) Ltd.], Petaro Road Jamshoro (DML #000010) has requested to change the registration status of following products from M/s. GlaxoSmithKline Pakistan Ltd, Karachi to their name. Detail is 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.	000817	Panadol Tablet Each tablet contains: Paracetamol…..500mg	1-15-08-2019 2- Transfer of Registration in the name of M/s GSK Pakistan Ltd., D/43, Textile Avenue, SITE, Karachi vide Letter No.3-3/2003-Reg-II (M-179) dated 15th September 2003. 3- Permission for extension in contract manufacturing issued to M/s GSK F-268, Karachi (dated 12-10-2015) **valid upto 30.06.2020.** 4-Last Renewal Application Dated 13-06-2018	M/s GSK Pakistan Ltd., F-268, S.I.T.E, Karachi (DML#000233) On contract manufacturing from M/s Pharmatec Pakistan (Pvt) Ltd, D-86/A, S.I.T.E, Karachi	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) UK MHRA approved formulation.
2.	008492	Children's Panadol Liquid Each 5ml contains: Paracetamol BP……160mg	1- F.No.6-7/85-Reg-II (M-80) dated 05-11-1985 in the name of M/s Sterling Products (Pak) Ltd, Karachi. 2- Transfer of Registration in the name of M/s GSK Pakistan Ltd., D/43, Textile Avenue, SITE, Karachi vide Letter No.3-3/2003-Reg-II (M-179) dated 15th September 2003. 3- Permission for extension in contract manufacturing issued to M/s GSK F-268, Karachi (dated 12-10-2015) **valid upto 30.06.2020.** 4-Last Renewal Application Dated 13-06-2018	M/s GSK Pakistan Ltd., F-268, S.I.T.E, Karachi (DML#000233) On contract manufacturing from M/s Pharmatec Pakistan (Pvt) Ltd, D-86/A, S.I.T.E, Karachi	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) Oral solution is available in Health Canada with status of "DORMANT"
3.	008556	Children's Panadol Drops Each 0.8ml contains: Paracetamol BP ……80mg.	1-F.No.6-7/85-Reg-II (M-80) dated 05-11-1985 in the name of M/s Sterling Products (Pak) Ltd, Karachi. 2- Transfer of Registration in the name of M/s GSK Pakistan Ltd., D/43, Textile	M/s GSK Pakistan Ltd., F-268, S.I.T.E, Karachi (DML#000233) On contract manufacturing from M/s	Duplicate Applications on From-5 along with photocopy fee challan of Rs.360,000/- (06-06-2016)

			Avenue, SITE, Karachi vide Letter No.3-3/2003-Reg-II (M-179) dated 15th September 2003. 3- Permission for extension in contract manufacturing issued to M/s GSK F-268, Karachi (dated 12-10-2015) **valid upto 30.06.2020.** 4-Last Renewal Application Dated 13-06-2018	Pharmatec Pakistan (Pvt) Ltd, D-86/A, S.I.T.E, Karachi	and Rs.900,000/- (27-06-2016) received on 17-06-2019 (Dy. No.560) USFDA approved as OTC product "INFANTS SILAPAP-acetaminophen solution/ drops" (Dailymed)
4.	012437	Panadol Extra Tablets Each Tablet contains: Paracetamol BP..500mg Caffeine BP…….65mg	1-21-03-1991 2- Transfer of Registration in the name of M/s GSK Pakistan Ltd., D/43, Textile Avenue, SITE, Karachi vide Letter No.3-3/2003-Reg-II (M-179) dated 15th September 2003. 3- Permission for extension in contract manufacturing issued to M/s GSK F-268, Karachi (dated 12-10-2015) **valid upto 30.06.2020.** 4-Last Renewal Application Dated 13-06-2018	M/s GSK Pakistan Ltd., F-268, S.I.T.E, Karachi (DML#000233) On contract manufacturing from M/s Pharmatec Pakistan (Pvt) Ltd, D-86/A, S.I.T.E, Karachi	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) Standard formulation approved by RRAs (TGA) is "**film coated**"
5.	000394	Iodex CMS Ointment (As per copy of Registration Letter dated 24-03-1976 the composition is not mentioned)	1- Letter No.Nil dated 24-03-1976 in the name of M/s Smith Kline and French of Pakistan Ltd, 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 30thAugust, 2003. 3- Last Renewal Application Dated 13-06-2018. **Remarks of RRR Section** Registration Board granted the renewal w.e.f 30-8-2018 to 29-08-2023 (Ref. F.No.3-10/2019-RRR (M-288 Dated 26-06-2019)	GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi (DML#000233)	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: Iodex CMS Ointment Sublime Iodine ….4%w/w Methylsalicylate ……..5%w/w As per information submitted by the

					firm, formulation is approved in Mexico
6.	016868	ENO Lemon Powder Contains: Sodium Bicarbonate …….34.16%w/w Sodium Bicarbonate Fine…..11.39%w/w Citric Acid (anhydrous)…….43.10%w/w Sodium Carbonate (anhydrous)…….10.00%w/w Sodium Carbonate Decahydrate…….0.25%w/w	1- F.No.3-1/95-Reg-II (M-112) dated 18-04-1995 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 13-06-2018 **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)	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: ENO Fruit Salt Lemon Each 5gm contains: Sodium Bicarbonate ….2.277gm Sodium Carbonate.0.5gm Citric Acid ….2.155gm Label claim needs to be standardized/ corrected as per UK MHRA
7.	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 13-06-2018 **Remarks of RRR Section (27-07-2019)** ENO Fruit Salt Orange Reg No. 019645 as mentioned by the concerned section and	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

			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 (L, R,A).		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.
8.	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 15th September, 2003. 3- Last Renewal Application Dated 13-06-2018 **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)	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.

9.	073487	Panadol Expectorant Syrup Each 5ml contains: Guaifenesin..100mg Phenylephrine HCl ….....5mg Triprolidine HCl ……..1.25mg	1- Letter. No. 3-8/2010-Reg-II (M-229) dated 16-11-2012. 2- 1st Renewal Application Dated 12-10-2017	GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi (DML#000233)	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) As per information submitted by the firm, formulation is approved in Singapore.
10.	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 consider in meeting of Registration Board for the regularization of renewal application of 2016 and validity granted till 09-06-2021	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.

11.	029329	Hydrozole Cream Hydrocortisone……. 1% w/w Clotrimazole…1% w/w	1- F.No3-7/2002-Reg-II (M-175) dated 14-12-2002 in the name of M/s Stiefel Laboratories, Gujranwala. 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.	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) TGA approved formulation.
12.	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,	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.

			West Wharf Karachi dated **26-06-2019**		
13.	076453	Panadol Forte Suspension Each 5ml contains: Paracetamol…..250mg (BP Specifications)	1- F.No.3-2/2014-Reg-II (M-243) dated 10-07-2014. 2- Last Renewal Application Dated 08-05-2019	GlaxoSmithKline Pakistan Limited F-268, S.I.T.E, Karachi (DML#000233)	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.

Decision: Registration Board decided as follows:

i. **Cancellation of registration of products at S.No. 1-4 from the name of M/s GlaxoSmithKline Pakistan Ltd., F-268, S.I.T.E, Karachi (DML #000233).**

ii. **Approved registration of products at S.No. 1-4 in the name of M/s. GlaxoSmithKline Consumer Healthcare Pakistan Ltd., Petaro Road Jamshoro (DML #000010) through contract manufacturing by M/s. Pharmatec Pakistan (Pvt) Ltd., D-86/A S.I.T.E., Karachi. Furthermore, fee challan shall be verified as per procedure approved by the Borad 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. 5-13 for confirmation of approval status of required manufacturing facilities from Licensing Division. Furthermore, w.r.t products at S.No. 5, 6, 9 & 10, the Board also advised the firm for submission of evidence of approval status of applied formulations in Reference Regulatory Authorities.**

Case No.2: Approved Products of M/s Bloom Pharmaceuticals, Hattar

Registration Board in its 277th meeting, held on 27-29th December, 2017, approved the following products of M/s Bloom Pharmaceuticals Hattar.

Sr.#	Product Name & Composition	Decision of M-277
1.	Blutant 12.5mg capsule Each capsule contains: Sunitinib (as Malate)……..12.5mg	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.
2.	Blutant 25mg capsule Each capsule contains: Sunitinib (as Malate)……25mg	
3.	Blufenib 200mg tablets Each film coated tablet contains: Sorafenib (as Tosylate)……...200mg	
4.	Bluhydra 500mg capsule Each capsule contains: Hydroxyurea……..500mg	

Later on, Registration Board in its 282nd meeting, held on 14th - 15th May, 2018, while considering manufacturing requirements for "cytotoxic drugs", decided as under:

Registration Board deliberated the case in detail and decided as under:

a. *The manufacturing of cytotoxic drug shall be carried out in a dedicated or self-contained facilities and manufacturer's shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.*
b. *"Anti-neoplastic Drugs (L01 class)" of WHO Anatomical Therapeutic Chemical (ATC) classification (ATC) system shall be considered as reference for categorization of drugs as Cytotoxic/Antineoplastic.*

In accordance with the above mentioned decision, registration certificate of above mentioned products, for being categorized under **"WHO-ATC L01 Class",** has been withheld.

Decision: Registration Board decided to reject the applications at S.No.1-4 of above table since M/s Bloom Pharmaceuticals, Hattar does not have requisite manufacturing facility. Furthermore, the approval of above mentioned products in 277th meeting shall be considered as redundant.

Case No.3: Review/ Suspension/Cancellation of Previously Granted Approvals/ Registrations.

Registration Board in its 282nd meeting held on 14th - 15th May, 2018 decided to issue show-cause to M/s Bryon Pharmaceuticals, Peshawar with respect to their following approved/registered products inadvertently approved vide 274th meeting of Registration Board, however, the firm does not possess requisite manufacturing facility.

S#	Name of Firm	Requisite Section	Name of Product, Composition & Registrations Number	Reference of RB meetings for grant of approvals
I	***II***	***III***	***IV***	***V***
1	M/s Bryon Pharma (Pvt) Ltd, Peshawar	Capsule Section (Cephalosporin)	Cloratec 250 mg Capsule Each capsule contains: Cefaclor as monohydrate…….250mg (USP Specifications) (086998)	M-274 (Approved under the brand name of Uniclor)
			Cloratec 500 mg Capsule Each capsule contains: Cefaclor as monohydrate…….500mg	M-274 (Approved under the brand name of Uniclor)

			(USP Specifications) (086999)	
			Ledroxil 500 mg Capsule Each capsule contains: Cefadroxil as monohydrate…500mg (USP Specification) (Registration letter under process)	M-274 (Approved under the brand name of Ledroxil)
		Dry Suspension Section (Cephalosporin)	Caredrox 250 mg Oral Suspension Each 5ml contains: Cefadroxil as monohydrate….250mg (USP Specifications) (086995)	M-274 (Approved under the brand name of Ledroxil)
			Cloratec 125 mg Oral Suspension Each 5ml contains: Cefaclor as monohydrate….125mg (USP Specifications) (086996)	M-274 (Approved under the brand name of Uniclor)
			Cloratec 250 mg Oral Suspension Each 5ml contains: Cefaclor as monohydrate ….250mg (USP Specifications) (086997)	M-274 (Approved under the brand name of Uniclor)

Accordingly, the firm was issued show cause notice on 17-10-2018. However, the firm has now been issued Dry powder suspension (Ceph) & Capsule (Ceph) sections vide Licensing Division letter No. F.3-7/92-Lic (Vol-I) dated 28-01-2019. Furthermore, the firm has also submitted reply to show cause notice stating that "they had never applied registration of Cephalosporin products with any deceitful intent. They applied for registration only when they had their section ready and had submitted a request for inspection, moreover they didn't misuse the registration by manufacturing any of these products". Furthermore, the firm has assured that not a single unit of any of these products was either manufactured nor would be manufactured till that time DRAP official approved the section and permission is granted to start production.

Decision: **Registration Board considered the reply of the firm and noted that the firm has made application for approval of Cephalosporin Section to Licensing Division before filing registration applications. Moreover, the firm has also submitted that they had filed registration applications in anticipation that their section will be approved by the time their registration applications are considered by the Registration Board. However, due to some unforeseen reasons approval for section was delayed. The firm further stated that they had never manufactured the products since the grant of registration.**
The Board, in view of the position explained above decided that the previous registration approvals may continue, however the firm may be warned for not apprising the updated status of approved section in time.

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

a) M/s Hudson Pharma (Pvt) Ltd., Karachi Pakistan

Registration Board in its 282nd meeting, held on 14th - 15th May, 2018, approved the following products of M/s Hudson Pharma (Pvt) Ltd.' D-93, North Western Industrial Zone Port Qasim, Karachi Pakistan.

Sr. No.	Product Name & Composition	Decision of M-282
1.	Nepasone Eye Drops 0.1% Each ml contains: Nepafenac…..10mg	Approved. Reference will be sent to Budget & Accounts Division for verification of challan and Board authorized its Chairman for the issuance of registration letter.

As per duplicate dossier received from PEC, the firm has applied as under:

"Nepasone Eye Drops 0.1%
Each ml con tains:
Nepafenac…..1mg"

Registration Certificate has been issued accordingly.

b) M/s Getz Pharma, Karachi

S.#	Product Name & Composition	Decision of M-262	Correct/standard composition/ label claim
1.	Rocurex 50mg/5ml Solution for Injection Each ml contains: Rocuronium Bromide…50mg	Approved. Reference will be sent to B&A Division for verification of challan and Chairman RB will authorize issuance of registration letter	Each ml contains: Rocuronium Bromide….10 mg
2.	Rocurex 100mg/10ml Solution for Injection Each ml contains: Rocuronium Bromide…100mg	Approved. Reference will be sent to B&A Division for verification of challan and Chairman RB will authorize issuance of registration letter	Each ml contains: Rocuronium Bromide….10 mg
3.	Acuria 50mg/5ml Injection Each ml contains: Atracurium Besylate ….50 mg	Approved. Reference will be sent to B&A Division for verification of challan and Chairman RB will authorize issuance of registration letter	Each ml contains: Atracurium Besylate ….10 mg

M/s Getz, Karachi requested for issuance of registration certificate with correct label claim (as mentioned in last column of above table) and submitted DRAP's acknowledged receipt of instant application along with copy of form-5 & fee deposit slips as evidence for their applied formulation/label claim. Registration Certificates has been issued accordingly.

Decision: Registration Board noted the information regarding correction in label claims of above mentioned products as mentioned alongside each case in the last column of above table.

Case No.5: Request for Change in Registration Status of Products from M/s Zafa Pharmaceuticals Laboratories (Private) Ltd, Baluchistan To Zafa Pharmaceuticals Laboratories (Private) Ltd, Karachi.

M/s. Zafa Pharmaceuticals Laboratories (Private) Ltd, L-4/1 A&B, Block 21, Federal B Industrial Area, Karachi (DML 000040) has requested to change the registration status of following products from M/s. Zafa Pharmaceuticals Laboratories (Private) Ltd, Plot No.C-208- & C-217. H.I.T.E, Lasbella, Baluchistan (DML # 000470) to their name. Details are as under:

Sr. No.	Reg. No.	Name of Drug (s) & Composition	1.Initial letter of registration 2. Renewal status.	Dy. No. & Date/ Remarks
1.	031287	CP Zaf Infusion 0.2% w/v Each ml contains:- Ciprofloxacin (as Lactate) BP …..2mg	1. Initial Reg. Letter Dated 02-10-2003 Renewal dated: 21-08-2008 16-07-2013 **Remarks of RRR Section (23-05-2019)** Renewal application of year 2018 received on 30-07-2018 i.e., within time under Rule 27 of Drugs LRA Rules, 1976	Dy.No.1858 (31-8-2018) Rs.20,000/- (2-01-2015) Duplicated Dossier Applied Label claim as per form-5: Each 100ml contains:- Ciprofloxacin Lactate eq. to Ciprofloxacin ……..200mg (BP Specification)
2.	026232	Metrida I.V Infusion Each 100ml contains:- Metronidazole……..500mg	Dated: 19-09-2000 Renewal dated: 12-07-2005 17-08-2010 & 09-06-2015	Dy.No.1857 31-08-2018 Rs.20,000/-

			Remarks of RRR Section (23-05-2019) Renewal application of year 2015 received on 09-06-2015 i.e., within time under Rule 27 of Drugs LRA Rules, 1976	(02-01-2015) Duplicated Dossier Demanded Specifications: BP

The management of the firm has provided following documents:-

i. Application on Form-5 with Fee of Rs. 20,000/- for each product (Duplicate).
ii. Copies of initial letters of registration and renewal status as stated in column V above.
iii. Section (Liquid Injectable Vial) approval of M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd., L-4/1 A&B, Block 21, Federal B Industrial Area, Karachi (DML 000040), verified from panel inspection report for renewal of DML dated 11-02-2018.
iv. Copy of last GMP inspection report of M/s. Zafa, Karachi (DML 000040) dated 18-07-2019 (Conclusion: Firm is operating with acceptable level of compliance of cGMP and need extensive work plan for improvement).
v. DML of M/s. Zafa, Karachi dated 30-05-2015.
vi. NOC from M/s. Zafa Pharmaceuticals Laboratories (Private) Ltd, Plot No.C-208- & C-217. H.I.T.E, Lasbella, Baluchistan (DML # 000470) dated 09-08-2019.
vii. Undertakings in the light of SOPs approved vide M-283.

Decision: Registration Board decided as follows:

i. Cancellation of registration of products at S.No. 1-2 from the name of M/s. Zafa Pharmaceuticals Laboratories (Private) Ltd, Plot No.C-208- & C-217. H.I.T.E, Lasbella, Baluchistan (DML # 000470).

ii. Approved registration of products at S.No. 1-2 in the name of M/s. Zafa Pharmaceuticals Laboratories (Private) Ltd, L-4/1 A&B, Block 21, Federal B Industrial Area, Karachi (DML 000040). Furthermore, fee challan shall be verified as per procedure approved by the Borad in its 285th meeting.

iii. Reference will be sent to Costing and Pricing Division for confirmation of maximum retail price (MRP).

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

Registration Board in its 289th meeting, held on 14th -16th May, 2019 approved the following products of M/s Aries Pharmaceuticals Peshawar.

I	II	III
Sr. No.	**Brand name of drug with composition and demanded specifications**	**Decision of M-289**
1.	Kecef IV/IM Injection 250mg Each vial contains: Cefotaxime as Sodium…….250mg USP	Approved.
2.	Kecef IV/IM Injection 500mg Each vial contains: Cefotaxime as Sodium…….500mg USP	Approved.
3.	Kecef IV/IM Injection 1000mg Each vial contains: Cefotaxime as Sodium…….1000mg USP	Approved.

4.	Arizon IV Injection 250mg. Each vial contains: Ceftriaxone as Sodium…….250mg. USP	Approved.
5.	Arizon IV Injection 500mg. Each vial contains: Ceftriaxone as Sodium…….500mg. USP	Approved.
6.	Arizon IV Injection 1.0gm. Each vial contains: Ceftriaxone as Sodium…….1.0gm. USP	Approved.

However, while processing for issuance of registration certificate, the firm informed that above mentioned formulations are already registered in the name of M/s Aries, Peshawar on contract basis from M/s Medicraft, Peshawar (valid upto 30-06-2020). However, the firm has now been granted approval for "Dry Powder Vial Injection (Cephalosporin)" by CLB in its 269th meeting. Accordingly, the firm has now requested for cancellation of below mentioned registrations.

S.No	Reg. No.	Name of Drug (s) & Composition	Contract manufacturer
1	054672	Arizon 250 mg Injection I.V. Each vial contains:- Ceftriaxone Sodium ≡ Ceftriaxone…….250 mg (USP Specification)	M/s. Medicraft, Pharmaceuticals Peshawar
2	054673	Arizon 500 mg Injection I.V. Each vial contains:- Ceftriaxone Sodium ≡Ceftriaxone…,……..…500 mg (USP Specification)	-do-
3	054674	Arizon 1 gm Injection I.V. Each vial contains:- Ceftriaxone Sodium ≡Ceftriaxone……1 gm (USP Specification)	-do-
4	054675	Kecef 250 mg Injection Each vial contains:- Cefotaxime Sodium Sterile ≡ Cefotaxime…….250 mg (USP Specification)	-do-
5	054676	Kecef 500 mg Injection Each vial contains:- Cefotaxime Sodium Sterile ≡ Cefotaxime…….500 mg (USP Specification)	-do-
6	054677	Kecef 1 gm Injection Each vial contains:- Cefotaxime Sodium Sterile ≡ Cefotaxime…….1 gm (USP Specification)	-do-

Decision: Registration Board decided to de-register/cancel the products at S.No. 1-6 of above table, registered in the name of M/s. Aries Pharmaceuticals (Pvt) Ltd,

1-W, Industrial Estate, Hayatabad, Peshawar on contract manufacturing from M/s Medicraft Pharmaceuticals, Peshawar.

Case No.7: Request For De-Registration of Products By M/s GSK Pakistan Ltd, Karachi.

M/s GSK Pakistan Limited, Karachi has applied for de-registration of their following registered products.

S. No.	Reg. No.	Brand name and composition	Justification	Alternate Brands	Date of Reg. & Last Renewal Status
I	II	III	IV	V	VI
1.	005487	Amikin Injection 250mg/ml Each 2ml contains: Amikacin ……...250mg	➢ Suitable therapeutic alternatives and advanced therapies are available in the market. ➢ Better/ new molecules to cater the same portfolio are also available in the market. ➢ Virtually there is no demand of this product in local market.	1. Amikaye 2. Amkay 3. Grasil	24-02-1986 17-09-2015
2.	009002	Azactam Injection 1gm Each vial contains: Azetreonam…….1gm		1. Tanzo 2. Tazocin 3. Tazopip	24-02-1986 17-09-2015
3.	009001	Azactam Injection 500mg Each vial contains: Azetreonam…….500mg		1. Tanzo 2. Tazocin 3. Tazopip	24-02-1986 17-09-2015
4.	034392	Cefzil Suspension 250mg/5ml Each 5ml contains: Cefprozil……..…250mg		1. Neozole 2. Zilpro 3. Buticef	13-11-2004 17-09-2015
5.	034391	Cefzil Suspension 125mg/5ml Each 5ml contains: Cefprozil……..…125mg		1. Neozole 2. Zilpro 3. Buticef	13-11-2004 17-09-2015
6.	046990	Halovate 0.5mg Cream Each gm contains: Halobetasol Propionate….0.50mg (USP)		1. Cutivate 2. Ticovate 3. Cosvate	20-09-2007 18-08-2016
7.	046989	Halovate 0.5mg Ointment Each gm contains: Halobetasol Propionate….0.50mg (USP)		1. Dermafuse-H 2. Fucimega-H 3. Cutivate	20-09-2007 18-08-2016
8.	046991	Halovate 0.5mg Lotion Each ml contains: Halobetasol Propionate….0.50mg (USP)		1. Clobederm-S 2. Clobetrex-S 3. Ticovate	20-09-2007 18-08-2016
9.	010300	Kenacomb Otic Drops Each gm contains: Triamcinolone Acetonide …..1mg Neomycin base (as Neocmycin Sulphate) included 10% excess……..2.75mg Gramicidin includes 10% 0.275mg Nystatin includes…..35% excess 135,000 Units Plastibase 5W q.s……..1gm		1. Xecomb 2. Otosporin 3. Otocaine	19-02-1990 17-09-2015
10.	005026	Kenacomb Ointment (Composition is not mentioned on Registration Letter)		1. Ulticomb 2. Econophen 3. Fucidin-H	08-09-1979 17-09-2015
11.	005807	Kenacort A Tincture Contains:- Triamcinolone Acetomide…..0.2%		1. Lonacort Oitment 2. Kenalog in	11-04-1981 17-09-2015

		Benzal Konium Chloride….0.05% Salicylic Acid……..2%		Orabase	
12.	004725	Kenacort Tablet 4mg (Composition is not mentioned on Registration Letter)		1. Lonacort 2. Tricort 3. Medikort	01-07-1979 17-09-2015
13.	006076	Kenoidal Rectal Ointment Per gram contain: Thriamcinolone Acetonide……1mg Lidocaine Base U.S.P……..50mg		-	13-06-1982 17-09-2015
14.	003600	Moditen 1mg Tablet (Composition is not mentioned on Registration Letter)		1. Dosik 2. Medinac 3. Serenace	07-05-1985 17-09-2015
15.	001864	Vagmycin Vaginal Cream Each 4gm contains: Tetracycline……100mg (as Hydrochloride) Amphotericin B……50mg		1. Supramycin-100 2. Vibramycin 3. Nordox	12-05-1988 17-09-2015
16.	001865	Vagmycin Vaginal Tablet Each tablet contains: Tetracycline……100mg (as Hydrochloride) Amphotericin B……50mg		1. Supramycin-100 2. Vibramycin 3. Nordox	12-05-1988 17-09-2015
17.	004819	Volog Cream		1. Cortival 2. Cosvate 3. Cutivate	01-07-1979 17-09-2015

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 referred the case to DRAP's committee for availability of drugs for their opinion.

Case No.8: Request for De-Registration of Bulk Import/Local Repack of Omega Infusion by M/s Ferozsons Laboratories Limited, Nowshera

M/s Ferozsons Laboratories Limited, Amangarh, Nowshera has applied for de-registration of bulk import/local repack of "Omega Infusion" & no objection to grant brand name of "Omega" to BF Biosciences Limited.

S. No.	Reg.No.	Brand name and composition	Date of Reg. & Last Renewal Status
I	II	III	III
1.	029023	Omega Infusion Each vial contains: Omeprazole Sodium 42.6mg eq. to Omeprazole……40mg Import in bulk from Changzhou Siyno China and repacking locally for a period of 2 years.	02-12-2008 29-11-2017

The firm has provided following information/ documents:-

a) Application.

b) Copy of registration letter and last renewal status.

c) Justification stating BF Biosciences Limited, Lahore (A subsidiary of Ferozsons Laboratories, Nowshera) has been granted approval for local manufacturing of Omeprazole Infusion with brand name of Omera 40mg Infusion (Reg # 098036)

d) An undertaking that:

i. No case is pending at any forum / court of law regarding this product.

ii. Provided information/ documents are true/ correct.

Decision: **Registration Board acceded to the request of M/s Ferozsons Laboratories Limited, Amangarh, Nowshera for de-registration of bulk import/local repack of "Omega Infusion (R#029023)" & no objection to grant brand name of "Omega" to BF Biosciences Limited.**

Case No.9: Request For Change in Registration Status of Products From M/s OBS Pakistan (Pvt.) Ltd, Karachi To M/s. Aspin Pharma, Karachi.

Registration Board, in its 289th meeting held on 14th -16th May, 2019, deferred the request of M/s. Aspin Pharma (Pvt.) Ltd; Plot No.10 & 25, Sector 20, Korangi Industrial Area Karachi-74900 for change of registration status of following product from M/s. OBS Pakistan (Pvt.) Ltd; Karachi to their name ***for submission of evidence of approval status of applied formulation by Reference Regulatory Authorities***. Details are given as under:

S. No.	Reg.No.	Brand name and composition	Registration History	Remarks
I	II	III	IV	V
1.	075820	Obsarib Capsule Each capsule contains: Ribavirin .....400mg (Manufacturer's specification)	Initial date of Reg. 03-04-2013 Last Renewal 18-01-2018	Dy.No7412 (R&I) 20-02-2019 Rs.20,000/- Duplicate Dossier

Management of the firm has submitted following documents/information:

i. Applications on CTD along with Original Fee challan for each product as mentioned in Column V.

ii. Copies of initial letters of registration and renewal status as stated in column IV above.

iii. Section approval of M/s Aspin verified from Licensing Division's letter for renewal of DML (dated 09th June, 2016) confirming following sections;

- Tablet (General)
- Capsule (General)
- Liquid Syrup
- Ointment/ Cream.

iv. Copy of last GMP inspection report of M/s Aspin, Karachi dated 08th August, 2018 indicating "Satisfactory" level.

v. NOC from M/s. OBS Pakistan (Pvt.) Ltd; Karachi dated 03-April 2019 & 31-12-2018.

vi. DML of M/s Aspin dated 31st May, 2015.

The firm has now submitted WHO Model List of Essential Medicines 2019 (21st Edition) stating **"Ribavirin in Solid Oral Dosage Form: 200mg; 400mg; 600mg"** for the treatment of viral hemorrhagic fevers.

Decision: **Registration Board deferred the case and advised the firm to submit evidence of approval status of applied formulation in Reference Regulatory Authorities.**

Case No.10: Registration for the products of M/s. English Pharmaceuticals Industries, Lahore.

Registration Board in 237th meeting considered the products of M/s. English Pharmaceuticals Industries, Lahore as per detailed below:-

Sr.No	Name of product and composition	Demanded pack size	Demanded MRP	Fee submission date	Decision (237th meeting)/ Remarks
1.	Coline 1gm Injection Each 4ml contains:- Citicoline sodium…..1gm	1's	-do-	Rs.8000/- dated 08.05.2009 Rs.52000/- dated 26.02.2013 ***Duplicate dosseir***	Formulation in instant strength is not approved in any of the reference drug agencies.
2.	Coline Syrup Each 5ml contains:- Citicoline sodium …..500mg	60ml	-do-	Rs.8000/- dated 08.05.2009 Rs.52000/- dated 26.02.2013 ***Duplicate dosseir***	Approval status in SRA not confirmed

Firm has submitted following documents:-

i. Application with fee or evidence of fee for this purpose
ii. Copy of Form-5
iii. Last GMP inspection report dated 16th January 2018

Registration Board in its 287th meeting deferred products for approval status in RRA. The products are avaialbe in **spain** and the firm has requested to grant them registration.

Decision:- Registration Board approved registration of products at Sr.1-2 in the name of M/s English Pharmaceutical Industries, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.

Case No.11: Registration of Drug(s) of M/s. Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd; Lahore.

Registration Board in its 236th meeting approved the following products of M/s. Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd; 137, Shahrah Maulana Jalauddin Roomi, Lahore, however, registration letter was not yet issued. The detail is as under:-

Sr.#	Name of Drug (s) and Composition	Pack Size	Demanded MRP	Decision of 236th RB
1.	Opidep Injection Each ampoule 1ml contains:- Naloxone HCl……0.4mg (Opioid antagonist)	1's 5's	Rs.150.00 Rs.750.00	Approved subject to the submission of SOP of HVAC system.
2.	Lefmid 20mg Tablets Each tablet contains:-	1's 10's	Rs.35.00 Rs.350.00	Approved subject to the submission of SOP of HVAC

	Leflunomide…….20mg			system and dissolution test.
3.	Uriflo Tablets 2mg Each tablet contains:- Doxazosin (as mesilate)…….2mg (selective alpha-1 blocker)	1's 20's	Rs.17.07 Rs.341.37	Approved subject to the submission of SOP of HVAC system and dissolution test.
4.	Clonac Tablets Each film coated tablet contains:- Aceclofenac BP……100mg (non-steroidal anti-inflammatory)	1's 20's	Rs.10.00 Rs.200.00	Approved subject to the submission of SOP of HVAC system and dissolution test.

Firm has requested to grant the registration of abovementioned products and submitted following documents for this purpose.

i. Copies of Form-5.
ii. Copy of fee challans of Rs.8,000/- for each products.
iii. Undertaking on stamp paper that they have not received the registration of above products earlier.
iv. DML renewal inspection report along with SOP's of HVAC.

Registration Board in 290th meeting deferred the request of firm for submission of remaining fee Rs.12,000 for each product for consideration by Registration Board. The firm has deposited fee of Rs.12,000/- for each product and requested to grant them registration of above products.

Decision:- Registration Board approved the registration of products at Sr.1-4 in the name of M/s. Lahore Chemical & Pharmaceutical Works (Pvt.) Ltd; Lahore.

Case No.12: De-Registration of Pulmonal DM Syrup of M/s CCL phamarceuticals (Pvt) Ltd, Lahore.

M/s CCL Pharmaceuticals (Pvt) Ltd, Lahore has requested for de-registration of Pulmonal DM syrup as per following details:

Reg.No.	Brand Name & Composition	Reason for de-Registration	Remarks
068110	Pulmonal DM Syrup Each 5ml contains: Dextromethorphan Hydrobromide….10mg Pseudoephedrine HCl….300mg	Firm is not interested to market the product as same category therapeutic products are frequently available in market.	The firm has also applied for change of brand name of Epinol Cough Syrup to Pulmonal DM Syrup.

Registration Board in its 279th referred the case to DRAP's committee for availability of drugs for their opinion.

The firm has again submitted application alongwith following documents as per SOPs for de-registration of above product.

1. Copy of registration letter and last renewal.
2. List of alternative brands/FPPs available in the country.
3. An undertaking regarding no case is pending at any forum/court of law of this product and provided informatuion/documents are true.

Decision: - Registration Board deferred the request of the firm for scientific justification.

Case No.13: De-Registration of Drug(s) of M/s. Albro Pharmaceuticals, Lahore

M/s. Albro Pharmaceuticals (Pvt.) Ltd; 340-S, Industrial Estate, Kot Lakhpat Lahore has requested for de-registration of following products. Below products at Sr.No.1-2 are registered through contract manufacturing by M/s. Shrooq Pharma, Lahore and remaining are registered through contract manufacturing by M/s. Synchro Pharmaceuticals, Lahore. The firm has stated that there are so many product of same formulation are available in the market:-

Sr.#	Name of Drug (s) and Composition	Reg.No
1.	Albadrox 250mg Suspension Each 5ml contains:- Cefadroxil (as Monohydrate) …….. 250mg	050577
2.	Albadrox 500mg Suspension Each 5ml contains:- Cefadroxil (as Monohydrate) …….. 500mg	050578
3.	Alfur 125mg/5ml Dry Suspension Each 5ml contains:- Cefuroxime (as Acetil) …….. 125mg	055168
4.	Alfur 250mg Capsule Each capsule contains:- Cefuroxime (as Acetil) …….. 125mg	055169
5.	Alfur 250mg Injection Each vial contains:- Cefuroxime (as Acetil) …….. 250mg	055170
6.	Alfur 750mg Injection Each vial contains:- Cefuroxime (as Acetil) …….. 750mg	055171
7.	Tezda 500mg Injection Each vial contains:- Ceftazidine (as Pentahydrate) ….. 500mg	055176
8.	Tezda 1gm Injection Each vial contains:- Ceftazidine (as Pentahydrate) ….. 1gm	055177

Decision: - Registration Board acceded to request of the M/s. Albro Pharmaceuticals, Lahore and decided to cancel registration products at Sr. No. 1-8.

Case No. 14: Registration of M/s. Medipak Limited, 132, Industrial Estate, Kot Lakhpat, Lahore.

The Registration Board has deferred following products of M/s Medipak, Lahore in 243rd meetings for Product specific inspection by panel comprising of Director DTL, Lahore & area FID, Lahore .

S. No.	Name of Drug(s) with formulation	Demanxded MRP/Pack size	Remarks
1.	Napro Tablet Each tablet contains:- Naproxen (as sodium)…….550mg	As per SRO	USFDA approved formulation contains Naproxen sodium 550mg
2.	Napro Tablet Each tablet contains:- Naproxen (as sodium)……..275mg	As per SRO	USFDA approved formulation contains Naproxen sodium 275mg

The firm is requesting for approval of above mentioned products for registration.

Firm has submitted following documents:

a) Latest GMP inspection report dated 17.10.2017
b) Evidence of fee submission (Rs 12000/-) for each product.

Registration Board in its 286th meeting deferred the above products for confirmation of approval status in RRA. The products are available in USFDA as Naproxen base 250mg and 500mg.

Decision:- Registration Board approved the registration of products at Sr.1-2 in the name of M/s. Medipak Limited, 132, Industrial Estate, Kot Lakhpat, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.

Case No. 15: Registration of M/s. Hansel Pharmaceuticals, Lahore.

Following products of M/s. Hansel Pharmaceuticals (Pvt.) Ltd; Plot No.2 Pharma City, 30 Km, Multan Road, Lahore were approved in 231st meeting and registration letter was not issued. Accordingly decision of Registration Board is as under:

S.No.	Name of Drug(s)	Demanded Pack size	Demanded MPR	Decision of RB	Ramarks
1.	Queen Injection Each 1ml contains:- Mderoxyprogesterone Acetate (USP)……..150mg	1ml x 1s	As per SRO	Approved	Available in MHRA
2.	Progynor Injection Each 1ml ampoule contains:- Estradiol Valerate (USP)……10mg	1ml x 3s	As per SRO	Approved	Available in USFDA
3.	Gravinan Injection Each ml contains:- Hydroxyprogesterone Caproate(USP)……..250mg Estradiol Valerate (USP)……5mg	1ml x 1s 2ml x 1s	As per SRO	Approved	Needs RRA confirmation

Furthermore, following application was considered in 234th meeting and registration letter was not issued. Accordingly decision of Registration Board is as under:

S.No.	Name of Drug(s)	Demanded Pack size	Demanded MPR	Decision of RB	Ramarks
4.	Spasmae Injection Each 4ml ampoule contains:- Hydrated Phloroglucinol... 40mg Trimethylphloroglucinol. 0.04mg	4mlx6's	As per SRO	Deferred for salt review that whether the drug is suitable for human use or otherwise	Availabe in ANSM France.

Firm submitted following docuemtns:-

i. Applicaton dossier on Form-5.
ii. Ramining fee of Rs.12,000/- for each product.
iii. Copy of last DML renewal inspection report dated 15-5-2019 alongwith GMP certificate of liquid injectable (General) dated 18-07-2019. GMP certificate for liquid injectable (Hormone) is not granted till now due to reallocation of section from first floor to ground floor. In DML renewal inspection, penel also recommended approval of reallocated areas.
iv. Proof of manufacturing facility.

Decision: - Registration Board decided as follows: -

i. Approved the registration of products at Sr.1-2 & 4 in the name of M/s. Hansel Pharmaceuticals, Lahore.
ii. Deferred the product at Sr. No 3 for evidence of approval status of formulation in the reference regulatory authorities.

Case No. 16: Registration of M/s. Fynk Pharmaceuticals, Lahore.

The Registration Board in its 228th meeting deferred the following product of M/s. Fynk Pharmaceuticals 19-km G.T Road, Kalashah Kaku, Lahore as per following details:-

S.No.	Name of Drug(s) with composition	Demanded pack size	Demanded MRP	Decision of RB
1.	Citoclin Injection Each ml contains:- Citicoline….1gm	4ml	As per SRO	Deferred for review committee

The firm has further submitted that they had applied 1gm/4ml (Proof is copy of fee challans) and the same formulation already approved by Registration Board in its 275th meeting in favour fo M/s. Mediate Pharmaceuticals, Karachi. The firm has submitted copies of challans of Rs. 8000/- & Rs.12000/- respectively and requested to grant them registration of above product. Product is available in Spain.

Decision:- Registration Board approved the registration of above product 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.17. Change of Brand name of Product of M/s. CCL Pharmaceuticals, Lahore.

Registration Board in its 282nd meeting approved the following products of M/s. CCL Pharmaceuticals, Lahore as per following details:-

465.	Name and address of manufacturer / Applicant	CCL Pharmaceuticals (Pvt) Ltd 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pulmonol M Syrup 250mg/5ml Each 5ml contains:- Carbocysteine….250mg
	Diary No. Date of R& I & fee	
	Composition	Dy No. 476, 29-01-2015; PKR 20,000/-, 28-01-2015
	Pharmacological Group	(mucolytic agent)
	Type of Form	Form 5
	Finished product Specification	As per Innovator
	Pack size & Demanded Price	120mL/ As per brand leader
	Approval status of product in Reference Regulatory Authorities.	Mucodyne syrup 250mg/5ml by Lexon (MHRA Approved)
	Me-too status	Rhinathiol syrup by Sanofi Aventis
	GMP status	Last inspection report dated 8-3-2017 confirms satisfactory compliance to GMP
	Previous remarks of the Evaluator.	Firm has provided specifications of the innovator and also the commitments to conduct validation of analytical method. The submitted specifications (claimed to be of innovator) contains tests for physical description, pH, taste, odor, identification and assay while according to MHRA and Irish assessment report the specification of mucodyne should be as per pharmacopoeial monograph for 'Liquid preparations for oral use'. The general monograph for liquid preparations for oral use contains tests for fill volume, uniformity of mass and uniformity of dosage units as well.

Previous decision(s)	Deferred for following submission (M-269): ● Change of brand name as the same is registered for different active ingredient ● Latest GMP inspection report conducted within 1 year ● Clarification regarding the submitted innovator's specification as they do not contain test of general monograph for "liquid preparations for oral use" including fill volume, uniformity of mass and uniformity of dosage units as mentioned in the Irish and MHRA assessment report. ● Deferred for further deliberation for brand name of Pulmonol M for applied formulation (M-274). ● Registration Board deferred the case and advised PEC to present the case with detailed composition of already registered Pulmonol brands. Moreover Registration Board referred the case to QA & LT Division to conduct GMP inspection of Firm on priority (M-281).

Evaluation by PEC

- Firm has stated that "Pulmonol" is our registered trademark having TM No. 085475 dated (18-02-1985) in class 5 under section 33 of the Trade mark ordinance 2001, and following products are already registered in different composition and indicated for wide range of indications of upper respiratory tract disorders which are in line extension of Pulmonol range:
  i. Pulmonol syrup, Reg.# 00874
  ii. Pulmonol Flu Syrup, Reg.# 068109
  iii. Pulmonol DM Syrup, Reg.# 068110
  iv. Pulmonol Junior Syrup, Reg.# 068111
  v. Pulmonol CF Tablets, Reg.# 023982
- A similar case of change of brand name was presented n 263rd meeting of Registration Board wherein M/s. CCL Pharmaceuticals (Pvt) Ltd, Lahore had requested for change of brand name of their following product:

Names of Drug(s) with formulation	Reg. No.	New proposed names
Epinol CF Tablet Each tablet contains: Paracetamol……500mg Pseudoephedrine HCl….60mg Chlorpheniramine Maleate..4mg	023982	Pulmonol CF Tablet

Registration Board deliberated that suffix of brand name is different, thus the Board approved request of firm for change of brand name from Epinol CF Tablet to Pulmonol CF Tablet.

- The firm described that Pulmonol is their flagship brand name which covers the product indicated in disorder of upper respiratory tract especially cough and cold in different combination. Furthermore as per business strategy and marketing norms one brand name can be used for minutely different formulations of same category of products e.g Hydryllin syrup, Hydryllin DM syrup, Hydryllin Day syrup etc.
- Firm has submitted revised finished product specifications including test of filled volume, deliverable volume & Uniformity of dosage unit.
- Copy of Panel inspection conducted on 20-04-2018 & 24-04-2018 concluded that the firm was found to be operating at a satisfactory level of GMP compliance.
- The firm has submitted that we already have following four products registered with brand name Pulmonol in different composition and indicated for wide range of indications for upper respiratory tract disorders especially cough & cold. The detailed compositions of pulmonol brand names is as follows:

Brand Name	Composition
Pulmonol Syrup	Each 5ml contains: Chlorpheniramine Maleate BP …...5mg Terpin Hydrate USP …… 10mg Pot. Bicarbonate BP ……. 0.1mg Ammonium Chloride BP …….. 25mg Tr. Senega BP …….. 0.05ml Menthol BP …….. 1mg Aminophylline Ph. Eur. …….. 32mg Pot. Guaiacol Sulphate USP ……. 5mg Pot. Citrate BP ……... 0.1mg
Pulmonol Flu Syrup	Each 5ml Contains: Chlorpheniramine Maleate ….……1mg Pseudoephedrine HCI…….. 15mg Paracetamol …… 160mg Dextromethorphan HBr …….. 7.5mg
Pulmonol DM Syrup	Each 5ml Contains: Pseudoephedrine HCI …… 30mg Dextromethorphan HBr ……. 10mg
Pulmonol Junior Syrup	Each 5ml Contains: Promethazine HCl ……. 1.5mg Pholcodine …… 1.5mg Absolute Alcohol …… 3.8%
Pulmonol CF Tablet	Each tablet contain: Paracetamol ……..… 500mg Pseudoephedrine HCI …….…….60mg Chlorpheniramine Maleate ….. 4mg

Decision: Registration Board did not accede to firm's request for assigning brand name of "Pulmonol" for applied formulation because it can lead to medication errors due to different compositions. Hence Registration Board approved the applied formulation with change of brand name.

466.	Name and address of manufacturer / Applicant	CCL Pharmaceuticals (Pvt) Ltd 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Pulmonol M Capsule 375mg Dy No. 475, 29-01-2015; PKR 20,000/-, 28-01-2015 Each capsule contains:- Carbocysteine….375mg
	Diary No. Date of R& I & fee	
	Composition	
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished product Specification	Innovator's specifications
	Pack size & Demanded Price	30's/ As per Brand leader
	Approval status of product in Reference Regulatory Authorities.	Mucodyl Capsule by Sanofi (MHRA Approved)
	Me-too status	Rhinathiol Capsule by Sanofi
	GMP status	Last inspection report dated 21-03-2016 recommends the grant of renewal of DML
	Previous remarks of the Evaluator.	● Firm has provided specifications of the innovator without detailed method of analysis and also the commitments to conduct validation of analytical method. The submitted specifications (claimed to be of innovator) contains dissolution test with specification NLT 70% (Q) in 30 minutes

	Previous decision(s)	Deferred for following (M-269): ● Change of brand name as the same is registered for different active ingredient ● Latest GMP inspection report conducted within 1 year ● Clarification regarding the submitted innovator's specification as dissolution test parameters Q mentioned in the reply to letter is NLT 70%, while the value of Q mentioned in original dossier was NLT 80% in 30 minutes Deferred for following (M-271): ● Word "Pulmonol" is not stated on copy of trade mark certificate submitted. Clarification is required in this regard. ● Clarification from R-V section regarding approval of "Pulmonol" brand name for various formulations.
	Evaluation by PEC: ● Firm has submitted following: ● Copy of Panel inspection conducted on 20-04-2018 & 24-04-2018 concluded that the firm was found to be operating at a satisfactory level of GMP compliance. ● Clarification that they regret for the typographical mistake as the original value of Q is NLT 80% in 30 minutes. ● Moreover firm has stated that "Pulmonol" is our registered trademark having TM No. 085475 dated (18-02-1985) in class 5 under section 33 of the Trade mark ordinance 2001, and following products are already registered in line extension of Pulmonol range: vi. Pulmonol Cough syrup, Reg.# 00874 vii. Pulmonol Flu Syrup, Reg.# 068109 viii. Pulmonol DM Syrup, Reg.# 068110 ix. Pulmonol Junior Syrup, Reg.# 068111 x. Pulmonol CF Tablets, Reg.# 023982 In light of above details the Firm has requested to allow brand name of Pulmonol Capsule 375 mg in line extension of their Pulmonol range **Decision: Registration Board did not accede to firm's request for assigning brand name of "Pulmonol" for applied formulation because it can lead to medication errors due to different compositions. Hence Registration Board approved the applied formulation with change of brand name.**	

Now the firm has submitted that the brand name Pulmonol is a household name in the respiratory tract disorder and currently covering cough, cold and sore throat indications. They have requested that the brand name "**Pulmonol-M"** is a line extension of umbrella brand name because of mucolytic effect of Carbosysteine falling under same category of respiratory tract disorders.

Decision: Registration Board deferred the request of the firm for scientific justification

Case No.18: Registration of Drug of M/s. BJ Pharmaceuticals, Lahore.

The Registration Board in its 237th meeting approved the following product of M/s. BJ Pharmaceuticals, Lahore:-

S.No.	Name of Drug(s)	Demanded Pack size	Demanded MRP	Decision of RB
1.	Be-Koff Syrup Each 5ml contains:- Ammonium chloride…..100mg Sodium citrate….58mg Chlorpheniramine maleate….2mg (expectorant/antihistamine)	60ml 120ml 400ml 450ml	As Per SRO	Approved.

Then case was presented in 256th meeting of registration Board with following detail:-

Firm informed that due to typographical mistake, they missed one of the active ingredient of the product i.e. menthol 1mg/5ml. Now firm has submitted revised dossiers to be considered by the Board with composition as under:-

Each 5 ml contains

i. Ammonium Chloride …. 100 mg
ii. Sodium Citrate …….. 58mg
iii. Chlorphenarmine maleate 2mg
iv. Manthol 1mg

Decision:- Registration Board deferred the product for evidence of approval status of formulation in the reference regulatory authorities.

Case No.19: Registration M/s. Friends Pharma (Pvt) Ltd, Lahore.

Registration Board in its different meetings approved the following product of M/s. Friends Pharma (Pvt) Ltd, Lahore as per detailed below:

Sr.No	Name of the drugs with composition	Pack Size	Proposed Price	Decision	Remarks
1.	Fativan-1 Tablets Each tablet contains:- Lorazepam….1 mg (Benzodiazepine)	Per tablet	As per SRO	Approved M-227	MHRA, USFDA approved Evidence for section approval by CLB not confirmed
2.	Dorfen Tablets Each tablet contains:- Midazolam (as Maleate)….7.5mg (Benzodiazepine)	Per tablet	As per SRO	Approved M-227	Netherland's approved.. Evidence for section approval by CLB not confirmed
3.	Pain-Gay Plus Cream Each tube (25g) contains:- Methyl Salicyalate….15% Ibuprofen….10% (Counter irritant)	Per tube	As per SRO	Approved M-227	RRA approval status not confirmed. Evidence for section approval by CLB not confirmed

4.	Profen Cream Each 100g contains:- Ibuprofen….10g (Analgesic)	100g	As per SRO	Approved M-227	RRA approval status not confirmed Evidence for section approval by CLB not confirmed

Firm has submitted last GMP inspection report (dated 06.10.2016) and undertaking for non-issuance of registration letters. Firm has requested for issuance of registration letter of above mentioned products.

Registration Board in its 276th meeting noticed that Central Licensing Board had granted Tablet (Psychotropic) section at the time of grant of DML to M/s Friends Pharma, Lahore. Therefore, Registration Board considered the products at Sr. 1-2 of above table in the light of this decision. However, request of the firm was deferred for fresh GMP inspection report and verification copies of fee challans of Rs: 12000 per product from B&A section that was deposited as differential fee. Further, product at Sr. 2,3 and 4 were also deferred for confirmation in reference regulatory authorities.

The firm has submitted GMP inspection report dated 26-01-2019 and requested to grant them registration of above products. However, the verification of challans of Rs.12,000/- is still required.

Decision: - Registration Board decided as follows: -

i. **Approved the registration of products at Sr.1-2 in the name of M/s. Friends Pharma (Pvt) Ltd, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.**
ii. **Deferred the products at Sr. No 3 & 4 for evidence of approval status of formulation in the reference regulatory authorities.**

Case No.20: Registration of Drug(s) M/s. Friends Pharma, Lahore.

Following products of M/s. Friends Pharma, Lahore were deferred in different meeting of Registration Board. The details are given as under:-

S#	Name of Drug(s)	Demanded MRP	Approved MRP & Pack	Decision of RB	Remarks
.1	Friendomol-L Injection Each 2ml ampoule contains: Paracetamol B.P …… 150mg Lidocaine USP …..….10mg	10x2ml 100x2ml	10x2ml 100x2ml Approved subject to verification of the fee challan in 214 meeting of RB.	Registration Board deferred for confirmation of formulation approval status by reference regulatory authorities and further deliberation in forthcoming Registration Board meeting.	M-255 RRA status is not confirmed.

.2	Clovir Injection Each vial contains: Lyophilized Acyclovir…250mg.	1's	1's As per SRO	Deferred Subject to confirmation of existing me-too lyophilized dosage form, and process of manufacture whether from lyophilized powder of liquid.	M-234 MHRA approved
.3	Clovir Injection Each vial contains: Lyophilized Acyclovir…500mg	1's	1's As per SRO	Deferred Subject to confirmation of existing me-too lyophilized dosage form, and process of manufacture whether from lyophilized powder of liquid.	M-234 MHRA approved
.4	Ferifend Injection Each ml contains: Piroxicam…….20mg (Analgesic)	Form-5 Dy. No: 547 dated. 28-05-2011 Rs.8000/- Rs.12,000/- As per SRO	International availability not confirms. Feldene By M/s Pfizer Laboratories.	Deferred for approval status of same formulation in reference regulatory authorities and for Finished product specification	M-257 Italy approved
.5	Nootrofil Injection Injection Each ml contains: Piracetam……..200mg (Nootropic Drug)	Form-5 Dy. No: 553 dated. 28-05-2011 Rs.8000/- Rs.12,000/- As per SRO/200mg/ ml	International availability not confirm Ceremin injection by M/s Schazoo labs.	Deferred for approval status of same formulation in reference regulatory authorities and for Finished product specification	M-257 Spain approved
.6	Tationil-600 Injection Each Vial contains:- Lyophilized Glutathione (B.P)…600mg Antioxidant	Form 5-D Dy. No. 424 11-08-2014 Rs.20,000/- Rs. 30,000/- 29.01.15 As per SRO Not confirmed.	1. Deferred in **248th** Meeting. Final notice for 30 days for rectification of below mentioned shortcomings/ observations. a. An undertaking/commitment regarding Label claims and prescribing information being same as approved by reference drug agencies e.g., FDA, TGA, MHLW, EMA and Health Canada is required. b. International availability of formulation in reference Stringent Regulatory	Deferred for evidence of approval of applied formulation by refrence regulatory authorities & shortcomings stated above	M-265 Italy approved.

			Agencies not confirmed. c. Evidence and verification of lyophilizer by area FID that the said instruments is in functional condition are required. d. Lab scale stability studies e. Undertaking that in case of resemblance of brand name and packaging of applied product, the firm will change these; is required.		
.7	Somafin Injection 250mg /ml Each ml contains:- Citicolin (as sodium) …..250mg Neutrotonic	Form 5 31-3-2015 Dy No. 463 Rs 8,000/- 23-05-2011 + Rs 12,000/- 31-3-2015 1x10's As per SRO	Rs 8000, fee challan is not in original. Reference Authority status cannot be confirmed. Firm has claimed Mfg. Specs & product is not present in available versions of BP &USP (B.P 2013 & USP 39)	Deferred for clarification of composition as applied formulation is approved in France with strength of 250mg/2 ml	M-266 RRA is not confirmed.

Decision: -Registration Board decided as follows: -

i. **Approved the registration of products at Sr.2-6 in the name of M/s. Friends Pharma (Pvt) Ltd, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.**
ii. **Deferred the products at Sr. No 1 & 7 for evidence of approval status of formulation in the reference regulatory authorities.**

Case No.21: Registration of M/s. Derma Techno, Lahore.

Registration Board in its 234th Meeting approved following drugs of M/s. Derma Techno, Lahore, as per detailed below:-

Sr. No.	Name of firm	Product name and composition	Demanded pack size	Demanded MRP	Decision /remarks
1.	M/s. Derma Techno, Lahore,	Alpzole 30mg Capsule Each capsule contains: Lansoprzole (eteric coated pellets) 30mg (proton inhibitor)	2 x 7's	Rs.10.00/ per capsule	Approved Source of pellets not provided
2.	-do-	Mupical Cream Each gram contains:- Mupirocin calcium…..43mg	10gm	Rs.75.00	Approved Approval status in RRA not confirmed

Last GMP inspection report has been submitted by firm dated **21.05.2018 and 05.07.2018** (GMP compliant)**,** firm has been requesting for issuance of Registration letters.
Differential fee Rs 12000/- each product submitted on 05.01.2017.

Registration Board in its 286th meeting deferred product at Sr. no. 1 for source of pellets product at Sr. no. 2 for approval status in RRA. The firm has stated that they will purcahse pellets from M/s. Vision, Islamabad and RRA status of product at Sr.No. 2 is still not confirmed.

Decision: - Registration Board decided as follows: -

i. **Approved the registration of products at Sr. No. 1 in the name of M/s. Derma Techno, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.**
ii. **Deferred the products at Sr. No 2 for evidence of approval status of formulation in the reference regulatory authorities.**

Case No.22: Registration of M/s. Derma Techno, Lahore.

Registration Board in its 234th Meeting deferred following drugs of M/s. Derma Techno, Lahore, as per detailed below:-

S. No.	Name of Drugs & Composition	Demanded MRP & Pack Size	Approved MRP by Pricing	Decision	Remarks if any
1.	Dermolimus Cream Each gram contains:- Tacrolimus ….0.3mg	5gm/ Rs.150.00	Rs. 137.00/10 gm	Approved	Approval status not confirmed

Last GMP inspection report has been submitted by firm dated 21.05.2018 and 05.07.2018, Firm has been requesting for issuance of Registration letters.
Differential fee Rs 12000/- each product submitted on 05.01.2017.
Registration Board in its 286th deferred product at Sr. no. 3 for approval status in RRA. The product is approved in Netherlands.

Decision: - Registration Board approved the registration of above mentioned product in the name of M/s. Derma Techno, Lahore. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.

Case No.23: Registration of Drug(s) M/s. Panacea Pharmaceuticals, Islamabad.

Following products of M/s. Panacea Pharmaceuticals Islamabad were approved in different meetings. The details are given as under:-

Sr. No.	Meeting No.	Name of Drug(s) with Composition	Applied MRP	Intl. Availability	Specification	Decision of RB
1.	265th meeting of RB	Ciroline 500mg Tablets Each tablet contains:- Citicoline….. 500mg (Neurotonics) Phosphatidyl Chlorine Stimulant	Form 5 24-02-2015 Dy.No.1080 Rs.8000/= Rs.12,000/= 24-02-2015 10's As Per SRO	International Availability not provided Local Availability: Qusel by M/s Hilton Pharmaceutical Pakistan Last inspection	Firm claimed Mfg specification while the product is not present in available pharmacopoeia (BP: 2013 and USP39)..	Deferred for confirmation of approval of applied formulation in reference regulatory authorities

				report 8-12-2016 The firm is complying GMP		
Remark: RRA status still not confirmed.						
2.	277th meeting of RB	Cipride 1mg Tablets Each tablet contains:- Cinitapride Hydrogen Tartrate ……1mg (Propulsive/Gastroprokinetic)	Form 5 16-02-2015 Dy.No.968 Rs.8000/= Rs.12,000/= 16-02-2015 10's As Per SRO	GMP inspection report within 1 year could not be confirmed	Deferred for the confirmation of approval in reference regulatory authorities (M-265)	Deferred for submission of last GMP inspection conduted within the last 01 year.
Remarks: The firm submitted GMP inspection dated 2019 alongwith letter for confirmation of GMP Status dated 26-08-2019 and (Cidine 1 mg Tablets by M/ ALMIRALL, S.A. (Spanish Agency of Medicines and Health Products Approved).						
3.	266th meeting of RB	Clofin 50mg Tablets Each tablet contains:- Clomiphene Citrate ….. 50mg (Estrogen receptor inhibitor) USP Specs	Form 5 16-02-2015 Dy.No.970 Rs.8000/= Rs.12,000/= 16-02-2015 10's 20's 30's As Per SRO	Clomid by Sanofi Aventis USFDA Cerophene by Hilton Last inspection report 8-12-2016 GMP status: Good.		Deferred for decision regarding requirement of manufacturing facility for Clomiphene Citrate

Remarks: Decision: Registration Board in 271st meeting deliberated the matter in light of above information and decided as under:

a) There is no need for segregated / dedicated / self contained premises / facilities for the production of drugs belonging to the categories namely immunosuppressants, aromatase inhibitors (letrozole, anastrozole) and clomiphene. However, drugs of these classes are found highly hazardous for workers and personnel which remain in direct contact or are involved in close handling of these drugs. Aforementioned drugs are present in NIOSH (National Institute for Occupational Safety and Health, USA) list of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2016, prepared by Center for Disease Control & Prevention and National Institute for Occupational Safety and Health. Therefore, the safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs shall be required to be established by the manufacturers.

b) Registration Board decided to grant registration of these products in general manufacturing areas with condition that manufacturer shall provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.

c) Advised to compile data for already deferred cases of immunosuppressants, aromatase inhibitors (letrozole, anastrozole) and clomiphene in the previous meetings of the Registration Board and placed before Registration Board after completion of application including fee, rectification of shortcomings final decision on these application.

d) Registration Board also advised to issue an advisory for manufacturing units of immunosuppressants, aromatase inhibitors (letrozole, anastrozole) and clomiphene to provide safety and protective measures for workers and personnel which remain in direct contact or are involved in close handling of these drugs.

e) Registration Board appreciated Pharmaceutical Evaluation Cell for adequate compilation of all relevant information.

They have therefore, requested to grant them registration of above products.

Decision: - Registration Board decided as follows: -

i. **Approved the registration of products at Sr. No. 2 & 3 in the name of M/s. Panacea Pharmaceuticals, Islamabad.**
ii. **Deferred the products at Sr. No 1 for evidence of approval status of formulation in the reference regulatory authorities.**

CaseNo.24: Contraindicated/Banned injection vitamin K3 10mg/ml (menadione/menaphthone) being used in Pakistan.

The request of M/s GT pharma, Lahore was presented in 284th meeting of Registration and the firm was written a letter wherein attention has been drawn toward usage of vitamin K3 (Menadione/menaphthone) 10mg/ml in Pakistan, which is contraindicated to neonates and infant as mentioned in BNF reference. Moreover USFDA has banned vitamin K3 for human use however it is being used in animals/pets as dietary supplement.
It is intimated that most of the Govt hospitals and primary & secondary care health departments have taken initiative to replace Inj. Vitamin k3 10mg/ml (MENADIONE) with vitamin K1 (PHYTOMENADIONE 2mg/ml, oral, IM/IV ampoule). But most of the hospitals are still using vitamin K3 inj 10mg/ml which is banned by USFDA in human.

Vitamin K3 is one of the many manmade versions of vitamin K. Also called menadione, this yellowish, synthetic crystalline substance is converted into the active form of the K2 vitamin inside of the animal body. While a vitamin K deficiency can be dangerous, especially to infants that may easily suffer from extensive hemorrhaging, an overdose can be as equally detrimental. Newborns that are administered too great a dosage of vitamin K3 can suffer from kernicterus, a form of severe brain damage that may produce decreased movement, loss of appetite, seizures, deafness, mental retardation, and even death. This condition is associated with an abnormally high concentration of bilirubin, a bile pigment, in the tissues of the brain, which can be caused by the presence of K3. For this reason, K3 is less often utilized medically than it was in former times. Despite the fact that it can serve as a precursor to various types of vitamin K, menadione is generally not used as a nutritional supplement. Large doses of menadione have been reported to cause adverse outcomes including hemolytic anemia due to G6PD deficiency, neonatal brain or liver damage, or neonatal death in some cases. Moreover, menadione supplements have been banned by the FDA because of their high toxicity.

Keeping in view position it is requested to take necessary action against vitamin K3 inj 10mg/ml, in the better interest of public health.
List of registered products containing menadione injection 10mg/ml is given below:

S. NO	Reg. No	Product name and composition	Name of firm	Renewal status
1	046497	Vital-K Injection Each 1ml contains:- Menaphthone Sodium Bisulphite…10mg. (USP)	M/s. Murfy Pharmaceuticals, 8-KM, Raiwind Road, Lahore.	valid
2	027974	Vitamin K Injection Each ml contains:- Anhydrous Menaphthone Sodium Bisulfite (Eq. to 10mg base)	M/s. Venus Pharma 23 K.M Multan Road, Lahore.	Valid
3	017433	Vitamin-K Injection Each 1ml contains:- Menaphthone Sodium Bisulphite…10mg.	Importer name: Shaheen Agency, Karachi Pakistan Manufacturer country CHINA	Valid

4	043081	Vitamin-K Injection Each 1ml contains:- Menaphthone Sodium Bisulphite…10mg.	Importer name: United International, Karachi Pakistan Manufacturer: M/s Shijiazhuang pharmaceutical group, CHINA	Not confirmed
5.	003832	Menaphthone sodium Bisulphate injection Each ml contains:- Menaphthone Sodium Bisulphite…10mg.	Importer name: M/s Hakeem Agencies Karachi Manufacturer: M/s Schiwa Germany	Not confirmed
6.	004620	Vitamin-K Injection Each 1ml contains:- Menaphthone Sodium Bisulphite…10mg.	Importer name: Not Available in record Manufacturer: M/s Sarm Italy	Not confirmed
7.	005360	Minadione Sodium Bisulphate Each ampoule contains: Vitamin K…10mg/ml	Importer name: Not Available in record Manufacturer: M/s Vis Farama, Italy.	Not confirmed
8.	009915	Menaphthone sodium Bisulphate injection Each ml contains:- Menaphthone Sodium Bisulphite…10mg.	M/s Indus pharma, Karachi	Not confirmed
9.	017644	Vitamin K injection 10mg/ml Each 1ml contains:- Menaphthone Sodium Bisulphite…10mg.	M/s Munawar pharma (pvt) Ltd 31km ferozepur road, Lahore	Valid

Registration Board in its 284th meeting decided to issue show cause to above mentioned firms for cancellation of registrations of above mentioned products. The Board further authorized Chairman for issuance of show cause notice for already registered products.

Show cause notices were served to above mentioned firms and in compliance of rule, all the above mentioned firm have been called to give them an opportunity of personal hearing before the Registration Board for their views / comments in the matter.

Discussion: - All the above firms were called for personal hearing. However, only representative of M/s. Indus Pharma, Karachi, Mr. Saif Ur Rehman Burki appeared before the Board and informed that they are willing to withdraw the registration of their product Menaphthone sodium Bisulphate injection (Reg # 009915).

Decision: - **Registration Board deliberated matter in detail and Keeping in view position narrated above, status of product in reference regulatory authorities and safety, quality and efficacy of drugs, the Board accordingly decided to cancel the registration of all above mentioned products containing Vitamin K3 (Menadione, Menaphthone) as API under the provisions of Section 7(11) (b,c & d) and 42 of Drug Act, 1976 and Rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976. The Board further decided that if these firms apply for grant of registration of products in line with approval of reference regulatory authorities then these applications shall be considered on priority.**

VETERINARY CASES

Case No.25: Request of M/s. Rotass Universal Trading Co. Rawalpindi for change of address (local) for their already registered veterinary drugs.

M/s. Rotass Universal Trading Co. Rawalpindi 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)/Composition	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.	018822	Quintox 3 20% Liquid (Norfloxacin)	M/s. Rotass Universal Trading Co. 103-A/1, Race Course Scheme, Peshawar Road, Rawalpindi.	M/s. Rotass Universal Trading Co. House No. 149-A, Street No.5, Race Course Road, Rawalpindi.	02-04-1996 22-01-2016
2.	018823	Electrolyte Poultry Powder			02-04-1996 22-01-2016
3.	019064	Tetracure 20% Powder			29-08-1996 04-08-2016
4.	019066	Vita Liquid	-do-	-do-	29-08-1996 04-08-2016
5.	020111	Oxytet 20% LA Injection	-do-	-do-	01-12-1997 30-10-2017
6.	020112	Quintox 3 Feed Premix Powder (Norfloxacin)	-do-	-do-	01-12-1997 30-10-2017
7.	020113	Quinflume 500 Liquid	-do-	-do-	01-12-1997 30-10-2017
8.	020811	Enrocure 10% Liquid	-do-	-do-	16-10-1998 02-11-2017
9.	020812	Tylocure 20% Injection	-do-	-do-	16-10-1998 02-11-2017
10.	020813	Quintox 10% Injection (Norfloxacin)	-do-	-do-	16-10-1998 02-11-2017
11.	021287	Genta Cure 20% Injectable	-do-	-do-	16-05-1998 23-04-2018
12.	021288	Cocoban 500 Water Soluble Powder	-do-	-do-	16-05-1998 23-04-2018
13.	022777	Quincide Solution	-do-	-do-	17-04-1999 19-03-2014
14.	025782	Quinflume 15% Injectable	-do-	-do-	14-10-2000 22-09-2015
15.	027464	Amoxycure 15% LA Injection	-do-	-do-	24-04-2002 15-04-2017
16.	027465	Tylox Oral Powder	-do-	-do-	18-04-2002 15-03-2017
17.	034561	Vitox K3 Water Soluble Powder.	M/s. Rotass Universal Trading Co., H.No.305/10, Street No.19, Opp Amna Medical Building, Peshawar Road, Rawalpindi	-do-	09-12-2004 17-10-2014
18.	034562	Doxytox 50% Water Soluble Powder.	-do-	-do-	09-12-2004 17-10-2014

19.	034563	Colitox 48% Water Soluble Powder.	-do-	-do-	09-12-2004 17-10-2014
20.	034564	Albatox 10% Oral Solution.	-do-	-do-	09-12-2004 17-10-2014
21.	043595	Tylodox 100/200 Water Soluble Powder	-do-	-do-	19-01-2007 14-12-2016
22.	043596	Doxycol 100/100 Water Soluble Powder	-do-	-do-	19-01-2007 14-12-2016

The firm has deposited fee of Rs.5000 x 22 = Rs.110000/- and submitted following documents:-

a) Copies of initial Registration letters.
b) Renewals of above drugs are not submitted.
c) Copy of previous Drug Sale License is submitted.
d) Copy of new Drug Sale License is submitted.

It is pertinent to mention that for product at Sr.No.13 firm has not provided evidence of latest renewal (due in April, 2019).

Decision:- Registration Board decided as follows:

- **Approved M/s. Rotass Universal Trading Co. Rawalpindi's request for change of local storage facility address from "*103-A/1, Race Course Scheme, Peshawar Road, Rawalpindi*" to "*House No. 149-A, Street No.5, Race Course Road, Rawalpindi*" for products at Sr.No.1-12 & 14-22 in accordance with drug sales license, on same terms and conditions. Approval letter shall be issued after verification of storage facility of new site.**
- **Deferred product at Sr.No.13 for provision of the latest renewal status/ evidence for further processing of the matter.**

Case No.26: Request of M/s. ICI Pakistan ltd, Karachi for withdrawal of registration application.

Registration Board in its 285th meeting approved following veterinary drug of M/s. ICI Pakistan Limited Life Sciences, 45-KM, off Multan Road, Lahore. However, processing of the product for issuance of registration letter was withheld due to reason that firm has requested for withdrawal of registration application due to commercial obligation.

S.No.	Name of Drug(s)/Composition	Pack Size	Decision
1.	Rescosin AC (Aqueous Concentrate) Oral Liquid Each ml contains:- Tilmicosin (as Tilmicosin Phosphate)……..250mg	100ml 240ml 450ml 960ml	Approved with innovator's specification.

Decision:- Registration Board acceded to firm's request and rejected the registration application of product "Rescosin AC".

Case No.27: Request of M/s. Naseem Traders International, Rawalpindi for change of head office address.

M/s. Naseem Traders International, Rawalpindi has requested for change of head office address for their following registered imported products as per following details:-

S. No	Reg. No.	Name of Drug(s)/Composition	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.	019910	Mycofix Plus Contains:- Inactivated yeast (specific types of Saccharomyces)….31% Specially treated diatomaceous earth…….55.2% Zeolite…….….13.0% Emulsifier……..0.8%	M/s. Naseem Traders International, 2, Khuram Plaza Chandni Chowk, Rawalpindi. **Godown**: Property No.BL-297/2, Kuri Road, Muslim Town, Rawalpindi.	M/s. Naseem Traders International, Flat No.12, First Floor Satellite Shoping Center, 6th Road, Rawalpindi. **Godown**: Property No.BL-297/2, Kuri Road, Muslim Town, Rawalpindi.	25-09-1996 19-09-2016
2.	022171	Lisovit R Powder Contains:- Lysozyme……22.0% Vitamin % 50 SD….0.5%			04-12-1998 27-11-2018

The firm has deposited fee of Rs. 5,000 x 2 = Rs.10,000/- and submitted following documents:-

a) Copies of initial Registration letters.
b) Renewals of above drugs.
c) Copy of previous and new Drug Sale License.

Decision:- **Registration Board approved firm's request for change of head office address from "*2, Khuram Plaza Chandni Chowk, Rawalpindi"* to "*Flat No.12, First Floor Satellite Shoping Center, 6th Road, Rawalpindi*" for products at Sr.No.1 & 2 in accordance with DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site. The Board further advised to verify status of rest or products registered in name of firm at old site.**

Case No.28: Request of M/s. Binsadiq International, Lahore for change of address (local) for their already registered veterinary drugs.

M/s. Binsadiq International, 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)/Composition	Name & Address of Importer (as per Registration Letters)	Name & Address of Importer (as per New DSL)	Initial date of Registration
1.	083810	Alamycin LA 200mg/ml Solution for Injection	M/s. Binsadiq International, 89-A, Canal View Housing Society, Lahore.	M/s. Binsadiq International, 307-A, Canal View Housing Society, Lahore.	16th June, 2017
2.	083811	Pen & Strep Suspension for Injection	-do-	-do-	16th June, 2017
3.	083812	Betamox LA Suspension for Injection	-do-	-do-	16th June, 2017
4.	088648	Doxiciclina 50% Water Soluble Powder	-do-	-do-	06th April, 2018
5.	088649	Amoxifarma Soluble Powder for Oral Solution 800mg	-do-	-do-	06th April, 2018
6.	088650	Amprosid Liquid Water Soluble 250mg/ml	-do-	-do-	06th April, 2018

7.	088859	TAF Oral Solution 25%	-do-	-do-	16th May, 2018
8.	083813	Sogecoli Oral Solution	-do-	-do-	23rd June, 2017
9.	083814	Doxyval 50% Oral Powder	-do-	-do-	23rd June, 2017
10.	084840	Endospec 10% SC Oral Suspension	-do-	-do-	16th August, 2017
11.	084841	Bilosin 200mg/ml Solution for Injection	-do-	-do-	16th August, 2017

The firm has deposited fee of Rs.5,000/- for each product, however, for products at Sr.No.1-3 the fee deposited is not endorsed by statistical officer (firm has been informed) and submitted following documents:-

a) Copies of initial Registration letters.
b) Copy of previous Drug Sale License.
c) Copy of new Drug Sale License.

Decision:- Registration Board decided as follows:

- **Approved M/s. Binsadiq International, Lahore's request for change of local storage facility address from "*89-A, Canal View Housing Society, Lahore*" to "*307-A, Canal View Housing Society, Lahore*" for products at Sr.No.4-11 in accordance with DSL, on same terms and conditions. Approval letter shall be issued after verification of new local storage facility site.**
- **Deferred products at Sr.No.1-3 for provision of endorsement of submitted fee by statistical officer, DRAP.**

Case .No. 29: Request of M/s. La-Vie Pvt. Ltd. Lahore for withdrawal of Registration Application.

M/s. La-Vie Pvt Ltd., Lahore has informed that their principal aborad has terminated market authorization of below mentioned approved product stating the reason as delay in regsitration process.

S. No.	Name of Importer/ Manufacturer	Name of Drug(s)/ Composition	Board Decision (M-282)
1.	M/s. La-Vie Pvt. Ltd. 53-A XX, Commercial Block, Phase II, Khayaban-e-Iqbal DHA, Lahore. **Manufacturer & Marketing Authorization Holder:-** M/s. Kolmar Korea Co., Ltd., 245 Sandan-gil, Jeonui-myeon, sejong-si, Republic of Korea.	DUKAY Topical Gel 1 g of gel contains:- Clindamycin as clindamycin phosphate…10mg Anhydrous benzoyl peroxide as hydrous benzoyl peroxide….50 mg	Approved as per Policy for inspection of manufacturer abroad.

Decision:- Registration Board deferred the case for confirmation of me-too products of abovementioned formulations.

Case No.30: Request of M/s. Nawan Laboratories (Pvt) Ltd., Karachi for grant of additional packs for their already registered veterinary drugs.

M/s. Nawan Laboratories (Pvt) Ltd., Karachi has applied for grant of additional packs of their following registered veterinary drugs as per details mentioned against each:-

S. No.	Regn. No.	Name of Drug(s)/ Composition (as per initial	Already Pack Size	Demanded Additional	Initial registration	Justification

		registration letter)	Granted	Pack	with renewal	
1.	035063	ADE Minerals Each kg contains:- Vitamin A……..…0.5MU Vitamin D……..0.080MU Vitamin E……...0.300gm Calcium……..225.0gm Phosphorous..…120.0gm Magnesium……...25.0gm Sodium……....20.0gm Iron (as Ferrous).....1.0gm Zinc…….3.0gm Manganese……..2.0gm Copper……....0.600gm Cobalt ……0.010gm Iodine…….....0.020gm Selenium …….....0.003gm	1Kg 5Kg	25Kg	13-12-2004 10-12-2014	• Marketing demand. • Customer convenience. • Economical, easier to administration and affordable for farmers, suppliers and customers.
2.	021306	L.S. Minerals Powder Each kg contains: - Calcium……155gm Phosphorous……..135gm Magnesium……..55gm Sodium…….....45gm Iron (as Ferrous)…....1gm Zinc……..…..3gm Maganese……...2gm Copper……....0.6gm Cobalt…….…...0.01gm Iodine……....0.04gm Selenium…….....0.003gm	1Kg 5Kg	25Kg	11-05-1998 08-05-2018	-do-

M/s. Nawan Laboratories (Pvt) Ltd., Karachi has deposited fee of Rs.5,000 x 2 = Rs. 10,000/- and submitted following supporting documents:-

(i) Attested copies of initial registration letters and latest renewal status.
(ii) Details of previously granted pack size.
(iii) Undertaking that the provided information/documents are true/correct.
(iv) GMP inspection conducted by DRAP during last 12 months.
(v) Attested copy of Drug Manufacturing License.
(vi) Attested copy of CRF provided.
(vii) Justification of proposed change.

The demanded packs are not given to other firms.

Registration Board in its 286th meeting decided to refer the case to Expert Working Group on Veterinary Drugs for their recommendations on demanded additional pack sizes.

The case was accordingly discussed in 6th meeting of Expert Working Group on Veterinary Drugs held on 20th March, 2019 and the working group decided as follow;

"Keeping in view the need of packing in large size farms, recommended the grant of additional pack of 25Kg for above mentioned products demanded by the firm."

Registration Board in its 289th meeting deferred the case for obtaining details from the firm regarding facility/equipments w.r.t their capacity of mixing/ preparation/ filling of demanded pack sizes.

Firm has now provided the following details;

a. Approval of "Dry powder Sachet Section (General) by CLB.
b. List of equipments used in preparation and filling of dry powder sachet section (General).

S.No.	Name of Machine	Quantity	Capacity
1.	Powder Mixer Ribbon Blender	01	500 Kg
2.	Powder Mixer Ribbon Blender	01	1000 Kg
3.	Pneumatic Powder Transfer System	01	1000 Kg
4.	Powder Storage Sylo	01	1000 Kg
5.	Sealing/ Stitching Device	01	40 bags/hours
6.	Electric Heated Tray Dryer	01	100 Kg

Decision:- Registration Board approved M/s. Nawan Laboratories (Pvt) Ltd., Karachi's request for grant of following additional pack sizes to their already registered veterinary products as per following details, on same terms and conditions;

S.No	Regn. No.	Name of Drug(s)/	Approved Additional Pack
1.	**035063**	**ADE Minerals**	**25Kg**
2.	**021306**	**L.S. Minerals Powder**	**25Kg**

Case No. 31: Veterinary drugs containing Furaltadone

(A) Registration Board in its 289th meeting rejected registration applications of veterinary drugs containing ***Furaltadone*** having strong potential of causing genotoxicity and cytotoxicity due to possible residual effects. A number of other veterinary products having Furaltadone as an API, are registered in favor of number of firms as per following details:-

SR. NO.	REGN. NO.	NAME OF DRUG(S)/COMPOSITION	NAME OF APPLICANT/ MANUFACTURER
1.	002017	FURASOL POWDER CONTAINS:- **FURALTADONE**……..…….20%	M/S. SMITH KLINE AND FRENCH OF (PAKISTAN) LTD, KARACHI.
2.	002102	TYLOFER POWDER EACH KILO CONTAINS:- TYLOSINE TARTRATE ERYTHROMYCIN……50,000MG THIOCIANATE…….62,500MG **FURALTADONE** TARTRATE……150000MG VIT A …….2500000 I.U VIT D3 ……...1000000 I.U VIT E……...10000MG	M/S. CONIMPEX MULTAN.
3.	007364	GALLIFAN I.C.C **FURALTADONE** + ANTIBIOTICS	M/S. CONIMPEX MULTAN.
4.	013674	AMPROFURA POWDER 1000GM CONTAINS: - AMPROLIUM……200MG **FURALTADONE** TARTRATE……150MG SODIUM LAURIL SULPHATE…….5000MG	M/S. CONIMPEX MULTAN
5.	014596	GALLIFUR W/S POWDER EACH KG CONTAINS: - **FURALTADONE** TARTRATE….150.000MG ERITHROMYCINE…….55000M	M/S. CONIMPEX MULTAN CANTT

6.	014598	ICCOBACTIN W/S POWDER EACH KG CONTAINS: - **FURALTADONE** TARTRATE……...150.000MG	M/S. CONIMPEX MULTAN CANTT
7.	007203	NORCOX SOLUBLE POWDER CONTAINS:- SULFADIMERAZINE NA……200GM SULFAQUINOXALINE NA……..25GM PYRIMETHAMINE HCL……...25GM **FURALTADONE** HCL…….100GM VITAMIN A ……...15000000 I.U VITAMIN K3 …….……..5GM CARRIER Q.S…….…….... AD 1KG	M/S. EASTERN AGEN CORP.
8.	007232	ANUPCO FURALTADONE PLUS **FURALTADONE**……8.8G VIT A……525000 I.U VIT D3……..150000 I.U VIT E ……...45 I.U VIT K…….…….150MG VIT B2 …….……..150MG VIT B6 ……75MG VIT B12……375MCG NICOTINIC ACID ……525MG PANTOTHENIC AID……180MG VITAMIN C……..30MG	M/S. BIO VET.
9.	007625	FURAGALLI ERYTHROMYCIN ACTIVITY (AS THIOCYNATE)…….13GM **FURALTADONE** (AS HYDROCHLORIDE)……..…20GM SOLUBLE EXCIPIENT AD …….100GM	M/S. RAHI ENTERPRISERS.
10.	007626	CEVAPROL AMPROLIUM……10G **FURALTADONE**……10G CARRIER Q.S. AD……...100G	M/S. RAHI ENTERPRISERS.
11.	008318	FURAVEEX SOLUTION CHLORAMPHENICOL……12.5GM **FURALTADONE**…….10GM	M/S. AIMS TRADER KARACHI.
12.	012916	COLIN PLUS HYDRO SOLUBLE EACH ML CONTAINS: - ERYTHROMICIN……50MG **FURALTADONE**……....125MG	M/S. AIMS TRADERS.
13.	018412	COLIMICINA COMPLEX WATER SOLUBLE POWDER EACH KG CONTAINS: - TYLOSIN TARTRATE……25MG COLISTIN SULFATE……...14.6GM **FURALTADONE** HCL……...75GM	M/S. AIMS TRADERS KARACHI
14.	012991	OMYCIN-F POWDER EACH KG CONTAINS: - OXYTETRACYCLINE HCL…….50GMS **FURALTADONE**……30GMS NEOMYCIN…….…...14GMS	M/S. EPLA LABS. KARACHI.

15.	029628	CRF-100 POWDER EACH KG CONTAINS:- CHLORTATRACYCLINE HCL…….40GM NEOMYCIN BASE (AS SULPHATE)…...12GM **FURALTADONE** (A HCL)…….30GM	M/S. EPLA LABS. KARACHI.
16.	013012	FAKMAS AMIDIOSTAT POWDER EACH 100GM CONTAINS: - AMPROLIUM HL…….20% **FURALTADONE** HYDROCHLORIDE…...20%	M/S. FAKMA LAHORE.
17.	013217	FURAMIX POWDER EACH KG CONTAINS: - **FURALTADONE**……..180GMS VIT A ……..2000000 IU VIT D3 ……..200000 IU VIT E 2GM, VIT B2 …….…….2GM VIT B6…… 1.3GM VIT B 12(1%)……... 5MG VIT K3…….……700MG NICOTINIC AID …….…...3.5GM VIT C ……..20GM	M/S. ANIMA NUTRITION PRODUCT ISLAMABAD
18.	013668	ERYSOL FD WATER DISPERSABLE POWDER EACH 100GM CONTAINS: - ERYTHROMYCIN THIOCYANATE BVET C…….12GM **FURALTADONE** HCL……..8GM SODIUM CARBOXYMETHYL CCLLULOSE BP……...2GM	M/S. MEDICURE LABS KARACHI.
19.	032208	MEDISOL- FD W/S POWDER EACH 100GM CONTAINS:- ERYTHROMYCIN THIOCYANATE...12.00GM **FURALTADONE** HCL……8.00GM	M/S. MEDICURE LABORATORIES, KARACHI
20.	014588	PG-FOR-150 POWDER EACH 1000GM CONTAINS: - **FURALTADONE** TARTRATE……..150MG	M/S. PAK GENERAL PRODUCTS LAHORE.
21.	015497	FURONFORT ORAL W/S POWDER EACH 100GM CONTAINS: - TYLOSIN TARTRATE……..38GM SULPAMETHOXYPIRIDAZINE……..75GM TRIMETHOPRIM……...15GM **FURALTADONE** HCL……..50GM PHENILBUTAZONE…….….25GM DEXTRONETHORPHAN	M/S. RAJPUT ENTERPRISES KARACHI.
22.	017117	COCISOL POWDER EACH GM CONTAINS:- SULFADIMERAZINE NA……..200MG SULFAQUINOXALINE……25MG PYRIMETHAMINE……..25MG **FURALTADONE** HCL…….25MG VITAMIN A…….15000 IU VITAMIN K 3…….5MG	M/S. INTERNATIONAL CHAMPHARMA LAHORE.
23.	017953	MYCOSIN GRANULES EACH 100GM CONTAINS: - ERYTHROMYCIN THIOCYANATE……..6GM **FURALTADONE** HCL……15GM	M/S. WELLCOME PAKISTAN LTD KARACHI

		TYLOSIN TARTARATE……..5GM	
24.	019083	AMFURA POWDER EACH KG CONTAINS:- AMPROLIUM……200GM **FURALTADONE** HCL……..200GM	M/S. MEDIGENT LAHORE
25.	021280	SANCOX-20 POWDER EACH 100GM POWDER CONTAINS:- AMPROLIUM…….…..20GM **FURALTADONE** HCL……20GM	M/S. SANNA LABS FAISALABAD
26.	025367	SANFURA ORAL POWDERS CONTAINS: - **FURALTADONE** HCL……100% W/W	M/S. SANNA LABS FAISALABAD
27.	021403	VETY-COCX POWDER FOR ORAL ADMINISTRATION EACH 100GM CONTAINS: - SULPHAQUINOXALINE NA……4GM SULPHAMERAZINE NG…….20GM **FURALTADONE** HCL……..15GM PYRIMETHAMINE HCL……2GM VIT A 1.2MIU, VIT K3 ……..2GM	M/S. VETY-CARE PHARMACEUTICALS ISLAMABAD
28.	021441	COCCI-AF POWDER EACH KG CONTAINS: - AMPROLIUM……200GM **FURALTADONE** HCL…….200GM	M/S. GLOBAL VETERINARY RAWALPINDI
29.	022759	ECM 350 POWDER EACH KG CONTAINS: - OXYTETRACYCLINE HCL…….150GM NEOMYCIN SULPHATE…….60GM **FURALTADONE**……150GM	M/S. ISLAMABAD PHARMACEUTICAL PRODUCTS ISLAMABAD
30.	022779	PANTA COX W/S POWDER EACH GM POWDER CONTAINS: - SULPHAMERAZINE SODIUM……200MG SULPHAQUINOXALINE SODIUM ….25MG DYRIMETHAMINE HCL……...25MG **FURALTADONE** HCL……..100MG VIT K3…….……5MG VIT A…….15000IU	M/S. PANTEX PHARMACEUTICALS LAHORE
31.	023480	SNOWPAK-F POWDER EACH KG CONTAINS: - OXYTETRACYCLINE…….…..250GM NEOMYCIN SULPHATE……..150MG **FURALTADONE**……250GM SODIUM SULPHATE ……..060GM VITAMIN A ……....2500000 IU VITAMIN D3…….……500000 IU VITAMIN E …….…..1GM VITAMIN C ……...100GM	M/S. REDEX PHARMACEUTICAL INDUSTRIES (PVT) LTD FAISALABAD
32.	025358	AMFUSTAT POWDER EACH KG CONTAINS: - AMPROLIUM HCL …….……200.00GM **FURALTADONE** HCL ……200.00GM	M/S. NAWAN LABS KARACHI

33.	025729	N.C. DONE-M WATER SOLUBLE POWDER EACH KG CONTAINS: - NEOMYCINE SULPHATE CHLOROTETRACYCLINE HCL……40GM **FURALTADONE** HCL…….30GM	M/S. MANHATTAN PHARMA KARACHI
34.	057037	TYCOLIDONE LIQUID EACH ML CONTAINS: - TYLOSIN TARTRATE……25MG COLISTIN SULPHATE…..3,00,000 IU **FURALTADONE** HCL……...75MG	M/S. MANHATTAN PHARMA KARACHI
35.	026491	NFC-100 ORAL POWDER EACH 1000G CONTAINS:- CHLOROTETRACYCLINE……..…..40GM NEOMYCIN SULPHATE……..…….12GM **FURALTADONE**……30GM	M/S. DELUX CHEMICAL INDUSTRIES KARACHI
36.	028526	REO-EF POWDER EACH 100GM CONTAINS:- ERYTHROMYCIN THIOCYNATE……...24GM **FURALTADONE** HCL……16GM	M/S. DELUX CHEMICAL INDUSTRIES, KARACHI.
37.	029672	REOMICINIA COMPOUND ORAL POWDER. EACH 1000GM CONTAINS:- TYLOSIN ……..…..25GM COLISTINE ……..…..300MIU **FURALTADONE** …….....75GM	M/S. DELUX CHEMICAL INDUSTRIES, KARACHI.
38.	035084	TYLOTECH-E POWDER. EACH 1000GM CONTAINS:- TYLOSIN TARTRATE……..…..20GM ERYTHROMYCIN THIOCYNATE……..30GM **FURALTADONE**……50GM	M/S. DELUX CHEMICAL INDUSTRIES, KRACHI.
39.	027436	COXIFIN POWDER. EACH 100GM CONTAINS:- AMPROLIUM HCL ….. ……..…...200GM **FURALTADONE** HCL …. ……..…… 200GM VITAMIN A ……..…….4000000 I.U VITAMIN D ….. ……2000000 I.U VITAMIN K3…….10GM	M/S. STAR LABORATORIES (PVT) LTD., LAHORE.
40.	027492	STR-600 POWDER. EACH 1000GM CONTAINS:- OXYTETRACYCLINE HCL……..250GM NEOMYCINE SULFATE……100GM **FURALTADONE**…….250MG SODIUM SULFATE……..……60GM VITAMIN A ……2500000 I.U VITAMIN C ……...100GM VITAMIN D3 …….5000000 I.U VITAMIN E……1GM (ANTIBIOTIC WITH VITAMINS).	M/S. STAR LABS. LAHORE.
41.	027500	ERYDONE-T POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……...20.00GM ERYTHROCIN……30.00GM **FURALTADONE**……50.00GM (ANTIBIOTIC).	M/S. REGENT LABS., KARACHI

42.	028502	E-COLIMICINA COMPOUND POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……..25.00G COLISTIN SULFATE…….300,000,000 I.U **FURALTADONE** HCL……..75.00GM (ANTIBIOTICS).	M/S. REGENT LABS., KARACHI
43.	029615	TRIFLE POWDER EACH KG CONTAINS: - CHLORTETRACYCLINE HCL…….100.000GM NEOMYCIN AS SULPHATE……..30.000GM FURALTADONE……..75.000GM	M/S. SELMORE PHARMACEUTICALS (PVT) LTD., LAHORE
44.	057017	RALCOSIN POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……200GM COLISTINE SULPHATE…..10,000,000IU **FURALTADONE**…….200GM	M/S. SELMORE PHARMACEUTICALS (PVT) LTD MULTAN ROAD LAHORE
45.	029635	TY-CO-FURA POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……...200GM **FURALTADONE** …. …….200GM COLISTIN SULPHATE……..10,000,000 I.U	M/S. FARM AID GROUP PAKISTAN, HATTAR, HARIPUR, N.W.F.P.
46.	033276	TYLOFURCIN PLUS POWDER. EACH 1000GM CONTAINS:- TYLOSIN TARTRATE……...20GM ERYTHROMYCIN THIOCYONATE……50GM **FURALTADONE** HCL……100GM VITAMIN A …….2,500,000IU VITAMIN D3 ……..…..1,500,000IU VITAMIN E……10GM	M/S. FARM AID GROUP PAK., HATTAR.
47.	033278	F.N. CHLOR 82 WATER SOLUBLE POWDER. EACH KG CONTAINS:- CHLORTETRACYCLINE HCL…….40GM NEOMYCIN BASE AS SULPHATE….12GM **FURALTADONE** AS HCL…….30GM	M/S. FARM AID GROUP PAK., HATTAR.
48.	043237	FURALIUM POWDER. EACH 100GM CONTAINS:- AMPROLIUM HCL……...20GM **FURALTADONE** HCL……..20GM	M/S. FARM AID GROUP PAK., HATTAR.
49.	043239	FAR-COX ORAL POWDER. EACH KG CONTAINS:- SULFADIMMERAZINE,NA (BP)……..….20GM SULFAQUINOXALINE,NA(BP)……25GM PYRIMETHAMINE ……25GM **FURALTADONE** HCL ……100GM VITAMIN A……15MIU VITAMIN K …… …….5GM	M/S. FARM AID GROUP PAK., HATTAR.
50.	045000	E.F. TYLO PLUS ORAL POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE …….. 60.0GM **FURALTADONE** HCL……150.0GM BROMHEXINE HCL……...5.0GM ERYTHROMYCIN THIOCYNATE…..40.0GM (ANTIBIOTICS).	M/S. FARM AID GROUP PAK INC., HATTAR.

51.	029677	HIRA TYLO PLUS W.S. POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……60GM ERYTHROMYCIN THIOCYANATE….40GM **FURALTADONE**……150GM	M/S. HIRRA PHARMACEUTICAL LABORATORIES, LAHORE.
52.	031426	IMAGICIN ORAL POWDER EACH 100GM CONTAINS:- TYLOSIN TARTRATE…….5GM ERYTHROMYCIN THIOCYANATE…..…6GM **FURALTADONE** HCL……...15GM (ANTIBACTERIAL).	M/S. MEDIEXCEL PHARMACEUTICALS, ISLAMABAD.
53.	035176	XS-COXI WATER SOLUBLE POWDER. EACH 100GRAM CONTAINS:- SULPHAQUINOXALINE SODIUM …4.00GM SULPHAMERAZINE SODIUM …….20.00GM **FURALTADONE** HCL …. ……15.00GM PYRIMETHAMINE HCL ……..……2.00GM VITAMIN A ……..…….1200000IU VITAMIN K3 ……2.00GM	M/S. MEDIEXCEL PHARMACEUTICALS, ISLAMABAD.
54.	043227	CUBAR PLUS SOLUTION EACH 100ML CONTAINS:- TRIMETHOPRIM.....…… 2000.00MG SULPHADIAZINE.....10000.00MG **FURALTADONE** HCL…….2500.00MG COLISTIN SULPHATE….25,000,000IU HEXAMINE……...5000.00MG	M/S. MEDIEXCEL PHARMACEUTICALS, ISLAMABAD.
55.	043230	MEDICINA COMPLEX WATER SOLUBLE POWDER. EACH 1000GRAM CONTAINS:- TYLOSIN TARTRATE…….25.00GM **FURALTADONE** HCL…..……75.00GM	M/S. MEDIEXCEL PHARMACEUTICALS, ISLAMABAD.
56.	031428	CRD CURE ORAL POWDER EACH KG CONTAINS:- TYLOSIN TARTRATE…….200GM **FURALTADONE** ……..……100GM COLISTINE SULPHATE……30,000,000 I.U	M/S. AVICENNA LABORATORIES (PVT) LTD., SHEIKHUPURA.
57.	031506	FURACHLOR-N W/S POWDER EACH KG CONTAINS:- CHLORTETRACYCLINE……..50GM **FURALTADONE**……40GM NEOMYCIN ……12.5GM	M/S. AVICENNA LABORATORIES (PVT) LTD., SHEIKHUPURA
58.	031507	FOXYCOL W/S POWDER EACH KG CONTAINS:- OXYTETRACYCLINE HCL……200GM **FURALTADONE**……...100GM COLISTINE SULPHATE……..25,000,000 I.U	M/S. AVICENNA LABORATORIES (PVT) LTD., SHEIKHUPURA
59.	033257	ZECOX POWDER. EACH 100GM CONTAINS:- AMPROLIUM HCL…….20GM **FURALTADONE** HCL……20GM	M/S. UNIVET PHARMACEUTICALS, RAWALPINDI.
60.	033281	SUPER TCF POWDER. EACH 1000GM CONTAINS:- TYLOSIN TARTRATE……..…50GM COLISTIN SULFATE ……600,000 I.U **FURALTADONE** HCL……..….150GM	M/S. LEADS PHARMAS (PVT) LTD., ISLAMABAD.

61.	033282	VETY TYLO E.F. PLUS POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……20GM ERYTHROMYCIN THICOYNATE……...50GM **FURALTADONE** HCL……..100GM VITAMIN A ……...2,500,000 I.U VITAMIN D3 ……1,500,000 I.U VITAMIN E ACETATE……..10GM	M/S. LEADS PHARMAS (PVT) LTD., ISLAMABAD.
62.	043152	NEO-CF POWDER. EACH 1000GM CONTAINS:- CHLORTETRACYCLINE HCL …. …..40GM NEOMYCIN SULPHATE ……. ……12GM **FURALTADONE** HCL ……..30GM	M/S. LEADS PHARMA (PVT) LTD., ISLAMABAD.
63.	043165	ICC-O-BACTIN POWDER. EACH KG CONTAINS:- **FURALTADONE** ……200GM (ANTIBIOTIC).	M/S. LEADS PHARMA (PVT) LTD., ISLAMABAD.
64.	044916	FURACIN-PLUS POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……. ……. 25GM COLISTIN SULPHATE…….300,000IU **FURALTADONE** HCL ……75MG VITAMIN A ...……..30GM	M/S. LEADS PHARMA (PVT) LTD., ISLAMABAD.
65.	043515	AMPROFUR POWDER. EACH KG CONTAINS:- **FURALTADONE** HCL ……200GM AMPROLIUM HCL……200GM (ANTIBIOTICS).	M/S. LEADS PHARMA (PVT) LTD., ISLAMABAD.
66.	046587	COXICURE POWDER. EACH 100GM CONTAINS:- SULPHAQUINOXALINE NA,……. 20GM SULPHAMERAZINE ……..2.5GM **FURALTADONE** ……2.5GM PYRIMETHAMINE …….……2.5GM VITAMIN A ……. ……..….1.5MIU VITAMIN K3 ……0.5GM (ANTIBIOTIC).	M/S. LEADS PHARMA (PVT) LTD., ISLAMABAD
67.	046663	VETY AMPRO PLUS POWDER. EACH KG CONTAINS:- AMPROLIUM……200MG **FURALTADONE** …… 200MG VITAMIN A ……4000000IU VITAMIN D3 ……2000000IU VITAMIN K3……. 10MG (MYCOLYTIC/VITAMIN).	M/S. LEADS PHARMA (PVT) LTD., ISLAMABAD
68.	057062	SPF POWDER. EACH KG CONTAINS:- SULPHAQUINOXALINE …….. 25GM SULPHADIMERAZINE …….... 200GM PYRAMETHAMINE …… ….….25GM **FURALTADONE** ….. ……..…..100GM VITAMIN A …… 1500000 IU VITAMIN K ……....…. 5GM	M/S. LEADS PHARMA (PVT) LTD ISLAMABAD.

69.	033293	VITRAL WATER SOLUBLE POWDER. EACH 100GM CONTAINS:- TYLOSIN TARTRATE……..20GM ERYTHROMYCIN THIOCYANATE…..50GM **FURALTADONE** HCL…….10GM VITAMIN A ……..….25,00,000 I.U VITAMIN D3 ……15,00,000 I.U VITAMIN E ……..10GM	M/S. REX PHARMACEUTICAL PAKISTAN, KARACHI.
70.	033298	FURAMYCIN POWDER. EACH 100GM CONTAINS:- ERYTHROMYCIN PHOSPHATE 13GM. **FURALTADONE** HCL 20GM.	M/S. REX PHARMACEUTICAL PAKISTAN, KARACHI.
71.	034511	TYLOFURADAD-C WATER SOLUBLE POWDER. EACH GM CONTAINS:- TYLOSIN TARTRATE……..250MG **FURALTADONE** HCL ……150MG COLISTIN SULPHATE ……200000 I.U	M/S. VETNOCARE PHARMACEUTICAL INT., LAHORE
72.	034567	ANZAH-FURA WATER SOLUBLE POWDER. EACH KG CONTAINS:- **FURALTADONE** TITRATE……..200GM	M/S. BIO-LABS (PVT) LTD, ISLAMABAD
73.	039988	FNC 100 WATER SOLUBLE POWDER. EACH KG CONTAINS:- **FURALTADONE**…….30GM NEOMYCIN SULPHATE……...12GM CHLORTETRACYCLINE HCL…….40GM	M/S. BIO-LABS (PVT) . LTD. ISLAMABAD
74.	043177	HITCOX WATER SOLUBLE POWDER. EACH GM CONTAINS:- SULPHAMERAZINE SODIUM ……..200MG SULPHAQUINOXALINE SODIUM …….25MG PYRIMETHAMINE HCL……25MG **FURALTADONE** HCL……..100MG VITAMIN A ……...16,000IU VITAMIN K……...5MG	M/S. BIO-LABS (PVT) LTD, ISLAMABAD
75.	043182	MYCODOXYN POWDER. EACH 100GM CONTAINS:- DOXYCYCLINE HCL……..10% TYLOSINE TARTRATE……5% **FURALTADONE** HCL……15% ERYTHROMYCIN THIOCYANATE..6%	M/S. BIO-LABS (PVT) LTD, ISLAMABAD
76.	025328	FURADOX WATER SOLUBLE POWDER CONTAINS: - DOXYCYCLINE HCL……25% **FURALTADONE**…….25%	M/S. ALINA COMBINE PAKISTAN (PVT) LTD KARACHI
77.	035096	MICOLI COMPLEX WATER SOLUBLE POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……..25GM **FURALTADONE** HCL…….……75GM COLISTIN SULPHATE……..300MIU	M/S. ALINA COMBINE PAKISTAN (PVT) LTD., KARACHI.

78.	035097	NEOTETRADON WATER SOLUBLE POWDER. EACH KG CONTAINS:- CHLORTETRACYCLINE HCL……100GM **FURALTADONE** HCL……75GM NEOMYCIN SULPHATE……...30GM VITAMIN A ……0.5MIU VITAMIN D3 ……..……..0.1MIU VITAMIN E ……..…250MG VITAMIN C ……..10000MG	M/S. ALINA COMBINE PAKISTAN (PVT) LTD., KARACHI.
79.	043574	NEOCLIN POWDER. EACH KG CONTAINS:- CHLORTETRACYCLINE HCL……40GM NEOMYCIN SULPHATE ….. ….……12GM **FURALTADONE** ……...…30GM (ANTIBACTERIAL).	M/S. ALINA COMBINE PHARMACEUTICALS (PVT) LTD., KARACHI.
80.	043575	TEF POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE ……..60G ERYTHROMYCIN THIOCYNATE…….40GM **FURALTADONE** ……...150GM (ANTIBACTERIAL).	M/S. ALINA COMBINE PHARMACEUTICALS (PVT) LTD., KARACHI.
81.	046674	ARALDONE WATER SOLUBLE POWDER EACH GM CONTAINS:- AMPROLIUM HCI.....200MG **FURALTADONE** HCI.....200MG (ANTIBACTERIAL).	M/S. ALINA COMBINE PHARMACEUTICALS (PVT) LTD. KARACHI.
82.	048113	SULFACOX WATER SOLUBLE POWDER. EACH KG CONTAINS:- SULFADIMERAZINE SODIUM B.P…...200GM SULFAQUINOXALINE SODIUM B.P…..25GM PYRIMETHAMINE HCL B.P…….25GM **FURALTADONE** HCL MFG. SPEC…100GM VITAMIN A B.P……..15000000 I.U VITAMIN K3 B.P……..5GM	M/S. ALINA COMBINE PHARMACEUTICALS (PVT) LTD., KARACHI.
83.	035044	AMPRO COC ORAL POWDER. EACH KG CONTAINS:- AMPROLIUM HCL…….200GM **FURALTADONE** HCL……200GM	M/S. A&K PHARMACEUTICALS, FAISALABAD.
84.	035119	ERYTYL-F ORAL POWDER EACH KG CONTAINS:- TYLOSINE…….50GM ERYTHROMYCIN THIOCYNATE…….60GM **FURALTADONE** HCL……140GM	M/S. A&K PHARMACEUTICALS, FAISALABAD.
85.	035120	O-NEFUR ORAL POWDER EACH KG CONTAINS:- OXYTETRACYCLINE…….……..50GM NEOMYCIN……14GM **FURALTADONE**……30GM	M/S. A&K PHARMACEUTICALS, FAISALABAD.
86.	035121	CNEF WATER SOLUBLE POWDER. EACH KG CONTAINS:- CHLORTETRACYCLINE HCL……...100GM NEOMYCIN SULPHATE……...30GM **FURALTADONE**…….75GM	M/S. A&K PHARMACEUTICALS, FAISALABAD.

87.	044913	ERYFUR WATER SOLUBLE POWDER. EACH 100GM CONTAINS:- ERYTHROMYCIN THIOCYANATE……13GM **FURALTADONE** HCL……...20GM	M/S. A&K PHARMACEUTICALS, FAISALABAD.
88.	041203	TYFOCOLIN-100 POWDER. EACH 1000GM CONTAINS:- TYLOSIN TARTRATE…….25.0GM COLISTIN SULPHATE ……3,00,000 I.U **FURALTADONE** HCL ……75.0GM (ANTI-BACTERIAL).	M/S. JFRIN PHARMACEUTICALS, HUB INDUSTRIAL ESTATE BALOCHISTAN.
89.	041212	JF-FYLO PLUS ORAL POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……60GM ERYTHROMYCIN THIOCYANATE…40GM **FURALTADONE** HCL…….150GM (ANTI-BACTERIAL/ ANTIBIOTIC).	M/S. JFRIN PHARMACEUTICALS, HUB INDUSTRIAL ESTATE BALOCHISTAN.
90.	041277	FCN-100 POWDER. EACH 100GM CONTAINS:- CHLORTETRACYCLINE HCL…….40GM NEOMYCIN SULPHATE……..12GM **FURALTADONE** HCL)…….30GM	M/S. LEXICON PHARMACEUTICALS (PVT) LTD., KARACHI.
91.	043262	COLITYL POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE …. ……..25GM COLISTIN SULPHATE……..300,000,000 IU **FURALTADONE** HCL……..75GM	M/S. LEXICON PHARMACEUTICALS (PVT) LTD., KARACHI
92.	043263	TEFCON POWDER. EACH KG CONTAINS: - TYLOSIN TARTRATE.....60GM ERYTHROMYCIN…... ……40GM **FURALTADONE**.....150GM	M/S. LEXICON PHARMACEUTICALS (PVT) LTD., KARACHI.
93.	049760	FUROLIUM WATER SOLUBLE POWDER. EACH KG CONTAINS:- AMPROLIUM HCL……..200GM **FURALTADONE** HCL…….200GM VITAMIN K3……..…...5GM	M/S. LEXICON PHARMACEUTICALS (PVT) LTD., 158-D, TORO GADAP ROAD, SUPER HIGHWAY, KARACHI.
94.	041293	TRICID WATER SOLUBLE POWDER. EACH GM CONTAINS:- CHLORTETRACYCLINE HCL …..….100MG NEOMYCIN SULPHATE……75MG **FURALTADONE** HCL..….....30.000MG	M/S. PRIX PHARMACEUTICA (PVT) LTD., LAHORE.
95.	043290	ERYTAC WATER SOLUBLE POWDER. EACH GM CONTAINS:- ERYTHROMYCIN THIOCYANATE……60MG **FURALTADONE** HCL……...150MG TYLOSIN TARTRATE.. …. …….50MG	M/S. PRIX PHARMACEUTICA (PVT) LTD., LAHORE.
96.	043292	COPRIX WATER SOLUBLE POWDER. EACH GM CONTAINS:- SULFADIMERAZINE SODIUM……200MG SULFAQUINOXALINE SODIUM……..25MG PYRIMETHAMINE HCL ……25MG **FURALTADONE** HCL……....100MG VITAMIN A…….…15,000IU VITAMIN K3 [MENADIOL SODIUM PHOSPHATE]……...0.5.000MG	M/S. PRIX PHARMACEUTICA (PVT) LTD., LAHORE.

97.	043121	EL-TCF POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE……25.0GM COLISTIN SULPHATE……300,000,000IU **FURALTADONE** HCL……75.0GM	M/S. ELKO ORGANIZATION (PVT) LTD., KARACHI.
98.	046551	N.C.F. – 100 POWDER. EACH KG CONTAINS:- CHLORTETRACYCLINE HCL (BP)…….40GM NEOMYCIN SULPHATE BP…….12GM **FURALTADONE** HCL BP(VET)……..30GM (ANTIBIOTIC).	M/S. SYMANS PHARMACEUTICALS (PVT) LTD., LAHORE.
99.	046574	AMPRODONE WATER SOLUBLE POWDER. EACH GM CONTAINS:- AMPROLIUM HCL……200MG **FURALTADONE** HCL……...200MG (ANTICOCCIDIAL/ANTIBACTERIAL).	M/S. NOA HEMIS PHARMACEUTICALS, KARACHI.
100.	048108	TYLOCOL F-100 WATER SOLUBLE POWDER. EACH KG CONTAINS:- TYLOSIN TARTRATE…….25GM COLISTIN SULPHATE…….300MIU **FURALTADONE** HYDROCHLORIDE..75GM	M/S. NOA HEMIS PHARMACEUTICALSKARACHI.
101.	046593	TYLOFURA-E ORAL POWDER EACH 100GM CONTAINS:- TYLOSIN TARTRATE BP/USP ……5.0GM ERYTHROMYCIN THIOCYANATE BP …….6.0GM **FURALTADONE** BP VET……15.0GM	M/S. INTERVAC (PVT) LTD., LAHORE.
102.	046683	AMIDIFAS POWDER. EACH 100GM CONTAINS:- AMPROLIUM HCL …….20GM **FURALTADONE** HCL ……20GM	M/S. INTERVAC (PVT) LTD., SHEIKHUPURA.
103.	048258	CHLOROFURA-N WATER SOLUBLE POWDER. EACH 100GM CONTAINS:- CHLOROTETRACYCLINE HCL BP VET. ……10.0GM NEOMYCIN SULPHATE BP ……3.0GM **FURALTADONE** BP VET…….7.5GM (ANTI-BACTERIALS).	M/S. INTERVAC (PVT) LTD., LAHORE.
104.	046620	TEF-MALL POWDER. EACH KG CONTAINS:- TYLOSIN ……..60GM ERYTHROMYCIN……40GM **FURALTADONE**…….150GM (ANTIBIOTIC).	M/S. MALLARD PHARMACEUTICAL (PVT) LTD., MULTAN.
105.	049564	WEALCOC POWDER. EACH KG CONTAINS:- AMPROLIUM……...200GM **FURALTADONE** ……200GM VITAMIN K3 ……. 5GM (COMBINE ANTICOCCIDIOL & ANTIBIOTIC).	M/S. MALLARD PHARMACEUTICAL (PVT) LTD., MULTAN

106.	053963	AR TNF 100 ORAL POWDER EACH KG CONTAINS: - OXYTETRACYCLINE……..……..250G NEOMYCINE SULPHATE……100G **FURALTADONE** HYDROCHLORIDE…250G SODIUM SULPHATE…….60G VITAMIN A……...2500,000 IU VITAMIN D3……...500,000 IU VITAMIN E……...1G VITAMIN C……...100G	M/S. MALLARD PHARMACEUTICAL (PVT) LTD LAHORE
107.	053966	DEKCOC ORAL POWDER EACH KG CONTAINS: - **FURALTADONE**……95,000MG VITAMIN A…….17,500,000 IU VITAMIN D……....2450,000 IU VITAMIN E……..5000MG VITAMIN K……..8000MG	M/S. MALLARD PHARMACEUTICAL (PVT) LTD LAHORE
108.	053969	TCF GUARD ORAL POWDER EACH KG CONTAINS: - TYLOSIN TARTRATE……..200G COLISTIN SULPHATE……10000000 IU **FURALTADONE**……...200G	M/S. MALLARD PHARMACEUTICAL (PVT) LTD LAHORE
109.	046638	TYCOL – FDS WATER SOLUBLE POWDER EACH 1000GM CONTAINS:- TYLOSIN TARTRATE …….50GM COLISTIN SULPHATE ……30GM **FURALTADONE** HYDROCHLORIDE..150GM (ANTI-BACTERIAL).	M/S. ZUMARS PHARMA FTY (PVT) LTD., KARACHI.
110.	048114	FURANEC SUPER WATER SOLUBLE POWDER. EACH 1000GM CONTAINS:- CHLORTETRACYCLINE HYDROCHLORIDE……100GM NEOMYCIN (AS SULPHATE) ……...30GM **FURALTADONE**……75GM	M/S. ZUMARS PHARMA FTY (PVT) LTD., KARACHI.
111.	049556	NEOCEF WATER SOLUBLE POWDER. EACH 1000GM CONTAINS:- CHLORTETRACYCLINE HYDROCHLORIDE…….40GM NEOMYCIN (AS SULPHATE)……..12GM **FURALTADONE**…….30GM	M/S. ZUMARS PHARMA FTY (PVT) LTD., KARACHI.
112.	048156	TYLOZAK PLUS POWDER. EACH KG CONTAIN:- TYLOSIN TARTRATE B.P. (VET) ……...25GM **FURALTADONE** B.P. (VET) …. ……..75GM COLISTIN SULPHATE B.P. (VET) …..300MIU (ANTIBIOTIC).	M/S. ZAKFAS PHARMACEUTICALS (PVT) LTD., MULTAN.
113.	048188	COCCIMONT WATER SOLUBLE POWDER. EACH 1000GM CONTAINS:- SULPHAMERAZINE SODIUM ……200GM SULPHAQUINOXALINE SODIUM …..25GM PYRAMETHAMINE HCL……...25GM **FURALTADONE** HCL …….100GM VITAMIN K3 ……. ……..5GM VITAMIN A……. 15000000 IU (ANTI-MICROBIAL).	M/S. WESTMONT PHARMACEUTICAL INDUSTRIES, GUJARKHAN.

114.	049776	BIOTIC PLUS POWDER EACH 100G CONTAINS: - TYLOSIN TARTRATE BP……..…..…5GM DOXYCYCLINE HCL BP……..….10GM ERYTHROMYCIN THIOCYANATE BP.6GM **FURALTADONE**……15GM	M/S. ATTABAK PHARMA ISLAMABAD
115.	053904	NEO.F WATER SOLUBLE POWDER. EACH 1000GM CONTAINS:- NEOMYCIN AS SULPHATE (BP) ……28GM OXYTETRACYCLINE HCL (BP)……100GM **FURALTADONE** HCL……....60GM	M/S. ATTABAK PHARMACEUTICALS ISLAMABAD.
116.	053905	N.C.BAK WATER SOLUBLE POWDER. EACH 100GM CONTAINS:- NEOMYCIN AS SULPHATE (BP)……12GM CHLORTETRACYCLINE HCL (BP) …...40GM **FURALTADONE** HCL……..…..30GM	M/S. ATTABAK PHARMACEUTICALS ISLAMABAD.
117.	053923	COCCIS POWDER EACH GM CONTAINS:- SULFADIMERAZINE SODIUM……..… 200MG SULFAQUINOXALINE SODIUM ……...25MG PYRIMETHAMINE…….25MG **FURALTADONE** ……..…25MG VITAMIN A ……15,000 I.U VITAMIN, K3, …….5MG	M/S. ATTABAK PHARMACEUTICALS ISLAMABAD.
118.	053924	CARCOX POWDER EACH GM CONTAINS:- SULFADIMERAZINE SODIUM…….200MG SULFAQUINOXALINE SODIUM ….…..25MG PYRIMETHAMINE ……...25MG **FURALTADONE** HCL ……....100MG VITAMIN A ……15,000 I.U. VITAMIN, K3, ……..5MG	M/S. ATTABAK PHARMACEUTICALS ISLAMABAD.
119.	073965	FURNEOCIN ORAL POWDER EACH 1000GM CONTAINS:- CHLOROTETRACYCLINE……..40GM NEOMYCIN ……..…12GM **FURALTADONE**……..……30GM	M/S. NAWAL PHARMACEUTICALS, PLOT NO.11-A PUNJAB SMALL INDUSTRY ESTATE TAXILA, RAWALPINDI.
120.	073968	ERY-TYLODON ORAL POWDER EACH 100GM CONTAINS:- TYLOSIN…….5GM ERYTHROMYCIN……..…6GM **FURALTADONE**…….....15GM	M/S. NAWAL PHARMACEUTICALS, PLOT NO.11-A PUNJAB SMALL INDUSTRY ESTATE TAXILA, RAWALPINDI.

Decision:- **Keeping in view the strong potential of causing genotoxicity and cytotoxicity due to possible residual effects by Furaltadone and complete ban of the same by US-FDA and Euroepan Union, Registration Board decided to issue show casue notices to all firms having registered products containing Furaltadone under the provisions of Section 7(11)(b,c & d) and 42 of Drug Act, 1976 and Rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976.**

(B) The following products, containing ***Furaltadone,*** were approved in various meetings of Registration Board. However, registration letters of the said products were withheld till policy decision regarding the use of Furaltadone. Now, Registration Board in its 289th meeting rejected

registration applications of veterinary drugs containing ***Furaltadone*** having strong potential of causing genotoxicity and cytotoxicity due to possible residual effects.

Sr. No.	Name of Manufacturer	Name of Drug(s)/Composition	Pack Size(s)	Meeting No.
1.	M/s. Bio-Oxime Pharmaceuticals, Faisalabad.	CNF-GOLD Oral Powder Each 1000gm contain: ChloroTetracycline……..40gm Neomycin Sulphate B.P…..12 gm **Furaltadone B.P……30 gm**		Approved 249th meeting
2.	-do-	Eflosin Oral Powder Each 1000gm contains:- Tylosin Tartrate……..…50gm **Furaltadone……140gm** Erythromycin……..…..60g	10gm 30gm 100gm 500gm 1000gm 5000gm	Approved 254th meeting.
3.	M/s. Mallard Pharmaceutical (Pvt) Ltd., 23 Km. Lahore Road, Qadirpur Rawan, Multan.	NF-Chlor Powder Each Kg contains:- Chlortetracycline…….50g Neomycin sulphate……..12.5g **Furaltadone HCL……..….40g**	100gm 150gm 250gm 500gm 1000gm 2.5Kg	Approved 250th meeting.
4.	-do-	CTNF-205 Powder Each gm contains:- Chlortetracycline……100mg Neomycin sulphate……..30mg **Furaltadone HCL……..…..75mg**	100gm 150gm 250gm 500gm 1000gm 2.5Kg	Approved 250th meeting.
5.	M/s. Ras Pharmaceuticals (Pvt) Ltd., Multan.	AF-200 Oral Powder Each 100gm contains:- Amprolium…….....20gm **Furltadone……20gm**	100gm 500gm 1 Kg 2.5 Kg 5 Kg 25 Kg	Approved 253rd meeting.
6.	-do-	RESPICARE Oral Powder Each 100gm contains:- Tylosin Tartrate…….5g Erythromycin thioicynate…….6g **Furaltadone HCL……..…..14g**	100gm 500gm 1 Kg 2.5 Kg 5 Kg 25 Kg	Approved 253rd meeting.
7.	M/s. Zakfas Pharmaceuticals Pvt Ltd., Multan.	TMO Powder 100 Each 1000gm contains:- OxytetracyclineHCl……...150mg Neomycin Sulphate……..…60gm **FuraltadoneHCl……..…..150gm**	100gm 500gm 1Kg	Approved 255th meeting.
8.	M/s. ICI Pakistan Limited, Life Sciences, 45-KM, Off. Multan Road, Lahore.	Eflosin Oral Powder Each Kg contains:- Tylosin Tartrate……60gm Erythromycin Thiocyanate……..40gm **Furaltadone as HCl……..150g**	100gm 250gm 500gm 1Kg 5Kg 25Kg	Approved 257th meeting.
9.	M/s. International Pharma Labs. Raiwind Road, Bobhtian Chowk,	I-Amprofort-40 Oral Powder Each 100gm contains:- Amprolium HCL……..20gm **Furaltadone HCL……...20gm**	50gm 100gm 250gm 500gm	Approved 264th meeting.

	Defence Road, 1-Km Towards Kahna, Lahore.		1000gm 5000gm 25000gm	

Decision:- Keeping in view the strong potential of causing genotoxicity and cytotoxicity due to possible residual effects by Furaltadone and complete ban of the same by US-FDA and Euroepan Union, Registration Board decided to issue show casue notices to all firms having registered/approved products containing Furaltadone under the provisions of Section 7(11)(b,c & d) and 42 of Drug Act, 1976 and Rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976.

Case No. 32: Veterinary drugs containing Furazolidone.

Registration Board in its 289th meeting rejected registration applications of veterinary drugs containing ***Furazolidone*** having strong potential of causing genotoxicity and cytotoxicity due to possible residual effects. A number of other veterinary products having Furazolidone as an API, are registered in favor of number of firms as per following details;-

S.No	Regn. No.	Name Of Drug(S)/Composition	Name Of Applicant/ Manufacturer
1.	002038	RIMAZONE SUPPLEMENT EACH POUND CONTAINS:- **FURAZOLIDONE**……...100GMS VITAMIN A…….500,000 UNITS VITAMIN D…….390,000 UNITS VITAMIN E……150 UNITS RI-BOFLAVIN……..650MG D-PANTOTHENIC ACID..1050MG NIACINAMIDE…….….6000MG VITAMIN K……..180MG VITAMIN B12……...500MCG	M/S. RISMA LAB KARACHI.
2.	002039	RIMAZONE PREMIX EACH POUND CONTAINS:- **FURAZOLIDONE**…….20GMS VIT A…….100000 UNITS VIT D3……18,000 UNITS VIT E…….30 UNITS RIBOFLAVIN……...130MG D-PANTOTHENIC ACID…210MG NIACINAMIDE……600MG VIT K……..36MG VIT B12……..100MCG	M/S. RISMA LAB KARACHI.

3.	003353	AURO-F DISPERSIBLE POWDER EACH 5KG CONTAINS:- AUREOMYCIN CHLORTETRACYCLINE…..50MG **FURAZOLIDONE**……...30GM VITAMIN A…….2500,000 I.U. VITAMIN D……...250,000 I.U. MENADIONE SOD BISULPHATE…….……...1580MG VITAMIN E……100,000 I.U. PYRIDOXINE……600MG NIACIN……...13GM D. CALCIUM PANTOTHENATE……4.5GM RIBOFLAVIN……..2 GM CYANOCOBALAMIN……...2MCG	M/S. CYANAMID PAKISTAN LTD, KARACHI.
4.	005133	FURAZOLIDONE POWDER CONTAINS:- **FURAZOLIDONE**……..5%	M/S. STAR LABS LAHORE.
5.	005134	FURAZOLIDONE POWDER CONTAINS:- **FURAZOLIDONE**…….20%	M/S. STAR LABS LAHORE.
6.	006303	ERYTHRO-FB POWDER EACH KG CONTAINS:- FRYTHROMYCIN……6GMS **FURAZOLIDONE**…….30GM	M/S. EPLA LAB KARACHI.
7.	006304	FURATIN SUPPLEMONT CONTAINS:- **FURAZOLIDONE**…….10%	M/S. EPLA LAB KARACHI.
8.	006305	NITROSOL POWDER EACH KG CONTAINS:- NITROFURAZONE…….500MG **FURAZOLIDONE**……...72.5MG	M/S. EPLA LAB KARACHI.
9.	010695	FUDON (VETERINARY) POWDER EACH KG CONTAINS:- **FURAZOLIDONE**…….22.4% W/W	M/S. KAILGON AGRO KARACHI.
10.	028506	OXIFUR FP PLUS FEED PREMIX. EACH KG CONTAINS:- OXYTETRACYCLINE DIHYDRATE……200GM **FURAZOLIDONE**…….100GM	M/S. KAILGON AGRO INDUSTRIES (PVT) LTD., BALUCHISTAN.
11.	013260	VF-18 POWDER EACH KG CONTAINS:- **FURAZOLIDONE**……...168000MG VITAMIN A ……..2100000 IU VITAMIN D3……...210000 IU VITAMIN E……1050MG VITAMIN K …….525MG	M/S. N.H. SHAHANI FAISALABAD.
12.	014574	FURAZONE-M FEED SUPPLEENT POWDER EACH 1000GM CONTAINS:- **FURAZOLIDONE**….244GM	M/S. MANHATTAN PHARMA KARACHI.
13.	015435	NEFRON SUPPLEMENT POWDER EACH KG CONTAINS: - **FURAZOLIDONE**……..240GMS	M/S. MEDICURE LABORATORIES KARACHI.

14.	015438	FURAMIX POWDER EACH KG CONTAINS:- **FURAZOLIDONE** B.P. ….246GMS KAOLIN LIGHT…….754GMS	M/S. REGENT LABORATORIES KARACHI.
15.	016242	ERYDON POWDER EACH 1KG CONTAINS:- ERYTHROMYCINE THIOCYANATE…….....240GM **FURAZOLIDONE**……126GM	M/S. VITAL MARK LABORATORIES TOBA TEK SINGH.
16.	016297	BISLONG POWDER EACH KG CONTAINS:- **FURAZOLIDONE**……..10GM	M/S. SELMORE AGENCIES LAHORE.
17.	019069	AMOVIT-M POWDER EACH 5 KG CONTAINS:- VIT.A ACETATE……....15MU VIT. D3……..…2MU VIT.E……....0.03MU VIT K3 50%.....3000MG VIT. B1……3000MG VIT. B2……8000MG VIT. B6……4000MG VIT. B12 1%.....30MG NICOTINIC ACID……...45000MG PANTOTHENIC ACID….15000MG FOLIC ACID……...1500MG BIOTIN 2%.....150MG ZINC BACITRACIN…...200000MG CHOLINE CHLORIDE 50%.....600000MG **FURAZOLIDONE**…….50000MG LYSINE MONO HCL.....800000MG METHIONINE.....1000000MG MANGANESE SULPHATE.....200000MG COPPER SULPHATE…...50000MG FERROUS SULPHATE.....200000MG ZINC SULPHATE……...150000MG	M/S. MORNING ENTERPRISES LTD SHEIKHUPURA.
18.	023406	REOTHIN-H FEED SUPPLEMENT CONTAINS:- **FURAZOLIDONE**……24.4% W/W	M/S. DELUX CHEMICAL INDUSTRIES KARACHI.
19.	023453	REOTIN-F FEED PREMIX EACH 100GM CONTAINS:- **FURAZOLIDONE**…….4.5GM	M/S. DELUX CHEMICAL INDUSTRIES KARACHI.
20.	023435	FURASYM POWDER EACH KG CONTAINS:- **FURAZOLIDONE**……950GM	M/S. SYMANS PHARMACEUTICALS (PVT) LTD LAHORE.
21.	026408	FURAZOL SUPER POWDER EACH KG CONTAINS:- **FURAZOLIDONE**……950GM	M/S. FARIM AID GROUP HAIRPUR.

22.	031593	ENDOMET OINTMENT WITH INJECTOR EACH 20GM INJECTOR CONTAINS:- OXYTETRACYCLINE HCL…… 500MG. IODOCHLOROHYDROXY QUINOLINE…….500MG. **FURAZOLIDONE**……....500MG. VITAMIN E……200MG.	M/S. ELKO ORGANIZAITON (PVT) LTD KARACHI.
23.	035019	SANFURA-25 ORAL POWDER. EACH KG POWDER CONTAINS:- **FURAZOLIDONE**…….....250GM.	M/S. SANNA LABORATORIES, FAISALABAD.
24.	035062	UTACARE PESSARY. EACH GM PESSARY CONTAINS:- CHLORTETRACYCLINE HCL……. 1.00GM. **FURAZOLIDONE**…….0.500GM. METRONIDAZOLE……1.00GM.	M/S. NAWAN LABORATORIES (PVT) LTD., KARACHI.
25.	046588	N.F-16 POWDER. EACH KG CONTAINS:- **FURAZOLIDONE** ……160,000MG. VITAMIN A ……20,00,000 IU. VITAMIN D3 ……200,000 I.U. VITAMIN E ……...1000MG. VITAMIN K …….500MG.	M/S. LEADS PHARMA (PVT) LTD., ISLAMABAD.
26.	002015	NEFTIN PREMIX POWDER CONTAINS:- **FURAZOLIDONE** IN A CALCIUM CARBONATE BASE……4.4%	M/S. SMITH KLINE AND FRENCH OF (PAKISTAN) LTD, KARACHI.
27.	002018	BIFURAN SUPPLEMENT POWDER CONTAINS:- NITROFURAZONE……...3.6% **FURAZOLIDONE** IN CALCIUM CARBONATE BASE……..25%	M/S. SMITH KLINE AND FRENCH OF (PAKISTAN) LTD, KARACHI.

Decision:- Keeping in view the strong potential of causing genotoxicity and cytotoxicity due to possible residual effects by *Furazolidone* and complete ban of the same by US-FDA and Euroepan Union, Registration Board decided to issue show casue notices to all firms having registered products containing Furazolidone under the provisions of Section 7(11) (b,c & d) and 42 of Drug Act, 1976 and Rule 24(17) of Drugs (Licensing, Registration & Advertising) Rules, 1976.

Case No. 33: Cancellation of distribution agreement of M/s. SS Associates, Lahore by their principal abroad (Turkey).

M/s. Medicavet, Turkey informed vide letter about termination of distribution agreement with M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, Mozang Chungi Jail Road, Lahore ***w.e.f. 18-01-2019*** and further informed about appointment of *M/s. Unicare Enterprises, Faisalabad* (Head Office: M/s. Unicare Enterprises, Commercial -06, 1st Floor, Block-A, Kazimabad, Model Colony, Karachi, Pakistan-75100) (Regd. Office: Reg. Office: Plot No. 587/1-B, Street No.3, Punjab Small Industrial Estate, Nalka Kohala, Sargodha Road, Faisalabad) as their new distributor. M/s. Medicavet, Turkey also provided a copy of termination notice addressed to M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, MozangChungi Jail Road, Lahore.

Details of registration applications submitted by M/s. SS Associates, Lahore from the above mentioned principal is as follow:-

S.No	Name of Drugs/Composition / Meeting No.	Name of Manufacturer	Remarks
1.	Mediquinol 10% Oral Liquid Each ml contains:- Enrofloxacin……100mg **(M-277)**	M/s. Medicavet, TarimHayvancilikIlacveKimya San. Tic. Ltd. Sti. ItosbEski Ankara AsfaltiUzeri 12. Cadde No: 1 34959 Tepeoren Tuzla Istanbul, Turkey.	Inspection of the manufacturer abroad has been carried by the nominated panel on 27th& 28th September, 2018 and recommended the facility.
2.	Medicol 24% Oral liquid Each ml contains:- Colistin Sulfate…240mg **(M-277)**	-do-	-do-
3.	Nemason Water Soluble Powder Each gram contains:- Levamisole hydrochloride……150mg **(M-277)**	-do-	-do-
4.	Synercid Water Soluble Powder Each gm contains:- Amoxicillin (as trihydrate)……720mg Colistin Sulphate...180 mg **(M-284)**	-do-	Panel for inspection of Penicillin Section of manufacturer has been constituted comprised of Mr. Abdullah and Mr. Ajmal Sohail Asif.

Decision:- Keeping in view the termination of distribution agreement of M/s. SS Associates, Lahore by M/s. Medicavet, Turkey, Registration Board decided to issue show cause notice to M/s. SS Associates, S-77-R8/10 Ground Floor Back Side Nirala Sweet, Mozang Chungi Jail Road, Lahore as to why the approval for registration of veterinary products may not be cancelled because of termination of their distribution agreement.

Case No.34: M/s. Noble Pharmaceuticals, Old Industrial Area, Mirpur, AJK.

Registration Board in its 289th meeting decided to issue show cause notice to M/s. Noble Pharma, Mirpur Azad Kashmir for cancellation of registration of below mentioned penicillin containing products for not possessing segregated/dedicated penicillin manufacturing facility.

S.No	Reg. No.	Name of drug(s) & Composition.
1.	058725	Nobi-PSBC Powder Each 1000gm contains:- Procain Penicillin……..…12gm Streptomycin Sulpahte…..…36gm Zinc Bacitracin…….52gm Colistin Sulpahte……...60IU
2.	071009	Nobimox Powder Each Kg contains:- AmoxycillinTrihydrate…...150gm Colistine Sulphate…..…..50 M.I.U

Accordingly, show cause notice was issued to the firm. In response to which the firm replied as follows;

(i) The manufacturing license 000652 was granted at 30-01-2009. From that day till FID-III, Islamabad inspection was conducted at 16-11-2018 no one can advise us for separation of penicillin section nor any letter from Registration Board.

(ii) After advise of FID-III, Islamabad we stopped the manufacturing of penicillin drugs mentioned in your letter.

(iii) We already buy another Plot No.B-3 other then existing 4 cannals adjacent to existing Plot No.B-1 consisting pharmaceutical manufacturing licensed building for the establishment of veterinary penicillin powder and general veterinary bolus manufacturing. Proposed layout plan was submitted in DRAP L&A Section for approval.

(iv) We want to appear before the decision of Honorable Registration Board so we can justify our position properly.

Firm is being called for personal hearing, as desired by them.

Discussion:- *Director of M/s. Noble Pharma, Mirpur Azad Kashmir, Mr. Faisal appeared before the Board and informed that they are in process of developing a separate veterinary penicillin powder & general veterinary bolus manufacturing section and at present they had stopped the manufacturing of penicillin containing drugs. He also requested that permission for contract manufacturing of penicillin containing products shall be granted to them till development of separate/dedicated penicillin manufacturing facility.*

Decision:- Registration Board suspended the registration of below mentioned products registered in the name of M/s. Noble Pharma, Mirpur Azad Kashmir for not possessing the penicillin manufacturing facility till the firm make necessary arrangements for contract manufacturing of these products as per their statement submitted before the Board.

S.No	Reg. No.	Name of drug(s)
1.	058725	Nobi-PSBC Powder
2.	071009	Nobimox Powder

Case No. 35: Registration of Veterinary Drug under Drug Act, 1976.

Registration Board in its 237th meeting approved following product of M/s. Ghazi Brothers, Karachi for import from M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China subject to inspection of manufacturer abroad as per import policy and verification of storage facility (where applicable) as per detailed mentioned against each:-

S. No.	Name of Importer/ Manufacturer	Name of Drugs/ Composition & Meeting	Decontrolled/ Packs Size	Shelf Life	Decision/ Remarks
1.	M/s. Ghazi Brothers, Karachi. / M/s. Hebei Yuanzheng Pharmaceutical Co. Ltd., Shijiazhuang City, Hebei Province, China.	Sinomox LA Suspension for Injection Each ml contains:- Amoxicillin….150mg (15%)	10ml 50ml 100ml 250ml	2 years	Approved

While processing for issuance of registration letter it was observed that the said product is already registered in the name of M/s. Genome Pharma, Islamabad with brand name **"**Amoxygen LA Injection" (Reg.No. 057143) from the same manufacturer/product license holder. M/s. Ghazi

Brothers was informed accordingly about the status of the case.

Now, M/s. Ghazi Brothers, Karachi has provided legalized and attested termination letter in favor of "*M/s. Genome Pharma, Islamababd-Pakistan*" from the manufacturer/principal M/s. Hebei Yuanzheng Pharmaceutical Co., Ltd., No. 16 Liuyuan Road, Chang, An District, Shijiazhuang City, Hebei Province, China.

It is pertinent to mention that inspection of above mentioned manufacturer has already been carried out by nominated panel on 04th and 05th April, 2017 and rated the manufacturing facility as "Good".

Decision:- Keeping in view the termination of distribution agreement of M/s. Genome Pharma, Islamabad for product "Amoxygen LA Injection" (Reg.No. 057143) by M/s. Hebei Yuanzheng Pharmaceutical Co., Ltd., No. 16 Liuyuan Road, Chang, An District, Shijiazhuang City, Hebei Province-China, Registration Board decided to issue show cause notice to M/s. Genome Pharma, Islamabad as to why the registration of aforesaid product may not be cancelled because of termination of distribution agreement.

Case No. 35: Show Cause Notices issued to the firms having registration of products containing Novaminsulfon.

Registration Board in its 289th meeting decided to call up all the firms, having registered veterinary products containing Novaminsulfon (metamizole), for personal hearing after serving them a show cause for cancellation of registration.

Initially, Registration Board in its 277th meeting held on 27-29th December, 2017 meeting, while rejecting registration applications of veterinary drugs containing Novaminsulfon, due to earlier decisions of cancelling registration of metamizole for being associated with serious adverse effects like agranulocytosis. Accordingly, show cause notices were issued to the firms having registrations of aforementioned drug formulation. A number of firms have responded with their point of view including request for personal hearings.

It has been discussed during 289th meeting, while considering registration applications of veterinary products containing "antipyrine", that Metamizole Sodium is an organic sodium salt of antipyine. Furthermore, it is pertinent to mention that a number of products are registered with DRAP having antipyrine as active pharmaceutical ingredient.

Decision:- Registration Board referred the case to Expert Working Group on veterinary drugs for further deliberation.

HUMAN IMPORT

Case.No.36: APPROVAL FOR IMPORT IN FINISHED FORM, CHANGE OF MANUFACTURING SITE & ADDITION OF PRODUCT LICENSE HOLDER.

Registration Board in its 283rd meeting held on 27th to 29th june, 2018 approved the change of registration status/ permission from bulk import and local repacking to import in finished form, change of manufacturing site & addition of product license holder of their already registerd product Pletaal 50mg Tablet (Reg. No.029294) and Pletaal 100mg Tablet (Reg. No.029295) of M/s Otsuka Pakistan Ltd, Lasbella Balochistan as per following details:-

S. No	Subject	Previously Approved Status	New Approved Status
1	Registration Status / Permission	Bulk Import & Local Repacking	Finished Form Import
2	Manufacturing Site & Product License Holder	M/s Otsuka Pharmaceutical Co.,Ltd, Kandu Tsukasa-cho, Chiyoda-Ku, Tokyo, 1018535, Japan	M/s Korea Otsuka Pharmaceutical Co., Ltd, 27, Jeyakgongdan 3-gil, Hyangnam-eup, Hwaseong-si, Gyeonggi-do, Republic of Korea

The inspection of same manufacturer i.e M/s. Otsuka Korea has already been carried out by a panel comprised of Dr.Saif-ur-Rehman Khattak and Mr. Salateen Waseem Philip on 16-17th June, 2014 for the product Mucosta 100mg Tablet (Rebapimide). The firm has also provided a letter from Otsuka Japan wherein it has been declared that "*we has given permission/license to Korea Otsuka Pharmaceutical Co., Ltd to manufacture Pletal 50mg and 200mg Tablets at their plant in Korea*"**.**

The firm has requested for exemption of inspection aborad on 02th April 2018. Now 5 years has been passed from the date of abroad panel inspection**.**

Decision of 206th :

For the purpose of economy and facilitation to the firms Registration Board decided as a policy that:-

i). Inspection of manufacturer abroad already conducted shall also be considered for the subsequent registration applications submitted by the same importer if the application is field with in 5 years of date of earlier inspection of the same section of the firm already inspected, from where fresh applied drugs are intended to be imported.

ii). Inspection of manufacturer abroad already conducted shall also be considered for the subsequent registration applications submitted by the importer other than who arranged the earlier inspection if the application is field within 3 years of the date of earlier inspection of the same section of the firm already inspected, from where fresh applied drugs are intended to be imported.

Decision of 262nd :

Registration Board deliberated the case in light of Import Policy for Finished Drugs and decided that as prevailing requirement is for dosage form specific inspection, thus inspection conducted

under the current policy shall be considered as valid for 05 years w.e.f date of conduction of inspection. Aforementioned decision will also be applicable to already conducted inspections.

Registration Board deliberated that inspection of manufacturer abroad already conducted shall also be valid if applicant apply for exemption with in 5 years of date of earlier inspection of the same section of the firm already inspected, from where fresh applied drugs are intended to be imported.

Decision: **As firm has applied for exemption within 5 years of earlier inspection thus Registration Board granted the exemption for Inspection abroad for product Pletaal 50mg Tablet (Reg. No.029294) and Pletaal 100mg Tablet (Reg. No.029295). Manufacturer of the product is Product license holder as well.**

Case.No.37: REQUEST OF M/S. ELI LILLY (PAKISTAN) (PVT) LTD, KARACHI TO UPDATE LEAFLET (GEMZAR 200MG INJ & 1GM).

M/s Eli Lilly Pakistan (Pvt) Ltd, Karachi has stated that the following changes in the leaflet of Gemzar 200mg Injection (Reg. No.019574) and Gemzar 1gm Injection (Reg. No.019573) have approved by Swedish Medical Product Agency and the same would like to incorporate in their leaflet:

- Update section 4.8 of the SmPC to add Infections and Sepsis, Thrombotic microangiopathy and Pseudocellulitis as adverse drug reaction.
- Revised wording of section 5.2 on pharmacokinetics of olanzapine in hepatically impaired patients to improve clarity.

The firm has submitted the following information / documents: -

- A fee of Rs.10,000/-.
- Copy of registration letter.
- Justification of proposed change.
- Confirmation and undertaking.
- Copy of Swedish Medical Product Agency approval.
- Copy of existing and proposed leaflet.

Now the firm has requested for grant the approval to adopt the leatest leaflet.

Decision: **Registration Board approved adoption of the following points in the existing leaflet as approved by Swedish Medical Product Agency.**

- **Addition of Infections and Sepsis, Thrombotic microangiopathy and Pseudocellulitis as adverse drug reaction.**
- **Pharmacokinetics of olanzapine in hepatically impaired patients to improve clarity.**

Case No.38: Request of M/s GlaxoSmithKline Pakistan Limited, Karachi for Permission to Import in General Export (GE) Pack.

M/S Glaxosmithkline Pakistan Limited, Karachi has requested for permission to import the following products in General Export packs: -

Sr. No.	Product(s) Description	Reg.No.	Registered Source
1.	Ventolin Evohaler Per unit dose contains: - Salbutamol Sulphate….120.5mcg	041195	Spain
2.	Seretide Diskus 50/100mcg Powder for Inhalation Each inhalation (single dose) contains:- Salmeterol (as xinafoate) …….50mcg.	074726	France

	Fluticasone propionate ……100mcg		
3.	Seretide Diskus 50/250mcg Powder for Inhalation Each inhalation (single dose) contains:- Salmeterol (as xinafoate) 50mcg. Fluticasone propionate 250mcg.	074727	France
4.	Seretide Diskus 50/500mcg Powder for Inhalation Each inhalation (single dose) contains:- Salmeterol (as xinafoate) 50mcg. Fluticasone propionate 500mcg.	074728	France
5.	Seretide CFC-Free Inhaler 25/50ug Each actuation contains: Salmeterol Xinafoate 36.3ug Fluticasone Propionate 50.0ug	027381	Australia
6.	Seretide CFC-Free Inhaler 25/125ug Each actuation contains: Salmeterol Xinafoate 36.3ug Fluticasone Propionate 125.0ug	027382.	Australia
7.	Seretide CFC-Free Inhaler 25/250ug Each actuation contains: Salmeterol Xinafoate 36.3ug Fluticasone Propionate 250.0ug	027383	Australia
8.	Avamys Nasal Spray. Each actuation contains:- Fluticasone Furoate 27.5mg.	069525	U.K.
9.	Imuran Tablet Each tablet contains: - Azathioprine B.P. 50mg	010058	Germany
10.	Seroxat Tab 20mg Each tablet contains: - Paroxetine HCL….20mg	019501	Poland
11.	Avodart Capsule Each Capsule contains: - Dutasteride 0.5gm	041157	France
12.	Duodart Capsules. Each capsule contains:- Dutasteride…. …….0.5mg. Tamsulosin ……..0.4mg.	069515	Germany

The firm has mentioned following reasons to ensure sustained supply of the product: -

a. Manufacturing site has supply constraints and packaging of the product in country specific packs consumes more time and resources as compared to the packaging in General Export Packs which are being supplied to most of the markets.
b. Constraints in technical and commercial feasibility of the manufacturing site due to requirement of specialized packaging only for Pakistan.
c. We may often face stocks availability issues if do not import in readily available General Export Pack.

The firm has stated that product registration number, MRP and urdu text will be printed locally through laser jet printer at their licensed premises (i.e.F-268, SITE, Karachi DML No.000233 by way of formulation) prior to market the products for an initial period of 03 years.

The firm has provided the following documents along with the application: -

a. Fee challan of Rs.5000/- for each product
b. Copy of registration letter with post registration variation trial.

Decision: **Registration Board acceded to the request of the firm for import of already registered above products in Standard Export Packs. The Board advised the firm to locally print MRP and Registration Number along with Urdu Text before sale of drug at M/S Glaxosmithkline Pakistan Limited, F-268, SITE, Karachi DML No.000233 to comply requirement as per Drugs (Labelling & Packing) Rules, 1986. This permission shall be valid for two (02) years only.**

Case.No.39: Request of M/s. OBS Pakistan (Pvt) Ltd, Karachi for Registration of Products in their Name (ARIXTRA 5mg, 7mg & 10mg).

The subject case was presented in 286th meeting of Registration Board and deffered the same. Details are as under:

M/s. OBS Pakistan (Pvt) Ltd, Karachi has submitted applications for change of registration status of following products from the name of M/s. GSK Pakistan Ltd, Karachi to their own name. Details are as under: -

Product-2: Arixtra Injection 5mg/0.4ml (Reg.No.044825)		
S#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	Arixtra Injection 5mg/0.4ml solution for injection syringe Each 0.4ml contains: Fondaparinux Sodium…….5mg.
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. GSK Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi
4.	Detail of Drug Sale License	M/s. OBS Pakistan (Pvt) Ltd, C-14 Manghopir Road, SITE, Karachi
5.	Name and address of manufacturer.	As per Form-5A & approval letter:- M/s. Glaxo Wellcome Production, France. As per COPP:- M/s. Aspen Notre Dame de Bondeville, 1 Rue de I'Abbaye Notre Dame de Bondeville 76960, France.
6.	Name and address of marketing authorization holder (as per COPP)	M/s. Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street ST Leonards NSW 2065, Australia.
7.	Name of exporting country	France (Form-5A)
8.	Diary No. & Date of R& I	Dy. No. 11620 Dated 30/03/2018
9.	Pharmacological class	Factor Xa Inhibitor
10.	Shelf life	24 months (as per Form-5A/CoPP issued by TGA)
11.	Pack Size	7's (as per initial registration letter)
12.	**Remarks:** • The name of manufacturer mentioned in Form-5A and approval letter differ from the one mentioned in CoPP. The firm has informed that *the name of manufacturer has been changed from GSK to Apsen Notre Dame de Bondeville since Aspen has acquired GSK anaesthetic portfolio globally* and the firm provided revised Form-5A accordingly. • The CoPP mentions the comment as "*This product has been evaluated and approved by the TGA and is permitted to be supplied in Australia*. Further the CoPP also mentions Sponsor comments as "*The product is approved for supply in Australia but is not marketed at present for commercial reasons."*	

Product-3: Arixtra Injection 7.5mg/0.6ml (Reg.No.044826)		
S#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	Arixtra Injection 7.5mg/0.6ml solution for injection syringe. Each 0.6ml contains: Fondaparinux Sodium…….7.5mg.
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. GSK Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi
4.	Detail of Drug Sale License	M/s. OBS Pakistan (Pvt) Ltd, C-14 Manghopir Road, SITE, Karachi
5.	Name and address of manufacturer.	As per Form-5A & approval letter:- M/s Glaxo Wellcome Production, France. As per COPP:- M/s Aspen Notre Dame de Bondeville, 1 Rue de I'Abbaye Notre Dame de Bondeville 76960, France.
6.	Name and address of marketing authorization holder (as per COPP)	M/s. Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street ST Leonards NSW 2065, Australia.
7.	Name of exporting country	France (Form-5A)
8.	Diary No. & Date of R& I	Dy. No. 11622 Dated 30/03/2018
9.	Pharmacological class	Factor Xa Inhibitor
10.	Shelf life	24 months (as per Form-5A/CoPP issued by TGA)
11.	Pack Size	7's (as per initial registration letter)
12.	**Remarks:- S**ame as for product 2.	

Product-4: Arixtra Injection 10mg/0.8ml (Reg.No.044827)		
S#	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	Arixtra Injection 10mg/0.8ml solution for injection syringe Each 0.8ml contains: Fondaparinux Sodium…….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. GSK Pakistan Ltd, 35-Dockyard Road, West Wharf, Karachi
4.	Detail of Drug Sale License	M/s. OBS Pakistan (Pvt) Ltd, C-14 Manghopir Road, SITE, Karachi
5.	Name and address of manufacturer.	As per Form-5A & approval letter:- M/s. Glaxo Wellcome Production, France. As per COPP:- M/s. Aspen Notre Dame de Bondeville, 1 Rue de I'Abbaye Notre Dame de Bondeville 76960, France.
6.	Name and address of marketing authorization holder (as per COPP)	M/s. Aspen Pharmacare Australia Pty Ltd 34-36 Chandos Street ST Leonards NSW 2065, Australia.
7.	Name of exporting country	France (Form-5A)
8.	Diary No. & Date of R& I	Dy. No. 11621 Dated 30/03/2018
9.	Pharmacological class	Factor Xa Inhibitor
10.	Shelf life	24 months (as per Form-5A/CoPP issued by TGA)
11.	Pack Size	7's (as per initial registration letter)
12.	**Remarks:-** • Same as for product 2	

Decision of 286th Meeting.

For products-2, 3 and 4 the firm shall be advised to provide the free sale status of the said products in any RRA prescribed by Registration Board for not being in market of exporting country i.e Australia.

Fresh proceedings

Now, the firm has submitted legalized & attested COPP for the above products issued by EMA with free sale status in country of origin.

Decision:- Registration Board decided as follow;

- **Approved the registration of above products 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 said products.**

Case.No.40: Request of M/s. Atco Laboratories Ltd, Karachi for Adoption of Pharmacopoeial Specifications of Registered Products.

M/s Atco Laboratories Limited, B-18, SITE, Karachi has stated that their following products has now become available in Pharmacopoeia as finished product:-

S.No.	Name of Product / Composition	Demanded Specification	Reg.No.
1.	Intaxel 100mg Injection Each ml contains: - Paclitaxel USP…..6mg	USP	044882
2.	Cytarine 100mg Injection Each ml contains: - Cytarabine B.P. 100mg	BP	044871
3.	Cytarine 500mg Injection Each 5ml contains: - Cytarabine B.P. 500mg	BP	044872
4.	Cytarine 1gm Injection Each 10ml contains: - Cytarabine B.P. 1gm	BP	045710
5.	Dioplus-H Tablet 10/160/12.5mg Each film coated tablet contains: Amlodipine (as besylate).10mg Valsartan……160mg Hydrochlorothiazide….12.5mg	USP	080609
6.	Intaxel 30mg Injection Each ml contains: - Paclitaxel USP…..6mg	USP	044881
7.	Intaxel 300mg Injection Each ml contains: - Paclitaxel USP…..6mg	USP	045709
8.	Intaxel 150mg Injection Each ml contains: - Paclitaxel USP…..6mg	USP	045707
9.	Intaxel 260mg Injection Each ml contains: - Paclitaxel USP…..6mg	USP	045708

The firm has submitted following supporting documents:-

1) Fee of Rs.5000/- for each product.
2) Notarized copies of registration letters with post registration variation trial.
3) Finished product pharmacopoeial monograph.

4) Analytical report as per monograph of FPP (Finished pHarmaceutical Product)
5) Copy of DSL
6) Undertaking for above products that:
   a) The change is made exclusively to comply with the pharmacopeia of reference regulatory authorities or as per innovator's product specifications.
   b) No case is pending at any forum court of law regarding this product.
   c) 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 stock shall be recalled from the market immediately.
   d) The provided information documents are true correct.

Decision: Registration Board approved the change in Finished Product Specifications of above products.

Case.No.41: Request of M/s. Atco Pharma International (Pvt.) Ltd, Karachi for Adoption of Pharmacopoeial Specifications of Registered Products.

M/s Atco Pharma International (Pvt.) Ltd, B-18, SITE, Karachi has stated that their following products has now become available in Pharmacopoeia as finished product:-

S.No.	Name of Product / Composition	Demanded Specification	Reg.No.
1.	Adrim 50mg Injection Each 25ml contains: - Doxorubicin HCL 50mg	USP	044869
2.	Adrim 10mg Injection Each 5ml contains: - Doxorubicin HCL 10mg	USP	044870
3.	Vinelbine 50mg Injection Each ml contains: - Vinorelbine Tartrate USP equivalent to Vinorelbine 10mg	USP	045750
4.	Vinelbine 10mg Injection Each ml contains: - Vinorelbine Tartrate USP equivalent to Vinorelbine 10mg	USP	045751
5.	Fezimet Tablet 1mg Each film coated tablets contains:- Anastrozole IH….1mg	USP	047676
6.	Fytosid 100mg injection Each ml contains: - Etoposide USP 20mg	USP	044868
7.	Irinotel 100mg Injection Each ml contains: Irinotecan Hydrochloride Trihydrate 20.00mg	USP	045763
8.	Irinotel 40mg Injection Each ml contains: Irinotecan Hydrochloride Trihydrate 20.00mg	USP	045764
9.	Zexate 500mg Injection Each ml contains: - Methotrexate USP 25mg	USP	047542
10.	Kemocarb 150mg Injection Each ml contains: - Carboplatin USP 10.0mg	BP	045753
11.	Kemocarb 450mg Injection Each ml contains: - Carboplatin USP 10.0mg	BP	045754

The firm has submitted following supporting documents:-

1) Fee of Rs.5000/- for each product.
2) Notarized copies of registration letters with post registration variation trial.
3) Finished product pharmacopeoeil monograph.
4) Analytical report as per monograph of FPP (Finished pHarmaceutical Product)
5) Copy of DSL
6) Undertaking for above products that:
   a) The change is made exclusively to comply with the pharmacopeia of reference regulatory authorities or as per innovator's product specifications.
   b) No case is pending at any forum court of law regarding this product.
   c) 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 stock shall be recalled from the market immediately.
   d) The provided information documents are true correct.

Decision: Registration Board approved the change in Finished Product Specifications of above products.

Case.No.42: Request of M/S Atco Pharma International (Pvt.) Ltd., Karachi for Change in Manufacturing Site.

M/s Atco Pharma International (Pvt.) Ltd, B-18, SITE, Karachi has stated that their principal manufacturer M/s Fresenius Kabi Oncology Limited, India wants to transfer its products from existing manufacturing facility to its MHRA approved manufacturing facility while the name of manufacturer remain the same of their following registered products as per details given below: -

Table no. 1

S. No	Name / Composition / Reg. No.	Existing Manufacturing Site (as per approval)	Proposed Site / Manufacturer & Marketing Authorization Holder
1.	Fytosid 100mg Injection Each ml contains:- Etoposide USP ……20mg	**Manufacturer:** M/s Fresenius Kabi Oncology Limited, 19, HPSIDC, Industrial Area, Baddi, Distt. Solan, India	M/s Fresenius Kabi Oncology Limited, Village-Kishanpura, P.O. Guru Majra, Tehsil-Nalagarh, Distt. Solan (H.P.)-174101, India. Marketing Authorization Holder: As above
2.	Adrim 50mg/25ml Injection Each ml contains:- Doxorubicin HCL…..2mg	-do-	-do-
3.	Adrim 10mg/5ml Injection Each ml contains:- Doxorubicin HCL…. 2mg	-do-	-do-
4.	Zexate 50mg/2ml Injection Each ml contains:- Methotrexate Sodium Eq to Methotrexate USP 25mg	-do-	-do-
5.	Zexate 500mg/20ml Injection Each ml contains:- Methotrexate Sodium Eq to Methotrexate USP 25mg	-do-	-do-
6.	Irinotel 100mg/5ml injection Each ml contains: - Irinotecan Hydrochloride Trihydrate 20.00mg	-do-	-do-

7.	Irinotel 40mg/2ml injection Each ml contains: - Irinotecan Hydrochloride Trihydrate 20.00mg	-do-	-do-
8.	Kemocarb 150mg/15ml Injection Each ml contains: - Carboplatin BP 10.0mg	-do-	-do-
9.	Kemocarb 450mg/45ml Injection Each ml contains: - Carboplatin BP 10.0mg	-do-	-do-

The firm has submitted the following supporting documents:

a. Total fee of Rs.900,000/- (9x100,000/-) .
b. Original and legalized COPP's.
c. Attested copy of GMP certificate issued by MHRA based on the inspection conducted on 08-02-2016.
d. Initial Registration letters with renewal status
e. Copy of valid Drug License by way of whole sale.
f. Copy of site master file of new manufacturing site.
g. Copy of letter for change of manufacturer name from M/s Dabur Pharma Ltd, India to M/s Fresenius Kabi Oncology Ltd, India.

The initial registration letters issued on 15-02-2007 for the products mentioned at Sr. No.1 2 & 3 and due date was 14-02-2012, the firm has submitted renewal applications on 15-02-2012 which is one day late.

Decision of 289th meeting.

Registration Board deferred the products for the confirmation of renewal status.

The products mentioned at Sr. No.1 2 & 3 which renewals were one day late same have been regularized in 289th meeting by RRR section as under: -

S. No	Name / Composition / Reg. No.	Details of Renewal Status
1.	Fytosid 100mg Injection Each ml contains:- Etoposide USP ……20mg	Due date (14-02-2017) Firm submitted fee of Rs.7500/-on 15-02-2012.As the renewal application is received late but within 60 days after expiry of Registration Differential fee 0f Rs32,500, paid on 01-04-2019 **for the regularization of renewal application of year 2012.**
2.	Adrim 50mg/25ml Injection Each ml contains:- Doxorubicin HCL…..2mg	-do-
3.	Adrim 10mg/5ml Injection Each ml contains:- Doxorubicin HCL…. 2mg	-do-

Decision in 289th meeing for RRR:

Registration Board deferred the above cases for evaluation under Import Policy for Finished Drugs, however the renewal status shall be communicated to the concerned section for processing of post registration variation at their end.

Decision: Registration Board approved Change in Manufacturing Site of products, in respect of registered products in Table No. 1 subject to inspection of imported finished drug. Other terms and conditions remain the same.

Case No.43: Correction of Manufacturer Name for the Product ZEFEI 200mg & ZEFEI 1g for Injection of M/S AA Pharma, Karachi.

Registration Board in its 288th meeting approved the following products of M/s AA Pharma, 2nd floor, Shafi Court, Merewether Road, Civil Lines, Karachi. The Manufacturer name & address approved in 288th meeting are different from the one mentioned in CoPP. Details are as under;

Name & address as per Minutes (M-288)	Name & address as per COPP
M/s Jiangsu Hengrui Medicine Co., Ltd. 38 Huanghe Road, Economic and technical development Zone, Lianyungang, Jiangsu 222047, China	M/s Jiangsu Hansoh pharmaceutical group Co., Ltd. No.9 Dongjin Road, Economic and technical development Zone, Lianyungang, Jiangsu 222069, China

Accordingly, the correct/ ammended name & address of manufacturer according to submitted legalized & attested CoPP by M/s AA Pharma, Karachi has been granted.

Decision: Registration board noted the above correction.

Case No.44: Request of M/S Martin Down Limited, Karachi for Transfer of Registrations from M/S Roche Pakistan Ltd, Karachi.

The subject case of M/s Martin Down Limtied, Karachi was presented in 290th meeting of Registration Board as under; -

M/s Martin Down Limited, Plot No. 37 Sector 19, Korangi Industrial Area, Karachi has submitted application for transfer of registration of following products from the name of M/s Roche Pakistan Ltd, Karachi to their own name. Detail of each proposed product is as under: -

Product-1: Bonviva Solution for Injection in Pre-filled syrine (Reg.No.047663)		
Sr. No.	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	**As per approval** Boniva Solution for Injection in Pre-filled Syringe 3mg/3ml Each pre-filled syringe contains:- 3.375mg of Ibandronic acid monosodium salt, monohydrate (equivalent to 3mg ibandronic acid).
2.	Name and address of Applicant (transferee)	M/s Martin Down Limited, Plot No. 37 Sector 19, Korangi Industrial Area, Karachi
3.	Name of Transferor	M/s Roche Pakistan Limited, 37-C,Block 6, P.E.C.H.S., Karachi.
4.	Detail of Drug Sale License	M/s Martin Down Ltd, Plot No. 194 (Portion-A) Sector 23, K.I.A. Karachi **(Godown Address)**
5.	Name and address of manufacturer.	**As per record:-** M/s. Vetter Pharma- Fertigung GmbH & Co. KG, Germany **As per COPP** M/s. Vetter Pharma- Fertigung GmbH & Co. KG, Germany
6.	Name and address of marketing authorization holder (COPP)	M/s Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, UK.
7.	Name of exporting country	Germany

8.	Diary No. & Date of R&I	Dy. No. 3636 Dated 15-04-2019
9.	Finished Product Specification	Manufacturer spec
10.	Shelf life	2 years months (as per SmPC)
11.	Pack Size	1's (as per approval)
12.	**Remarks:** Authority letter (original & notarized) issued by Product License Holder for new proposed sole agent is not provided.	
Product-2: Bonviva Oral Tablets (Reg.No.044820)		
S. No.	**Name / detail of documents**	**Documents / information provided by firm**
1.	Product Name / Composition	**As per approval** Bonviva Oral Tablets. Each tablet contains:- Ibandronic Acid (as Ibandronic acid sodium monohydrate)……. 150mg.
2.	Name and address of Applicant (transferee)	M/s Martin Down Limited, Plot No. 37 Sector 19, Korangi Industrial Area, Karachi
3.	Name of Transferor	M/s Roche Pakistan Limited, 37-C,Block 6, P.E.C.H.S., Karachi.
4.	Detail of Drug Sale License	M/s Martin Down Ltd, Plot No. 194 (Portion-A) Sector 23, K.I.A. Karachi **(Godown Address)**
5.	Name and address of manufacturer.	**As per record:-** M/s Penn Pharmaceuticals Services Ltd Units 23-24 Tafamaubach Industrial Estate Tafamaubach, Tredegar Gwent NP22 3AA UK. **As per COPP** M/s Penn Pharmaceuticals Services Ltd Units 23-24 Tafamaubach Industrial Estate Tafamaubach, Tredegar Gwent NP22 3AA UK.
6.	Name and address of marketing authorization holder (as per COPP)	M/s Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, UK.
7.	Name of exporting country	United Kingdom
8.	Diary No. & Date of R&I	Dy. No. 3635 Dated 15-04-2019
9.	Finished Product Specification	Manufacturer spec
10.	Shelf life	5 years months (as per SmPC)
11.	Pack Size	1's &3's Tablet, (as per approval)
12.	**Remarks:** same as above.	

The firm has submitted the following supporting documents / information for approval of registrations of above mentioned products: -

a) Fee of Rs.200,000/- (100,000/- for each product).
b) Applications on Form-5A as well as on CTD
c) Copy of initial registration letter with complete renewal.
d) Original & legalized CoPPs for above products issued by EMA.
e) NOC (original) from M/s Roche Pakistan Limited, 37-C,Block 6, P.E.C.H.S., Karachi.in favour of M/s Martin Down Limited, Plot No. 37 Sector 19, Korangi Industrial Area, Karachi issued on 25th March, 2019.
f) Termination letter (From F.Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel, Switzerland (Roche) to terminate the authorization of M/s Roche Pakistan Ltd for above 2 products)
g) Transfer Notice Declaration (We, F.Hoffmann-La Roche Ltd, Grenzacherstrasse 124, 4058 Basel, Switzerland (Roche) owner of above 2 products transfers the owner right to M/s Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon, Essex SS14 3FR, UK.)

Decision of 290th :

The Registration Board deferred the case for the provision of Authority letter (original & notarized) issued by Product License Holder for new proposed sole agent and evaluation of CTD for the above products.

Fresh Proceedings: -

Now the firm has submitted Original & Notarized Authority letter issued by Product License Holder for new proposed sole agent i.e. M/s Martin Down Limited, Plot No. 37 Sector 19, Korangi Industrial Area, Karachi.

DETAILS OF CTD (M/S MARTIN DOWN LIMITED, KARACHI)

1. Bonviva PFS Injection 3mg/3ml		
	Name, address of Applicant	Martin Dow Limited, Plot 37, Sector19, Korangi Industrial Area, Karachi-74900, Pakistan
	Name, address of Marketing Authorization Holder	Atnahs Pharma UK Ltd., Basildon, Essex, United Kingdom.
	Name, address of Manufacturing site.	Vetter Pharma-Fertigung GmbH & Co. KG Eisenbahnstrasse 2-4 D-88085 Langenargen Germany.
	Status of the applicant	□ Manufacturer □ **Importer** □ Is involved in none of the above (contract giver)
	Dy No. and date of submission	15-04-2019
	Details of fee submitted	PKR 100,000/- 10-04-2019
	The proposed proprietary name / brand name	Bonviva PFS Injection 3mg/3ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each pre-filled syringe contains: 3.375 ibandronic acid mono-sodium salt, monohydrate equivalent to …..3mg ibandronic acid
	Dosage form of applied drug	Solution for Injection pre-filled in syringe
	Route of administration	Parenteral
	Pharmacotherapeutic Group of (API)	Anti-resorptive and Anti-hypercalcemic
	Pharmacopoeial reference	Firm has submitted: - "Innovators Specifications"
	Proposed Pack size	1's
	Proposed unit price	As per Innovator's Price
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Ibnate Reg no. 081544 Genix Pharma (Pvt) Ltd
	Valid drug manufacturing license/Drug Sale License	Copy of Drug manufacturing License by way of formulation issued on 09-02-2016 is submitted. Copy of Drug Sale License of Martin Dow Limited attached, valid from 17-06-2018 till 16-06-2020. Copy of Legalized and Notarized Drug Manufacturers authorization certificate dated 20-10-2015 is attached.

	Evidence of approval of manufacturing facility / approved section from licensing authority	Copy of legalized and Notarized Drug Manufacturers authorization license and GMP certificate is attached, issued from licensing Health authority of country of origin
	Type of Application	□ New Drug Product (NDP) □ **Generic Drug Product (GDP)**
	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	N/A
	List of registered products	Submitted in SMF
	Manufacturer's site master file and credentials (for importers)	Provided by Vetter pharma directly to DRAP
	Identification of signature of authorized persons, Incharge Production, Quality Control & Quality Assurance of manufacturer.	Yes
	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens	Yes
	Description of Batch numbering system	Yes
	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).	Yes
	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 its 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	N/A
	Electronic Review Package	Yes
	QIS (Quality Information Summary)	NA
	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	Roche Diagnostics GmbH Sandhofer Straße 116 68305 Mannheim Germany And / or F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 4070 Basel Switzerland
	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)	Drug is finished import
	MODULE 2: OVERVIEWS & SUMMARIES	
	Drug Substance	Firm has submitted overall summary of drug substance including general information, specification, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, manufacturing process development, container closure system, microbiological attributes and compatibility, controls of drug product, reference standards or materials and stability studies.
	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	Yes
	Manufacture	Yes
	Characterization	Yes
	Control of drug substance	Yes
	Reference standards or materials	Yes
	Container closure system	Yes
	Stability	Yes
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of drug substance, excipients, formulation development, overages, physicochemical and biological properties, manufacturing process development, container closure system, microbiological attributes and compatibility.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	N/A since compendial materials (EP current edition) are used only
	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	Submitted
	Stability	Firm has provided completed stability study data of 3 batches as per Zone IV-B
	Comparative dissolution profile	
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Yes

	Pharmacokinetics	Yes
	Toxicology	Yes
	MODULE 5: CLINICAL / EFFICACY	
	Firm has submitted that being a generic product clinical data is not Applicable while in-vitro dissolution tests complementary to bioequivalence studies.	

	2. Bonviva Tablet 150mg	
	Name, address of Applicant	Martin Dow Limited, Plot 37, Sector19, Korangi Industrial Area, Karachi-74900, Pakistan
	Name, address of Marketing Authorization Holder	Atnahs Pharma UK Ltd., Basildon, Essex, United Kingdom.
	Name, address of Manufacturing site.	Penn Pharmaceutical Services Limited Unit 23-24 Tafarnaubach Industrial Estate, Gwent, Tredegar NP22 3 AA, United Kingdom
	Status of the applicant	□ Manufacturer □ **Importer** □ Is involved in none of the above (contract giver)
	Dy No. and date of submission	15-04-2019
	Details of fee submitted	PKR 100,000/- 10-04-2019
	The proposed proprietary name / brand name	Bonviva Tablet 150mg
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each film coated Tablet contains: Ibandronic Acid ……150mg
	Dosage form of applied drug	Tablet
	Route of administration	Oral
	Pharmacotherapeutic Group of (API)	Anti-resorptive and Anti-hypercalcemic
	Pharmacopoeial reference	Firm has submitted: - "Innovators Specifications"
	Proposed Pack size	1's & 3's
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	USFDA Approved
	For generic drugs (me-too status)	Booneset Tablet Reg no. 075856 of Barret Hodgson (Pvt.) Ltd
	Valid drug manufacturing license/Drug Sale License	Copy of Drug manufacturing License by way of formulation issued on 09-02-2016 is submitted. Copy of Drug Sale License of Martin Dow Limited attached, valid from 17-06-2018 till 16-06-2020. Copy of Legalized and Notarized Drug Manufacturers authorization certificate is attached.
	Evidence of approval of manufacturing facility / approved section from licensing authority	Copy of legalized and Notarized Drug Manufacturers authorization license and GMP certificate is attached, issued from licensing Health authority of country of origin
	Type of Application	□ New Drug Product (NDP) □ **Generic Drug Product (GDP)**

	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	N/A	
	List of registered products	Submitted.	
	Manufacturer's site master file and credentials (for importers)	Yes	
	Identification of signature of authorized persons, Incharge Production, Quality Control & Quality Assurance of manufacturer.		Yes
	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens		Yes
	Description of Batch numbering system		Yes
	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).		Yes
	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 its 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		N/A
	Electronic Review Package		Yes
	QIS (Quality Information Summary)		NA
	Drug Substance related Document including following:		
	a. Name and address of API manufacturer.	Roche Diagnostics GmbH Sandhofer Straße 116 68305 Mannheim Germany And / or F. Hoffmann-La Roche Ltd Grenzacherstrasse 124 4070 Basel Switzerland	
	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)	Drug is finished import	
	MODULE 2: OVERVIEWS & SUMMARIES		

	Drug Substance	Firm has submitted overall summary of drug substance including general information, specification, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, manufacturing process development, container closure system, microbiological attributes and compatibility, controls of drug product, reference standards or materials and stability studies.

	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	Yes
	Manufacture	Yes
	Characterization	Yes
	Control of drug substance	Yes
	Reference standards or materials	Yes
	Container closure system	Yes
	Stability	Yes
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of drug substance, excipients, formulation development, overages, physicochemical and biological properties, manufacturing process development, container closure system, microbiological attributes and compatibility.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	N/A since compendial materials (EP current edition) are used only
	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	Submitted
	Stability	Firm has provided completed stability study data of 3 batches as per Zone IV-B
	Comparative dissolution profile	
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Yes
	Pharmacokinetics	Yes
	Toxicology	Yes
	MODULE 5: CLINICAL / EFFICACY	
	Firm has submitted that being a generic product clinical data is not Applicable while in-vitro dissolution tests complementary to bioequivalence studies.	

	REMARKS OF EVALUATOR

Decision:- Registration Board decided as follow;

a. Approved cancellation of registration of products 1 & 2 from the name M/s Roche Pakistan Limited, 37-C, Block 6, P.E.C.H.S., Karachi.

b. Approved the registration of products 1 & 2 in the name of M/s Martin Down Limited, Plot No. 37 Sector 19, Korangi Industrial Area, 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 said products.

Case.No.45: 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: Registration Board deferred the case for further deliberation.

Case.No.46: 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: Registration Board deferred the case for further deliberation.

Case.No.47: REQUEST OF M/S CCL PHARMACEUTICALS (PVT) LTD, LAHORE FOR DE-REGISTRATION OF THEIR PRODUCTS.

S. No	Product Name / Reg. No..	Reason for De-Reg	Alternative registered product
1.	Zoldic 4mg Injection. Each vial contains:- Monohydrated Zoledronic Acid (equivalent to anhydrous Zoledronic Acid 4mg) ……4.264mg. Reg. No. 045604	**Firm States as under:-** That our principle M/s Glenmark Generics S. A. Argentina has stopped the manufacturing of Zolid injection since 2012 and we have not imported the said product since then. Registration was valid till 6th August 2014 and we have not applied for renewal but by mistake could not apply for deregistration at that time. Further we have applied for registration of zoldic injection 4mg/5ml (Zolideronic acid) for local manufacturing which is approved in 285th meeting.	Kedronico Injection 4mg (Oncogene) Zoldria Injection 4mg (A.J. Mirza) Zometa Injection 4mg (Novartis) Edonax Injection 4mg (Ferozsons) Zoledron Injeciton 4mg (Scotman)
2.	Diluent for Zoldic 4mg Injection. Each diluent ampoule contains:- Distilled water for injection 5.00ml. Reg. No. 045605		
3.	Faast I.V. Infusion Each vial contains:- Omeprazole Sodium Ph.Eur. equivalent to Omeprazole 40mg. Reg. No. 052245	**Firm states as under: -** It is intimated that we have applied for transfer of registration from import to local but the manufacturer has not provided NOC for the same so far, consequently we did not submitted the application for renewal of registration of these products. Renewal of these products were due from 31-03-2019	1. Losec Infusion 40mg M/s Barret Hudgson. 2. Medizole Infusion 40mg M/s Mediate Pharma. 3. Omefill Infusion 40mg M/s Mediceena. 4. Omega Infusion 40mg M/s Ferozsons. 5. Risek infusion 40mg, M/s Getz. 6. Teph Infusion 40mg M/s Sami 7. M/s Zolat Infusion 40mg M/s English Pharma. 8. In Helezol Infusion M/s Biogenic.
4.	Solvent for Faast I.V. Infusion. Each 10ml vial contains:- Sodium Chloride……90mg. Reg. No. 053829		

Decision: Keeping in view availability status of products, Registration Board acceded to the request of firm and deregistered above products in name of M/S CCL Pharmaeuticals, Lahore.

Case.No.48: 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: Registration Board deferred the case for further deliberation.

Case.No.49: REQUEST FOR CHANGE OF MANUFACTURING SITE BY M/S HIMMEL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Himmel Pharmaceuticals (Pvt) Ltd. 793-D Block 'C', Faisal Town, Lahore, Pakistan has applied for change of manufacturing site of their following already registered product as per details given below:-

Table 1

S. #	Reg. No.	Name & Composition (as per approval & COPP).	Existing approved site (as per approval letters)	New Proposed Site / Manufacturer / PLH as per COPP
1.	084811	Docetaxel Aqvida 20mg/ml Concentrate for solution for IV infusion Each ml contains: Docetaxel…… 20mg	**Manufacturer as per Initial Reg.letter:** M/s. Samyang Biopharmaceuticals Corporation 79, Sinildong-ro, Daedeok-gu, 306-230 Daejeon, Korea. **Product License Holder:-** M/s. Aqvida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany.	**Manufacturer:** M/s AqVida GmbH Werkstr. 21 23942 Dassow Germany **Product License Holder:-** M/s. Aqvida GmbH, Kaiser-Wilhelm-Str.89, 20355 Hamburg, Germany.
2.	084812	Docetaxel Aqvida 80mg/4ml Concentrate for solution for IV infusion Each ml contains: Docetaxel…… 20mg	**-do-**	**-do-**

The firm has submitted the following supporting documents: -

a) Application on Form-5-F.
b) Fee of Rs.200,000/-
c) Registration letter (issued on 22nd June, 2017)
d) Original & legalized COPP issued by German Authority.
e) Site master file.
f) Letter of authorization
g) Copy of DSL (Name of firm on DSL is M/s Himmel Pharmaceuticals, 793-D Block 'C', Faisal Town, Lahore).
h) Undertaking that the provided information/ documents are true/ correct.

1. Docetaxel AqVida 20mg/ml Concentration for solution for Infusion		
	Name, address of Applicant / Marketing Authorization Holder	M/s Himmel Pharmaceuticals (Pvt) Ltd, 793-D, Block-C, Faisal Town,Lahore.
	Name, address of Manufacturing site.	AqVida GmbH, WrrkstraBe 21 23942 Dassow Germany
	Status of the applicant	□ Manufacturer □ **Importer** □ Is involved in none of the above (contract giver)
	Diary No. and date of submission	Dy No. 1921290, :19.06.2019
	Details of fee submitted	PKR 100,000/-: 19.06.2019
	The proposed proprietary name / brand name	Docetaxel AqVida 20mg/ml Concentration for solution for Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Injection contains: Docetaxel Anhydrous…… 20mg
	Dosage form of applied drug	Injection

	Route of administration	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Taxane,ATC Code: L01CD02
	Pharmacopoeial reference	Firm has submitted:- "USP Specifications"
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	
	For generic drugs (me-too status)	Taxotere Concentrate by M/s Sanofi Aventis
	Valid drug manufacturing license/Drug Sale License	Copy of Drug Sale License issued on 06-2-2018 is submitted.
	Evidence of approval of manufacturing facility / approved section from licensing authority	NA
	Type of Application	□ New Drug Product (NDP) □ **Generic Drug Product (GDP)**
	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	NA
	List of registered products	NA
	Manufacturer's site master file and credentials (for importers)	Yes
	Identification of signature of authorized persons , Incharge Production, Quality Control & Quality Assurance of manufacturer.	NA
	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	NA
	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 its letter head
	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.	NA
	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.	NA
	Information on Prior-related Applications	N/A
	Electronic Review Package	N/A
	QIS (Quality Information Summary)	Yes
	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	QILU Pharmaceuticals Co., Ltd No.243 Gong Ye Bei Road China-250 100 Jinan, Shandong Province
	b. Approval of manufacturing facility of API by regulatory body of country and validity.	Approved & Validity 03 January 2021
	c. Vendor qualification / audit is	Document 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, specification, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, manufacturing process development, container closure system, microbiological attributes and compatibility, controls of drug product, reference standards or materials and stability studies.
	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	Exempted
	Manufacture	Exempted
	Characterization	Exempted
	Control of drug substance	Exempted
	Reference standards or materials	Exempted
	Container closure system	Exempted
	Stability	Exempted
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of drug substance, excipients, formulation development, overages, physicochemical and biological properties, manufacturing process development, container closure system, microbiological attributes and compatibility.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	N/A
	Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.
	Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards
	Container closure system	HDPE bottle with dessicant
	Stability	Firm has provided completed stability study data of 3 batches as per Zone IV-B
	Comparative dissolution profile	
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Firm has submitted that being a generic product non-clinical data is not Applicable
	Pharmacokinetics	Firm has submitted that being a generic product non-clinical data is not Applicable
	Toxicology	Firm has submitted that being a generic product non-clinical data is not Applicable
	MODULE 5: CLINICAL / EFFICACY	
	Firm has submitted that being a generic product clinical data is not Applicable while in-vitro dissolution tests complementary to bioequivalence studies.	
	REMARKS OF EVALUATOR	

Docetaxel AqVida 80mg/4ml Concentration for solution for Infusion		
	Name, address of Applicant / Marketing Authorization Holder	M/s Himmel Pharmaceuticals (Pvt) Ltd, 793-D, Block-C, Faisal Town,Lahore.

	Name, address of Manufacturing site.	AqVida GmbH, WrrkstraBe 21 23942 Dassow Germany
	Status of the applicant	□ Manufacturer □ **Importer** □ Is involved in none of the above (contract giver)
	Diary No. and date of submission	Dy No. 1921292, :19.06.2019
	Details of fee submitted	PKR 100,000/-: 19.06.2019
	The proposed proprietary name / brand name	Docetaxel AqVida 80mg/4ml Concentration for solution for Infusion
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each Injection contains: Docetaxel Anhydrous…… 20mg
	Dosage form of applied drug	Injection
	Route of administration	Intravenous Infusion
	Pharmacotherapeutic Group of (API)	Taxane,ATC Code: L01CD02
	Pharmacopoeial reference	Firm has submitted:- "USP Specifications"
	Proposed Pack size	1's
	Proposed unit price	As per SRO
	The status in reference regulatory authorities	
	For generic drugs (me-too status)	Taxotere Concentrate by M/s Sanofi Aventis
	Valid drug manufacturing license/Drug Sale License	Copy of Drug Sale License issued on 06-2-2018 is submitted.
	Evidence of approval of manufacturing facility / approved section from licensing authority	NA
	Type of Application	□ New Drug Product (NDP) □ **Generic Drug Product (GDP)**
	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	NA
	List of registered products	NA
	Manufacturer's site master file and credentials (for importers)	Yes
	Identification of signature of authorized persons , Incharge Production, Quality Control & Quality Assurance of manufacturer.	NA
	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	NA
	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 its letter head
	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by	NA

	the Manufacturer.	
	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.	NA
	Information on Prior-related Applications	N/A
	Electronic Review Package	N/A
	QIS (Quality Information Summary)	Yes

	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	QILU Pharmaceuticals Co., Ltd No.243 Gong Ye Bei Road China-250 100 Jinan, Shandong Province
	b. Approval of manufacturing facility of API by regulatory body of country and validity.	Approved & Validity 03 January 2021
	c. Vendor qualification / audit is	**Document 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, specification, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, manufacturing process development, container closure system, microbiological attributes and compatibility, controls of drug product, reference standards or materials and stability studies.

	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	Exempted
	Manufacture	Exempted
	Characterization	Exempted
	Control of drug substance	Exempted
	Reference standards or materials	Exempted
	Container closure system	Exempted
	Stability	Exempted
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of drug substance, excipients, formulation development, overages, physicochemical and biological properties, manufacturing process development, container closure system, microbiological attributes and compatibility.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.
	Control of excipients	N/A
	Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.
	Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards
	Container closure system	HDPE bottle with dessicant
	Stability	Firm has provided completed stability study data of 3 batches as per Zone IV-B
	Comparative dissolution profile	

	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Firm has submitted that being a generic product non-clinical data is not Applicable
	Pharmacokinetics	Firm has submitted that being a generic product non-clinical data is not Applicable
	Toxicology	Firm has submitted that being a generic product non-clinical data is not Applicable
	MODULE 5: CLINICAL / EFFICACY	
	Firm has submitted that being a generic product clinical data is not Applicable while in-vitro dissolution tests complementary to bioequivalence studies.	
	REMARKS OF EVALUATOR	

Decision: **Registration Board approved the above change i.e. Change in Manufacturer and Manufacturing Site as per details in Table 1 (above) , in respect of registered products Docetaxel Aqvida 80mg/4ml Concentrate for solution for IV infusion (Reg.No 084812) and Docetaxel Aqvida 20mg/ml Concentrate for solution for IV infusion (Reg.No 084811) subject to policy for imported finished drug registration. Other terms and conditions remain the same.**

Case.No.50: REQUEST FOR CHANGE OF MANUFACTURING SITE BY M/S HILTON PHARMA (PVT) LTD, KARACHI.

M/s Hilton Pharma (Pvt) Ltd, Plot No. 13 & 14, Sector 15, Korangi Industrial Area, Karachi has stated that their principle has informed that they have shifted their bulk manufacturing site from USA to Italy. Details are given below:-

S. #	Reg. No.	Name & Composition (as per approval & COPP)	Existing approved site (as per approval letters)	New Proposed Site / Manufacturer / PLH as per COPP
1.	093936	Halaven Solution for Injection Each 2ml vial contains: Eribulin mesialte eq. to 0.88 mg eribulin	**Manufacturer as per Initial Reg.letter:** M/s. Biogen U.S. Corporation, 900 Davis Drive, Research Triangle Park, NC 27709, USA. **Batch Release, QC &Secondary Packaging by:** M/s Eisai Manufacturing Ltd. European Knowledge Centre, Mosquito Way Hatfield, Hertfordshire, AL109SN, United Kingdom. **Product License Holder:-** M/s Eisai Europe Ltd. European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom.	**Manufacturer:** M/s BSP Pharmaceuticals S.P.A.-Via Appia Km 65,561 (loc. Latina Scalo), 04013 Latina (LT) Italy. **Batch Release, QC &Secondary Packaging by:** M/s Eisai Manufacturing Ltd. European Knowledge Centre, Mosquito Way Hatfield, Hertfordshire, AL109SN, United Kingdom. **Product License Holder:-** M/s Eisai Europe Ltd. European Knowledge Centre, Mosquito Way, Hatfield, Hertfordshire, AL10 9SN, United Kingdom
Remarks: - The following documents is not found with firm's application:- • Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name), where the manufacturer and product license holder are different entities.				

The firm has submitted the following supporting documents: -

a) Application on Form-5-F.
b) Fee of Rs.50,000/-

c) Registration letter (issued on 24th Jan, 2019)
d) Original & legalized COPP issued by AIFA.
e) Site master file.
f) Undertaking that the provided information/ documents are true/ correct.

DETAILS OF CTD (M/S HILTON PHARMA (PVT.) LTD)

1.	Name, address of Applicant / Marketing Authorization Holder	Name: Hilton Pharma (Pvt.) Ltd. Address: Plot No. 13-14 sector, 15 Korangi Industrial Area, Karachi, Pakistan
	Name, address of Manufacturing site.	**Name:** BSP Pharmaceuticals S.P.A. **Address:** Via Appia Km 65,561 (loc. Latina Scalo), 04013 Latina (LT), Italy. **Resposibilities of M/s BSP** :- Physical, Chemical, Microbiological QC testing **Name:** Eisai Manufacturing Ltd,. **Address:** Mosquito Way Hatfield Hertfordshire AL109SN UK **Resposibilities of M/s Eisai** :- Physical, Chemical QC release testing. Secondary packaging and labelling Batch release.
	Status of the applicant	□ Manufacturer ☑ **Importer** □ Is involved in none of the above (contract giver)
	Dy No. and date of submission	Dy No. 729 , : 14-03-2019
	Details of fee submitted	PKR 50,000/-: 14-03-2019
	The proposed proprietary name / brand name	Halaven Injection 0.44 mg/ml
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each ml contains: Eribulin mesilate Equivalent to Eribulin….0.44mg
	Dosage form of applied drug	Injection
	Route of administration	Intravenous
	Pharmacotherapeutic Group of (API)	Anti-cancer
	Pharmacopoeial reference	Firm has submitted:- “Innovators Specifications”
	Proposed Pack size	As per DPC
	Proposed unit price	As per DPC
	The status in reference regulatory authorities	MHRA Approved
	For generic drugs (me-too status)	Could not be confirmed
	Valid drug manufacturing license/Drug Sale License	Firm has submitted GMP certificate of M/s BSP pharmaceuticals SPA issued by competent authority of Italy.
	Evidence of approval of manufacturing facility / approved section from licensing authority	Firm has submitted GMP certificate of M/s BSP pharmaceuticals SPA issued by competent authority of Italy, having Sterile Products (Terminally sterilized, small volume liquids, Cytotoxics/Cytostatics) section.
	Type of Application	☑New Drug Product (NDP) □ Generic Drug Product (GDP)

	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	No
	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.	Not Available
	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.	Not Available
	Information on Prior-related Applications	Yes
	Electronic Review Package	Yes
	QIS (Quality Information Summary)	Yes
	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	M/s Eisai Co., Ltd. Kashima Plant 22 Sunayama Kamisu-shi Ibaraki-ken Japan
	b. Approval of manufacturing facility of API by regulatory body of country and validity.	Not Available
	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, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control

		of excipients, control of Drug Product, Reference standards or materials, container closure system and stability studies.
	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	General information on Structure, Nomenclature are provided
	Manufacture	Eisai Co, Ltd, Kashima Plant, 22 Sunayama, Kamisu-shi Ibaraki-Ken Japan is the manufacturer, packaging, release testing, and stability testing responsibility. Manufacture process and process control data , control of material is submitted.
	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 7 batches.
	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	Clear glass vial , a rubber stopper, and an aluminium over-seal
	Stability	Firm has provided completed stability study data of 3 batches as per Zone IV-B
	Comparative dissolution profile	Not Applicable
	MODULE 4: NON-CLINICAL / SAFETY	
	Pharmacology	Firm has submitted Pharmacology.
	Pharmacokinetics	Firm has submitted Pharmacokinetics.
	Toxicology	Firm has submitted Toxicology.
	MODULE 5: CLINICAL / EFFICACY	
	Firm has submitted Clinical data.	

Decision: Registration Board deferred the case for provision of Proof/ evidence of the contract between Product License Holder & manufacturer (with changed/ new name).

Case.No.51: 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: Registration Board deferred the case for further deliberation.

Case No. 52: Registration of Vitamin Formulations.

Registration of vitamin formulations are pending since quite long time. Various discussions at different forums are as under:-

216th Reg.Board Meeting

Registration Board in its 216th meeting considered following recommendations for finalization of vitamin policy, as under: -

a) PPMA & Pharma Bureau collectively adopted a stand that vitamins shall remain under the Drugs Act, 1976.
b) That the formulations approved by the Regulatory Authorities of the developed countries will remain register in the identical strengths of active ingredients with special focus on the optimum level of the Vitamin A, Vitamin D, Vitamin E and certain Trace Elements which exhibit toxicity because the dietary habits of Pakistan population are full of the Vitamins. It will be mandatory that free sale certificate would be submitted to the Ministry of Health for continuation of the formulation or new registrations identical.
c) The formulations which were registered up to December, 1997 will also remain in the market. However, their ingredient's strength levels will be rationalized at uniform formula.
d) Rest of the formulations will be reviewed in the light of Para **"b & c**". In case of formulations not in line with the "b & c", the firms will be allowed to adopt

similar formulations available in the light of the Para "b & c" or surrender the formulation.

e) All the pending applications will be decided in the light of Para **"b & c**".
f) Mandatory stability studies along with validation of testing methods will be pre-requisite for the grant of registrations.
g) Pricing issues will be decided by the PRC.
h) The firms seeking manufacturing permission for minerals will be required to possess the facility of the atomic absorption.
i) A committee comprising of two members each from PPMA & Pharma Bureau along with MOH will scrutinize the pending applications in the light of above recommendation in the light of Para "b & c". This committee would submit their recommendations for finalization of formulations in line with "b & c". They will also report about the food supplements fate. A comprehensive report will be submitted for final consideration of the Drugs Registration Board.
j) No new registration will be permitted to the Vitamins and Minerals formulations which will not be identical with the formulations in "b & c" or free sale certificate will be provided from the developed countries.
k) Single ingredient vitamin preparations shall be considered for registration
l) Pharmacopoeial standard vitamin preparations and vitamin products which has expired patents shall also be considered for registration.
m) Only applications of firms having atomic absorption and flame photometer shall be considered for registration.

217th Reg.Board Meeting

Decision: -

The board after discussion approved following policy.

S#	PROPOSED RECOMMENDATIONS FOR MINISTRY OF HEALTH
1	Due to flood of unregistered vitamin products in the market under the garb of nutritional or food supplements, there is a need for a definite policy regarding registration of vitamins or vitamin with minerals
2	All the preparations would be classified as drugs. They should require registration under Drugs Act 1976 by Ministry of Health
3	Vitamin and mineral preparations will be divided into two categories (a) Vitamin supplements: Preparations containing vitamins and minerals upto the level of Recommended Dietary Allowance (RDA) (b) Therapeutic vitamins and minerals: Preparations containing vitamins and minerals in quantities above the RDA quantities intended for therapeutic use will be deemed as therapeutic class.
4	The Board decided that the pharmaceutical companies which don't have "Atomic Absorption" equipment for the analysis of minerals + vitamins combination products will be granted registration of such products subject to analysis of minerals + vitamins from any PNAC Accredited Laboratory. This permission will be valid for two years and during this time firm will be bond to have this facility in its own pharmaceutical unit. Moreover, all the Government (Provincial and Federal) drugs testing laboratories will equip themselves for testing of these preparations. For this purpose Research and Development Section will put proposal for strengthening of these Laboratories. The section will propose a mechanism for outsourcing of testing / analysis of vitamins and minerals. R& D and QA wings will also be consulted.
5	The registration of vitamin and mineral preparations are subject to price fixation by the

Price Advisory Committee.

6 Import of vitamin and mineral preparations will be allowed as per Import Policy for Drugs of Ministry of Health.

7 The minimum level of each vitamin and / or mineral contained in a vitamin and mineral supplement per daily portion of consumption as suggested by the manufacturer should be atleast 15% of the recommended daily intake

8 Combination of vitamins with analgesic or antibiotics will not be allowed except combination of pyridoxine with isoniazid.

9 High doses of vitamin E can increase the effect of blood-thinning medications well beyond the desired result. Such preparations need to have a clear warning for patients on warfarin.

10 Only vitamins and minerals listed in annex I, in the forms listed in annex II may be used for the manufacture of vitamin supplements. The units to be used for vitamins and minerals shall be those specified in annex I.

ANNEXURE-I

Vitamins & minerals which may be used in the manufacture of food supplements

Vitamins

1. Vitamin A (µg re)	14. Calcium
2. Vitamin D (µg)	15. Magnesium
3. Vitamin E (mg α-te)	16. Iron
4. Vitamin K (µg)	17. Copper
5. Vitamin B1 (mg)	18. Manganese
6. Vitamin B2 (mg)	19. Sodium
7. Niacin (mg ne)	20. Potassium
8. Pantothenic acid (mg)	21. Selenium
9. Vitamin B6 (mg)	22. Chromium
10. Folic acid (µg)	23. molybdenum
11. Vitamin B12 (µg)	24. Fluoride
12. Biotin (µg)	
13. Vitamin C (mg)	

ANNEXURE-II

A. Vitamins

1. Vitamin A	5. Folic acid
i. Retinol	i. Pteroylmonoglutamic acid
ii. Retinyl acetate	6. Vitamin B12
iii. Retinyl palmitate	i. Cyanocobalamin
iv. Beta-carotene	ii. Hydroxocobalamin
2. Vitamin D	7. Biotin
i. Cholecalciferol	i. D-biotin
ii. Ergocalciferol	8. Vitamin C
3. Vitamin E	i. L-ascorbic acid
i. D-alpha-tocopherol	ii. Sodium-l-ascorbate
ii. Dl-alpha-tocopherol	iii. Calcium-l-ascorbate
iii. D-alpha-tocopheryl acetate	iv. Potassium-l-ascorbate
iv. Dl-alpha-tocopheryl acetate	v. L-ascorbyl 6-palmitate
v. D-alpha-tocopheryl acid succinate	
4. Vitamin B6	
i. Pyridoxine	
ii. Pyridoxine hydrochloride	
iii. Pyridoxine 5'-phosphate	

B. Minerals	
1. Calcium carbonate	23. Manganese chloride
2. Calcium chloride	24. Manganese citrate
3. Calcium salts of citric acid	25. Manganese gluconate
4. Calcium gluconate	26. Manganese glycerophosphate
5. Calcium glycerophosphate	27. Manganese sulphate
6. Calcium lactate	28. Sodium bicarbonate
7. Calcium salts of orthophosphoric acid	29. Sodium carbonate
	30. Sodium chloride
8. Calcium hydroxide	31. Sodium citrate
9. Calcium oxide	32. Potassium lactate
10. Magnesium acetate	33. Potassium hydroxide
11. Magnesium carbonate	34. Potassium salts of orthophosphoric acid
12. Magnesium chloride	
13. Ferrous lactate	35. Sodium selenate
14. Ferrous sulphate	36. Sodium hydrogen selenite
15. Ferric diphosphate (ferric pyrophosphate)	37. Sodium selenite
	38. Chromium (iii) chloride
16. Ferric saccharate	39. Chromium (iii) sulphate
17. Elemental iron (carbonyl+electrolytic+ hydrogen reduced)	40. Ammonium molybdate (molybdenum (vi))
	41. Sodium molybdate (molybdenum (vi))
18. Cupric carbonate	
19. Cupric citrate	42. Potassium fluoride
20. Cupric gluconate	43. Sodium fluoride
21. Cupric sulphate	
22. Copper lysine complex	

11 Vitamin supplements would be purely meant for nutritional purpose and no claims will be made about prevention, cure, diagnosis, mitigation or treatment of diseases

12 Vitamin supplement manufacturers may claim that their products benefit, the structure and function of the human body or promote "General well-being".

13 The CBR/customs will be informed that all imported vitamin supplement therapeutic products treated as drugs.

The Board directed to present applications for registration of vitamins and mineral preparations in forthcoming meeting of Registration Board for decision.

39th meeting of Authority:

Vitamin policy was discussed in the 39th meeting of Authority.

"Decision:- The Authority decided that:-

1. No nutraceutical product or alternative medicines already registered as drugs under the Drugs Act, 1976 shall be allowed for switch over from drug category to alternative medicines or Health & OTC (non-drug) category. Therefore, those who want to switch for price de-regulation due to such switching will not arise.
2. Those who are interested for enlistment under alternative medicines enlistment rules where applicable may apply fresh under new brand names. Brand names even registered as drug will not be allowed to be registered under Alternative Medicines / Health & OTC (non-drug) products. It was further decided that brand names already registered under the Drugs Act, 1976 will not be allowed by the Health & OTC (non-drug) Division for enlistment purpose. Even already registered name with some suffix or prefix shall also

not be allowed to avoid any confusion, misinterpretation or misleading patient and prescriber, so as to avoid any confusion or risk to patient. So use of same or similar names or similar sonic (sound alike or look alike) can create problems and legal complications for the DRAP and risk to patient.

3. For future, it was decided that nutraceutical products with therapeutic claims and using ingredients above RDI shall continue to be registered as drugs while rest shall be enlisted by the Health & OTC (non-drug) Division under their respective rules.
4. Division of Alternative Medicines/Health & OTC (non-drug) was also advised to review their rules of enlistment/ the enlisted products for any required correction or for removal of any anomaly and also to review, if they have already deviated from the policy.
5. The decision be shared for discussion with stakeholders."

It was also discussed in meeting that registration of vitamin with therapeutic claims is also pending because of non-finalization of vitamin policy. After the approval of vitamin policy, registration of combinations as well as single ingredient or with high potency will start addressing. Those with therapeutic claim will be considered for registration as drugs while those without any therapeutic claim and at RDI will be considered for enlistment under Health & OTC (non-drug) Division.

40th meeting of Authority:

The Authority recommended for approval to the Policy Board.

18th meeting of Policy Board:

1. Approved the Vitamin Policy as recommended by the Authority and is as follows.
2. Directed the Authority to devise a mechanism to regulate prices of Alternative medicines, Health and OTC (non-drug) products.

270th Reg.Board Meeting

Decision: Registration Board deferred the case for further deliberations.

271st Reg.Board Meeting

(Source Vitamin and Mineral Safety published by Council for Responsible Nutrition, 3rd Edition, 2014)

Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN) ,US Institute of Medicine (IOM),European Commission on Safety of Food (ECSCF) or European Food Safety Authority (EFSA), UK Expert group on Vitamins Minerals (EVM) and Japan Consumer Affairs Agency (JCAA).

Nutrient Vitamins and Minerals	CRN UL (amount/ day)	US IOM UL (amount/ day)	EC SCF/EFSA UL (amount/ day)	UK SVM SUL or GL (amount/ day)	Japan (Amount per Unit)
Vitamin A	10,000 IU (3,000 µg RAE)	10,000 IU	10,000 IU	5,000 IU	2000 IU
Beta Carotene	25mg non-smokers, smokers should not use.	Not determined	Not determined	7 mg supplements, smokers should not use.	
Vitamin D	250 µg (10,000 IU)	100 µg (4,000 IU)	100 µg (4,000 IU)	250 µg (1,000 IU)	2000 IU

Vitamin E	1000mg(1600IU)	1000mg(1600IU)	300mg	540mg	150mg
Vitamin k	10mg	Not determined	Not determined	1mg	150µg
Vitamin C	2000mg	2000 mg	Not determined	1000mg	1000 mg
Vitamin B1 (Thiamine)	100mg	Not determined	Not determined	100mg	25mg
Vitamin B2 (Riboflavin)	200mg	Not determined	Not determined	40mg supplement 43 mg total (GL)	12mg
Nicotinic acid	500mg	35mg	10mg	17mg	
Nicotinamide	1500mg	35mg	900mg	500mg supplement 560 mg total (GL)	60mg
Pyridoxine	100mg	100mg	25mg	10mg	10mg
Folic Acid	1000µg	1000µg	1000 µg	1000 µg	200µg
Vitamin B12	3000 µg	Not determined	Not determined	2000 µg	60µg
Biotin	2500 µg	Not determined	Not determined	900 µg	500µg
Pantothenic Acid	1000mg	Not determined	Not determined	200mg supplement 210mg total (GL)	30mg

Tolerable upper intake level (UL), of Vitamins and Minerals in Supplements defined by Council for Responsible Nutrition (CRN) ,European Food Authority (EFSA), UK Expert group on Vitamins and Minerals (EVM),European Commission on Safety of Food (ECSCF), US Institute of Medicine (IOM) and Japan Consumer Affairs Agency (JCAA).

Nutrient Vitamins and Minerals	**CRN UL (amount/ day)**	**US IOM UL (amount/ day)**	**EC SCF/EFSA UL (amount/ day)**	**UK SVM SUL or GL (amount/ day)**	**Japan (Amount per Unit)**
Calcium	1500mg	2500mg	2500mg	1500mg	600mg
Phosphorous	1500mg	4000mg.	not determined	250 mg supplement 2400 mg total (GL)	
Magnesium	400mg	350mg	250mg	400mg supplement (GL)	300mg
Potassium	1500mg (500mg thrice)	Not determined	Not determined	3700 mg supplement (GL)	2800 mg
Boron	6mg	`20mg	`10mg	9.6mg (SUL)	
Chromium	1000mcg	1000mcg	Not determined	10 mg (10,000 µg) total (GL)	
Copper	9mg	10mg	5mg	10 mg total (SUL)	6.0mg
Fluoride	No ULS (UL=6 mg)	10	7mg	Not determined	
Iodine	500µg	1100µg	600µg	500 µg supplement 930µg total (GL)	
Iron	60mg (full stomach)	45mg (empty stomach)	Not determined	17mg supplement (GL)	10 mg
Manganese	10mg	11mg	Not determined	4 mg supplement 12.2mg total (GL)	300mg
Molybdenum	350µg	2000µg	600µg	230µg food (GL)	
Selenium	200 µg	400 µg	300 µg	350 µg supplement	

				450 µg total (SUL)	
Zinc	30mg	40mg	25mg	25 mg supplement 42 mg total (SUL)	15 mg

CRN: Council for Responsible Nutrition
US IOM: United States Institute of Medicine
ECSCF: European Commission on Safety of Food
EFSA UL European Food Authority (EFSA)
GL: Guidance Level (may apply to total or supplemental intake)
UK EVM: UK Expert group on Vitamins and Minerals (EVM)
SUL: Safe Upper Tolerable Limit
UL: Tolerable upper intake level

Decision of 271st meeting:

Registration Board deferred agenda item for further detailed deliberation In forthcoming meeting.

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

i. **Those vitamins and minerals above RDA as defined in the Vitamin Policy (18th meeting of Policy Board) will be considred as drug. If any one of the ingredient of multiple ingredient dosage form falls above RDA, it will be considered as a drugs.**
ii. **Those combinations already having registration in Pakistan and marketing proof of availability of 5-7 years in market with no reported adverse reactions, shall be considered as reference for safety and efficacy of these combinations.**
iii. **For new combinations, availability in already defined reference regulatory authorities will be considered as a reference.**
iv. **For already submitted dossier, applicant will be given 3 months time for amendment / correction in their applied formulations in light of above recorded decision and submission of differential fee and registration application.**
v. **Registration dossiers will be considered on FIFO basis from date of completion of dossiers including all codal formalities.**

Case No.53: Request for Extension of Permission of Bulk Import & Local Repacking of Drug (s) of M/s. Atco Laboratories, Karachi.

M/s. Atco Laboratories Ltd; Karachi has requested for extension of permission of bulk import and local repacking of their following already registered products:-

S.No.	Name of Drug(s) with existing formulation	Reg.No.	Registration history
1.	Hirudoid Cream 100gm Each 100gm contains:- Mucopolysacchride Polysulfuric acid ester … 0.3gm	014995	The firm was granted previous extension of permission for bulk import & local repacking on 13-12-2012 which was valid till 5 years. The approved manufacturer was Sankyo Pharma GmBH, Germany.
2.	Hirudoid Gel 100gm Each 100gm contains:- Mucopolysacchride Polysulfuric acid ester … 0.3gm	017481	-do-

They have further stated that have equipped their facility to manufacture the above product and the manufacturer did not allow them to manufacture these products locally in Pakistan. They have therefore, requested to extend the permission of bulk import and local repacking for further 5 years.

The management of the firm has provided following documents:-

i. Original challans of fee of Rs. 1,00,000/- per product for this purpose.
ii. Copies of initial letters of registration and subsequent permission letters.

The Committee in its 3rd meeting deferred the case for provision of complete documents as per approved SOPs and placement before Registration Board. Now the firm has provided original & legalized CoPP and requested for extension of bulk import and local repacking permission as requested above.

As per CoPP provided by the firm for the above products following information has been retrieved:-

S.No.	Name of active ingredient	Name of Manufacturer	Product License Holder
1	100 g ointment contains:- 300mg Chondroitin polysulfate from Bovine tracheal cartilage 300 gm corresp. 25000 U* *Units determined by means of the activated partial thromboplastin time (APTT).	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany
2.	100 g Gel contains:- 300 mg Chondroitin polysulfate from Bovine tracheal cartilage 300 gm corresp. 25000 U* *Units determined by means of the activated partial thromboplastin time (APTT).	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.

The manufacturer is Mobilat Productions GmbH, Germany.

Decision of M-281

Registration Board in its 281st meeting deferred the case and advised the firm to confirm whether the composition mentioned in the initial registration letter and composition mentioned in the CoPP is same.

The firm has now submitted original signed clarification issued by their principal manufacturer M/s Mobilat Produktions GmbH, Germany, clarifying that the composition mentioned in the initial registration certificate is same as mentioned in certificate of pharmaceutical product with scientific rationale, stated as under:

The active substance mucopolysaccharide Polysulfate has different names, such as Mucopolysaccharide polysulphuric acid ester, Chondroitin polysulfate, Glycosaminoglycan Polysulfate, however the stand all for the same active ingredient that is manufactured based on bovine tracheal cartilage. Mucopolysaccharide Polysulfate is the proprietary name for the active substance. The systematic chemical name (IUPAC) is 2-acetamido-2-deoxy-D-galacto-D-glucurnoglycan-polysulfate sodium. Depending on the Health Authorities and Drug application, one of the above names are indicated in the drug registration and thus the CoPPs.

As per evaluation of the dossier/documents submitted by the firm, certain clarifications were sought from the firm. Detail of queries along with firm's response has been placed below:

Sr.#	Queries	Response/ Documents Provided By M/s Atco, Karachi
1.	Clarification is required regarding dosage form, as the registered product is "cream" whereas CoPP states "ointment".	Actually, the product name is "Hirudoid Cream", we have already been argued to our principal manufacturer to provide CoPP mentioning dosage form as cream but, they denied by giving reason that: "We cannot provide CPP indicating wording a cream instead of ointment. We hope you understand our situation and you may advice to compare the formulation. Sorry for inconvenient may cause you.
2.	Clarification is required regarding name of manufacturer	The firm has informed that they have already got approval for change of name of manufacturer from Daiichi Sankyo GmbH, Germany to Mobilat Produktions GmbH, Germany for Hirudoid Cream and Hirudoid Gel vide letter dated 16-11-2011

Decision of M-287:

Registration Board deferred the case due to following reasons:

- **i.** Submission of rational justification regarding dosage form of "Hirudoid Cream" mentioned on CoPP.
- **ii.** Clarification regarding Marketing Authorization/License Holder & manufacturer of above mentioned products.

Updated Status:

Now, the firm has submitted clarification letter from principal manufacturer of Hrudoid ointment/gel i.e Mobilat Produktions GmbH, Germany (original/legalized) clarifying that:

a) Hirudoid cream as approved in Pakistan is identical to Hirudoid ointment as approved in Germany and Hirudoid cream as approved in Switzerland
b) There is no change in Marketing Authorization Holder in Germany, STADA GmbH, Germany.
c) The provided CoPP of Hirudoid cream is issued from regulatory authority of Switzerland (original/legalized) which is DRAP defined reference authority. In Switzerland the marketing authorization holder and product owner is Medinova AG but in Germany it is STADA GmbH.

The MAH/Product license holder and manufacturer is clarified as under:

S.No.	Reg. No.	Product name and composition	Name of Manufacturer	Product License Holder
1	014995	Hrudoid cream Each 100g contains: Mucopolysaccharide polysulphuric acid ester…….0.3g	.M/s Mobilat Produktions GmbhH, Germany	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany

2.	017481	Hirudoid gel Each 100g contains: Mucopolysaccharide polysulphate ……..300mg	M/s Mobilat Produktions GmbhH, Germany	STADA GmbH Stadastraβe 2-28 61118 Bad Vilbel, Germany.

It is submitted that approval of above mentioned manufacturer was granted on 16th November 2011 vide Letter No. F1-43/2010-Reg-I (Vol-I) while manufacturer mentioned on last approval letter for extension in permission (for bulk import and local repacking) was rendered as M/s Sankyo pharma GmbH, Germany. Firm did not apply for correction considering aforementioned approval as permission for extension in permission of bulk import and local repacking, merely. Since they got separate approval for name change of manufacturer.

Decision: Registration Board deferred the request of firm for comparison of formulations of Hirudoid ointment (approved in Germany) and Hirudoid cream (approved in Switzerland).

Case No.54: Change of Name of Manufacturer of Registered Drugs for Bulk Import & Local Repack of M/s Martin Dow Limited, Karachi.

M/s Martin Dow Limited, Plot No.37, Sector 19, Korangi Industrial Area, Karachi has requested for the change of Name of Manufacturer of their following registered drugs for Bulk Import & Local Repack at M/s Martin Dow Ltd, Karachi; however, the **manufacturing site will remain the same.** The details of drugs are as under;

Sr. No.	Name of Drug with composition & Registration Number	Date of i. Initial Reg. ii. Renewal Status	Existing Name of Manufacturer	Proposed Name of Manufacturer
1.	Rivotril 2mg Tablet Each tablet contains: Clonazepam……2mg (Reg. No. 003626)	i. 5-Jan-78	**M/s Roche Farma S.A.** Calle Severo Ochoa, 13 28914 Leganes (Madrid), Spain. **License Holder:** M/s F.Hoffmann–LA Roche Ltd, Basel, Switzerland.	**M/s Recipharm Leganes S.L.U.,** Calle Severo Ochoa, 13 28914 Leganes (Madrid), Spain. **License Holder:** M/s F.Hoffmann–LA Roche Ltd, Basel, Switzerland.
2.	Rivotril 0.5mg Tablet Each tablet contains: Clonazepam……0.5mg (Reg. No. 001049)	i. 15-Aug-76		
3.	Rivotril Drops 0.25% Each ml contains: Clonazepam……0.25% (Reg. No. 001047)		**Manufacturer:** M/s Roche S.p.A. Via Carnevale 1 20090 Segrate (MI), Italy. **License Holder:** M/s F.Hoffmann – LA Roche Ltd, Basel, Switzerland.	**Manufacturer:** M/s Delpharm Milano S.R.L. Via Carnevale 1 20090 Segrate–(MI), Italy **License Holder:** M/s F.Hoffmann – LA Roche Ltd, Basel, Switzerland.

In this regard, the firm has submitted the following documents;

i. Fee of Rs. 5,000/- for each product (dated 9-July-2019).
ii. Copies of Initial Registration Letters and Renewal Status **(Renewal confirmed till 28-Jun-2020 for Sr.No.1-2 & for product at Sr.No.3 approved in M-286)**.
iii. Original & Legalized Certificate of Pharmaceutical Products.

- cGMP of M/s Recipharm Leganes S.L.U., Spain **issued on 8-June-2018 & valid till 03 years.**
- cGMP of M/s Delpharm Milano S.R.L. Italy **issued on 31-January-2019 & valid till 03 years**.

iv. Legalized & Notarized evidence for the new titles of the firms.
v. Original & Legalized contract between Product License Holder & Manufacturers.
vi. Undertakings.

Decision: **Registration Board acceded to request of firm for change in title (manufacturing site remains same) as follows:**

a. **Products at S.No.1 and 2: From M/s Roche Farma S.A Calle Severo Ochoa, 13 28914 Leganes (Madrid), Spain to M/s Recipharm Legane S.L.U., Calle Severo Ochoa, 13 28914 Leganes (Madrid), Spain.**
b. **Product at S.No.3: From M/s Roche S.p.A. Via Carnevale1-20090 Segrate–(MI), Italy to M/s Delpharm Milano S.R.L. Via Carnevale1-20090 Segrate–(MI), Italy.**
c. **Quality control release of above products shall be at M/s Martin Dow Ltd, Karachi.**

Case No.55: Change of Finished Product Specifications/Composition of Registered Drugs by M/s Atco Laboratories Ltd, Karachi.

M/s Atco Laboratories Ltd, B-18, S.I.T.E., Karachi has requested to change the composition and finished product specifications of their following registered drug:-

Sr. No	Reg. No.	Name of Drug(s) with existing formulation	Name of Drug(s) with proposed formulation	Proposed Specification
1.	035285	Bronkal Respirator Solution Each 100ml contains: Salbutamol (as Sulphate)…..**0.5gm** (Last Renewal 20-Nov-14)	Bronkal Respirator Solution Each **5ml** contains: Salbutamol (as Sulphate)…….**5mg**	BP Specification

The applied formulation exists in British pharmacopeia. According to firm, their registered pack size of 20ml therefore they want to rationalize the label claim with respect of pack size that is 20ml and also standardize the formulation in accordance with the innovator's product i.e. ventoline respirator solution 5mg/5ml (Glaxo Wellcome UK Limited).

The firm has submitted the following documents;

Sr.#	Requirement as per SOP	Submission
a.	Application with required fee as per relevant SRO **(Rs.5,000/- dated 21-Mar-19)**.	Provided
b.	Copy of registration letter and last renewal status.	Provided
c.	Document in support of proposed change.	Provided
d.	Analytical reports as per monograph of FPP.	
e.	Undertaking that: i. The change is made exclusively to comply with the pharmacopeia of Reference Regulatory Authorities or as per Innovator's product specifications. ii. No case is pending at any forum/court of law regarding this product. iii. In case of any quality complaint/ OOS result observed by the marketing authorization holder as a result of this change, the same shall be reported to registration board and all the stock shall be recalled from the market immediately. iv. The provided information/ documents are true/ correct**.**	Provided

Decision of M-289:

Registration Board deferred request of firm for further review of proposed change in formulation/label claim and differential fee of Rs. 15,000 for this purpose.

Updated Status:

The firm has stated that they have requested for standardization of formulation in accordance with the Innovator's Product/Reference Regulatory Authority and adoption of BP Specification for finished product but not for change in composition / formulation. Hence, there is no need for submission of differential fee of Rs.15,000/-.

It is hereby clarified that previously proposed change was mistakenly mentioned as 5mg/5ml instead of 5mg/ml, same has been approved by MHRA (UK) i.e. ventoline respirator solution 5mg/ml (Glaxo Wellcome UK Limited).

Decision: Registration Board considered request of firm and decided as follows:

a) **Approved finished product specification as BP**
b) **Approved Standardization of formulation in accordance with the MHRA (UK) approved product i.e. ventoline respirator solution (Glaxo Wellcome UK Limited) as: Bronkal Respirator Solution**

Each ml contains:
Salbutamol (as Sulphate)…….5mg

Case No.56: Similarity of Brand Name of M/s. Genome Pharmaceuticals (Pvt.) Ltd, Karachi.

In pursuance of decision of 27-Meeting of PRVC, M/s. Hilton Pharma (Pvt.) Ltd, Karachi was advised vide letter No.F.27-PRVC/19 (PR-I) dated 14-May-2019 to change the brand name of their registered products i.e. Dulan 20mg (Reg.No.055446); 30mg (Reg.No. 055447); 60mg (Reg.No.055448); 90mg (Reg.No.061839) (Desloratadine) tablets which have close resemblance with the already registered products of M/s. Genome Pharmaceuticals (Pvt.) Ltd, 16/1, Hattar-Haripur i.e. Dulin tablet.

In pursuance of authority's advice, M/s Hilton Pharma (Pvt.) Ltd, Karachi has intimated that their product is available in the Market for last 10 years securing good reputation among the healthcare professionals and patients. However, the same brand name DULAN is also their Trade Mark registered by IPO, Pakistan since 4th June, 2009. Furthermore, the firm has also intimated that the brand name **Dulin has not been launched in the market by M/s Genome Pharmaceuticals so far.**

Decision (31-PRVC):

The Committee referred the case to Registration Board.

Decision: Registration Board advised to confirm marketing status of Dulin tablet (Reg.No.053565) from M/s Genome Pharmaceuticals (Pvt.) Ltd.

Case No.57: Change in Finished Product Specification of Drug of M/s AGP Limited, Karachi.

The request for change of finished product specification of following registered drug of M/s AGP Limited, B-23, SITE, Karachi was presented before the 31st meeting of Post Registration Variation Committee (PRVC) held on 22-August-2019.
(Dy.No.7252(R&I)/19-Feb-2019)

Sr.No.	Reg. No.	Name of Drug with composition & Specification	Proposed Specification
1.	055574	Mecovate 500mcg tablet Each tablet contains: Mecobalamin…….500mcg (Manufacturer's Specification)	USP Specification

In this regard, the firm has submitted the following documents;

i. Fee of Rs.5,000/- (Dated:00-Feb-19)
ii. Copies of Transfer of Registration & Renewal Status (Dated 23-Feb-16).
iii. Analytical reports as per USP monograph **(Dietary)**.
iv. Undertaking.

Decision (31-PRVC):

The Committee referred the case to Registration Board.

Decision: Registration Board deferred request of firm for further deliberation.

Case No.58: Request for Permanent Change in Registration Status from Local Manufacturing to Bulk Import (Blister) & Local Repacking (Secondary Packaging Only)

M/s Pfizer Pakistan Ltd, B-2, SITE, Karachi has requested for granting permission for bulk import and local repacking of their product Arthrotec 50mg tablet permanently. According to firm, they are already importing bulk blister from M/s Piramal Healthcare UK Ltd, UK. In order to ensure continuous availability of the product in Pakistan, they have requested for permanent approval of the registration status of Arthrotec 50mg tablet for bulk import and local repack.

However, there shall be no change in manufacturing or packaging site as approved earlier but previously approval was granted for interim period to be renewed from time to time. The details of product are as under;

Sr. No.	Name of Drug with composition, Reg. No. & Dy. No. /date of application	Bulk Manufacturer	Secondary repacking site & Quality Control Relief	Remarks
1.	Arthrotec 50mg Tablet Each tablet contains: Diclofenac Sodium …….50mg Misoprostol……..200mg (Reg.No.023362) **Dy.No.11178 (R&I)/ 9-Jul-19**	M/s Piramal Healthcare UK Limited, Whalton Road, Morpeth, Northumberland, NE61 3YA, United Kingdum	M/s Pfizer Lab, Karachi.	Last approval granted on **09-Jun-14** for the period of 05 Years.

In this regard, the firm has submitted the following documents;

i. Application on Form-F along-with Fee of Rs.100,000/- (Dated 9-Jul-19)
ii. Copies of Initial Registration and last approval letters for Bulk Import & Local Repack.
iii. Transfer of registration from M/s Park Devis to M/s Pfizer Pakistan Limited.
iv. Original Legalized CoPP of Bulk Manufacturer from MHRA.
v. Undertaking.

Decision (31-PRVC):

The Committee referred the case to Registration Board.

Decision: **Registration Board granted permission for bulk import of Arthrotec 50mg Tablet from M/s Piramal Healthcare UK Limited Whalton Road, Morpeth, Northumberland, NE61 3YA, United Kingdom and local repacking and Quality control release at M/s Pfizer Lab, Karachi for further 5 years.**

Case No.59: Grant of approval of Route of Administration of Registered Drugs by M/s Cirin Pharmaceuticals (Pvt.) Ltd, Hattar.

M/s Cirin Pharmaceuticals (Pvt.) Ltd, Plot No.32/2-A, Phase-III, Industrial Estate, Hattar has requested for the grant of approval for "Route of Administration" of Zeemox Injection. The details of registered drugs are as follows;

Sr. #	Reg. No.	Name of Drug with composition	Proposed Route of Administration	Date of Initial Reg. & Renewal Status	Remarks
I	II	III	IV	V	VI
1.	015969	Zeemox Injection Each vial contains: Amoxycillin Sodium B.P. eq. to Amoxycillin base……250mg	I.V	i. 20-Sep-94 ii. 17-Sep-14	(AMOXIL VIALS FOR INJECTION) The standard recommended route of administration is by **intravenous injection** or **intravenous infusion**. Intramuscular administration should only be considered when the intravenous route is not possible or less appropriate for the patient. ***https://www.medicines.org.uk/emc/product/94/smpc***
2.	015970	Zeemox Injection Each vial contains: Amoxycillin Sodium B.P. equivalent to Amoxycillin base……500mg	I.V		
3.	017719	Zeemox Injection Each vial contains: Amoxycillin sodium equivalent to Amoxycillin base……..1gm	I.V	i. 18-Jul-95 ii. 10-Jul-15	

In this regard, the firm has submitted the following documents;

i. Fee of Rs.5,000/- for each product.
ii. Reference approvals **(MHRA)**
iii. Undertaking

Decision of 30-PRVC:

The Committee referred the case to Registration Board.

Decision: **Registration Board approved I.V route of administration in accordance with SmPC of MHRA (UK) approved product i.e Amoxil injection.**

Case No.60: Change of Brand Names of Registered Products of M/s GSK OTC (Pvt.) Ltd, 35-Dockyard Road, West Wharf, Karachi.

Sr. #	Name of Brand Name with composition & Reg. No.	Proposed Brand Names	Date of Initial Reg. & Date Renewal Application	Justification / Remarks/ Deficiency (if any)
I	II	III	IV	V
1.	Qalsan-D Chewable Tablet Each chewable tablet contains: Calcium Carbonate 1250mg eq. to Elemental Calcium……..500mg Vitamin D_3…….……....125iu (Reg. No.083220) (P.#20-28/C)	**QalSium D Chewable Tablet**	17-May-17	Licensing of Trade mark granted to GSK by Novartis is going to expire and they will not be allowed to use the products containing Sandoz in brand name like **Calcium Sandoz** and **San** in term of brand name like Qalsan, Santevinin etc. Rs.5,000/- as fee has been submitted for each product dated 23-Apr-2019. The firm was also directed to submitted the differential fee of Rs.15,000/- dated 22-May-2019 for each product. The firm has also requested to change the name of title of firm from M/s GlaxoSmithKline OTC (Pvt.) Ltd, to M/s GlaxoSmithKline Consumer Healthcare Pakistan Limited as endorsed by Licensing Division (**P.# 62/C**) dated 4-May-2019. The firm has also requested for the change in title/name of the firm for their registered products which has been initiated. The same products of change of brand name have also been included therein at **Case No.08**.
2.	Qalsan Jr. Tablet Each chewable tablet contains: Calcium (as Calcium Carbonate) …….250mg Iron (as Ferrous Fumarate) ……..5mg Zinc (as Zinc sulphate)…..……..5mg (Reg. No.084637) (P.#29-33/C)	**QalSium Jr. Chewable Tablet**		
3.	Qalsan Chewable Tablet Each chewable tablet contains: Calcium Carbonate Precipitated ……..1250mg (Reg. No.084636) (P.#34-38/C)	**QalSium Chewable Tablet**		
4.	QalsanVit Tablet Each chewable tablet contains: Calcium (as Calcium Carbonate) …….250mg Zinc (as Zinc sulphate)…..……..5mg Vitamin C (as Ascorbic Acid.....40mg Vitamin A (as Vitamin A Acetate) ……...0.25mg Vitamin E.....4mg (Reg. No.084638)(P.#39-43/C)	**QalSium Vit Tablet**		
5.	Santevini Plus Syrup Each 15ml contains: Total Proteins ……..1500mg Calcium Lactate……....570mg Magnesium Sulphate Mononitrate ……...61.5mg Magnesium Sulphate ……..3.15mg Thiamine Mononitrate ……..…0.60mg Riboflavin ……..……0.90mg Nicotinamide ……..……10mg Pyridoxine HCl ……..……10mg Cyanocobalamine ……0.0010mg (Total protein consistes of: Soya protein Hydrolysate, peptone, L-Lysine HCl, Di-methionine and glycine) (Reg. No.084639) (P.#44-48/C)	**QalSium Vit Syrup**		
6.	Qalsan Forte Tablet (Calcium Forte Effervescent Tablets) Each tablet contains:	**QalSium Forte Tablet**		

	Calcium Lactate Gluconate…….2.94g Calcium Carbonate ……..……0.3g (Reg. No.084640) (P.#49-54/C)			
7.	Calcium Sandoz Syrup Each 5ml contains: Calcium Glubionate ……1.437gm (2.36 mmoles) Calcium Lactobionate ..……0.295gm (110mg Ca++) (Reg. No.084641) (P.#55-59/C)	**QalSium Syrup**		

Decision of 28-PRVC:

The Chairman Registration Board has considered the requests of the firms for change of brand names and decided as under;

Deferred request of the firm for submission of documents/evidence regarding Trade Mark registry in Pakistan and provision of undertaking that firm will not use these brand names for any other therapeutic good, for products at Sr.No.4–10.

Updated Status:

Now, the firm has submitted undertaking/commitment for not using aforementioned brand names for any therapeutic good and NOC issued by M/s Novartis Pharma (Pakistan) Ltd that they have no objection for the grant of brand names to M/s GSK OTC (Pvt.) Ltd., Karachi.

Decision of 30-PRVC:

The Committee referred the case to Registration Board.

Undertaking also provided from M/s Novartis Pharma (Pakistan) Ltd for not using above mentioned brand names for any therapeutic good and for other purpose whatsoever.

Above mentioned products are registered in the name of M/s GlaxoSmithKline Consumer Healthcare Pakistan Limited, Petaro Road, Jamshoro (previously M/s GlaxoSmithKline OTC Pakistan Limited) .

Decision: **Keeping in view undertaking/commitment submitted by M/s Novartis Pharma (Pakistan) Ltd for not using brand name "Qalsan" for any therapeutic good. Registration Board acceded to request of M/s GlaxoSmithKline Consumer Healthcare Pakistan Limited, Petaro Road, Jamshoro for change of brand names of above mentioned products as proposed in Column III.**

Case No.61: Extension in Contract Manufacturing of Registered Drugs of M/s Novartis Pharma (Pakistan) Ltd, Karachi.

Background:

M/s Novartis Pharma (Pakistan) Limited 15 West Wharf Road, Karachi has requested for grant of contract manufacturing permission of their following products from M/s GlaxoSmithKline OTC (Pvt.) Ltd, Karachi. The firm has stated that they have applied for expansion of their manufacturing operation at their licensed manufacturing site located at 15th West Wharf, Dockyard Road Karachi (DML No. 000193 Formulation). The firm has stated that currently these products manufactured required approval for contract manufacturing as allowed

under provision of Rule 20A(1) "c" of Drugs (Licensing, Registering and Advertising) Rules, 1976 to continue their availability in market:

> "As a special case of for genuine reasons, including break down, renovation, up-gradation, as may be determined by the honourable Registration Board, provided that the contract manufacturing under this clause shall be for a period not exceeding thirty months".

Furthermore, firm has requested for contract manufacturing for 30 months period may be allowed to them to continue supply of products currently manufactured at DML # 000010 (GlaxoSmithKline OTC (Pvt.) Limited, Petaro Road, Jamshoro) till they are able to develop their own manufacturing site and shift their manufacturing processes to the new site. The firm has further stated that an early approval in order to ensure there is no interruption in production and avoid any shortage of important and life-saving products in market.

Meanwhile, M/s Novartis Pharma filed a suit no. 873/2017 in Hon'ble High Court of Sindh at Karachi and challenged notification S.R.O. 152/(I)/2014 dated 05-03-2014 for grant of contract manufacturing permission for these products. However, M/s Novartis Pharma have only one section at their West Wharf, Dockyard Road Karachi (DML No. 000193 Formulation) site and they have already exhausted option of 5 products per section under the conditions specified by S.R.O 152(I)/2014.

As per the Rule 20 A, the permission for the contract manufacturing can be granted;

a) For encouraging local production of imported drugs;
b) For meeting export requirements of a local manufacturer or a foreign pharmaceutical company, provided that a drug manufactured under this arrangement shall not be sold in Pakistan; and
c) As a special case and for genuine reasons, including breakdown, renovation, up-gradation, as may be determined by the Registration Board, provided that the contract manufacturing under this clause shall be for a period not exceeding thirty months;

Decision 270th meeting:

An opportunity of personal hearing was given to M/s Novartis, Karachi who was represented by Mr. Shahab Rizvi, CEO and Mr. Zia Anwar Khan Regulatory Affairs Manager who appraised the Board as follows:

i. Novartis Pharma (Pakistan) Limited has been operating in Pakistan since 1960, initially as Ciba and Sandoz and subsequently as Novartis.

ii. As part of a Global arrangement between two MN C's (GSK & Novartis), a new global Joint Venture company was formed under the name of GSK Consumer Healthcare in which Novartis has a 35% global stake.

iii. As part of this arrangement certain assets of Novartis Pakistan have been transferred to the local subsidiary of this newly formed global company in Pakistan i.e. GSK OTC (Private) Limited. The transferred assets include the Novartis manufacturing site at Jamshoro.

iv. Novartis has been operating the Jamshoro site since 1970. Novartis has been manufacturing its global brands at the Jamshoro site to the full satisfaction of DRAP's cGMP requirements and has continued to invest in upgrading this site regularly. The products manufactured at Jamshoro meet the highest quality standards defined by DRAP as well as the Quality standards of Novartis. Patients of these products have come to rely and trust these brands manufactured at the

Jamshoro site, moreover some of these products can be classified as life-saving medicines.

v. *Fully recognizing the needs of patients in Pakistan and the significance of these quality medicines, Novartis wishes to continue sourcing these brands from the same site where these products have been manufactured for the past +30 Years thereby ensuring availability of these quality medicines throughout Pakistan. Many of the products manufactured at the Jamshoro site cannot be easily replaced by substitutes e.g. medicines used for the management of Epilepsy (narrow therapeutic drug), Psychiatric illnesses and Blood Pressure Control.*

vi. *Novartis fully recognizes the restrictions of the DRAP's existing Contract Manufacturing Policy, however given this genuine reason which has risen as a result of a 'Special Case', Novartis requests the Registration Board for grant of permission to continue sourcing its quality medicines from the Jamshoro facility at least for the next 30 months (as permitted within the existing Policy under the provision of Rule 20 A (1) 'c'.*

vii. *During this period Novartis is committed to evaluate alternate sourcing options for its locally manufactured portfolio including the expansion of its existing facility located at West Wharf site in Karachi. During this period Novartis is committed to find local manufacturing solution in Pakistan, and is currently evaluating technical feasibility.*

viii. *Noavrtis has already submitted layout plan for its west wharf site in licensing Division, DRAP and during 30 months' time, they shall develop it for manufacturing of these contract products.*

Registration Board deliberated the case in detail and keeping in view the reasons presented by the Novartis Pharma, Pakistan, Registration Board decided as follows:

- *Registration of products of M/s Novartis Pharma, West wharf, Karachi at same terms and conditions and contract manufacturing by M/s GSK OTC (Pvt) Limited, Jamshoro under claused 1(c) of Rule 20 A Drugs (L, R & A) Rules, 1976 for a period of 30 months. Contract manufacturing permission will be issued after following steps.*
    - *Confirmation of renewal status of products from RRR section.*
    - *M/s Novartis Pharma, Pakistan will submit timelines for establishment of manufacturing facility for above products at West wharf, Karachi. Firm will submit quarterly progress report on the activities undertaken under the aforementioned submitted plan for appraisal of Registration Board. In case of non-compliance for above time lines, case shall be placed before Registration Board for taking necessary action.*

Registration Board in its **279th** and **286th** meeting discussed that project completion timelines as submitted by M/s Novartis, Pakistan at the time of permission of contract manufacturing under Rule 20A (c) and commitments made by the firm for completion of extension of their own facility is till December, 2019 and same has already been communicated to M/s Novartis, Pakistan.

Accordingly, Registration Board decided to direct M/s Novartis, Pakistan for completion of the submitted extension project of West Wharf facility by the firm within stipulated time period as required in Rule 20A (c) of Drug (Licensing, Registering and Advertising) Rules, 1976 and commitments / undertaken by the firm.

Now the firm has submitted following summary on the progress report for further proceeding:

Summary on the Progress Report of the Local Manufacturing Project

Novartis would like to continuously assure DRAP that it upholds the commitment to its 1 million patients in Pakistan to re-establish a manufacturing footprint for continuous supply of quality and trusted products. We are grateful to DRAP for its kind understanding in granting Novartis an opportunity to effect a solution which will not compromise the current patients receiving treatment from Novartis products. As per the progress report, we informed DRAP that we would be focusing on 2 options which are:

1. The expansion of the West Wharf manufacturing facility in Karachi ("West Wharf") (DML No 000193)
2. The acquisition of an existing manufacturing facility by Novartis

Option #1: The Expansion of the West Wharf Manufacturing Facility in Karachi

Novartis has continued to progress its plans between the years 2017 to 2019 in upgrading the existing West Wharf, which are:

- In 2017, Novartis undertook an extensive review of the West Wharf facility (including multiple site visits by the Novartis Technical Operations (NTO) Global Manufacturing Science & Technology team.
- In reference to the NTO review, the engineering conceptual design was developed and validated by the global technical specialists and external experts over the course of 9 months, which resulted in moving milestones. (Progress Report submitted to DRAP in July 2018.)[3]
- In order to proceed with any additional investments for the purpose of upgrading the West Wharf facility, internal Novartis approval from senior management was required. The approval was recently secured marking significant progress to the overall project milestones where the upgrading of existing West Wharf manufacturing line, intended to manufacture Psychotropic products. Facility inspection is scheduled by end of September 2019.
- The approval allows installation of a second manufacturing line expected to commence without delay in the event Novartis is unable to execute one of the other possible options set out for the below acquisition.

Option #2: The Acquisition of an Existing Manufacturing Facility

- As a result of the determination that additional facility apart from West Wharf is required due to growing Pakistan population, increasing public disease awareness and early diagnosis, Novartis began considering all other available options in H2 2017.
- Hence, significant amount of global senior management time was allocated over the last two years to review various options, including:[2,4]
  1. Acquisition of an existing manufacturing business
  2. Acquisition of an existing site
  3. Acquisition of a land parcel to enable construction of a new Novartis manufacturing facility
- The above acquisition options were in compliance with the global regulatory requirements including providing adequate above country support to facilities, as well as the right quality and cost base. These are critical decision criteria to deliver not only quality but also affordable treatment options to patients.

During 2019, Novartis has been actively pursuing the acquisition of an operational third-party drug manufacturing facility. Although we have made significant progress towards executing a transaction to acquire this facility, some important details are in process of negotiations for commercial agreement to be finalised.

Novartis Key Asks to Government via the Drug Regulatory Authority of Pakistan

In summary, Novartis has extensively evaluated every option available to it, balancing long-term financial viability with both adherence to the both regulatory requirements and global Novartis requirements. Decisions of such significance are time consuming and Novartis carefully considers all investment decisions before proceeding, particularly in light of the global network transformation and optimization program.

Whilst significant milestones have been attained over the past two years, and Novartis remains focused on its goal to re-establish a local manufacturing footprint in Pakistan, Novartis requires additional timeline to complete the set goal. Hence, we would like to kindly request from DRAP the **permission to continue the manufacturing of our products by GSK at the Jamshoro facility, for one further term of 30 months** as per same terms and conditions in order to enable a smooth transition from the Jamshoro facility to Novartis owned operations.

Moreover, taking into consideration the opinion by one of the reputable law firms that extension of the permission to contract manufacture under Rule 20A of the 1976 Rules ("Opinion") is permissible as the SRO has delegated its authority to the Registration Board to grant permission and/or extend such permission as it deems fit. Attached with this letter is the Opinion herewith in support of the request and/or application.

The firm has requested **for permission for extension in contract manufacturing** of the following registered drugs as per details below;

S.#	Regn No.	Name of Product with Composition	Initial Date of permission	Validity
1	007823	Mepresor 100mg tablets Each tablet contains: Metoprolol……100mg	21-Jul-2017	30 months
2.	001576	Methergin Sugar Coated tablets Each sugar coated tablet contains: Methylergometrine Maleate……..0.125mg	21-Jul-2017	30 months
3.	021528	Caflam 50mg tablets Each tablet contains: Diclofenac Potassium……50mg	21-Jul-2017	30 months
4.	006144	Mosegor sugar coated tablet Each tablet contains: Pizotifen……..0.5mg	21-Jul-2017	30 months
5.	021529	Tegral 200mg tablets Each tablet contains: Carbamazepin……200mg	21-Jul-2017	30 months
6.	041184	Trioptal 300mg tablet Each film coated tablet contains: Oxcarbazepin……..300mg	21-Jul-2017	30 months

7.	041185	Trioptal 600mg tablet Each film coated tablet contains: Oxcarbazepin……..600mg	21-Jul-2017	30 months
8.	021525	Voltral 50 tablet Each enteric coated tablet contains: Diclofenac sodium….50mg	21-Jul-2017	30 months
9.	018615	Axcin 250mg tablet Each tablet contains: Ciprofloxacin HCl……291.50mg eq. to Ciprofloxacin……250mg	21-Jul-2017	30 months
10.	018616	Axcin 500mg tablet Each tablet contains: Ciprofloxacin HCl……583.00mg eq. to Ciprofloxacin……500mg	21-Jul-2017	30 months
11.	045415	Azomox 500mg capsules Each capsule contains: Azithromycin(as trihydrate)……500mg	21-Jul-2017	30 months
12.	018063	Nocid 20mg tablets Each tablet contains: Famotidine……20mg	21-Jul-2017	30 months
13.	018064	Nocid 40mg tablets Each tablet contains: Famotidine……40mg	21-Jul-2017	30 months
14.	023372	Quvasc tablet 2.5mg Each tablet contains: Amlodipine Besylate…….. 2.5mg	21-Jul-2017	30 months
15.	023373	Quvasc tablet 5mg Each tablet contains: Amlodipine Besylate…… 5mg	21-Jul-2017	30 months
16.	023374	Quvasc tablet 10mg Each tablet contains: Amlodipine Besylate…… 10mg	21-Jul-2017	30 months
17.	005642	Zatofen Tablet Each film coated tablets contains: Ketotifen…….1mg (as hydrogen fumarate)	21-Jul-2017	30 months
18.	014315	Ternelin 4mg tablets Each tablet contains: Tizanidine HCl…….4mg	18-Aug-17	30 months
19.	014316	Ternelin 2mg tablets Each tablet contains: Tizanidine HCl…….2mg	18-Aug-17	30 months
20.	013208	Lamisil 125mg tablets Each tablet contains: Terbinafine……..125mg	18-Aug-17	30 months
21.	013209	Lamisil 250mg tablets Each tablet contains: Terbinafine……..250mg	18-Aug-17	30 months
22.	021524	Voltral 25 tablet Each enteric coated tablet contains: Diclofenac sodium…25mg	18-Aug-17	30 months
23.	021526	Voltral SR 100mg tablets Each tablet contains: Diclofenac Sodium…100mg	18-Aug-17	30 months

24.	070803	Tegral Suspension Each 5ml contains: Carbamazepin……100mg	18-Aug-17	30 months
25.	048407	Glory 1mg tablets Each tablet contains: Glimeprie …….1mg	31-Aug-17	30 months
26.	048408	Glory 2mg tablets Each tablet contains: Glimepride ……..2mg	31-Aug-17	30 months
27.	048409	Glory 3mg tablets Each tablet contains: Glimeprie …….3mg	31-Aug-17	30 months
28.	048410	Glory 4mg tablets Each tablet contains: Glimeprie …….4mg	31-Aug-17	30 months
29.	007533	Dermazin Cream 1% Each gm contains: Silver Sulphadiazine…10mg	31-Aug-17	30 months
30.	021521	Rimactal Syrup 2% Each 100ml contains: Rifampicin…….2mg	31-Aug-17	30 months
31.	022200	Azomax 250mg Capsule Each capsule contains: Azithromycin…..……250mg	31-Aug-17	30 months
32.	022201	Azomax 200mg/5ml Suspension Each 5ml contains: Azithromycin…..……200mg	31-Aug-17	30 months
33.	004714	Parlodel 2.5mg tablet Each tablet contains: Bromocriptine Mesylate…..…… 2.5mg	20-Sep-17	30 months
34.	006282	Mosegor Syrup Each 5ml contains: Pizotifen……0.25mg	20-Sep-17	30 months
35.	036125	Mepresor SR 200mg tablets Each sustained release tablet contains: Metoprolol Tartrate……200mg	9-Jan-18	30 months
36.	007820	Clomfranil 10mg Each tablet contains: Clomipramine Hydrochloride…10mg	16-Jan-18	30 months
37.	007821	Clomfranil 25mg tablets Each tablet contains: Clomipramine Hydrochloride…..25mg	16-Jan-18	30 months
38.	024660	Annuva Dispersible Tablet Each tablet contains: 46.50 Diclofenac Free Acid eq. to 50mg of diclofenac sodium	7-Nov-17	30 months
39.	005804	Zatofen Syrup Each ml contains: Ketotifen……0.2mg	7-Nov-17	30 months

In this regard, the firm has submitted the following documents;

i. Fee of Rs.50,000/- for each product (Dated 05-July-2019)
ii. Copies of Transfer of registration letters.

Decision: An opportunity of personal hearing was given to M/s Novartis, Karachi who was represented by Dr. Imran Rasheed, Country President, Mr. Zia Anwar Khan, Head of Regulatory Affairs, Mr. Simon Yang, Regional Head of strategic projects (Asia), Mr. Fariduddin Butt, Head of Legal Affairs and Mr. M. Nadeem Rustam, Regulatory Liaison Manager, who appraised the Board as follows:

a) **Since 2017, Novartis has been aggressively working on this project with Global Technical Operations team based in Basel, Switzerland.**
b) **Novartis has been sharing quarterly reports with DRAP , for the same.**
c) **Novartis undertook an extensive review of our own West Wharf facility and multiple external parties. Company's senior management based in Basel , Switzerland has recently approved investments for the purpose of upgrading the West Wharf facility. Facility inspection by DRAP is scheduled by the end of September 2019.**
d) **Whilst significant milestones have been attained over the past two years , and Novartis remains focused on its goal to reestablish a local manufacturing footprint in Pakistan, we require additional timeline to complete the set goal. Hence we have requested DRAP to grant us permission to continue the manufacturing of our products by GSK at the Jamshoro facility, for one further term of 30 months as per same terms and conditions in order to enable a smooth transition from the Jamshoro facility to Novartis owned operations.**

Mr. Aamar Latif, Deputy Director (Legal Affairs), DRAP informed the Board that earlier permission of contract permission was granted to M/s Novartis Pharma (Pakistan) Ltd, Karachi for a period of thirty months under rule 20A(1)(c) of the Drugs (Licensing, Registration and Advertising) Rules, 1976. The proviso to rule 20A(1)(c) clearly stipulates that permission granted under the said rule cannot exceed a period of thirty months. Now the company has submitted an application for *extension* of contract manufacturing permission under the same clause i.e. rule 20A(1)(c). The Black's Law Dictionary (9th Edition) defines the term "extension" as a period of additional time to take an action, make a decision, accept an offer, or complete a task. The proviso to rule 20A(1)(c) bars the Registration Board, in unequivocal terms, for granting contract manufacturing permission beyond a period of thirty months. Hence, the request of M/s Novartis for *extension* of contract manufacturing permission beyond thirty months is not covered under the relevant rules.

M/s Novartis also submitted a "legal opinion" of M/s Khalid Anwar & Co. on rule 20A of the Drugs (Licensing, Registration and Advertising) Rules, 1976. The executive summary of the legal opinion is reproduced below along with comments of the Legal Affairs Division, DRAP:-

Sr.	Executive Summary	Comments
a.	That whilst the proviso to Rule 20A(1)(C) sets a time limitation of thirty months for contract manufacturing, it does not prohibit Novartis from filing a fresh application under this Rule and consequently the Registration Board from considering a fresh application for the same period. Even through, the application filed under this Rule will be fresh per se, however, considering the unique circumstances, it may be considered as a mere extension of the permission granted earlier;	Even a fresh application filed under rule 20A(1)(c) on the same grounds in continuity of previous application would be mere extension in contract manufacturing permission which is against the spirit of rule 20A(1)(c) as the said rule explicitly limits the period of contract manufacturing to a *maximum* of thirty months. It is also pertinent to mention that M/s Novartis has filed application for *extension* of contract manufacturing permission under rule 20A(1)(c) and not a fresh application.

b.	**That Novartis can also file an application under Rule 20A(1)(a) on the basis that if it contract manufacturing is not permitted to it then these drugs will be imported in Pakistan which is against the spirit of Rule 20A(1)(a) the purpose of which is to promote, inter alia, foreign investment in Pakistan and discourage imports in Pakistan; and**	**M/s Novartis did not file any application under rule 20A(1)(a), hence no comments.**
c.	**That Registration Board is empowered to grant permission (in special cases) for contract manufacturing even if the conditions/ instances set out under Rule 20A(1)(a), (b) and (c) are not satisfied by Novartis.**	**It is discretion of the Board. However, discretion so exercised by the Board under rule 20A has to meet criteria laid down in section 24A of the General Clauses Act, 1897.**

The representative of M/s Novartis presented two judgments of Hon'ble Supreme Court reported as 2018 SCMR 2039 and PLD 2019 SC 112 wherein the Hon'ble Court laid down certain principles to distinguish where the directions of the legislature are imperative and where they are directory. The representative argued that the word "shall" used in rule 20A(1)(c) of the Drugs (Licensing, Registration and Advertising) Rules, 1976 is directory in nature and not mandatory because it does not provide for a penalty or a consequence in case of its nonobservance or non-compliance. The Board, however, was of the view that language of rule 20A(1)(c) is not ambiguous and does not require interpretation. The plain meaning of proviso to rule 20A(1)(c) suggests that permission granted under this rule cannot exceed a period of thirty months.

The Registration Board deliberated the case in detail in light of opinion of Legal Affairs Division of DRAP and member from Law & Justice Division did not accede to request of M/s Novartis Pharma (Pakistan) Ltd, Karachi for extension in contract manufacturing permission being not covered under the rules.

Case No.62: Permission of Contract Manufacturing of Registered Drugs of M/s Indus Pharma (Pvt.) Ltd, Karachi.

M/s Indus Pharma (Pvt.) Ltd, Plot No.65, Sector 27, Korangi Industrial Area, Karachi has requested for the grant of permission for manufacturing of their following registered drugs **from M/s Stallion Pharmaceuticals (Pvt.) Ltd, 17/24, 581-Sundar Industrial Estate, Lahore on contract manufacturing basis** due to unavailability of manufacturing facility. The details are as under;

Sr. No.	Reg. No.	Name of Product with composition	Date of i. Initial Reg. ii. Renewal Status
1.	042108	Hictime 500mg Injection Each vial contains: Imipenem……500mg Cilastatin……..500mg	i. 20-Dec-05 ii. 12-Nov-15
2.	042010	Maxnem 500mg Injection (IV) Each vial contains: Meropenem (as Sterile Meropenem Powder for Injection)……..500mg	i. 7-Dec-05 ii. 12-Nov-15
3.	042011	Maxnem 1g Injection (IV) Each vial contains: Meropenem (as Sterile Meropenem Powder for Injection)……..1g	

In this regard, the firm has submitted the following documents;

i. Application on Form-5 along-with Fee of Rs.50,000/-for each product. (Date:28-Feb-2019).
ii. Copies of Registration Letters & Renewal Status (Fee of Rs.10,000/- for each product).
iii. Copy of cGMP Certificate of M/s Stallion Pharma, Lahore dated 10-Dec-2018.
iv. Copy of agreement b/w M/s Stallion Pharma (Pvt.) Ltd, Lahore & M/s Indus Pharma (Pvt.) Ltd, Karachi (dated: 11-Feb-2019).
v. Section Approval of Carbapenem of M/s Stallion Pharma, Lahore dated: 8-Feb-16.
vi. Undertaking of M/s Indus Pharma, Karachi.

Decision: **Registration Board granted contract manufacturing permission to above mentioned products of M/s Indus Pharma (Pvt.) Ltd, Karachi from M/s Stallion Pharmaceuticals (Pvt.) Ltd, 17/24, 581-Sundar Industrial Estate, Lahore. Its post registration variation and shall not be considered towards renewal of product.**

Case No.63: Approval for Change of Title/Name of Manufacturer & Marketing Authorization of Imported Registered Product of M/s Pfizer Pakistan Ltd, Karachi and change of registration status from import to local manufacturing.

M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi has requested for the change of title / name of manufacturer and MAH (Pakistan) of their following imported registered product; however, the manufacturing site will remain the same. The details are as under;

Sr. No.	Reg. No.	Name of Drug with composition	Existing Manufacturer & Marketing Authorization	Proposed Manufacturer & Marketing Authorization
1.	018574	Dalacin-V Cream Each gram contains: Clindamycin Phosphate eq. to 20mg Clindamycin base.	**Manufacturer:** M/s Pharmacia & Upjohn Company, 7000 Portage Road, Kalamazoo Michigan, USA. **Marketing Authorization Holder:** M/s Park Davis & Company, B-2, S.I.T.E. Karachi.	**Manufacturer:** M/s Pharmacia & Upjohn Company **LLC**, 7000 Portage Road, Kalamazoo Michigan, USA. **Marketing Authorization Holder:** M/s Pfizer Pakistan Limited, B-2, S.I.T.E. Karachi.

In this regard, the firm has submitted the copies of following documents;

i. Application along-with Fee of Rs.10,000/- dated: 13-Nov-2017).
ii. Copy of registration letter (DoR: 17-Mar-1996) & Renewal Status (Fee of Rs.20,000/- Dated: 24-Aug-17).However letter written to RRR section for confirmation of renewal status. Reply awaited.
iii. Evidence/Certificate of Change of Name/Title of Manufacturer (dated: 21-Aug-2017).
iv. Copy of approval of Name/Title of M/s Pfizer Pakistan Ltd, Karachi (dated:7-Sep-2010).

Meanwhile, the firm i.e. M/s Pfizer Pakistan Limited, Karachi has submitted the request for the change in registration status of the above said product form import to local manufacturing. In this regard, the firm has also submitted the attested copies of following documents;

i. Fee of Rs. 20,000/- (dated: 25-May-2018).

ii. NOC from principal Manufacturer (M/s Pharmacia & Upjohn Company, USA) dated 26.07.2019

Last inspection conducted on 30.10.2017 for the purpose of DML renewal , relevant section (cream/ointment/gel/lotion) is approved by CLB.

Decision: Registration Board considered request of firm and decided as follows:

a) **Approved change of title from M/s Park Davis & Company to M/s Pfizer Pakistan Limited.**
b) **Approved change in registration status from import to local manufacturing by M/s Pfizer Pakistan Limited, Karachi.**

Case No.64: Approval for Addition in the Label Claim of Famila 28 F Tablet of M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, Karachi

M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, A-46, S.I.T.E. Super Highway, Karachi has requested for the addition of the Label Claim in their following registered Drug due to objection raised by Government Analyst/Provincial Drug Testing Laboratories Balochistan, Quetta to label the sample as required by B.P. Pharmacopeia. The details are as under;

Sr. No.	Reg. No.	Name of Drug & composition with Existing Label Claim	Name of Drug & composition with Proposed Label Claim
I	II	III	IV
1.	023941	Famila 28 F Tablet Each tablet contains: Levonorgestrel……...0.15mg Ethinylestradiol…….0.03mg Each tablet contains: Ferrous Fumarate ……..75.0mg	Famila 28 F Tablet Each tablet contains: Levonorgestrel……...0.15mg Ethinylestradiol…….0.03mg Each tablet contains: Ferrous Fumarate BP 75.0mg equivalent to 24.37mg of Ferrous Iron.

According to BP Pharmacopeia, 200mg of Ferrous Fumarate contains 65mg of iron. Thus 75mg of Ferrous Fumarate will contain 24.37mg of iron.

In this regard, the firm has submitted the copies of following documents;

i. Application along-with Fee of Rs.5,000/- (Photocopy).
ii. Copy of registration letter (DoR: 6-Feb-02) & Renewal Status (confirmed by RRR Section on 10-May-19 for submission of application by the firm within due date).
iii. Reference from BP Pharmacopeia containing Ferrous Fumarate tablet

Decision: Registration Board acceded to request of firm for correction in composition as mentioned in column IV in accordance with BP

Case No.65: Standardization of Formulation in Accordance with Innovator's Product of Registered Drug of M/s Barrett Hodgson Pakistan (Pvt.) Ltd, Karachi.

(Dy.No.9410 (R&I) Dated: 24-Jun-19)

M/s Barrett Hodgson Pakistan (Pvt.) Ltd, F/423, SITE, Karachi has requested for standardization of formulation of their following registered drug in accordance with the innovator's specification. The details are as under;

Sr. No.	Reg. No.	Name of drug with Existing formulation & Specification	Name of drug with Proposed formulation & Specification
1.	067693	Clotnil Plus Tablet 75mg+75mg Each tablet contains: Clopidogrel bisulphate equivalent to Clopidogrel……..75mg Aspirin…….75mg (Manufacturer's Specification)	Clotnil Plus Tablet 75mg+75mg Each **film coated** contains: Clopidogrel bisulphate equivalent to Clopidogrel USP……..75mg Aspirin USP…….75mg (Innovator's Specification)

In this regard, the firm has submitted the following documents;

i. Application along-with Fee of Rs.5,000/- **(dated: 3-Jun-2019).**
ii. Copy of Reg. letter **(DoR: 15-Apr-11)** & Renewal Status **(dated: 31-Dec-15).**
iii. Evidence of TGA Australia approval.
iv. Undertaking.

Decision: Registration Board deferred the request of firm for confirmation of innovator's formulation whether bi-layered (tablet within tablet) or single layered.

Case No.66: Change of Secondary Packaging of Registered Product of M/s GlaxoSmithKline Pakistan Limited, Karachi.

M/s GlaxoSmithKline Pakistan Limited, F-268, SITE, Karachi requested for the change of secondary packaging material of their following registered products which were considered in 28 meeting of PRVC (PR-I) held on 29-May-2019 and referred to Registration Board for consideration. The details are as under;

Sr. No.	Reg. No.	Name of Drugs	Date of i. Initial Reg. ii. Renewal application	Justification
1.	000287	**Ventolin Syrup**	i. 20-Apr-76 ii.2-Aug-18	The firm intends to supply the products to the market without carton. As PET Bottles are durable with less chances of breakage during transportation as compared to glass bottle. This will not affect on efficacy, quality and availability of the products in market.
2.	000299	**Piriton Expectorant Linctus**		

In this regard, the firm has submitted the following documents;

i. Fee of Rs.5,000/- for each product.
ii. Copies of Reg. letter and renewal status.
iii. Justification for the proposed change.
iv. Undertaking.
v. Approval for PET bottle granted on 06th June,2018.

Decision: Registration Board advised to send a reference to Cost & Pricing Division for confirmation of MRP in light of firm's request.

Case No.67: Registration of Drug (s) of M/s Seraph Pharmaceuticals Plot No.210 Industrial Triangle, Kahuta Road Islamabad 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.	Form5D
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.1-16/2016-Lic dated 12.06.2017
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from panel inspection dated 11.07.19
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 products is given below:

Sr.#	Name of Drug(s) with composition	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	**Tradol 100mg Capsule** Each capsule contains: Tramadol Hydrochloride….100mg	Locally registered formulation in SR form (ADOLAN by Siza international Pvt Ltd) RRA reference is not found **Remarks:** Firm has submitted purchase order from Nigeria.	Dy. No.810/2019-PE&R-(EFD) 21.08.2019. Rs.30000/- dated 07.08.2019 Rs.20000/- dated 26.07.2019

Decision: Registration Board approved above mentioned product of M/s Seraph Pharmaceuticals Plot No.210 Industrial Triangle, Kahuta Road Islamabad 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 product.

Case No.68: Export Registration of M/s. Herbion Pharma Pakistan Pvt. Ltd. Industrial Triangle Kahuta Road Humak, Islamabad.

Firm has applied for registration of drug(s) only for export purpose alongwith as per following details:

Requirements As Per SOP	**Submitted Documents [Ref.F.No.27-PRVC/2019-(EFD)-DRAP].**
Application on Form 5/Form 5-D with required fee as per relevant SRO.	Applications on Form5 D; Rs.50, 000/- dated 06.03.19
Copy of DML (Renewal status) along with approval of relevant sections verified by licensing Division or inspection report for renewal of DML before 2005.	Copy of DML dated 25-03-2014 (Page.1281/C). Approval of relevant section verified from letter No.F.1-21/2012-Lic dated 03.12.2018
GMP Status.(Copy of Inspection report/GMP certificate)	GMP certificate Issued on inspection report conducted on 12.07.18
Undertakings that the applied product is exclusively for export purpose and the proposed names/ label/ colour do not resemble with already registered brands in importing country.	Provided.

Detail of products is given below:

Sr.#	**Name of Drug(s) with composition**	**Generic/RRA Status**	**Diary No. and date.**
I	**II**	**III**	**IV**
1.	**Novex Powder** Each sachet of powder for oral solution contains: Paracetamol.....325mg Pheniramine Maleate..... 20mg Phenylephrine .....10mg Ascorbic Acid.....50mg	Not confirmed	Dy. No.451 /2019-PE&R-(EFD) 21.03.2019

Decision (27th PRVC): - Chairman Registration Board has deferred the product for submission of evidence of approval in RRAs.

Updated Status: Applied formulation is neither registered locally nor available in RRA , however firm has submitted evidence of registration of applied formulation in importing country (Kazakhstan) i.e Theraflu by GSK Healthcare (Russia) and purchase order (from Kazakhstan).

Decision: **Registration Board approved above mentioned product of M/s. Herbion Pharma Pakistan Pvt. Ltd. Industrial Triangle Kahuta Road Humak, Islamabad for export registration.**

Since applied formulation is neither registered for local use nor approved by any RRA (as decided by Registration Board 285th meeting) hence manufacturer and importing country shall be responsible for safety, efficacy and quality of product.

Case No.69: Registration of Drug(s) of M/s Biogen Pharma, 8-KM, Chakbeli Road, Rawat 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 [Ref.F.No.30-PRVC/2019 (EFD)].**
Application on Form-5/ Form 5-D with required fee as per relevant SRO.	Form5
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 renewed dated 19.06.2013 (Approval of relevant sections verified from Licensing Division letters No. F.1-4/2007-Lic-(Vol-I) dated 09.07.2015
GMP Status. Copy of Inspection report/GMP certificate.	GMP status verified from GMP inspection dated 26.10.2018 rated as satisfactory
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.	Formicgen 60% Injection Each ml contains: Formic acid…….600mg	Purchase order from Afghanistan	Dy. No.666/2019-PE&R-(EFD) 02.07.2019. Rs.50000/- dated 25.06.2019
2.	Bekchlogen 5% Injection Each ml contains: Benzalkonium Chloride…..50mg	Purchase order from Afghanistan	Dy. No.667/2019-PE&R-(EFD) 02.07.2019. Rs.50000/- dated 25.06.2019

Decision: Registration Board deferred above mentioned products of M/s Biogen Pharma, 8-KM, Chakbeli Road, Rawat for evidence of approval of applied formulations in importing country.

Case No.70: Extension In shelf Life of Registered Drugs of M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd, Islamabad for export purpose.

M/s Focus & Rulz Pharmaceuticals (Pvt.) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad has requested for the grant of extension in shelf life of their registered products, from 2 years to 3 years, exclusively for export purpose, as per requirement of importing countries..

Decision: Registration Board deliberated and decided that manufacturer may mention shelf life on products meant for export purpose as per requirement of importing countries.

Case No. 71: M/s. Saffron Pharmaceuticals (Pvt.) Limited, Lahore

The request of M/s. Saffron Pharmaceuticals (Pvt.) Limited, Lahore for change of primary packaging of their following registered product was deferred in 27th PRVC meeting as per following details:

S. No	Reg. No.	Existing Name of Drug(s) & Composition	Desired corrections	Remarks	Initial Reg. Date Renewal status
1	064665	Normiron injection Each vial contains:- Iron Sucrose ……100mg (Saffron's Specs)	Normiron injection Each **ampoule** contains:- Iron as Iron Sucrose ……100mg/5ml (Saffron's Specs)	• The official monograph of the applied formulation exists bothin**USP and BP,** specifications may be granted accordingly. • Formulation may be standardized in line with that approved in MHRA, Each 5 ml contains: 100 mg iron as iron sucrose (iron(III)-hydroxide sucrose complex) • The product is available in both type I glass **vial and ampoule** in MHRA.	Registration letter:- 14-7-2010 Renewal due: 13-07-2015 Renewal applied:- 29-04-2015

The case was deferred for reasons mentioned in column II of table below:-

Sr. No.	Reasons for deferment	Firm's submission/reply
I	**II**	**III**
1	Fee	Photocopy of fee challan Rs.5,000/- dated 20-02-2017
2	Status of Manufacturing tillnow	Not a single batch is manufactured yet.
3	existing and proposed container closure system with differences (e.g. description, materials of construction of primary packaging components, specifications, if appropriate) highlighted in tabular form	Type I glass vial to type I glass ampoule

The case was again presented in 28th PRVC meeting and referred to the Registration Board.

Evidence of liquid Injection ampoule (General) Section as revealed by letter No. F. 1-1/99-Lic dated 18-10-2008

Decision: **Registration Board acceded to the request of firm for change of primary packaging from "Glass vial to Glass ampoule (type-I)" and approved the product with USP Specification. Fee shall be verified as per procedure adopted by Registration Board in 285th meeting.**

Case No.72: Contract manufacturing permission of already registered product of M/s. Global pharmaceuticals (Pvt.) Limited, Islamabad from M/s Vision pharmaceuticals, Islamabad.

Duplicate dossier (R&I dated 06-08-2015)

M/s. Global pharmaceuticals (Pvt.) Limited, Islamabad has applied for the permission of contract manufacturing of their already registered drug as per following details:

S. No.	Reg. No	Contract Giver	Contract Acceptor	Name of Drug(s) & composition	Remarks
1	075070	M/s. Global pharmaceuticals (Pvt.) Limited, Islamabad	M/s Vision Pharmaceuticals, Islamabad	Fevonor Infusion Each 100ml vial contains: Paracetamol....1000mg (Global's Specs.)	Official monograph of the applied formulation does not exist in any available pharmacopoeia.

The firm has submitted the justification for contract manufacturing that they do not have the facility Of Liquid Injectable (General) section, therefore the permission to manufacture their product from M/s Vision Pharmaceuticals, Islamabad on contract basis may be granted.

Firm has submitted the following documents:

1.Application on Form-5
2. Fee. Rs. 50,000/- deposited via slip no 0315147(Yellow copy submitted)
3. Copy of initial registration letter dated 26th December, 2012 and last renewal applied on 24th November, 2017.(Pvt.) Limited, Islamabad
4. Copy of contract manufacturing agreement betweenM/s. Global pharmaceuticals and M/s Vision Pharmaceuticals, Islamabad dated 12-06-2015
5. Liquidvial (General) section approval of M/s Vision Pharmaceuticals, Islamabad as evident from section approval letter dated 06-06-2016
6. Total number of approved sections of M/s. Global pharmaceuticals (Pvt.) Limited, Islamabad: 18 and total number of products already approved for contract manufacturing in the name of applicant: 05

Decision: Registration Board acceded to the request of firm for contract manufacturing from M/s Vision Pharmaceuticals, Islamabad and approved the product with as per Innovator's Specifications. It is post registration variation and will not be considered towards renewal of the product.

Case No.73: Permission for transfer of contract manufacturing of already registered products of M/s Paramount Pharmaceuticals, Islamabad.

M/s. Paramount Pharmaceuticals, Islamabad applied for transfer of contract manufacturing permission from M/s. Caraway Pharmaceuticals, Islamabad to M/s. Mediate Pharmaceuticals, Pvt. Ltd. Karachi for the following drugs:-

Sr. No.	Reg. No.	Name of Drug (s) & Composition	Diary No. & Date of application/ Fee	Contract manufacturing permission validity date	Remarks
1	093298	**Mecolmin 500mcg Injection** Each ampoule (1ml) contains: Mecobalamin…….500mcg (As per innovator's specifications)	16293 (R&I) dated 07-3-2019 Rs. 20,000/- (07-3-2019) Rs. 30,000/- (12-7-2019)	30-10-2023	-

2	093299	**Xiron Injection** Each ampoule (5ml) contains: Iron (III) hydroxide sucrose complex eq. to elemental iron…….100mg (USP specifications)	16287 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	-
3	093300	**Parapime 500mg Injection IV/IM** Each vial contains: Cefepime hydrochloride with L-Arginine eq. to Cefepime……...500mg (USP specifications)	16285 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	-
4	093301	**Parapime 1gm Injection IV/IM** Each vial contains: Cefepime hydrochloride with L-Arginine eq. to Cefepime ……...1gm (USP specifications)	16286 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	-
5	093302	**Parabid 1gm Injection** Each vial contains: Cefoperazone (as sodium)……...500mg Sulbactam (as sodium)……...500mg (JP specifications)	16288 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	The brand name which was granted to this firm (i.e. Parabid) resembles with already registered brand name Paracid (Reg.No.002508) of M/s. Geofman.
6	093303	**Parabid 2gm Injection** Each vial contains: Cefoperazone (as sodium)……...1000mg Sulbactam (as sodium)……...1000mg (JP specifications)	16289 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	The brand name which was granted to this firm (i.e. Parabid) resembles with already registered brand name Paracid (Reg.No.002508) of M/s. Geofman.
7	093304	**Para-cef 250mg Injection IM** Each vial contains: Ceftriaxone as sodium ……...250mg (USP specifications)	16290 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	Firm has applied for following alternate brand names (Tazorid, Rophin, Unixon, Signizon, Paratix, Exizon) which resembles with already registered brand names.
8	093305	**Para-cef 500mg Injection IM** Each vial contains: Ceftriaxone as sodium ……...500mg (USP specifications)	16291 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	Firm has applied for following alternate brand names (Tazorid, Rophin, Unixon, Signizon, Paratix, Exizon) which resembles with already registered

					brand names.
9	093306	**Para-cef 1gm Injection IV** Each vial contains: Ceftriaxone as sodium ……...1gm (USP specifications)	16292 (R&I) dated 07-03-2019 Rs. 20,000/- (07-03-2019) Rs. 30,000/- (12-07-2019)	-do-	Firm has applied for following alternate brand names (Tazorid, Rophin, Unixon, Signizon, Paratix, Exizon) which resembles with already registered brand names.

In this regard firm has submitted following documents: -

i) Application form with fee of Rs.50,000/- for each product
ii) Copy of Registration letter dated 31-10-2018
iii) NOC from M/s Caraway Pharmaceuticals, Islamabad.
iv) Contract manufacturing permission valid till 30-10-2023.
v) Photocopy of Agreement between M/s Paramount Pharmaceuticals, Islamabadand M/s. Mediate Pharmaceuticals, Pvt. Ltd. Karachi dated 02-03-2018
vi) GMP inspection report (dated 20-07-2018) of M/s. Mediate Pharmaceuticals Pvt. Ltd., Karachi.
vii) Liquid ampoule (General) and Dry powder injection (Cephalosporin) Sections approval as evident from last inspection report of M/s. Mediate Pharmaceuticals, Pvt. Ltd. Karachidated **20-07-2018.**

Decision: Registration Board approved change of contract manufacturer of above products from M/s. Caraway Pharmaceuticals, Islamabad to M/s. Mediate Pharmaceuticals, Pvt. Ltd. Karachi with change of brand name for Sr. No. 5-9.

Case No.74: Transfer of Registration status of Products of CCL Pharmaceuticals (Pvt.) Ltd., from their own facility to Contract Manufacturing from M/s Pharmasol (Pvt.) Ltd, Plot no. 549, Sundar Industrial Estate, Lahore.

The request of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore for transfer of registration status of already registered products from their own facility to contract manufacturing from M/s Pharmasol (Pvt.) Ltd, Plot no. 549, Sundar Industrial Estate, Lahore was deferred in 290th meeting of the Registration Board.

The firm submitted that they are proceeding for PIC/S certification for their existing manufacturing facility. It is the requirement that Cephalosporin & non-Cephalosporin manufacturing areas should not be in one facility. Accordingly, they have decided to close Cephalosporin manufacturing areas in current plant and intend to shift their following cephalosporin products to contract manufacturing from M/s. Pharmasol (Pvt.) Ltd, Plot no. 549, Sundar Industrial Estate, Lahore.

S. No.	Reg. No.	Name of Product(s)	Initial registration date	Renewal Status	RRAs/ Remarks
I	II	III	IV	V	VI
1.	033949	Cef-OD Suspension 100mg/5ml Each 5ml of reconstituted susp. contains:- Cefixime (as trihydrate) ….. 100mg (USP Specifications)	14-09-2004	19-08-2014	• USFDA approved

2.	052704	Cef-OD DS Suspension 200mg/5ml Each 5ml of reconstituted suspension contains:- Cefixime (as trihydrate) ….. 200mg (USP Specifications)	21-10-2008	03-08-2018	• USFDA approved
3.	034756	Cef-OD Capsule 400mg Each capsule contains:- Cefixime (as trihydrate) ….. 400mg (Manufacturer's Specifications)	02-12-2004	19-11-2014	• USFDA approved • Official monograph of the applied formulation exists in JP
4.	019114	Baxan Capsule 250mg Each capsule contains:- Cefaclor (as monohydrate).. 250mg (Manufacturer's Specifications)	18-04-1996	18-01-2016	• USFDA approved • Official monograph of the applied formulation exists in USP
5.	019115	Baxan Capsule 500mg Each capsule contains:- Cefaclor (as monohydrate).. 500mg (Manufacturer's Specifications)	18-04-1996	18-01-2016	• USFDA approved • Official monograph of the applied formulation exists in USP
6.	019116	Baxan Suspension 125mg/5ml Each 5ml contains:- Cefaclor (as monohydrate).. 125mg (Manufacturer's Specifications)	18-04-1996	18-01-2016	• USFDA approved • Official monograph of the applied formulation exists in USP
7.	019117	Baxan Suspension 250mg/5ml Each 5ml contains:- Cefaclor (as monohydrate) ….. 250mg (Manufacturer's Specifications)	18-04-1996	18-01-2016	• USFDA approved • Official monograph of the applied formulation exists in USP
8.	016077	Ceftoringe Injection 250mg Each vial contains:- Cefotaxime (as sodium) ….. 250mg (USP Specifications)	05-06-1997	04-08-2015	Claforan 250mg Injection by Sanofi Aventis (**Netherland** Approved)
9.	046329	Ceftoringe Injection 500mg Each vial contains:- Cefotaxime (as sodium) ….. 500mg (USP Specifications)	16-05-2007	19-04-2017	• USFDA approved • Official monograph of the applied formulation exists in USP
10.	016078	Ceftoringe Injection 1gm Each vial contains:- Cefotaxime (as sodium) ….. 1gm (USP Specifications)	05-06-1997	04-08-2015	• USFDA approved • Official monograph of the applied formulation exists in USP
11.	015213	Celex Injection 500mg Each vial contains:- Cephazolin (as sodium) ….. 500mg (Manufacturer's Specifications)	22-08-1994	05-04-2017	• USFDA approved • Official monograph of the applied formulation exists in USP
12.	015214	Celex Injection 1gm Each vial contains:- Cephazolin (as sodium) ….. 1gm (Manufacturer's Specifications)	22-08-1994	05-04-2017	• USFDA approved • Official monograph of the applied formulation exists in

					USP
13.	024927	Kefrox Injection 250mg Each vial contains:- Cefuroxime (as sodium).. 250mg (USP Specifications)	26-06-1999	20-03-2017	• MHRA approved
14.	024926	Kefrox Injection 750mg Each vial contains:- Cefuroxime (as sodium)….750mg (USP Specifications)	26-06-1999	20-03-2017	• MHRA approved
15.	026055	Kefrox Injection 1.5gm Each vial contains:- Cefuroxime (as sodium) ….. 1.5gm (USP Specifications)	12-09-2000	04-08-2015	• MHRA approved
16.	026054	Kefrox Suspension 125mg/5ml Each 5ml contains:- Cefuroxime (as axetil) ….. 125mg (Manufacturer's Specifications)	12-09-2000	04-08-2015	• MHRA approved • Official monograph of the applied formulation exists in USP
17.	086287	Kefrox Suspension Each 5ml contains:- Cefuroxime (as axetil) ….. 250mg (Manufacturer's Specifications)	20-12-2017	Due on 19-12-2022 Renewal not required	• TGA approve • Official monograph of the applied formulation exists in USP
18.	054137	Kefnir Capsule 300mg Each capsule contains:- Cefdinir ….. 300mg (Manufacturer's Specifications)	20-02-2009	04-12-2018	• USFDA approved • Official monograph of the applied formulation exists in USP
19.	054135	Kefnir Suspension 125mg/5ml Each 5ml contains:- Cefdinir ….. 125mg (Manufacturer's Specifications)	20-02-2009	04-12-2018	• USFDA approved • Official monograph of the applied formulation exists in USP
20.	054136	Kefnir Suspension 250mg/5ml Each 5ml contains:- Cefdinir ….. 250mg (Manufacturer's Specifications)	20-02-2009	04-12-2018	• USFDA approved • Official monograph of the applied formulation exists in USP
21.	012491	Monocef Injection 250mg Each vial contains:- Cephradine ….. 250mg (Manufacturer's Specifications)	12-05-1991	01-03-2016	• RRA status could not be confirmed • Official monograph of the applied formulation exists in USP
22.	012492	Monocef DS Injection 500mg Each vial contains:- Cephradine ….. 500mg (Manufacturer's Specifications)	12-05-1991	01-03-2016	• RRA status could not be confirmed • Official monograph of the applied formulation exists in USP
23.	011986	Monocef Capsule 250mg Each capsule contains:- Cephradine (as monohydrate) ……250mg	24-12-1990	03-11-2015	MHRA approved

		(USP Specifications)			
24.	011987	Monocef DS Capsule 500mg Each vial contains:- Cephradine (as monohydrate) ……. ….. 500mg (USP Specifications)	24-12-1990	03-11-2015	MHRA approved
25.	011988	Monocef Suspension 125mg/5ml Each 5ml contains:- Cephradine (as monohydrate) …….. ….. 125mg (USP Specifications)	24-12-1990	03-11-2015	RRA status could not be confirmed
26.	011989	Monocef DS Suspension 250mg/5ml Each 5ml contains:- Cephradine (as monohydrate) ……..250mg (USP Specifications)	24-12-1990	03-11-2015	MHRA approved
27.	025830	Snare Injection 250mg Each vial contains:- Ceftriaxone (as sodium)….. 250mg (USP Specifications)	12-08-2000	14-01-2016	USFDA approved
28.	067712	Snare Injection 500mg IM Each vial contains:- Ceftriaxone (as sodium).. 500mg (USP Specifications)	28-10-2010	13-08-2015	USFDA approved
29.	093509	Snare Injection 500mg IV Each vial contains:- Ceftriaxone (as sodium)….. 500mg (USP Specifications)	31-12-2018	Due on 30-12-2023	USFDA approved
30.	025831	Snare Injection 1gm Each vial contains:- Ceftriaxone (as sodium) ….. 1gm (USP Specifications)	12-08-2000	14-01-2016	USFDA approved

The firm have provided following documents in support of their request as per approved SOP:

a) Application on form-5 dated 05-03-2019 and required fee Rs.50, 000/- for each product.
b) Copy of initial registration letters and last renewal applied.
c) Evidence of Section as revealed by the GMP inspection reportDry Powder injection (Cephalosproin), Dry Powder Suspension (Cephalosproin), Capsule Section (Cephalosproin)
d) Copy of GMP inspection report dated 29-30 May 2017, 13-7-2017 & 3-4 October 2017
e) Total number of approved sections of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore: 12 and total number of products already approved for contract manufacturing in the name of applicant: 02

Registration Board in its 290th meeting decided as under:

Registration Board deferred the above products for submission of improvement plan.

Now firm has submitted detailed plan which is as under:

Sr.No.	Description	Response
1.	Closure of own facility	We are closing our cephalosporin facility to avoid cross-contamination between cephalosporin& non-cephalosporin products in lieu of international guidelines (copy of guidelines attached)

<table>
<tr><td>2.</td><td>Shifting of manufacturing</td><td>We have developed a comprehensive plan for the shifting of cephalosporin products (protocol for technology transfer from one site to another site attached)</td></tr>
<tr><td>3.</td><td>Plan for PIC/S approval</td><td>We are committed to get PIC/S approval (plan attached)
<table><tr><th>Duration</th><th>Start</th><th>Finish</th></tr><tr><td>492 Days</td><td>Tue 30-11-2019</td><td>Wed 05-04-2021</td></tr></table></td></tr>
<tr><td>4.</td><td>Plan for existing own cephalosporin facility</td><td>We have designed a proper plan for the utilization of cephalosporinfacility after its shifting (plan attached)
<table><tr><th>Duration</th><th>Start</th><th>Finish</th></tr><tr><td>162 Days</td><td>Tue 12-11-2019</td><td>Wed 22-04-2020</td></tr></table></td></tr>
</table>

Firm has also submitted timeline of each step during the said renovation period and layout plan, not approved from Licensing Division.

Decision: Registration Board acceded to the request of firm for contract manufacturing and decided as follows:-

i. **Firm shall submit approved revised layout plan from Licensing Division and will share a comprehensive plan for the shifting of cephalosporin products. Subsequently, approval letters will be issued as per following details:**
   a. **Approved contract manufacturing of products at Sr. No. 1-20, 23, 24, 26-30with specifications mentioned against each in coloumn VI, subject to submission of approval of layout plan from Licensing Division. It is post registration variation and would not be considered towards renewal of the product.**
   b. **Deferred the products at Sr. No. 21, 22 & 25 for evidence of approval of applied formulation in RRAs**

Case No.75: Contract manufacturing permission of already registered product of M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore from M/s Global Pharmaceuticals, Islamabad.

M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore has submitted that DRAP vide letter No. F.1-25/2015-DDG (R-I)/ (M-24) dated 9th March, 2015 draw their attention to manufacturing requirements of Carbapenem drugs and they informed vide letter No. CCL/15/R-116 dated March 31, 2015 that they would either build their own dedicated area or opt for contract manufacturing.

Now, the firm is planning to launch the said product and has applied contract manufacturing from M/s. Global Pharmaceuticals,Islamabad.

S. No.	Reg. No.	Name of Product(s) with composition	Initial registration date	Renewal Status	Remarks
I	II	III	IV	V	VI
1	045958	Cinam-500 Injection Each vial contains:- Imipenem…….500mg Cilastatin…….500mg	01-3-2007	Last renewal applied on 19-01-2017 (Rs. 10,000/-)	Formulation may be standardized in line with that approved in USFDA as under Each vial contains:- **Imipenem (as monohydrate)** ..500mg **Cilastatin (as sodium)**..500mg

The firm have provided following documents in support of their request as per approved SOP:

a) Application with form 5 and requirement fee amounting to Rs.50,000/-. .
b) Copy of registration letter dated 01-03-2007 and renewal applied on 19-01-2017.
c) Evidence of Section as revealed by letter No. F. 1-1/96-Lic (Vol-IV)
d) Copy GMP certificate issued based on inspection dated 11 & 24-10-2018
e) Total number of approved sections of**M/s CCL Pharmaceuticals (Pvt.) Ltd., Lahore**: 12 and total number of products already approved for contract manufacturing in the name of applicant: 02

Decision: Registration Board acceded to the request of firm for contract manufacturing from M/s Global Pharmaceuticals, Islamabad and approved the formulation mentioned in coloumn VI of above table.It is post registration variation and will not be considered towards renewal of the product.

Case No. 06: M/s. Wilshire Laboratories (Pvt.) Limited, Lahore

The request of M/s. Wilshire Laboratories (Pvt.) Limited, Lahore for correction of composition in Registration letter for following already registered product(s) was deferred in 290th meeting of the Registration Board as detailed below:

S. No	Reg. No.	Existing Name of Drug(s) & Composition	Desired corrections	Decision of 29th PRVC:-	Remarks
I	II	III	IV	V	VI
1	052509	Sizzle D 60mg tablets Each tablet contains:- Fexofenadine HCl…….60mg Pseudoephedrine…120mg (Wilshire's Specs.)	Sizzle D 60mg tablets Each **Extended Release** tablet contains:- Fexofenadine HCl …….60mg Pseudoephedrine **HCl** ……120mg **(USP Specs.)**	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. Wilshire Laboratories (Pvt.) Limited, Lahore to Registration Board after completion of required documents.	Now the firm has submitted the required documents .
2	090142	Sizzle D tablets Each tablet contains:- Fexofenadine HCl..180mg Pseudoephedrine…240mg (USP Specs.)	Sizzle D tablets Each **Extended Release** tablet contains:- Fexofenadine HCl …….180mg Pseudoephedrine **HCl** ……240mg (USP Specs.)		

The firm has provided following documents in support of their request as per approved SOP:

1. Application with required fee Rs. 5000/- for each product
2. Copy of registration letters dated 18-09-2008 & 13-06-2018 and renewal status dated 15-01-2018

3. Undertaking as per approved SOPs.

Decision: *Registration Board deferred the above products for confirming manufacturing status of the product.*

Fresh submission:

Firm has submitted that they have manufactured Sizzle D 60/120mg Tablet and sold the same in 2018, while Sizzle D 180/240mg was registered on 13-06-2018 and they could not manufacture this product due to non-availability of raw material.

For ready reference, following documents are being enclosed: -

- Registration letter no. F.13-2/2008-Reg-II- (M-213) dated 18-09-2008 for Sizzle D 60/120mg Tablet and Registration letter no. F.15-6/2018-Reg-V- (M-281) dated 13-06-2018 for Sizzle D 180/240mg Tablet
- Application for quota allocation of Pseudoephedrine HCl submitted on 07-01-2019
- Manufacturing Record of Sizzle 60/120mg Tablet
- Sales Record of Sizzle 60/120mg Tablet for the year 2017-2018
- Standard Manufacturing Procedure (SMP) of our both above products
- Standard Analytical Procedure (SA) of our both above products
- Letter no. F.02-042/2019 DD(CD) dated 26-06-2019 from Controlled Drugs Division, DRAP for provision of corrigendum letter for both above products
- Letter no. WLH/AA/162/2019 & letter no. WLH/AA/163/2019 both submitted on 27-03-2019 for issuance of corrigendum of our above products

Decision: **Registration Board deferred for confirmation of firm's request from registration application**

Case No. 77: Change of Packing due to resemblance with products of M/s. GSK Pakistan Limited, Karachi.

Chairman Registration Board in 3rd PRVC (held on 18 January 2018) considered the request of M/s. GSK Pakistan Limited, Karachi about resemblance of packging design and color scheme with products of **M/s. BJ Pharma Lahore and M/s. JawaPharma, Lahore.** Since the packing design and color scheme were granted to M/s. GSK Pakistan Limited, Karachi prior hence M/s. BJ Pharmaceutical, Lahore and M/s. Jawa Pharmaceutical where advised to change packing design and color scheme due to resemblance (dated 12th Feb, 2018). Since firm did not provided alternate packging design and color scheme hence ***Reminder-I*** also written to both firms (dated 09th May, 2018) but both firms have not responded yet.

S. #	*Regn. No.*	*Product name*	*Initial registration with renewal*	*Name of firm and resembling*	*Packaging appearance*
1.	000817	Panadol Tablet	15-Aug-1976 Last renewal 12.07.2013	Bemol Tablet of M/s. BJ Pharmaceutical, Reg.No. 074353	Color scheme appearance and approved beacon logo.

2.	021527	VoltralEmulgel 1%	23-May-1998 Prodcut transfer to GSK on 20th april 2017.	Jfenec Gel of M/s. Jawa Pharmaceutical, Reg.No. 071460	Color scheme appearance and approved beacon logo.

Registration Board in 286th meeting decided as under:

Registration Board decided to issue show cause to above mentioned firms since they have not applied alternate packings despite of intimation as well as reminder.

Accordingly, show cause notice dated 10-07-2019 was served to both the firms. M/s. Jawa Pharma, Lahore has redesigned and submitted the new packing alongwith the requisite fee (Rs. 5,000/-) dated 18-07-2019. M/s. BJ Pharma Lahore has provided alternate packging design and color scheme, which still resembles.

Now letter regarding personal hearing has been issued to M/s. BJ Pharam, Lahore.

Decision: Registration Board decided as follows:

i. **Registration of product at Sr. No. 1 shall remain suspended till submission of alternate packging design and colour scheme, verification and subsequent approval of Chairman Registration Board for new packging design and colour scheme and resumption of production.**

ii. **For product at Sr. No. 2, as M/s. Jawa Pharma, Lahore has redesigned and submitted the new packing thus Registration Board noted the information for its record. Firm shall comply all provisions of Drugs (Labeling & Packing) Rules, 1986.**

`RRR Section

Sr. No.	Item No.	No. of cases
1.	**Assistant Director (RRR-I & II)**	
2.	**Complete Cases**	
3.	Local manufacturing (Human)	294
4.	Local manufacturing (Veterinary)	08
5.	Finished Import (Human)	08
	Incomplete Cases	
6.	Local manufacturing (Human)	281
7.	Local manufacturing (Veterinary)	03
8.	Finished Import (Human)	05
9.	Finished Import (Veterinary)	07
10.	**Deferred Cases of Previous Meetings**	
11.	Local Manufacturing	387
12.	Finished Import	15
13.	**Miscellaneous Cases**	
14.	Case deferred in previous meetings/ referred from other divisions/ Typo errors etc.	11
15.	**Total:**	**1019**
16.	**Assistant Director (RRR-III)**	
17.	**Complete Cases**	
18.	Local manufacturing (Human)	105
19.	**Incomplete Cases**	
20.	Local manufacturing (Human) September	57
21.	Local manufacturing (Veterinary)	26
22.	Local Manufacturing (Human) November	166
23.	**Total:**	**354**
24.	**Assistant Director (RRR-IV)**	
25.	**Complete Cases**	
26.	Local manufacturing (Human)	233
27.	Local manufacturing (Veterinary)	17
28.	Finished Import (Human)	17
29.	**Incomplete Cases**	
30.	Local manufacturing (Human)	146
31.	Local manufacturing (Veterinary)	09
32.	Finished Import (Human)	29
33.	Finished Import (Veterinary)	03
	Total:	**454**
	Grand Total:	**1827**

Assistant Director (RRR-I & II)
COMPLETE CASES

Renewal section apprised the Board that evaluation of registration renewal applications are being done as Standard Operating Proceedure approved by the Board. Accordingly complete and incomplete cases have been placed below for the consideration of the Board. It is pertinent to mention that shortcoming letters of the incomplete cases are regularly issued to the individual firms but response by the applicants is very slow.

Afther deliberations, the Board advised to evaluate submitted registration renewal applications on priority as per approved Standard Operating Proceedure and shall issue shortcomings letters to the applicants. Moreover, the Board further advised to upload data of registration renewal applications with their shortcomings on DRAP's website so that registration holders can easily access status of their renewal applications alongwith respective shortcoimgs. After rectification of these shortcomings cases shall be placed before the Board for consideration.

Registration Board also advised stakeholders (PPMA, Pharma Bureau and PCDA) to advise their member companies for prompt response to renewal sortcomings letters to comply the regulatory requirements as envisaged in Drugs (Licensing, Registering & Advertising) Rules, 1976.

i. Local manufacturing (Human)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
i.	**M/s. Scotmann Pharmaceuticals, Plot No. 5-D, I-10/3 Industrial Area, Islamabad**					
1.	031864	Coxiscot Tablets Each tablet contains: Rofecoxib…….12.5mg	15-11-2003	Dy. No. 27475 dated 09-08-2018 10000/-	14-11-2023	w.e.f. 15-11-2018 to 14-11-2023
2.	031865	Dicloscot XR Tablets 100mg Each tablet contains: Diclofenac Sodium ……100mg	15-11-2003	Dy. No. 27475 dated 09-08-2018 10000/-	14-11-2023	w.e.f. 15-11-2018 to 14-11-2023
3.	031070	Nitroscot SR Tablets 2.6mg Each tablet contains: Nitroglycerin……..2.6mg	30-09-2003	Dy. No. 27475 dated 09-08-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023
4.	031071	Nitroscot SR Tablets 6.4mg Each tablet contains: Nitroglycerin…..6.4mg	30-09-2003	Dy. No. 27475 dated 09-08-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023

5.	052593	Pariz Tablets 12.5mg Each tablet contains: Paroxetine (as HCl)…….. 12.5mg	26-09-2008	Dy. No. 27475 dated 09-08-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
6.	052594	Pariz Tablets 25mg Each tablet contains: Paroxetine (as HCl)…….. 25mg	26-09-2008	Dy. No. 27475 dated 09-08-2018 10000/-	25-09-2023	w.e.f. 26-09-2018 to 25-09-2023
7.	031863	Bamiscot Tablets Each tablet contains: Bamifylline…..600mg	15-11-2003	Dy. No. 27475 dated 09-08-2018 10000/-	14-11-2023	w.e.f. 15-11-2018 to 14-11-2023
8.	031072	Carbascot SR Tablets 200mg Each tablet contains: Carbamazepine….200mg	30-09-2003	Dy. No. 27475 dated 09-08-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023
9.	031073	Carbascot SR Tablets 400mg Each tablet contains: Carbamazepine...400mg	30-09-2003	Dy. No. 27475 dated 09-08-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023
10.	054683	Levoscot Infusion. Each 100 ml contains: Levofloxacin (as Hemihydrate)...500mg.	31-12-2008	Dy. No. 27475 dated 09-08-2018 10000/-	30-12-2023	w.e.f. 31-12-2018 to 30-12-2023
11.	051177	Linel-Scot Cream Each Tube Contains: Lindane (Gamma Benzene Hexachloride)…1%w/w	05-09-2008	Dy. No. 27475 dated 09-08-2018 10000/-	04-09-2023	w.e.f. 05-09-2018 to 04-09-2023
12.	031069	Flupenscot Injection 100mg Each ml contains: Flupenthixol…..100mg	30-09-2003	Dy. No. 27475 dated 09-08-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023
13.	031068	Flupenscot Injection 40mg Each ml contains: Flupenthixol……..40mg	30-09-2003	Dy. No. 27475 dated 09-08-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023
14.	031067	Flupenscot Injection 20mg Each ml contains: Flupenthixol……..20mg	30-09-2003	Dy. No. 27475 dated 09-08-2018 10000/-	29-09-2023	w.e.f. 30-09-2018 to 29-09-2023
15.	054786	Litvea Capsules 67mg Each Capsules Contain: Fenofibrate…..67mg	01-01-2009	Dy. No. 39825 dated 3-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
16.	054787	Litvea Capsules 200mg Each Capsules Contain: Fenofibrate…..200mg	01-01-2009	Dy. No. 39825 dated 3-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
17.	054748	Dune Chewable 4mg Tablet Each Tablet contain: Montelukast as sodium…..4mg	01-01-2009	Dy. No. 39825 dated 3-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023

18.	054749	Dune Chewable 5mg Tablets Each Tablet contain: Montelukast as sodium…..5mg	01-01-2009	Dy. No. 39825 dated 3-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
M/s. Saffron Pharmaceuticals (Pvt) Ltd., 19-Km, Sheikhupura Road, Faisalabad						
19.	077081	Resbact 200mg/ 100ml Infusion Each 100ml contains: Linezolid ….200mg	01-01-2014	Dy. No. 43270 dated 19-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
20.	077082	Resbact 600mg /300ml Infusion Each 300ml contains: Linezolid…..600mg	01-01-2014	Dy. No. 43270 dated 19-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
21.	077083	Jupiter 2.5mg Tablet Each film coated tablet contains: Ibandronate sodium.2.5mg	01-01-2014	Dy. No. 43270 dated 19-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
22.	077084	Jupiter 150mg Tablet Each film coated tablet contains: Ibandronate sodium.150mg	01-01-2014	Dy. No. 43270 dated 19-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
ii.	**M/s. Tabros Pharma (Pvt.) Ltd., L-20/B,Sector-22,F.B. Industrial Area, Karachi.**					
23.	011150	Fenac Injection Each 3ml ampoule contains: Diclofenac Sodium….75mg	Transfer of Registration dated 31-10-1993 Change of brand name dated 03-10-1996	Dy. No. 26911 Dated 06-08-2018 10000/-	30-10-2023	w.e.f. 31-10-2018 to 30-10-2023
iii.	**M/s. Lisko Pakistan (Pvt.) Ltd., L-10/D,Block-21,Federal B Area, Karachi**					
24.	050431	Amoxipen Forte Syrup Each 5ml contains: Amoxycillin (as Trihydrate)….250mg	09-08-2008	Dy. No. 26359 Dated 01-08-2018 10000/-	08-08-2023	w.e.f. 09-08-2018 to 08-08-2023
iv.	**M/s. Welmark Pharmaceuticals, Plot No. 122, Block-B,Phase-V, Industrial Estate ,Hattar**					
25.	050935	Welresp Tablets 10mg Each tablet contains: Montelukast Sodium….10mg	05-08-2008	Dy. No. 26358 dated 01-08-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
26.	050936	Wincobal Tablets 500mcg Each tablet contains: Mecobalamin….500mcg	05-08-2008 Change of brand name dated: 29-10-2015	Dy. No. 26358 dated 01-08-2018	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
27.	050937	Welpram Tablets 10mg Each tablet contains: Citalopram as Oxalate…10mg	05-08-2008	Dy. No. 26358 dated 01-08-2018 10000/-	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023

28.	050939	Penmark Injection 40mg IV Each vial contains: Pantoprazole Sodium…40mg	05-08-2008	Dy. No. 26358 dated 01-08-2018	04-08-2023	w.e.f. 05-08-2018 to 04-08-2023
v.	**M/s. Ophth Pharma (Pvt) Ltd., Plot No. 241, Sector 24, Korangi Industrial Area, Karachi**					
29.	004308-EX	Optifen Eye Drops Each ml Contains: Ketotifen Fumarate eq. to Ketotifen Base…0.25mg	07-10-2013	Dy. No. 27336 dated 09-08-2018 10000/-	06-10-2023	w.e.f. 07-10-2018 to 06-10-2023
30.	004309-EX	NEPA Eye Drops Each ml Contains: NaphazolineHCl eq. to Naphazoline Base…0.25mg	07-10-2013	Dy. No. 27337 dated 09-08-2018 10000/-	06-10-2023	w.e.f. 07-10-2018 to 06-10-2023
vi.	**M/s. Lowitt Pharma (Pvt.) Ltd. Plot No. 24,Industrial Estate, Hayatabad, Peshawar**					
31.	050997	Motedone Syrup. Each ml contains: Domperidone …….1mg	12-08-2008	Dy. No. 26533 dated 01-08-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
32.	050998	Olan-Z 10mg Tablets. Each film coated Tablet contains: Olanzapine……..10mg.	12-08-2008	Dy. No. 26533 dated 01-08-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
33.	050999	T-Kast 10mg Tablets. Each film coated Tablet contains: Montelukast…….10mg.	12-08-2008	Dy. No. 26533 dated 01-08-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
34.	051000	Lowtral 50mg Tablets. Each film coated Tablet contains: Sertraline as HCl…..50mg.	12-08-2008	Dy. No. 26533 dated 01-08-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
35.	051001	T-Kast 5mg Tablets. Each film coated Tablet contains: Montelukast….5mg.	12-08-2008	Dy. No. 26533 dated 01-08-2018 10000/-	11-08-2023	w.e.f. 12-08-2018 to 11-08-2023
36.	052796	Napzol Capsule 20mg. Each capsule contains: Esomeprazole as Magnesium Trihydrate enteric coated pellets…….20mg Pellets are imported from India	11-11-2008	Dy. No. 26533 dated 01-08-2018 20000/-	10-11-2023	w.e.f. 11-11-2018 to 10-11-2023
37.	052797	Nurzol Capsules 20mg. Each Capsule contains: Omeprazole as enteric coated pellets…..20mg Pellets are imported from India	11-11-2008	Dy. No. 26533 dated 01-08-2018 20000/-	10-11-2023	w.e.f. 11-11-2018 to 10-11-2023

38.	052798	Letzol Capsule 30mg. Each capsule contains: Lansoprazole as enteric coated Pellets……..30mg Pellets are imported from India	11-11-2008	Dy. No. 26533 dated 01-08-2018 20000/-	10-11-2023	w.e.f. 11-11-2018 to 10-11-2023
vii.	**M/s. Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, <u>Karachi</u>**					
39.	009879	Iberet Drops Each 1ml contains: Ferrous Sulphate….125mg	19-09-1988 Change of brand name dated 23-09-1991	Dated 28-08-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
40.	009878	Vidaylin-F Chewable Tablets Each tablet contains: Flouride (as Sodium Flouride)….1mg Vitamin A……...2500IU Vitamin D……..400IU Vitamin E……...15IU Vitamin B1…….1.05mg Vitamin B2……1.2mg Vitamin B12…..4.5mcg Niacinamid…...13.5mg Vitamin C…..60mg Folic Acid…….0.3mg Vitamin B6……1.05mg	19-09-1988	Dated 28-08-2018 10000/-	18-09-2023	w.e.f. 19-09-2018 to 18-09-2023
viii.	**M/s Getz Pharma (Pvt) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi**					
41.	055420	Zoliget Tablet 15mg+4mg Each Tablet contain: Pioglitazone as HCL..15mg Glimepiride…4mg	14-03-2009	Dy. No. 43367 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
42.	055423	Artheget DS Tablet Each Tablet contain: Artemether….40mg Lumefantrine…240mg	14-03-2009	Dy. No. 43366 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
43.	055424	Ramy Tablet 1.25mg Each Tablet contain: Ramipril…….1.25mg	14-03-2009	Dy. No. 43380 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
44.	055425	Ramy Tablet 2.5mg Each Tablet contain: Ramipril…….2.5mg	14-03-2009	Dy. No. 43380 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
45.	055426	Ramy Tablet 5mg Each Tablet contain: Ramipril…….5mg	14-03-2009	Dy. No. 43380 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
46.	055427	Ramy Tablet 10mg Each Tablet contain: Ramipril…….10mg	14-03-2009	Dy. No. 43380 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024

47.	055428	Xicard Tablet 3.125mg Each Tablet contain: Carvedilol…..3.125	14-03-2009	Dy. No. 43368 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
48.	055435	Trevia Tablet 25mg Each film-coated tablet contain: Sitagliptin as phosphate Monohydrate….25mg	14-03-2009	Dy. No. 43376 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
49.	055436	Trevia Tablet 50mg Each film-coated tablet contains: Sitagliptin as Phosphate Monohydrate……50mg	14-03-2009	Dy. No. 43377 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
50.	055437	Trevia Tablet 50mg Each film-coated tablet contains: Sitagliptin as Phosphate Monohydrate……100mg	14-03-2009	Dy. No. 43378 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
51.	055440	Ferotein-S Injection 100mg/5ml Each 5ml contain: Iron as Iron sucrose …..100mg	14-03-2009	Dy. No. 43369 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
52.	055441	Covam Tablet 5mg+160mg Each film-coated tablet contain: Amlodipine…5mg Valsartan…..160mg	14-03-2009 14-03-2009 Change of brand name dated : 31-10-2016	Dy. No. 43372 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
53.	055442	Covam Tablet 10mg+160mg Each film-coated tablet contain: Amlodipine….10mg Valsartan….160mg	14-03-2009 Change of brand name dated : 31-10-2016	Dy. No. 43373 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
54.	055443	Treviamet Tablet 50mg+500mg Each film-coated tablet contain: Sitagliptin as phosphate Monohydrate….50mg Metformin HCL..500mg	14-03-2009	Dy. No. 43374 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
55.	055444	Treviamet Tablet 50mg+1000mg Each film-coated tablet contain: Sitagliptin as phosphate Monohydrate….50mg Metformin HCL..1000mg	14-03-2009	Dy. No. 43375 dated 20-12-2018 10000/-	13-03-2024	w.e.f 14-03-2019 to 13-03-2024
56.	001186-EX	Celcoxx Capsules 400mg Each Capsules contain: Celecoxib……400mg	01-04-2009	Dy. No. 44120 dated 27-12-2018 10000/-	31-03-2024	w.e.f 01-04-2019 to 31-03-2024

57.	001187-EX	Levocin I.V Infusion Each ml solution contain: Levofloxacin…5mg	01-04-2009	Dy. No. 44121 dated 27-12-2018 10000/-	31-03-2024	w.e.f 01-04-2019 to 31-03-2024
58.	001191-EX	Xalgetz Capsules 0.4mg Each Capsules contain: Tamsulosin HCL…0.4mg Source: M/s RA Chem Pharma Limited Clincal Research and Bioscience India.	01-04-2009	Dy. No. 44125 dated 27-12-2018 10000/- 10000/- dated 02-04-2019	31-03-2024	w.e.f 01-04-2019 to 31-03-2024
59.	004460-EX	Dipiget Tablet 25mg Each film coated Tablet contain: Sitagliptin as phosphate monohydrate…..25mg	28-03-2014	Dy. No. 44352 dated 28-12-2018 10000/-	27-03-2024	w.e.f 28-03-2019 to 27-03-2024
60.	004461-EX	Dipiget Tablet 50mg Each film coated Tablet contain: Sitagliptin as phosphate monohydrate…..50mg	28-03-2014	Dy. No. 44352 dated 28-12-2018 10000/-	27-03-2024	w.e.f 28-03-2019 to 27-03-2024
61.	004462-EX	Dipiget Tablet 100mg Each film coated Tablet contain: Sitagliptin as phosphate monohydrate…..100mg	28-03-2014	Dy. No. 44352 dated 28-12-2018 10000/-	27-03-2024	w.e.f 28-03-2019 to 27-03-2024
62.	004463-EX	Dipiget Plus tablet 50+500mg Each film coated Tablet contain: Sitagliptin as Phosphate monohydrate….50mg Metformin HCL..500mg	28-03-2014	Dy. No. 44352 dated 28-12-2018 10000/-	27-03-2024	w.e.f 28-03-2019 to 27-03-2024
63.	004464-EX	Dipiget Plus tablet 50+1000mg Each film coated Tablet contain: Sitagliptin as Phosphate monohydrate….50mg Metformin HCL..1000mg	28-03-2014	Dy. No. 44352 dated 28-12-2018 10000/-	27-03-2024	w.e.f 28-03-2019 to 27-03-2024
ix.	**M/s. ATCO Laboratories Limited, B-18, S.I.T.E., Karachi**					
64.	076145	Ascard Plus Forte Tablet Each film coated tablet contain: Acetylsalicylic Acid …162mg Clopidogrel Bisulphate eq. to Clopidogrel….75mg	06-01-2014	Dy. No. 42790 dated 14-12-2018 10000/-		Clarification regarding the formulation from the firm is required.
65.	053466	Scabfree 5% Lotion Each ml contain: Permethrin….5%	09-01-2009	Dy. No. 42790 dated 14-12-2018 10000/-	08-01-2024	w.e.f 09-01-2019 to 08-01-2024

66.	053460	Synephrine Injection Each ml contain: Phenylephrine HCL…1.00mg	19-01-2009	Dy. No. 42790 dated 14-12-2018 10000/-	18-01-2024	w.e.f 19-01-2019 to 18-01-2024
67.	053459	Milron Injection Each ml contain: Milrinone …..1.00mg	19-01-2009	Dy. No. 42790 dated 14-12-2018 10000/-	18-01-2024	w.e.f 19-01-2019 to 18-01-2024
68.	076164	Oxcym DR 20mg Capsules Each Capsules contain: Duloxetine (as HCL) enteric coated pellets….20mg Source: M/s Titan Laboratories Pvt Limited At E-27/1 MIDC Mahad Village Jite, Raigad Distt. Ragad Maharashtra India.	28-01-2014	Dy. No. 42790 dated 14-12-2018 20000/-	27-01-2024	w.e.f 28-01-2019 to 27-01-2024
69.	076175	Combinol-E cough Expectorant sugar free Each 5ml contain: Aminophylline…..32mg Diphenhydramine Hydrochloride….8mg Ammonium Chloride…….30mg	29-01-2014	Dy. No. 42790 dated 14-12-2018 10000/-	28-01-2024	w.e.f 29-01-2019 to 28-01-2024
x.	**M/s. Asian Continental (Pvt) Ltd., D/32, S.I.T.E., Super Highway, Karachi**					
70.	076219	Cotiphine 10mg Injection Each ml contain: Nalbuphine HCL (MS)……..…10mg	31-01-2014	Dy. No. 42786 dated 14-12-2018 10000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024
71.	076220	Cotiphine 20mg Injection Each ml contain: Nalbuphine HCL (MS)……20mg	31-01-2014	Dy. No. 42785 dated 14-12-2018 10000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024
xi.	**M/s Friends Pharma (Pvt) Ltd., 31-Km Ferozepur Road, Lahore**					
72.	001893-EX	Fluconobas Capsules Each Capsules contain: Fluconazole…150mg	01-01-2014	Dy. No. 43359 dated 20-12-2018 10000/-	31-12-2023	w.e.f. 01-01-2019 to 31-12-2023
xii.	**M/s. Opal Laboratories (Pvt) Ltd., Lc-41, L.I.T.E. Landhi Karachi**					
73.	032022	Venrith Tablet 250mg Each Tablet contain: Clarithromycin…250mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
74.	032023	Venrith Tablet 500mg Each Tablet contain: Clarithromycin…500mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
75.	032024	Vencef Capsules 400mg Each Capsules Contain: Cefixime ……400mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024

76.	032025	Vencef DS Suspension 200mg Each 5ml contain: Cefixime as trihydrate ……400mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
77.	032020	Pendoona Suspension 10mg Each 5ml contain: Famotidine…..10mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-		Clarification required regarding the formulation from the firm.
78.	032026	Tasartan Tablet 25mg Each Tablet Contain: Losartan Potassium……25mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
79.	032027	Tasartan Tablet 50mg Each Tablet Contain: Losartan Potassium……50mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
80.	036718	Cevil Ointment 30mg Each gm contain: Acyclovir…….30mg	28-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	27-01-2024	w.e.f. 28-01-2019 to 27-01-2024
81.	036720	Cevil Suspension 200mg Each 5ml contain: Acyclovir…….200mg	28-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	27-01-2024	w.e.f. 28-01-2019 to 27-01-2024
82.	036719	Cevil Tablet 200mg Each Tablet contain: Acyclovir…….200mg	28-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-	27-01-2024	w.e.f. 28-01-2019 to 27-01-2024
83.	076158	Macnaz oral Drops Each ml contain: Miconazole……20mg	09-01-2014	Dy. No. 44034 dated 27-12-2018 10000/-	08-01-2024	w.e.f. 09-01-2019 to 08-01-2024
xiii.	**M/s. Cirin Pharmaceuticals (Pvt) Ltd., 32/2A Phase III, Industrial Estate, Hattar**					
84.	000158-EX	Qumer Tablet 500mg Each film coated tablet contain: Ciprofloxacin USP..500mg	03-01-2004	Dy. No. 43276 dated 19-12-2018 10000/-	02-01-2024	w.e.f. 03-01-2019 to 02-01-2024
85.	000159-EX	Propase Tablet 40mg Each film coated tablet contain: Famotidine….40mg	03-01-2004	Dy. No. 43276 dated 19-12-2018 10000/-	02-01-2024	w.e.f. 03-01-2019 to 02-01-2024
86.	000160-EX	Levoline Tablet 500mg Each film coated tablet contain: Levofloxacin….500mg	03-01-2004	Dy. No. 43276 dated 19-12-2018 10000/-	02-01-2024	w.e.f. 03-01-2019 to 02-01-2024
87.	004428-EX	Tramol Tablet Each film coated tablet contain: Tramadol HCL….37.5mg Paracetamol…325mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024

88.	004429-EX	Xefix Tablet Each film coated tablet contain: Amoxycillin (anhydrous)…500mg Clavulanate acid…..125mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
89.	004430-EX	Xefix Powder for suspension Each 5ml contain: Amoxycillin (Anhydrous)…200mg Clavulanic acid….28.5	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
90.	004431-EX	Lossab 8mg Tablet Each film coated tablet contain: Lornoxicam ….8mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
91.	004432-EX	Alfutab 2.5mg Each extended release tablet contain: Alfuzocin HCL….2.5mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
92.	004433-EX	Alfutab 10mg Each extended release tablet contain: Alfuzocin HCL…..10mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
93.	004434-EX	Ambinoc 100mg Tablet Each film coated tablet contain: Minocycline HCL...100mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
94.	004435-EX	Entetab 0.5mg Tablet Each film coated tablet contain: Entecavir…..0.5mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
95.	004436-EX	Vzide Tablet Each Tablet contain: Gliclazide…..80mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
96.	004437-EX	Raloxin 60mg Tablet Each film coated tablet contain: Raloxifene HCL….60mg	14-03-2014	Dy. No. 43278 dated 19-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
97.	023030	Auropen capsules Each capsules contain: Cloxacillin sodium eq. to cloxacillin base B.P ..250mg	30-01-1999	Dy. No. 43279 dated 19-12-2018 10000/-	29-01-2024	w.e.f. 30-01-2019 to 29-01-2024
98.	023031	AuropenInj Each Injection Contain: Cloxacillin sodium eq. to cloxacillin base B.P ..250mg	30-01-1999	Dy. No. 43279 dated 19-12-2018 10000/-	29-01-2024	w.e.f. 30-01-2019 to 29-01-2024

99.	023032	Fortecin Tablet 1000mg Each Tablet contain: Amoxycillin Trihydrate eq. to Amoxycillin base…875mg Potassium Clavulanate…125mg	30-01-1999	Dy. No. 43279 dated 19-12-2018 10000/-	29-01-2024	w.e.f. 30-01-2019 to 29-01-2024
100.	054836	Insimax Tablet Each Tablet contain: Pioglitazone HCL equivalent to Pioglitazone…15mg Metformin HCL..500mg	23-01-2009	Dy. No. 43277 dated 19-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024
101.	054837	Insimax Tablet Each Tablet contain: Pioglitazone HCL equivalent to Pioglitazone…15mg Metformin HCL..500mg	23-01-2009	Dy. No. 43277 dated 19-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024
102.	054838	Throvex 75mg Tablet Each Tablet contain: Clopidogrel as Bisulfate ….75mg	23-01-2009	Dy. No. 43277 dated 19-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024
103.	054793	Zamocetrin Tablet 5mg Each tablet contain: Levocetirizine Dihydrochloride….5mg	12-01-2009	Dy. No. 43280 dated 19-12-2018 10000/-	11-01-2024	w.e.f. 12-01-2019 to 11-01-2024
104.	054796	Minizor Tablet Each Tablet contain: Ezetimibe…..10mg Simvastatin….10mg	12-01-2009	Dy. No. 43280 dated 19-12-2018 10000/-	11-01-2024	w.e.f. 12-01-2019 to 11-01-2024
105.	054797	Minizor Tablet Each tablet contain: Ezetimibe….10mg Simvastatin…20mg	12-01-2009	Dy. No. 43280 dated 19-12-2018 10000/-	11-01-2024	w.e.f. 12-01-2019 to 11-01-2024
106.	054798	Perivasc Tablet Each tablet contain: Amlodipine Besylae equivalent to Amlodipine….5mg Atorvastatin calcium equivalent to Atorvastatin….10mg	12-01-2009	Dy. No. 43280 dated 19-12-2018 10000/-	11-01-2024	w.e.f. 12-01-2019 to 11-01-2024
107.	054799	Perivasc Tablet Each tablet contain: Amlodipine Besylae equivalent to Amlodipine….5mg Atorvastatin calcium equivalent to Atorvastatin….20mg	12-01-2009	Dy. No. 43280 dated 19-12-2018 10000/-	11-01-2024	w.e.f. 12-01-2019 to 11-01-2024
108.	056467	Oropred Tablet 25mg Each tablet contain: Levosulpiride…25mg	31-03-2009	Dy. No. 43275 dated 19-12-2018 10000/-	30-03-2024	w.e.f. 31-03-2019 to 30-03-2024

109.	056468	Oropred Tablet 50mg Each tablet contain: Levosulpiride….50mg	31-03-2009	Dy. No. 43275 dated 19-12-2018 10000/-	30-03-2024	w.e.f. 31-03-2019 to 30-03-2024
110.	056469	Oropred Tablet 100mg Each tablet contain: Levosulpiride….100mg	31-03-2009	Dy. No. 43275 dated 19-12-2018 10000/-	30-03-2024	w.e.f. 31-03-2019 to 30-03-2024
xiv.	**M/s. Nabiqasim Industries (Pvt) Ltd., 17/24, Korangi Industrial Area, Korangi, Karachi**					
111.	001127-EX	Zexim suspension Each 5ml contain: Cefixime ……100mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
112.	001128-EX	Zexim 400mg Capsules Each Capsules contain: Cefixime…..400mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
113.	001129-EX	Minolip 10mg Tablet Each film coated tablet contain: Simvastatin….10mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
114.	001130-EX	Minolip 20mg Tablet Each film coated tablet contain: Simvastatin….20mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
115.	001131-EX	Minolip 40mg Tablet Each film coated tablet contain: Simvastatin…40mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
116.	001132-EX	Ketaflox 200mg Tablet Each film coated Tablet contain: Ofloxacin….200mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
117.	001133-EX	Ketaflox 400mg Tablet Each film coated tablet contain: Ofloxacin……400mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
118.	001134-EX	Broncoxil Syrup Each 5ml contain: Acefylline Piperazine…45mg Diphenhydramine HCL B.P 8mg	19-12-2008	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023
119.	001135-EX	Polifer Syrup Each 100ml contain: Ferric Ammonium Citrate USP…900mg Folic Acid USP…10mg Vitamin B1 USP…20mg Bitamin B6 USP…40mg Nicotinamide USP…200mg Liquid Glucose USP…Q.S	19-12-2008 Change of brand name dated: 11-06-2009	Dy. No. 42279 dated 10-12-2018 10000/-	18-12-2023	w.e.f. 19-12-2018 to 18-12-2023

120.	050383	Feveral Forte Tablet Each Tablet contain: Paracetamol….650mg Orphenadrine Citrate…..50mg	23-12-2008 Change of brand name dated: 05-06-2013	Dy. No. 42279 dated 10-12-2018 10000/-	22-12-2023	w.e.f. 23-12-2018 to 22-12-2023
xv.	**M/s. Barrett Hodgson Pakistan (Pvt) Ltd, F/423, S.I.T.E. Karachi**					
121.	055532	Synigan Ophthalmic Solution 20mg+5mg Each ml contains: Dorzolamide as HCL….20mg Timolol as Maleate….5mg	24-03-2009	Dy. No. 42262 dated 10-12-2018 10000/-	23-03-2024	w.e.f. 24-03-2019 to 23-03-2024
122.	055533	Malera Ds Tablet 40mg + 240mg Each Tablet contain: Artemether…..40mg Lumefantrine….240mg	24-03-2009	Dy. No. 42264 dated 10-12-2018 10000/-	23-03-2024	w.e.f. 24-03-2019 to 23-03-2024
123.	055534	Malera Dry Suspension 15mg+90mg Each 5ml contain: Artemether…..15mg Lumefantrine….90mg	24-03-2009	Dy. No. 42263 dated 10-12-2018 10000/-	23-03-2024	w.e.f. 24-03-2019 to 23-03-2024
124.	055535	Gencart Plus Caplet 500mg + 400mg Each Caplet contain: Glucosamine sulphate as potassium chloride……500mg Chondroitin Sulphate as sodium…….400mg	24-03-2009	Dy. No. 42267 dated 10-12-2018 10000/-	23-03-2024	w.e.f. 24-03-2019 to 23-03-2024
125.	055536	Lixer 5mg Tablet Each Tablet contain: Levocetirizine Dihydrochloride….5mg	24-03-2009	Dy. No. 42265 dated 10-12-2018 10000/-	23-03-2024	w.e.f. 24-03-2019 to 23-03-2024
126.	055537	Lixer 2.5mg/5ml syrup Each 5ml contains: Levocetirizine Dihydrochloride….2.5mg	24-03-2009	Dy. No. 42266 dated 10-12-2018 10000/-	23-03-2024	w.e.f. 24-03-2019 to 23-03-2024
127.	055538	Aerokast 4mg sachet Each Sachet contain: Montelukast sodium eq to Montelukast acid…..4mg	24-03-2009	Dy. No. 42268 dated 10-12-2018 10000/-	23-03-2024	w.e.f. 24-03-2019 to 23-03-2024
xvi.	**M/s. Pacific Pharmaceuticals Ltd., 30-Km, Multan Road, Lahore**					
128.	022896	Rifin 450 tablet Each Tablet Contain: Rifampicin….450mg Isoniazid…..300mg	18-12-1998	Dy. No. 42983 dated 17-12-2018 10000/-	17-12-2023	w.e.f. 18-12-2018 to 17-12-2023
129.	022893	Rifin P Tablets Each Tablet Contain: Isoniazid…50mg Pyrazinamide….300mg Rifampicin….120mg	18-12-1998	Dy. No. 42983 dated 17-12-2018 10000/-	17-12-2023	w.e.f. 18-12-2018 to 17-12-2023

xvii.	**M/s. EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad**					
130.	077701	Nodard 75mg Inj Each ampoule contains: Diclofenac Sodium…..75mg	16-12-2013	Dy. No. 42348 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
131.	077702	Dexitab 300mg Tablet Each Tablet Contain: Dexibuprofen …..300mg	16-12-2013	Dy. No. 42350 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
132.	077703	Avelon 400mg Infusion Each Vial Contain: Moxifloxacin……400mg	16-12-2013	Dy. No. 42350 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
133.	077704	Metrome 500mg Infusion Each 100ml vial Contain: Metronidazole…….500mg	16-12-2013	Dy. No. 42350 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
134.	077705	Podox 100mg Capsules Each Capsules Contain: Cefpodoxime(as Proxetil)…100mg	16-12-2013	Dy. No. 42350 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
135.	077706	Droxibid 500mg Capsules Each Capsules Contain: Cefadroxil…….500mg	16-12-2013	Dy. No. 42350 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
136.	077707	Selovef 250mg Capsules Each Capsules Contain: Cephradine…….250mg	16-12-2013	Dy. No. 42350 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
137.	077708	Opracid 20mg Capsules Each Capsules Contain: Omeprazole (Pellets).20mg M/s Vision Pharma Islamabad	16-12-2013	Dy. No. 42349 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
138.	077709	Opracid 40mg Capsules Each Capsules Contain: Omeprazole (Pellets).40mg M/s Vision Pharma Islamabad	16-12-2013	Dy. No. 42349 dated 11-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
xviii.	**M/s. Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi**					
139.	032196	Noacip Tablet Each Tablet Contain: Ciprofloxacin HCL eq. to Ciprofloxacin….250mg	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
140.	032197	Noacip 500Tablet Each Tablet Contain: Ciprofloxacin HCL eq. to Ciprofloxacin….500mg	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
141.	032198	Quinzi Tablet 200mg Each Tablet contain: Ofloxacin…….200mg	27-02-2004 Change of brand name dated 22-11-2006	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024

142.	032199	Roc Tablet 150mg Each Tablet Contain: Roxithromycin……150mg	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
143.	032200	Doricyl Capsules Each Capsules Contain: Doxycycline (as Hyclate)…..150mg	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
144.	032203	Calcrem Cream Contain: Clotrimazole w/w…..1%	27-02-2004 Change of brand name dated 21-03-2008	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
145.	032206	Multifax skin ointment Each gram contain: Polymyxin B sulphate 10000I.U Bacitracin Zinc…..500I.U	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
146.	032207	Gynotec Tablet 100mg Each Tablet Contain: Clotrimazole…..100mg	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
147.	032208	Gynotec Tablet Each Tablet Contain: Clotrimazole…..500mg	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
148.	032178	Vomisac Tablets Each Tablet Contain: Domperidone…..10mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
149.	032180	Ez-Card-5 Tablet Each Tablet Contains: Enalapril Maleate…5.0mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
150.	032181	Ez-Card-10 Tablet Each Tablet Contains: Enalapril Maleate……..10mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
151.	032182	Atromin-50mg Tablet Each Tablet Contains: Atenolol…50mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
152.	032183	Atromin-100mg Tablet Each Tablet Contains: Atenolol…100mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
153.	032184	Amovasc Tablets 5mg Each Tablet Contains: Amlodipine (as besylate)….5mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
154.	032185	Amovasc Tablets 10mg Each Tablet Contains: Amlodipine (as besylate)….5mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024

155.	032186	Anginil-20mg Tablets Each Tablet Contains: Isosorbide Mononitrate….20.0mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
156.	032187	Anginil-40mg Tablets Each Tablet Contains: Isosorbide Mononitrate….40.0mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
157.	032188	Lopaz Tablets Each Tablet Contains: Losartan Potassium……50mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
158.	032193	Diablo Tablets Each Tablet Contains: Glibenclamide……..5mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
159.	032194	Reviv Tablets Each Tablet Contains: Ranitidine (e.q to Ranitidine HCL)..150mg	27-02-2004	Dy. No. 42352 dated 11-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
xix.	**M/s. Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205, Industrial Triangle Kahota Road, Islamabad**					
160.	032155	DDS Lincomycin Injection 600mg Each 2ml Contain: Lincomycin…..600mg	19-02-2004	Dy. No. 43929 dated 26-12-2018 10000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
161.	030200	Mecomed Injection 500mcg Each 1ml Injection: Mecobalamin….500mcg	31-03-2003 Change of brand name dated 19-01-2009	Dy. No. 43929 dated 26-12-2018 10000/-	18-01-2024	w.e.f. 19-01-2019 to 18-01-2024
162.	026628	Mikacin Injection 100mg Each vial contain: Amikacin (as sulphate) 100mg	21-02-2001 Change of brand name dated 23-02-2004	Dy. No. 43929 dated 26-12-2018 10000/-	22-02-2024	w.e.f. 23-02-2019 to 22-02-2024
163.	027300	Mikacin Injection 500mg Each 2ml contains: Amikacin (as sulphate) 500mg	10-05-2002 Change of brand name dated 23-02-2004	Dy. No. 43929 dated 26-12-2018 10000/-	22-02-2024	w.e.f. 23-02-2019 to 22-02-2024
164.	032151	Orthomin Capsule 500mg Each capsule contain: Glucosamine Sulphate…500mg	19-02-2004	Dy. No. 43929 dated 26-12-2018 10000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
xx.	**M/s. Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E, Super Highway, Karachi**					
165.	076196	Chewron 100mg Injection Each 5ml contain: Iron sucrose eq. to elemental iron…100mg	29-01-2014	Dy. No. 44594 dated 31-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
166.	076195	Merynate 500mcg Injection Each ml contain: Mecobalamin…… 500mcg	29-01-2014	Dy. No. 44594 dated 31-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024

167.	053453	Quopine 25mg Tablet Each Tablet contain: Quetiapine….25mg	30-12-2008	Dy. No. 42662 dated 13-12-2018 10000/-	29-12-2023	w.e.f. 30-12-2018 to 29-12-2023
xxi.	**M/s. S.J. & G. FazulEllahie Ltd., E/46, S.I.T.E., Karachi**					
168.	076241	Malnate Tablet Each Co-Blister contain: 3Tablet: Each tablet contain: Sulfadoxine…500mg Pyrimethamine…25mg 6Tablet: Each Tablet contain: Artesunate I.P….100mg	03-02-2014	Dy. No. 44591 dated 31-12-2018 10000/-	02-02-2024	w.e.f. 03-02-2019 to 02-02-2024
xxii.	**M/s. Zephyr Pharmatec (Pvt) Ltd., A-39, S.I.T.E. II, Super Highway, Karachi**					
169.	055010	Cress Tablet Each tablet contain: Iron III Hydroxide polymaltose complex eq Elemental Iron…100mg Folic Acid…..0.35mg	13-01-2009	Dy. No. 44593 dated 31-12-2018 10000/-	12-01-2024	w.e.f. 13-01-2019 to 12-01-2024
170.	055011	Cress Capsules Each Capsules contain: Iron III Hydroxide polymaltose complex eq Elemental Iron…100mg Folic Acid…..0.35mg	13-01-2009	Dy. No. 44593 dated 31-12-2018 10000/-	12-01-2024	w.e.f. 13-01-2019 to 12-01-2024
171.	055012	Maloff Tablet Each Tablet Contain: Artemether….20mg Lumefantrine…120mg	13-01-2009 Change of brand name dated: 06-05-2009	Dy. No. 44593 dated 31-12-2018 10000/-	12-01-2024	w.e.f. 13-01-2019 to 12-01-2024
172.	036626	Folic-CP Tablet Each Tablet contain: Folic Acid…..5mg	26-01-2004 Change of brand name dated: 02-01-2018	Dy. No. 44593 dated 31-12-2018 10000/-	25-01-2024	w.e.f. 26-01-2019 to 25-01-2024
xxiii. xxiv.	**M/s. Rock Pharmaceutical Laboratories (Pvt) Ltd., Plot No. 134&135-B, Nowshera Industrial Estate, Risalpur**					
173.	004382-EX	Septra Suspension Each 5ml contain: Trimethoprim……40mg Sulphamethoxazole.200mg	13-12-2013	Dy. No. 42351 dated 11-12-2018 10000/-	12-12-2023	w.e.f. 13-12-2018 to 12-12-2023
174.	004383-EX	Mozal Suspension Each 5ml contain: Aluminum Hydroxide ……405mg Magnesium Hydroxide …..100mg	13-12-2013	Dy. No. 42351 dated 11-12-2018 10000/-	12-12-2023	w.e.f. 13-12-2018 to 12-12-2023
xxv.	**M/s. PharmEvo (Pvt) Ltd.,A-29, North Western Industrial Zone, Port Qasim, Karachi**					
175.	053494	Aflona 10mg Tablet Each Tablet contain: Leflunomide…10mg	10-01-2009 Change of Brand Name 29-12-2009	Dy. No. 44435 dated 31-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024

176.	053495	Aflona 20mg Tablet Each Tablet contain: Leflunomide…20mg	10-01-2009 Change of Brand Name dated 29-12-2009	Dy. No. 44435 dated 31-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
177.	053496	Aflona 100mg Tablet Each Tablet contain: Leflunomide…100mg	10-01-2009 Change of Brand Name dated 29-12-2009	Dy. No. 44435 dated 31-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
178.	053497	Delergia Syrup Each ml contain: Desloratadine…..0.5mg	10-01-2009	Dy. No. 44435 dated 31-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
179.	076157	Xcept 10mg Tablet Each Tablet contain: Rivaroxaban…10mg	09-01-2014	Dy. No. 44433 dated 31-12-2018 10000/-	08-01-2024	w.e.f. 09-01-2019 to 08-01-2024
180.	076259	Rixabac 550mg Tablet Each film coated tablet contain: Rifaximin…...550mg	17-02-2014	Dy. No. 44434 dated 31-12-2018 10000/-	16-02-2024	w.e.f. 17-02-2019 to 16-02-2024
181.	076260	Rixabac 200mg Tablet Each film coated tablet contain: Rifaximin…...200mg	17-02-2014	Dy. No. 44434 dated 31-12-2018 10000/-	16-02-2024	w.e.f. 17-02-2019 to 16-02-2024
xxvi.	**M/s. Neomedix, Plot No. 05, N/5, National Industrial Zone, Islamabad**					
182.	054635	Doxydix 100mg Capsules Each Capsules Contain: Doxycycline (as hyclate...100mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-	23-12-2023	w.e.f. 24-12-2018 to 23-12-2023
183.	054636	Lincomydix 500mg Capsules Each Capsules Contain: Lincomycin (as Hcl)…..500mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-	23-12-2023	w.e.f. 24-12-2018 to 23-12-2023
184.	054637	Pentidix 100mg Capsules Each Capsules Contain: Gabapentin …..100mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-	23-12-2023	w.e.f. 24-12-2018 to 23-12-2023
185.	054638	Pentidix 300mg Capsules Each Capsules Contain: Gabapentin …..300mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-	23-12-2023	w.e.f. 24-12-2018 to 23-12-2023
186.	054639	Pentidix 400mg Capsules Each Capsules Contain: Gabapentin …..400mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-	23-12-2023	w.e.f. 24-12-2018 to 23-12-2023
xxvii.	**M/s. Maple Pharmaceuticals, Plot No. 147, Sector-23, Korangi Industrial Area, Karachi**					
187.	053400	Sitaglip 25mg Tablet Each Tablet contain: Sitagliptin……25mg	18-12-2008	Dy. No. 42516 dated 12-12-2018 10000/-	17-12-2023	w.e.f. 18-12-2018 to 17-12-2023

188.	053401	Sitaglip 50mg Tablet Each Tablet contain: Sitagliptin……50mg	18-12-2008	Dy. No. 42516 dated 12-12-2018 10000/-	17-12-2023	w.e.f. 18-12-2018 to 17-12-2023
189.	053402	Sitaglip 100mg Tablet Each Tablet contain: Sitagliptin……100mg	18-12-2008	Dy. No. 42516 dated 12-12-2018 10000/-	17-12-2023	w.e.f. 18-12-2018 to 17-12-2023
190.	053403	Sitaglip Plus Tablet Each Tablet contain: Sitagliptin……50mg Metformin HCL….500mg	18-12-2008	Dy. No. 42516 dated 12-12-2018 10000/-	17-12-2023	w.e.f. 18-12-2018 to 17-12-2023
191.	053404	Sitaglip Forte Tablet Each Tablet contain: Sitagliptin……50mg Metformin HCL...1000mg	18-12-2008	Dy. No. 42516 dated 12-12-2018 10000/-	17-12-2023	w.e.f. 18-12-2018 to 17-12-2023
xviii.	**M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera, Khyber Pakhtunkhwa**					
192.	032028	Levo Tablets 250mg Each Tablet contain: Levofloxacin Hemihydrate eq to Levofloxacin..250mg	15-04-2004	Dy. No. 42419 dated 12-12-2018 10000/-	14-04-2024	w.e.f. 15-04-2019 to 14-04-2024
193.	032029	Levo tablets 500mg Each Tablet contain: Levofloxacin Hemihydrate eq to Levofloxacin.500mg	15-04-2004	Dy. No. 42419 dated 12-12-2018 10000/-	14-04-2024	w.e.f. 15-04-2019 to 14-04-2024
194.	032030	Selectiva capsule 100mg Each Capsule contain: Celecoxib…100mg	15-04-2004	Dy. No. 42419 dated 12-12-2018 10000/-	14-04-2024	w.e.f. 15-04-2019 to 14-04-2024
195.	032031	Selectiva Each capsule contain: Celecoxib…200mg	15-04-2004	Dy. No. 42419 dated 12-12-2018 10000/-	14-04-2024	w.e.f. 15-04-2019 to 14-04-2024
196.	032032	Diuret Each tablet contain: Hydrochlorothiazide …12.50mg.	15-04-2004	Dy. No. 42419 dated 12-12-2018 10000/-	14-04-2024	w.e.f. 15-04-2019 to 14-04-2024
197.	054747	Aurora tablet 40mg Each tablet contain: Rosuvastatin calcium eq to Rosuvastatin….40mg	02-01-2009	Dy. No. 42418 dated 12-12-2018 10000/-	01-01-2024	w.e.f. 15-04-2019 to 14-04-2024
xxix.	**M/s. Geofman Pharmaceuticals, 20/23, Korangi Industrial Area, Karachi**					
198.	053413	Geokacin Injection 100mg Each 2ml contain: Amikacin (as sulphate)…….100mg	22-12-2008	Dy. No. 43363 dated 20-12-2018 10000/-	21-12-2023	w.e.f. 22-12-2018 to 21-12-2023
199.	053414	Geokacin Injection 250mg Each 2ml contains: Amikacin (as sulphate)……250mg	22-12-2018	Dy. No. 43364 dated 20-12-2018 10000/-	21-12-2023	w.e.f. 22-12-2018 to 21-12-2023
200.	053415	Geokacin Injection Each 2ml Contain: Amikacin (as sulphate)……500mg	22-12-2008	Dy. No. 43365 dated 20-12-2018 10000/-	21-12-2023	w.e.f. 22-12-2018 to 21-12-2023

201.	053422	Linopril 10mg Tablet Each Tablet contain: Lisinopril (as Dihydrate)…..10mg	22-12-2008	Dy. No. 43360 dated 20-12-2018 10000/-	21-12-2023	w.e.f. 22-12-2018 to 21-12-2023
202.	053423	Linopril 20mg Tablet Each Tablet contain: Lisinopril (as Dihydrate)…..20mg	22-12-2008	Dy. No. 43361 dated 20-12-2018 10000/-	21-12-2023	w.e.f. 22-12-2018 to 21-12-2023
203.	053424	Linopril H- 10/12.5mg Each tablet contain: Lisinopril (as Dihydrate)…..10mg Hydrochlorothiazide ….12.5mg	22-12-2008	Dy. No. 43362 dated 20-12-2018 10000/-	21-12-2023	w.e.f. 22-12-2018 to 21-12-2023
xxx.	**M/s. TagmaPharma (Pvt) Ltd., 12.5-Km Raiwind Road, Lahore**					
204.	053666	T-Sone-N cream Each gram contain: Betamethasone….0.1% Neomycin Sulphate…0.5%	06-12-2008	Dy. No. 39826 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
205.	053667	T-Sone-N Ointment Each gram contain: Betamethasone….0.1% Neomycin Sulphate…0.5%	06-12-2008	Dy. No. 39826 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
206.	053668	Acne-Clear Cream Each gram contain: Tretinoin…..0.05%	06-12-2008	Dy. No. 39826 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
207.	053669	T-Scabidol Cream Each gram contain: Permethrin….5%	06-12-2008	Dy. No. 39826 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
208.	053670	Move-Ease Tablet Each Tablet Contain: Tizanidine as HCL…2mg	06-12-2008	Dy. No. 39826 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
209.	053671	Move-Ease Tablet Each Tablet Contain: Tizanidine as HCL…2mg	06-12-2008	Dy. No. 39826 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
210.	022524	Tulip-20 Tablet Each Tablet Contain: Famotidine….20mg	07-12-1998	Dy. No. 39826 dated 3-12-2018 10000/-	06-12-2023	w.e.f. 07-12-2018 to 06-12-2023
xxxi.	**M/s. Standpharm Pakistan (Pvt) Ltd., 20-Km, Ferozepur Road, Lahore**					
211.	053672	Normipil 10mg Tablet Each Tablet contain: Ramipril..…10mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
212.	053673	Thrombonil Plus 75mg Tablet Each Tablet Contain: Clopidogrel ….75mg Aspirin…75mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-		Clarification of formulation is required from the firm.

213.	053674	Thrombonil Plus 150mg Tab Each Tablet contain: Clopidogrel ….75mg Aspirin…150mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
214.	053675	Lopros 5mg Tablet Each Tablet contain: Terazosin (as Terazosin HCL)…5mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
215.	053676	Stanflox 250mg Tablet Each Tablet contain: Levofloxacin (as Hemihydrate)…250mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
216.	053677	Stanflox 500mg Tablet Each Tablet contain: Levofloxacin (as Hemihydrate)….500mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
217.	053678	Maltron Chewable Tab Each Tablet contain: Iron as Polymaltose Complex……100mg Folic Acid….0.35	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
218.	053679	Anemix Chewable Tab Each Tablet contain: Iron III Hydroxide Polymaltose complex eq. to Elemental Iron…100mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
219.	053680	Maltron Syrup Each 5ml contain: Iron as polymaltose Complex…50mg Folic Acid…0.35mg	06-12-2008	Dy. No. 39827 dated 3-12-2018 10000/-	05-12-2023	w.e.f. 06-12-2018 to 05-12-2023
xxxii. **M/s. Elite Pharma (Pvt) Ltd., 9.5-Km, Sheikhupura Road, Lahore**						
220.	053723	Elexin 250mg Capsules Each Capsules contain: Cephalexin ….250mg	16-12-2008	Dy. No. 39838 dated 4-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
221.	053724	Elexin 500mg Capsules Each Capsules contain: Cephalexin….500mg	16-12-2008	Dy. No. 39838 dated 4-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
222.	053727	Eliclor 250mg Capsules Each Capsules contain: Cefaclor (as Monohydrate)….250mg	16-12-2008	Dy. No. 39838 dated 4-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
223.	053728	Eliclor 500mg Capsules Each Capsules contain: Cefaclor (as Monohydrate)…500mg	16-12-2008	Dy. No. 39838 dated 4-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023

224.	053732	Droxilite 500mg Capsules Each Capsules contain: Cefadroxil (as Monohydrae)..500mg	16-12-2008	Dy. No. 39838 dated 4-12-2018 10000/-	15-12-2023	w.e.f. 16-12-2018 to 15-12-2023
xxiii.	**M/s. Derma Techno Pakistan, Plot No. 528, Sunder Industrial Estate, Raiwind Road, Lahore**					
225.	077078	Duowart Liquid Each ml contains: Salicylic acid …16.7mg Lactic acid…..16.7mg	31-12-2013	Dy. No. 43272 dated 19-12-2018 10000/-	30-12-2023	w.e.f. 31-12-2018 to 30-12-2023
226.	077079	Benzaplene Gel Each gram contain: Adapalene ….1mg Benzoyl peroxide…25mg	31-12-2013	Dy. No. 43272 dated 19-12-2018 10000/-	30-12-2023	w.e.f. 31-12-2018 to 30-12-2023
227.	077080	Fawotrex cream Each gram contain: Isotretinoin…0.5mg	31-12-2013	Dy. No. 43272 dated 19-12-2018 10000/-	30-12-2023	w.e.f. 31-12-2018 to 30-12-2023
xxxiv.	**M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi**					
228.	015044	Ronex Tablet Each film coated tablet contain: Cetirizine Dihydrochloride 10mg	27-02-1994	Dy. No. 39829 dated 3-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
229.	015045	ALP 0.5mg Tablet Each tablet contain: Alprazolam…0.5mg	27-02-1994	Dy. No. 39829 dated 3-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
230.	015046	ALP 1mg Tablet Each tablet contain: Alprazolam…1mg	27-02-1994	Dy. No. 39829 dated 3-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
231.	022592	Maxit Tablet 25mg Each tablet contain: Diclofenac potassium.…25mg	22-02-1999	Dy. No. 39829 dated 3-12-2018 10000/-	21-02-2024	w.e.f. 22-02-2019 to 21-02-2024
232.	032050	Hitop 25mg Tablet Each tablet contain: Topiramate….25mg	23-01-2004	Dy. No. 39829 dated 3-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024
233.	032051	Hitop 50mg Tablet Each tablet contain: Topiramate….50mg	23-01-2004	Dy. No. 39829 dated 3-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024
234.	032053	Neogab 100mg Capsues Each Capsules cotnain: Gabapentin….100mg	23-01-2004	Dy. No. 39829 dated 3-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024
235.	032054	Neogab 300mg Capsules Each Capsules cotnain: Gabapentin….300mg	23-01-2004	Dy. No. 39829 dated 3-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024

236.	032055	Neogab 400mg capsules Each Capsules cotnain: Gabapentin….400mg	23-01-2004	Dy. No. 39829 dated 3-12-2018 10000/-	22-01-2024	w.e.f. 23-01-2019 to 22-01-2024
237.	055015	Artem Plus Dry Suspension Each 5ml contain: Artemether…..15mg Lumefantrine….90mg	15-01-2009	Dy. No. 39829 dated 3-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
238.	076150	Vilzer 50mg Tablet Each tablet contain: Vildagliptin…50mg	07-01-2014	Dy. No. 39829 dated 3-12-2018 10000/-	06-01-2024	w.e.f. 07-01-2019 to 06-01-2024
239.	076166	Xink-D 10mg Tablet Each dispersible tablet contain: Zinc sulphate Monohydrate eq. to Elemental Zinc…10mg	29-01-2014	Dy. No. 39829 dated 3-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
240.	076167	DIPIP Dry Suspension Each 5ml contain: Dihydroartemisinin….15mg Piperaquine phosphate….120mg	29-01-2014	Dy. No. 39829 dated 3-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
241.	076168	DIPIP 40mg / 320mg Each tablet contain: Dihydroartemisinin..40mg Piperaquine phosphate ……320mg	29-01-2014	Dy. No. 39829 dated 3-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
242.	076169	Hetoxib 60mg Tablet Each film coated tablet contain: Etoricoxib…..60mg	29-01-2014	Dy. No. 39829 dated 3-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
xxxv.	**M/s. AGP (Pvt) Ltd., B-23, Sindh Industrial Trading Estate, Karachi**					
243.	076152	Urso suspension Each 5ml contain: Ursodeoxycholic Acid…..250mg	07-01-2014	Dy. No. 41225 dated 6-12-2018 10000/-	06-01-2024	w.e.f. 07-01-2019 to 06-01-2024
244.	031999	Melfax Injection Each 1ml contain: Meloxicam….7.5mg	08-01-2004	Dy. No. 41227 dated 6-12-2018 10000/-	07-01-2024	w.e.f. 08-01-2019 to 07-01-2024
245.	032000	Oxoderm Gel Each 1gm contain: Hydroxyzine HCL..50mg	08-01-2004	Dy. No. 41226 dated 6-12-2018 10000/-	07-01-2024	w.e.f. 08-01-2019 to 07-01-2024
xxxvi.	**M/s. High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi**					
246.	076201	Velker plus Tablet Each film coated tablet contain: Valsartan……160mg Hydrochlorothiazide.25mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024

247.	076202	Velker 80mg Tablet Each film coated tablet contain: Valsartan…..80mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
248.	076203	Tri-velker tablet Each film coated tablet contain: Amlodipine as besylate ……..…10mg Valsartan…..160mg Hydrochlorothiazide …….12.5mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
249.	076204	Tri-velker tablet Each film coated tablet contain: Amlodipine…5mg Valsartan……160mg Hydrochlorothiazide …12.5mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
250.	076205	Co-velker Each film coated tablet contain: Amlodipine as besylate…10mg Valsartan…..160mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
251.	076206	Co-velker Tablet Each film coated tablet contain: Amlodipine as besylate….5mg Valsartan……160mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
252.	076207	Velker Tablet Each film coated tablet contain: Valsartan……80mg Hydrohlorothiazide……..12.5mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
253.	076208	Co-velker Tablet Each film coated tablet contain: Amlodipine as besylate….5mg Valsartan…..80mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
254.	076209	Velder 160mg tablet Each film coated tablet contain: Valsartan……160mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024
255.	076210	Velker Plus Tablet Each film coated tablet contain: Valsartan…..160mg Hydrochlorothiazide ……..12.5mg	29-01-2014	Dy. No. 43271 dated 19-12-2018 10000/-	28-01-2024	w.e.f. 29-01-2019 to 28-01-2024

xxxvii.	**M/s. Mediate Pharmaceutical (Pvt) Ltd., Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi**					
256.	53461	Diazomil Injection Each 2ml Contains: Diazepam…...10mg	20-01-2009	Dy. No. 43809 dated 24-12-2018 10000/-	19-01-2024	w.e.f. 20-01-2019 to 19-01-2024
xxxviii.	**M/s. Albro Pharmaceuticals (Pvt) Ltd., 340-S, Industrial Area, KotLakhpat, Lahore**					
257.	004422	Becopan Tablets Each Tablet contain: Nicotinamide BP-15mg, B1(BP)-1mg, B2(BP)-1mg	15-01-1977	Dy. No. 43808 dated 24-12-2018 10000/-	14-01-2022	Confirmation of post registration variation if any.
xxxix.	**M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd., L-4/1, A&B, Block-21, Federal-B Industrial Area, Karachi**					
258.	055547	Firmofos Weekly Tablet 70mg Each Tablet Contain: Alendronate Sodium as Alendronic Acid…70mg	27-03-2009	Dy. No. 44429 dated 31-12-2018 10000/-	26-03-2024	w.e.f. 27-03-2019 to 26-03-2024
259.	023329	Xynosine Children formula nasal drops Contains: Xylometazoline HCL ……..0.05%	15-03-1999	Dy. No. 44428 dated 31-12-2018 10000/-	14-03-2024	w.e.f. 15-03-2019 to 14-03-2024
xl.	**M/s. CKD Pharmaceuticals Pakistan (Pvt) Ltd., 50/28, Korangi Industrial Area, Karachi**					
260.	015011	Aminofil-100 Tablet Each Tablet contain: Aminophylline…100mg	27-02-1994	Dy. No. 43858 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024 .
261.	015013	L-Mycitin Eye ointment Contains: Chloramphenicel…1% w/w	27-02-1994	Dy. No. 43858 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
262.	015012	Neomycin Skin Ointment Each cream contain: Neomycin sulphate USP…5mg	27-02-1994 Change of brand name 04-04-1996	Dy. No. 43858 dated 24-12-2018 10000/-	26-02-2024	w.e.f. 27-02-2019 to 26-02-2024
xli.	**M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd., A-46 SITE North Karachi**					
263.	055548	Acnot Tablet Each sugar coated tablet contain: Cyproterone Acetate..2.0mg Ethinyl estradiol….0.035mg	27-03-2009	Dy. No. 44426 dated 31-12-2018 10000/-	26-03-2024	w.e.f. 27-03-2019 to 26-03-2024
xlii.	**M/s. Aims Pharmaceutical, Plot No. 291, Industrial Triangle Kahuta Road, Islamabad**					
264.	077710	Slimaim 120mg Capsules Each Capsules contain: Orlistat….120mg Source: M/s Changqing Zein Pharmaceuticals Co., Ltd China.	30-12-2013	Dy. No. 44118 dated 27-12-2018 10000/-	29-12-2023	w.e.f. 30-12-2018 to 29-12-2023

xliii.	**M/s. Unimark Pharmaceuticals, Plot No. 7-A, Street No. S-7, National Industrial Zone, Rawat, Islamabad**					
265.	054791	Kaisen-250 Tablet Each Tablet Contain: Ciprofloxacin (as HCL)……250mg	10-01-2009	Dy. No. 42985 dated 17-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
266.	054792	Kaisen-500 Tablet Each Tablet Contain: Ciprofloxacin (as HCL)……500mg	10-01-2009	Dy. No. 42985 dated 17-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
xliv.	**M/s. Usawa Pharmaceuticals, 146-Special Industrial Zone (Export Processing Zone), Risalpure**					
267.	032010	Simroxy Tablets Each tablet contains: Piroxicam..20mg	16-01-2004	Dy. No. 43631 dated 21-12-2018 10000/-	15-01-2024	w.e.f. 16-01-2019 to 15-01-2024
268.	032013	Rapidon Tablet 10mg Each tablet contains: Domperidone…10mg	16-01-2004	Dy. No. 43631 dated 21-12-2018 10000/-	15-01-2024	w.e.f. 16-01-2019 to 15-01-2024
xlv.	**M/s. Macter International (Pvt) Ltd., F-216, S.I.T.E. Karachi**					
269.	053472	Mclevo 750mg Tablet Each Tablet Contain: Levofloxacin….750mg	10-01-2009	Dy. No. 43492 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
270.	053485	0ciproquine 750mg tablet Each Tablet Contain: Ciprofloxacin as Hydrochloride 750mg	10-01-2009	Dy. No. 43493 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
271.	076235	Mclevo 500mg/100ml Infusion Each 100ml Contains: Levofloxacin as hemihydrates…..500mg	31-01-2014	Dy. No. 43496 dated 20-12-2018 10000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024
272.	053471	Bonita 60mg Tablet Each Tablet Contain: Raloxifene HCL….60mg	10-01-2009	Dy. No. 43495 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
273.	076236	Philcor HCT 300mg/1205mg Tablet Each film coated tablet contain.: Aliskirin Hemifumarate…..300mg Hydrochlorothiazide….12.5mg	31-01-2014	Dy. No. 43494 dated 20-12-2018 10000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024
274.	053473	Witin 100mg Capsules Each Capsules contain: Gabapentin….100mg	10-01-2009	Dy. No. 43502 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
275.	053474	Witin 300mg Capsules Each Capsules contain: Gabapentin….300mg	10-01-2009	Dy. No. 43502 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024

276.	053475	Witin 400mg Capsules Each capsules contain: Gabapentin….400mg	10-01-2009	Dy. No. 43502 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
277.	053476	Pitaz 15mg Tablet Each Tablet Contain: Pioglitazone (As HCL)….15mg	10-01-2009	Dy. No. 43501 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
278.	53477	Pitaz 30mg Tablet Each Tablet contain: Pioglitazone (As HCL)….30mg	10-01-2009	Dy. No. 43501 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
279.	053478	Pitaz 45mg Each Tablet Contain: Pioglitazone (As HCL)….45mg	10-01-2009	Dy. No. 43501 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
280.	053479	Lefanor 20mg Tablet Each Tablet Contain: Leflunomide….20mg	10-01-2009	Dy. No. 43500 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
281.	053480	Lefanor 10mg Tablet Each Tablet contain: Leflunomide….10mg	10-01-2009	Dy. No. 43500 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
282.	053481	Alenor 5mg Tablet Each tablet contain: Desloratadine….5mg	10-01-2009	Dy. No. 43494-A 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
283.	053482	Siezab 25mg tablet Each Tablet contain: Topiramate 25mg	10-01-2009	Dy. No. 43499 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
284.	053483	Siezab tablet 50mg tablet Each Tablet contain: Topiramate 50mg	10-01-2009	Dy. No. 43499 dated 20-12-2018 10000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
285.	053484	Nefes 20mg tablet Each tablet contain: Zafirlukast..20mg	10-01-2009	Dy. No. 43497 dated 20-2-2018 19000/-	09-01-2024	w.e.f. 10-01-2019 to 09-01-2024
286.	076233	Telsitan-H Forte 12.5mg Tablet Each tablet contain: Telmisarton 80mg Hydrochlorothiazide 12.5mg.	31-01-2014	Dy. No. 43498 dated 20-12-2018 10000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024
287.	076234	Telsitan-H Forte 25mg Tablet Each tablet contain: Telmisarton 80mg Hydrochlorothiazide ….25mg	31-01-2014	Dy. No. 43498 dated 20-12-2018 10000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024

288.	004413-EX	Silo-Met 50+500mg Tablet Each Tablet Contain: Sitagliptin as phosphate monohydrate…..50mg Metformin HCL…..500mg	19-02-2014	Dy. No. 44119 dated 27-12-2018 10000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
289.	004414-EX	Silo-Met 50+1000mg Tablet Each Tablet Contain: Sitagliptin as phosphate monohydrate…..50mg Metformin HCL..1000mg	19-02-2014	Dy. No. 44119 dated 27-12-2018 10000/-	18-02-2024	w.e.f. 19-02-2019 to 18-02-2024
xlvi.	**M/s. Schazoo Pharmaceutical Laboratories (Pvt) Ltd., Kalalwala Stop, 20-Km Lahore-Jaranwala Road, District Sheikhupura**					
290.	001891-EX	Zyglia 25mg Tablet Each Tablet Contain: Lamotrigine…..25mg	26-12-2013	Dy. No. 42417 dated 12-12-2018 10000/-	25-12-2023	w.e.f. 26-12-2018 to 25-12-2023
291.	001892-EX	Zyglia 50mg Tablet Each Tablet contain: Lamotrigine…..50mg	26-12-2013	Dy. No. 42417 dated 12-12-2018 10000/-	25-12-2023	w.e.f. 26-12-2018 to 25-12-2023
xlvii.	**M/s. Highnoon Laboratories Ltd., 17.5-Km Multan Road, Lahore**					
292.	032076	Floaid 10mg Tablet Each Tablet Contain: 10.4mg Montelukast Sodium eq. to 10mg Montelukast acid	28-01-2004 Change of brand name dated: 14-11-2014	Dy. No. 42787 dated 14-12-2018 10000/-	27-01-2024	w.e.f. 28-01-2019 to 27-01-2024
293.	032075	Floaid 5mg Chewable Tablet Each Tablet Contain: 5.2mg Montelukast Sodium eq. to 5mg Montelukast acid	28-01-2004 Change of brand name dated: 14-11-2014	Dy. No. 42787 dated 14-12-2018 10000/-	27-01-2024	w.e.f. 28-01-2019 to 27-01-2024
294.	032071	Hitrazole Tablet 100mg Each Tablet Contain: Itraconazole….100mg	28-01-2004	Dy. No. 42787 dated 14-12-2018 10000/-		Confirmation of formulation in Reference Regulatory Agencies is required by firm.
295.	032072	Ulsanic suspension 500mg Each 5ml contain: Sucralfate……500mg	28-01-2004	Dy. No. 42787 dated 14-12-2018 10000/-	27-01-2024	w.e.f. 28-01-2019 to 27-01-2024
xlviii.	**M/s. Pearl Pharmaceuticals, Plot No. 204, Street No. 1, I-10/3, Industrial Area, Islamabad**					
296.	054813	Montone Tablets 10mg Each Tablets contain: Montelukast (as sodium)….10mg	15-01-2009	Dy. No. 43811 dated 24-12-2018 10000/-	14-01-2024	w.e.f. 15-01-2019 to 14-01-2024
297.	054828	Pramest Tablet 10mg Each Tablet Contain: Escitalopram (as Oxalate)….10mg	19-01-2009	Dy. No. 43812 dated 24-12-2018 10000/-	18-01-2024	w.e.f. 19-01-2019 to 18-01-2024

298.	054829	Trisone Cream Each gm contains: Fluocinonlone Acetonide…0.01%w/w Hydroquinone…4%w/w Tretinoin……0.05%w/w	19-01-2009	Dy. No. 43812 dated 24-12-2018 10000/-	18-01-2024	w.e.f. 19-01-2019 to 18-01-2024
M/s Getz Pharma (Pvt) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi						
299.	055434	Lizol Tablet 400mg Each tablet contain: Linezolid…..400mg	14-03-2009	Dy. No. 43379 dated 20-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
300.	055439	Lizol Tablet 600mg Each Tablet contain: Linezolid…..600mg	14-03-2009	Dy. No. 43379 dated 20-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
301.	055431	Lizol Infusion 200mg/100ml Each 100ml contain: Linezolid…..200mg	14-03-2009	Dy. No. 43379 dated 20-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
302.	055432	Lizol Infusion 400mg/200ml Each 200ml contain: Linezolid…..400mg	14-03-2009	Dy. No. 43379 dated 20-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024
303.	55433	Lizol Infusion 600mg/300ml Each 300ml contain: Linezolid…..600mg	14-03-2009	Dy. No. 43379 dated 20-12-2018 10000/-	13-03-2024	w.e.f. 14-03-2019 to 13-03-2024

II. 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**
i.	**M/s. Novartis Pharma (Pakistan) Limited, 15 West Wharf, Karachi**						
304.	078112	M/s Novartis Pharma stein AG Stein Switzerland	Signifor 0.3mg Solution for Injection Each ampoule of 1ml contain: Pasireotide 0.3mg	31-01-2014	Dy. No. 43630 dated 21-12-2018 20000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024
305.	078113	M/s Novartis Pharma stein AG Stein Switzerland	Signifor 0.6mg Solution for Injection Each ampoule of 1ml contain: Pasireotide 0.6mg	31-01-2014	Dy. No. 43630 dated 21-12-2018 20000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024
306.	078114	M/s Novartis Pharma stein AG Stein Switzerland	Signifor 0.9mg Solution for Injection Each ampoule of 1ml contain: Pasireotide 0.9mg	31-01-2014	Dy. No. 43630 dated 21-12-2018 20000/-	30-01-2024	w.e.f. 31-01-2019 to 30-01-2024

ii.	**M/s. Zam Zam Corporation, Suite No. 205 & 206, Beaumont Plaza, 6-CL-10 Beaumont Road, Karachi**						
307.	006054	M/s Leo Pharma A/S 55 Industriparken DK 2750 Ballerup Denmark.	One Alpha Capsules Each capsule contains: Alfacalcidol….0.25mcg.	14-04-1994	Dy. No. 43553 dated 21-12-2018 20000/-	13-04-2024	w.e.f. 14-04-2019 to 13-04-2024
308.	007958	M/s Leo Pharma A/S 55 Industriparken DK 2750 Ballerup Denmark.	One Alpha Capsules Each capsule contains: Alfacalcidol….1mcg.	14-04-1994	Dy. No. 43554 dated 21-12-2018 20000/-	13-4-2024	w.e.f. 14-04-2019 to 13-04-2024
iii.	**M/s Allied Distributors Akhai Arcade 1st Floor 103-K PECHS Shahra-e-Quideen Karachi**						
309.	021190	M/s Kyung Dong Pharm Co., Limited , 224-3 Jeyakdanji-ro Yanggam-myeon Hwaseong-si, Gyeonggi-do , Republic of Kora	Broadsaf 250mg IM/IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…250mg	15-10-1998	Dy. No. 22495 dated 28-06-2018 20000/-	14-10-2023	Registration Board acceded to the request of the firm and confirms the receipt of renewal application subject to prevailing Import Policy for Finshed Drugs
310.	021191	-do-	Broadsaf 500mg IM/IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base.500mg	15-10-1998	Dy. No. 22494 dated 28-06-2018 20000/-	14-10-2023	-do-
311.	021192	-do-	Broadsaf 1g IM/IV Injection Each Vial Contains: Ceftriaxone Sodium eq. to Ceftriaxone Sodium Base…1g	15-10-1998	Dy. No. 22496 dated 28-06-2018 20000/-	14-10-2023	-do-
iv.	**M/s. Liakat Pharma, Plot No. 12, Sector-15 Korangi Industrial Area, Karachi**						
312.	031340	M/s Fidia SPA Italy	Hyalgan Pre-filled syringe Each 2ml contains: Hyaluronic Acid Sodium Salt 20mg	10-01-2004	Dy. No. 42984 dated 17-12-2018 10000/-	Deferred for the rectification of following shortcoming : **i)** Drug Sale License (DSL) as the submitted DSL is of Matrix Pharma Pvt Limited Karachi. **ii)** Source of Hyaluronic Acid Sodium Salt. **iii)** Free sale status of	

						product in market. **iv)** CoPP submitted is not as per WHO Format moreover the GMP status is also not mentioned in the submitted CoPP. **v)** Original legalized valid GMP certificate is required as copy is submitted.
v.	**M/s. Hakimsons (Impex) (Pvt) Ltd., Hakimsons Building, 19 West Warf Road, Karachi**					
313.	078107	M/s. Celon Laboratories Limited,Plot No. 2,ALEAP Industrial Estate,Gujlaram aram,Ranga Reddy District,Andhra Pradesh,India	Xelocel-500 Each tablet contain: Capecitabine….500mg	09-01-2014	Dy. No. 43287 dated 19-12-2018 20000/-	Deferred for the rectification of following shortcoming : Valid legalized CoPP/ FSC & GMP issued by the Regulatory Authority of country of origin. Inspection report of manufacturer abroad at the time of registration. Latest DRAP attested import invoice.
vi.	**M/s Medisure Laboratories Pakistan Pvt Limited Karachi**					
314.	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 : i. Approval of formulation in reference drug agencies. ii. Evidence of submission of last renewal. iii. Differential fee as per SRO 1005 (I)/ 2017. iv. Valid legalized CoPP/ FSC and GMP v. Last DRAP attested import invoice. Valid Drug Sale License
315.	014004	M/s Remedica Ahmon 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 : i. Approval of formulation in reference drug agencies. ii. Evidence of submission of last renewal.

						iii. Differential fee as per SRO 1005 (I)/ 2017. iv. Valid legalized CoPP/ FSC and GMP v. Last DRAP attested import invoice. vi. Valid Drug Sale License.
M/s. Zam Zam Corporation, Suite No. 205 & 206, Beaumont Plaza, 6-CL-10 Beaumont Road, Karachi						
316.	005964	**Product** **License Holder:** M/s Leo Pharma A/S 55 Industriparken DK 2750 Ballerup Denmark. **Manufacturer:** M/s Laboratories LEO 39, Route De Chartres 28500Vernouille t France	Fucidin Tablet Contains: Sodium Fusidate Ph.Eur…..250mg	14-04-1994	Dy. No. 39822 dated 3-12-2018 20000/-	Deferred for rectication of shortcomings commincated vide letter dated 17-07-2019. Details are as under: Valid Legalized CoPP as the copy has been submitted. Last DRAP attested import invoice. Address of importer mentioned on registration letter varies from address on the DSL & Form-5B. Approval of change of name of manufacturer as per your letter dated 28-11-2014.
M/s. Ghazali Brothers, 19-SR-7 Campbel Street Azzainab Court Complex, Karachi						
317.	010085	M/s Shanghai Pharmaceutical Industry Corporation China	Dexamethasone Sodium phosphate Injection 4mg Each ml ampoule contain: Dexamethasone sodium phosphate……4mg	12-4-1989 Change of Manufactur er 26-05-1990 Re-Registratio n Dated 02-01-2009	Dy. No. 42261 dated 10-12-2018 20000/-	Deferred for rectication of shortcomings commincated vide letter dated 17-07-2019. Details are as under: Valid legalized CoPP/ FSC and GMP Last DRAP attested import invoice

III. FINISHED IMPORT (VET)

Sr. No	Reg. No.	Manufacturer	Brand Name, Composition	Initial date of Registration	Date of application (R&I) Fee submitted CoPP details	Remarks
i.	**M/s Vet Pharma Trading Company New Steel Market Near Reagent Cinema GT Road Gujranwala**					
318.	049741	M/s KBNP Inc Korea.	Avante Injection Each Vial contains: Ceftiofur (as	18-09-2008	Dy. No. 28525 dated 20-	Deferred for rectication of shortcomings commincated vide letter dated 11-07-

			Ceftiofur Sodium)…1000mg		08-2018 20000/-	2019, details are as under: a) Valid legalized CoPP/ FSC & GMP issued by the Regulatory Authority of country of origin. b) Inspection report of manufacturer abroad at the time of registration. c) Differential fee is required as renewal is submitted after due date but within sixty days for product are Sr. No 590.
319.	052301	M/s KBNP Inc Korea.	Ampros Solution Each Liter Contains: Amprolium…96gm Benzoic Acid…1gm	24-11-2008	Dy. No. 28528 20-8-2018 20000/-	-do-
320.	052302	M/s KBNP Inc Korea.	Estrim-P Water Soluble Powder EACH KG CONTAINS: Erythromycin Thiocyanate…90gm (pot) Sulfadiazine Sodium…75gm Trimethoprim…15gm	24-11-2008	Dy. No. 28528 dated 20-08-2018 20000/-	-do-
ii.	**M/s. International Chempharma (Pakistan), 33-Anarkali, Lahore**					
321.	031514	M/s Bio-Pharmachemic Co., Ltd Vietnam.	Genta-TylosinInj Each ml contain: Tylosin (as tartrate) 100mg. Gentamicin (as Sulphate) 50mg	09-12-2003	Dy. No. 41230 dated 6-12-2018 10000/-	Deferred for rectication of shortcomings commincated vide letter dated 03-07-2019,details are as under: a) Original valid legalized CoPP/ FSC and GMP. b) Address of manufacturer abroad in not mentioned on the copy of registration letter submitted. Copy of approval of import from M/s Franklin Pharmaceuticals Ireland is required. c) Copy of valid Drug Sale License (DSL). d) DRAP attested latest import invoice. e) Copy of inspection of manufacturer abroad for the product at Sr. No 2-4 before the grant

						of registration. f) Address of DSL varies from address on registration letter.
322.	031515	M/s Bio-Pharmachemic Co., Ltd Vietnam.	Bio-Tylo 200 Inj Each ml contain: Tylosin (as tartrate) 200mg	09-12-2003	Dy. No. 41230 6-12-2018 10000/-	-do-
323.	031516	M/s Bio-Pharmachemic Co., Ltd Vietnam.	Bio-Genta 10% Inj Each ml contain: Gentamicin (as Sulphate)	09-12-2003	Dy. No. 41230 6-12-2018 10000/-	-do-
324.	014529	M/s Franklin Pharmaceuticals Ireland.	Prednisolone 2.5% Inj Each Ml contain: Prednisolone acetate 25mg	07-12-1993	Dy. No. 41230 6-12-2018 10000/-	-do-

IV. LOCAL MANUFACTURING (VETERINARY)

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision/ Remarks (if any)
i.	**M/s. Star Laboratories (Pvt.) Ltd. 23 Km, Multan Road (Chung), Lahore**					
325.	022128	Tagafon Powder Each gm contains: Trichlorfon…..950mg Silicon Dioxide…50mg	16-09-1998	Dy. No. 28848 Dated 29-08-2018 10000/-	15-09-2023	w.e.f. 16-09-2018 to 15-09-2023
ii.	**M/s. S.J. & G. Fazul Ellahie Ltd., E/46, S.I.T.E., Karachi**					
326.	022710	Imec Injection Each ml contain: Ivermectin…..10mg/ml	09-02-1999	Dy. No. 44512 dated 31-12-2018 10000/-	08-02-2024	w.e.f. 09-02-2019 to 08-02-2024
iii.	**M/s. PDH Laboratories (Pvt) Ltd., 9.5-Km, Sheikhupura Road, Lahore**					
327.	007217	Polybiotic Injection 5gm Streptomycin Procaine vial Penicillin Inj…5gm	12-12-1983	Dy. No. 39823 dated 3-12-2018 10000/-	11-12-2023	w.e.f. 12-12-2018 to 11-12-2023
iv.	**M/s. Manhattan Pharma, 209/3-B, Sector-5, Korangi Industrial Area, Karachi**					
328.	052364	Pyramin Injection Each ml contain: Quinapyramine Sulphate…30mg Quinapyramine Chloride…20mg	30-12-2008	Dy. No. 41229 dated 6-12-2018 10000/-	29-12-2023	w.e.f. 30-12-2018 to 29-12-2023
329.	052366	Nitronil Injection Each ml contain: Nitroxynil (As N-ethylglucamine salt…340mg)	30-12-2008	Dy. No. 41229 dated 6-12-2018 10000/-	29-12-2023	w.e.f. 30-12-2018 to 29-12-2023
330.	052367	Diclocam injection Each ml contain: Meloxicam….20mg	30-12-2008	Dy. No. 41229 dated 6-12-2018 10000/-	29-12-2023	w.e.f. 30-12-2018 to 29-12-2023
331.	052368	Ivorok- plus Injection Each ml contain: Ivermectin…10mg Clorsulon….100mg	30-12-2008	Dy. No. 41229 dated 6-12-2018 10000/-	29-12-2023	w.e.f. 30-12-2018 to 29-12-2023

332.	052369	Emitryl Forte 20% Injection Each ml contain: Enrofloxacin (As base)	30-12-2008	Dy. No. 41229 dated 6-12-2018 10000/-	29-12-2023	w.e.f. 30-12-2018 to 29-12-2023
v.	**M/s. SB Pharma, Plot No. 5-E, Industrial Triangle, Kahuta Road, Islamabad**					
333.	052381	SB Amoxytin oral powder Each 100gm contain: Amoxicillin Trihydrate eq to e58amoxcillin Base 150g Colistin Sulphate eq. to Colistin base 500MIU	29-12-2008	Dy. No. 44351 dated 28-12-2018 10000/-		Deferred for rectification of shortcomings issued vide letter dated 03-07-2019,details are as under: i. Latest cGMP Inspection Report. ii. Undertakings as mentioned in SOP of renewal iii. Section approval letter for Penicillin issued by Licensing Division
vi.	**M/s. Kailgon Agro Industries (Pvt) Ltd., 849, Pathra RCD Road, Hub Chowki, Balochistan**					
334.	004380 -EX	Trizokail 50 Oral Suspension Each 100ml contain: Triclabendazole..5gm	02-12-2013	Dy. No. 41214 dated 6-12-2018 10000/-		Deferred for rectification of shortcomings issued vide letter dated 30-07-2019,details are as under: a) Valid DML. b) Section approval letter issued by Licensing Division. c) Latest cGMP Inspection Report. d) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. e) 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)**. f) Brief report of last batch manufactured. g) Differential fee is required as the renewal is submitted after due date but within sixty days.
vii.	**M/s. Manhattan Pharma, 209/3-B, Sector-5, Korangi Industrial Area, Karachi**					
335.	052365	Trimoxin Injection Each ml contain: Amoxicillin (As Amoxicillin Trihydrate)….150mg	30-12-2008	Dy. No. 41229 dated 6-12-2018 10000/-		Defferred for issuance of showcause under and section 42 of Drug Act 1976 read with Schedule B-I (5.2) of Drug (LRA) Rules 1976 to the firm regarding manufacturing facility for pencillins.

V. INCOMPLETE CASES OF 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)
i.	**M/s. Mediceena Pharma (Pvt) Ltd., 27-Km Raiwind Road, Lahore**					
336.	051126	Medi-Enam Injection, Each vial contains: Imipenem (as monohydrate)….250mg Cilastatin (as sodium)……...250mg	27-08-2008	Dy. No. 28096dated 17-08-2018 10000/-		Deferred for rectification of shortcomings issued vide letter dated: 12-06-2019 which has not been responded yet. Following are details: a) Section approval letter issued by Licensing Division. b) Latest cGMP Inspection Report. c) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. 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 **(on Stamp Papar)**. e) Brief report of last batch manufactured. f) Evidence of submission of last renewal. g) Description of all applied tablet dosage forms. h) Source of granules for Klaridox Suspension (031168) and in case of imported granules, the differential fee is required.
337.	051127	Bioceena 1gm Injection Each vial contains: Ampicillin (as sodium)……..500mg Cloxacillin (as sodium)……..500mg	27-08-2008	Dy. No. 28083dated 17-08-2018 10000/-		-do-
338.	051128	Bioceena Injection Each Vial Contains: Ampicillin (as sodium) …..125mg Cloxacillin (as sodium) …..125mg	27-08-2008	Dy. No. 28097dated 17-08-2018 10000/-		
339.	051129	Medi-clox Injection Each Vial Contains: Cloxacillin (as sodium) …..250mg	27-08-2008	Dy. No. 28107dated 17-08-2018 10000/-		-do-
340.	051130	Medi-clox Injection Each Vial Contains: Cloxacillin (as sodium) …..500mg	27-08-2008	Dy. No. 28108dated 17-08-2018 10000/-		-do-
341.	051131	Medi-clox Injection Each Vial Contains: Cloxacillin (as sodium) ……1gm	27-08-2008	Dy. No. 28081dated 17-08-2018 10000/-		-do-
342.	051132	Painrest – M Tablets Each tablet contains: Diclofenac sodium ……..50mg Misoprostol…..200mcg	27-08-2008	Dy. No. 28124dated 17-08-2018 10000/-		-do-
343.	051133	Quinocil Tablets Each tablet contains: Levofloxacin (as hemihydrate)…750mg	27-08-2008	Dy. No. 28103dated 17-08-2018 10000/-		-do-
344.	051134	Azimycin Tablets Each tablet contains: Azithromycin (as dihydrate)…..500mg	27-08-2008	Dy. No. 28086dated 17-08-2018 10000/-		-do-

345.	051135	Lincoceena Suspension Each 5ml contains: Lincomycin (as HCl) ……...250mg	27-08-2008	Dy. No. 28098dated 17-08-2018 10000/-		-do-
346.	031151	Xycam 10mg Tablets Each tablet contains: Piroxicam ……10mg	20-08-2003	Dy. No. 28082dated 17-08-2018 10000/-		-do-
347.	031152	Asmarax Tablets Each tablet contains: Ketotifen Fumarate…..1mg	20-08-2003	Dy. No. 28114dated 17-08-2018 10000/-		-do-
348.	031153	Asmarax Syrup Each ml contains: KetotifenFumarate…..0.2mg	20-08-2003	Dy. No. 28113dated 17-08-2018 10000/-		-do-
349.	031154	Painrest Tablet 50mg Each tablet contains: Diclofenac Sodium….50mg	20-08-2003 Change of brand name dated: 06-10-2003	Dy. No. 28122dated 17-08-2018 10000/-		-do-
350.	031155	Painrest-SR Tablet 100mg Each tablet contains: Diclofenac Sodium….100mg	20-08-2003 Change of brand name dated: 06-10-2003	Dy. No. 28123dated 17-08-2018 10000/-		-do-
351.	031156	Zogyl 200mg Tablets Each tablet contains: Metronidazole…….200mg	20-08-2003	Dy. No. 28119dated 17-08-2018 10000/-		-do-
352.	031157	Zogyl 400mg Tablets Each tablet contains: Metronidazole….400mg	20-08-2003	Dy. No. 28120dated 17-08-2018 10000/-		-do-
353.	031158	Zogyl Suspension 200mg Each 5ml contains: Metronidazole (as Benzoate)…200mg	20-08-2003	Dy. No. 28121dated 17-08-2018 10000/-		-do-
354.	031159	Medicoxib 100mg Tablets Each tablet contains: Celecoxib……100mg	20-08-2003	Dy. No. 28090dated 17-08-2018 10000/-		-do-
355.	031160	Erymox Tablets 250mg Each tablet contains: Erythromycin Stearate eq. to Erythromycin…250mg	20-08-2003	Dy. No. 28102dated 17-08-2018 10000/-		-do-
356.	031161	Erymox Tablets 500mg Each tablet contains: Erythromycin Stearate eq. to Erythromycin…500mg	20-08-2003	Dy. No. 28118dated 17-08-2018 10000/-		-do-
357.	031162	Erymox Suspension Each 5ml contains:	20-08-2003	Dy. No. 28117dated		-do-

		Erythromycin Ethyl Succinate eq. to Erythromycin…200mg		17-08-2018 10000/-		
358.	031163	Diloxamet DS Tablets Each tablet contains: Diloxanide Furoate……500mg Metronidazole….400mg	20-08-2003	Dy. No. 28112dated 17-08-2018 10000/-		-do-
359.	031164	Diloxamet Suspension Each 10ml contains: Diloxanide Furoate……250mg Metronidazole (as Benzoate)...200mg	20-08-2003	Dy. No. 28111dated 17-08-2018 10000/-		-do-
360.	031165	P-Floxin Tablets 400mg Each tablet contains: Pefloxacin…..400mg	20-08-2003	Dy. No. 28094dated 17-08-2018 10000/-		-do-
361.	031166	Klaridox Tablets 250mg Each tablet contains: Clarithromycin…250mg	20-08-2003	Dy. No. 28125dated 17-08-2018 10000/-		-do-
362.	031167	Klaridox Tablets 500mg Each tablet contains: Clarithromycin…500mg	20-08-2003	Dy. No. 28126dated 17-08-2018 10000/-		-do-
363.	031168	Klaridox Suspension Each 5ml contains: Clarithromycin…125mg	20-08-2003	Dy. No. 28127dated 17-08-2018 10000/-		-do-
364.	031169	Ciprobact Tablet 250mg Each Tablet contains: Ciprofloxacin….250mg	20-08-2003 Change of brand name dated: 06-10-2003	Dy. No. 28105dated 17-08-2018 10000/-		-do-
365.	031170	Ciprobact Tablet 500mg Each Tablet contains: Ciprofloxacin….500mg	20-08-2003 Change of brand name dated: 06-10-2003	Dy. No. 28106dated 17-08-2018 10000/-		-do-
366.	031171	Wormdox Tablets Each tablet contains: Mebendazole…100mg	20-08-2003	Dy. No. 28115dated 17-08-2018 10000/-		-do-
367.	031172	Wormdox Suspension Each 5ml contains: Mebendazole…100mg	20-08-2003	Dy. No. 28116dated 17-08-2018 10000/-		-do-
368.	031173	Medispan Tablets Each tablet contains: Cefixime……..400mg	20-08-2003	Dy. No. 28110dated 17-08-2018 10000/-		-do-
369.	031174	Medispan Suspension Each 5ml contains: Cefixime……..100mg	20-08-2003	Dy.# 28109 17-8-2018 10000/-		-do-

370.	031175	Bestmox Tablets 10mg Each tablet contains: Ebastine……..10mg	20-08-2003	Dy. No. 28095dated 17-08-2018 10000/-		-do-
371.	031176	Mebcidina Suspension Each 5ml contains: Mebhydrolin (as Napsylate)…….50mg	20-08-2003	Dy. No. 28084dated 17-08-2018 10000/-		-do-
372.	031177	Methacil Tablets Each tablet contains: Indomethacin……25mg	20-08-2003	Dy. No. 28104dated 17-08-2018 10000/-		-do-
373.	031178	Mediflam SR 100mg Tablets Each tablet contains: Diclofenac Potassium……100mg	20-08-2003	Dy. No. 28091dated 17-08-2018 10000/-		-do-
374.	031179	Respilax Tablets 4mg Each tablet contains: Salbutamol (as Sulphate).4mg	20-08-2003	Dy. No. 28100dated 17-08-2018 10000/-		-do-
375.	031180	Oxymed Tablets 250mg Each tablet contains: Oxytetyracycline (HCl)..250mg	20-08-2003	Dy. No. 28088dated 17-08-2018 10000/-		-do-
376.	031181	Ofcil Tablets 200mg Each tablet contains: Ofloxacin…….200mg	20-08-2003	Dy. No. 28089dated 17-08-2018 10000/-		-do-
377.	031182	Clonil Vaginal Tablets 500mg Each tablet contains: Clotrimazole…..500mg	20-08-2003	Dy. No. 28092dated 17-08-2018 10000/-		-do-
378.	031183	Zandin Tablets 2mg Each tablet contains: Tizanidine (as HCl)….2mg	20-08-2003	Dy. No. 28087dated 17-08-2018 10000/-		-do-
379.	031184	Ulceroc Suspension Each 5ml contains: Cimetidine…….200mg	20-08-2003 Change of brand name dated: 06-10-2003	Dy. No. 28099dated 17-08-2018 10000/-		-do-
380.	031185	Baclorax Tablets 10mg Each tablet contains: Baclofen…….10mg	20-08-2003	Dy. No. 28093dated 17-08-2018 10000/-		-do-
381.	031186	Cofcina-D Syrup Each 5ml contains: Dextromethorphan HBr.10mg Chlorpheniramine Maleate…4mg Pseudoephedrine HCl…..5mg Sodium Citrate…150mg	20-08-2003	Dy. No. 28085dated 17-08-2018 10000/-		-do-

382.	031187	Water for Injection Each 5ml contains: Water for injection……5ml	20-08-2003	Dy. No. 28101dated 17-08-2018 10000/-		-do-
ii.	**M/s. English Pharmaceuticals Industries Link Kattar Bund Road, Thokar Niaz Baig, Multan Road, Lahore.**					
383.	014310	Engvit-L Syrup Each 5ml contains: Vitamin B1 HCl….5mg Vitamin B2….1.66mg Vitamin B6 HCl….1mg Vitamin B12….10mcg Nicotinamide…20mg Panthenol….2.5mg Inositol….5mg Lysine Mono HCl…35mg	07-08-1993	Dy. No. 26918 Dated 06-08-2018 10000/-		Deferred for rectification of following shortcomings: a. Approval status of product in Reference Drug Agencies. b. Latest cGMP Inspection Report. c. Brief report of last manufactured batch. d. Copy of Monograph of BP for Diclofenac Potassium Capsule. e. Differential fee required for imported pellets for the regularization of renewal of year 2013 and 2018. a. Approval of the section / manufacturing facility (by Central Licensing Board).
384.	014311	Engpar Elixir Each 5ml contains: Piprazine Citrate equivalent to 750mg Piprazine Hydrate	07-08-1993	Dy. No. 26918 06-8-2018 10000/-		-do-
385.	014312	Panam Syrup Each 5ml contain: Paracetamol…120mg	07-08-1993	Dy. No. 26918 06-8-2018 10000/-		-do-
386.	051172	Engrol 75mg Capsules Each Capsule contains: Diclofenac Potassium…75mg Bulk import of Pellets from M/s. Amoli Organics (Pvt.) Ltd.,407 Dalamal House J.B. Road Nariman Mumbai	02-09-2008	Dy. No. 26919 Dated 06-08-2018 10000/-		-do-
387.	050150	E-Z Capsule 40mg Each Capsule contains: Esomeprazole as Magnesium Trihydrate…40mg Bulk import of Pellets from M/s. Similax Laboratories Ltd. Plot No.44,CIE Gandhi Nagar,Balanagar, Hyderabad, India.	08-08-2008	Dy. No. 26917 Dated 06-8-2018 10000/-		-do-

388.	050151	E-Z Capsule 20mg Each Capsule contains: Esomeprazole as Magnesium Trihydrate…20mg Bulk import of Pellets from M/s. Similax Laboratories Ltd. Plot No.44,CIE Gandhi Nagar,Balanagar, Hyderabad,India	08-08-2008	Dy. No. 26917 Dated 06-8-2018 10000/-		-do-
iii.	**M/s. Medicraft Pharmaceuticals (Pvt.) Limited 126-B,Industrial Estate, Hayatabad, Peshawar**					
389.	022209	Dyrid P Suspension Metronidazole (As Benzoate)….200mg		Dy. No. 26910 Dated 06-8-2018 10000/-		Deferred for rectification of following shortcomings: i. The firm has to submit notarized copy of initial registration letter and to submit original letter through Firm representative which may be returned after verification of date of registration. The firm has gain submitted the same notarized copy from the date of registration is not clear. ii. Change of brand name for Clocit Tablet is not submitted. iii. Evidence of submission of last renewal is not provided. iv. Approval letter of source of pellets for Omed Capsules is not submitted.
390.	022210	Medgel Suspension Each 5ml contains: Basic Aluminium Sucrose sulfate (Sucralfate)….1gm		Dy. No. 26910 Dated 06-8-2018 10000/-		-do-
391.	022211	Medgel 1gm Tablet Each tablet contains: Basic Aluminium Sucrose sulfate (Sucralfate)….1gm		Dy. No. 26910 Dated 06-8-2018 10000/-		-do-
392.	022212	Clocit Tablets 50mg Each tablet contains: Clomiphene Citrate…50mg		Dy. No. 26910 06-8-2018 10000/-		-do-
393.	022213	Omed 20mg Capsule Each capsule contains: Omeprazole ….20mg		Dy. No. 26910 06-8-2018 10000/-		-do-

394.	022214	Motil Suspension Each 5ml contains: Domperidone…5mg		Dy. No. 26910 06-8-2018 10000/-		-do-
395.	022215	Motil Tablet Each tablet contains: Domperidone….10mg		Dy. No. 26910 06-8-2018 10000/-		-do-
iv.	**M/s. Welmark Pharmaceuticals, Plot No. 122, Block-B,Phase-V, Industrial Estate ,Hattar**					
396.	050938	Lidcoron Injection Each 2ml contains: Diclofenac Na….75mg Lidocaine HCl….20mg	05-08-2008	Dy. No. 26358 dated 01-08-2018 10000/-		Deferred for rectification of following shortcomings: i. Evidence of approval of formulation submitted is not traceable.
v.	**M/s. Vega Pharmaceuticals (Pvt) Ltd., 30-Km Multan Road, Lahore**					
397.	077007	V-Es 20 mg Capsule Each delayed release capsule contains: Esomeprazole magnesium Trihydrate enteric coated Pellets 22.5%w/w ≡ Esomeprazole……20mg	29-10-2013	Dy. No. 26921 dated 06-08-2018 10000/-		Deferred for rectification of following shortcomings: i. Approval of source of pellets w.r.t your letter dated 09-03-2015 regarding request of change of source from M/s Spansules Limited India to M/s Vision Pharma.
398.	077008	V-Es 40 mg Capsule Each delayed release capsule contains: Esomeprazole magnesium trihydrateeenteric coated Pellets 22.5%w/w ≡ Esomeprazole……40mg	29-10-2013	Dy. No. 26921 dated 06-08-2018 10000/-		-do-
vi.	**M/s. Medicaids Pakistan (Pvt) Ltd., Plot No. 10, Sector 27, Korangi Industrial Area, Karachi**					
399.	006897	PETACIN TAB EACH TABLET CONTAINS: PENTAZOCINE HCL 25MG,	15-08-1983	Dy. No. 26352 dated 01-08-2018 10000/-		Defferred for rectifcation of following: a) Section approval letter issued by Licensing Division. b) Latest cGMP Inspection Report. c) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. 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 **(on Stamp Papar)**. e) Brief report of last batch manufactured. f) Evidence of submission of last renewal.
400.	014220	Orphagesic-P Tablet Each Tablet Contains: Paracetamol…450mg Orphenadrine Citrate…35mg	05-08-1993	Dy. No. 26353 01-08-2018 10000/-		-do-
vii.	**M/s. Lowitt Pharma (Pvt.) Ltd. Plot No. 24,Industrial Estate, Hayatabad, Peshawar**					
401.	050989	Lowpime Injection 500mg IV/IM. Each vial contains: Cefepime as HCl……500mg	12-08-2008	Dy. No. 26533 dated 01-08-2018 10000/-		Defferred for rectifcation of following: Confirmation of Cephalosporin Injectable section by the firm.
viii.	**M/s. Abbott Laboratories (Pakistan) Ltd., Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, <u>Karachi</u>**					
402.	022352	Arinac Forte Tablet Each Tablet Contains: Ibuprofen……..400mg Pseudoephedrine HCl….60mg	11-09-1998 Transfer of registration dated 19-07-2002 Transfer of registration from Abbott Korangi to Abbott Landhi SITE dated 02-11-2006	Dated 28-08-2018 10000/- Firm submitted evidence of renewal of year 2016 according to the date of transfer of registration		Deferred for submission of renewal for year 2013.
403.	022353	Arinac Suspension Each 5ml Contains: Ibuprofen…….100mg Pseudoephedrine HCl….15mg	11-09-1998 Transfer of registration dated 19-07-2002 Transfer of registration from Abbott Korangi to Abbott Landhi SITE dated 02-11-2006	Dated 28-08-2018 10000/- Firm submitted evidence of renewal of year 2016 according to the date of transfer of registration		-do-
404.	009876	Vidaylin-T Tablet Each Tablet Contains: Vitamin A……...2500IU Vitamin D……..400IU Vitamin E……...15IU	19-09-1988 Change of brand name dated 07-02-2005	Dated 28-08-2018 10000/- Firm submitted		-do-

		Vitamin B1…….1.05mg Vitamin B2……1.2mg Vitamin B12…..4.5mcg Niacinamid…...13.5mg Vitamin C…..60mg Folic Acid…….0.3mg Vitamin B6…..…1.05mg		evidence of renewal of year 2015 according to the date of change of brand name.		
ix.	**M/s. Cherwel Pharmaceuticals (Pvt) Ltd., Plot No. 20, Phase 4, Hattar Industrial Estate, <u>Hattar</u>**					
405.	52805	A-Gic Tablets 10mg Each Tablet Contain: Ebastine…….10mg	17-11-2008	Dy. No. 42553 dated 13-12-2018 10000/-		Deferred for rectification of following: **i)** Valid DML. **ii)** Latest GMP report **iii)** Description of all applied tablet dosage forms. **iv)** Evidence of approval of formulation in reference regulatory agencies for product at Sr. No. 13, **v)** Initial registration letter for product Azitab 250mg Tablet and Myzan 4mg Tablet **vi)** Differential fee is not submitted by the firm as application was submitted after due date but within sixty days.
406.	52806	Trizel Tablet 500mg Each Tablet Contains: Clotrimazole……500mg	17-11-2008	Dy. No. 42550 13-12-2018 10000/-		-do-
407.	52807	Moncher 5mg Tablet Each Tablet Contain: Montelukast Sodium…5mg	17-11-2008	Dy. No. 42561 13-12-2018 10000/-		-do-
408.	52808	Cherofex 120mg Tablet Each tablet contain: Fexofenadine…120mg	17-11-2008	Dy. No. 42560 13-12-2018 10000/-		-do-.
409.	52810	Bewel Tablet 20mg Each Tablet Contain: Piroxicam as Beta cyclodextrin….20mg	17-11-2008	Dy. No. 42565 13-12-2018 10000/-		-do-
410.	54533	Cherdox 100mg Capsule Each capsule Contain: Doxycycline as Hyclate....100mg	17-12-2008	Dy. No. 42557 dated 13-12-2018 10000/-		Deferred for rectification of following: i. Valid DML. ii. Latest GMP report iii. Description of all applied tablet dosage forms. iv. Evidence of approval of formulation in reference regulatory agencies for product at Sr. No. 13, v. Initial registration letter

						for product Azitab 250mg Tablet and Myzan 4mg Tablet
411.	54534	Histawel 10mg Tablet Each Tablet Contain: Loratadine……10mg	17-12-2008	Dy. No. 42554 13-12-2018 10000/-		-do-
412.	54535	Maxolide 150mg Tablet Each Tablet Contain: Roxithromycin…150mg	17-12-2008	Dy. No. 42555 13-12-2018 10000/-		-do-
413.	54536	Azitab 250mg Tablet Each Tablet Contain: Azithromycin Dihydrochloride eq. To Azithromycin....250mg	-Nil-	Dy. No. 42567 13-12-2018 10000/-		-do-
414.	54537	Alena 10mg Each Tablet Contain: Alendronate Sodium equivalent to Alendronic Acid….10mg	17-12-2008	Dy. No. 42556 13-12-2018 10000/-		-do-
415.	54538	Panther 40mg Tablet Each Tablet Contain: Pantoprazole Sodium sesquihydrate 45.1mg eq to Pantoprazole…40mg	17-12-2008	Dy. No. 42558 dated 13-12-2018 10000/-		-do-
416.	54539	Welcam 20mg Tablet Each Tablet Contain: Piroxicam……20mg	17-12-2008	Dy. No. 42549 13-12-2018 10000/-		-do-
417.	54540	Natwel 75mg Tablet Each Tablet Contain: Diclofenac Sodium…75mg	17-12-2008	Dy. No. 42566 dated 13-12-2018 10000/-		Deferred for rectification of following: Evidence of approval of formulation is not provided by the firm instead copy of USP monograph of formulation is submitted.
418.	54541	Twinks 20mg Tablet Each Tablet Contains: Paroxetine…..20mg	17-12-2008	Dy. No. 42563 dated 13-12-2018 10000/-		-do-
419.	54542	Clopigen 75mg Tablet Each Tablet Contain: Clopidogrel (as Bisulphate)….75mg	17-12-2008	Dy. No. 42552 13-12-2018 10000/-		-do-
420.	54543	Nano-Bid 250mg Tablets Each Tablet contain: Levofloxacin…..250mg	17-12-2008	Dy. No. 42564 13-12-2018 10000/-		-do-
421.	54544	Famwel 40mg Each Tablet Contain: Famotidine…..40mg	17-12-2008	Dy. No. 42559 13-12-2018 10000/-		-do-

422.	54558	Myzan 4mg Tablet Each Tablet Contain: Tizanidine 4mg/tab	Change of brand name dated : 16-04-2010	Dy. No. 42562 13-12-2018 10000/-		-do-
423.	54844	C-Zine Tablet 10mg Each Tablet Contain: Cetirizine Dihydrochloride..10mg	26-01-2009	Dy. No. 42551 13-12-2018 10000/-		-do-
x.	**M/s Getz Pharma (Pvt) Ltd., 29-30, Sector-27, Korangi Industrial Area, Karachi**					
424.	047481	Telart Tablet 20mg Each tablet contain: Telmisartan…20mg		Dy. No. 44126 dated 27-12-2018 10000/-		Deferred for rectification/ clarification of following: Firm was advised to submit initial registration letter instead the firm has again submitted the copy of approval of change of brand name for export purpose only dated 07-09-2009 wherein the firm was allowed to use name Telart for export purpose only. The approved name as per said letter is Tasmi for local marketing.
425.	047482	Telart Tablet 40mg Each Tablet Contain: Telmisartan…40mg		Dy. No. 44126 dated 27-12-2018 10000/-		Deferred for rectification/ clarification of following: Firm was advised to submit initial registration letter instead the firm has again submitted the copy of approval of change of brand name for export purpose only dated 07-09-2009 wherein the firm was allowed to use name Telart for export purpose only. The approved name as per said letter is Tasmi for local marketing.
426.	047483	Telart Tablet 80mg Each Tablet Contain: Telmisartan…80mg		Dy. No. 44126 dated 27-12-2018 10000/-		Deferred for rectification/ clarification of following: Firm was advised to submit initial registration letter instead the firm has again submitted the copy of approval of change of brand name for export purpose only dated 07-09-2009 wherein the firm was allowed to use name Telart for export purpose only. The approved name as per said letter is Tasmi for local marketing.
427.	19866	M-Low Tablet Each tablet contain: Amlodipine….10mg	30-06-1997	Dy. No. 43371 20-12-2018 10000/-		Deferred for rectification/ clarification of following: Confirmation of brand name is required.

xi.	**M/s. Libra (Pvt) Ltd., 77, Peshawar Industrial Estate, Hayatabad**					
428.	022905	Clomipril 10mg Each Tablet contain: Clomipramine HCL..10mg	19-12-1998 Change of brand name dated: 13-12-2000	Dy. No. 42299 dated 11-12-2018 10000/-		Deferred for rectification/ clarification of following: Decision of 266th Meeting of CLB Panel has been constituted for inspection and production will remain suspended till recommendation of panel.
429.	022906	Clomipril 25mg Each Tablet contain: Clomipramine HCL..25mg	19-12-1998 Change of brand name dated: 13-12-2000	Dy. No. 42299 11-12-2018 10000/-		-do-
430.	022909	Domipar suspension Each 5ml contain: Domperidone…5mg	19-12-1998 Change of brand name dated: 13-12-2000	Dy. No. 42299 dated 11-12-2018 10000/-		-do-
431.	022908	Domipar Tab Each Tablet contain: Domperidone…10mg	19-12-1998 Change of brand name dated: 13-12-2000	Dy. No. 42299 11-12-2018 10000/-		-do-
432.	022907	Hoff caps Each Capsules contain: Loperamide HCL…2mg	19-12-1998	Dy. No. 42299 dated 11-12-2018 10000/-		-do-
433.	022899	Swint 10mg Tab Each Tablet contain: Amlodipine Besylate..10mg	19-12-1998	Dy. No. 42299 11-12-2018 10000/-		-do-
434.	022898	Swint 5mg Tablet Each Tablet Contain: Amlodipine Besylate..mg	19-12-1998	Dy. No. 42299 11-12-2018 10000/-		-do-
435.	022913	Zag Syrup Each 5ml contain: Ketotifen …1mg	19-12-1998	Dy. No. 42299 11-12-2018 10000/-		-do-
xii.	**M/s. Healer Laboratories (Pvt) Ltd., 96/102C, S.I.T.E., Kohat Road, Peshawar**					
436.	053707	Oneedal Tablet Each Tablet Contain: Paracetamol….500mg Caffeine…….65mg Chlorpheniramine Maleate….2mg	30-12-2008	Dy. No. 43859 24-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 18-07-2019,details are as under: i. Latest GMP report (Inspection report dated 23-10-2018 and Show Cause Notice has been issued) ii. Evidence of submission of last renewal iii.Section approval letter

						issued by Licensing Division
437.	053709	Ramit SR Tablet Each Tablet Contain: Diclofenac Sodium…100mg	30-12-2008	Dy. No. 43859 dated 24-12-2018 10000/-		-do-
438.	053708	Cum-D Tablet Each Tablet Contain: Calcium (as carbonate)……125mg Vitamin D…..500IU	30-12-2008	Dy. No. 43859 dated 24-12-2018 10000/-		-do-
xiii.	**M/s. Shrooq Pharmaceuticals (Pvt) Ltd., 21-km Ferozpur Road, Lahore**					
439.	77076	Dantron Syrup Each 5ml contain: Ondensteron as Hydrochloride..4mg	18-12-2013	Dy. No. 42789 dated 14-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 17-07-2019,details are as under: **i)** Valid DML. **ii)** Approval of section **iii)** Undertakings as mentioned in for renewal.
xiv.	**M/s. Amros Pharmaceuticals, A-96, S.I.T.E., North Karachi**					
440.	022186	Phenobarbitone Injection Each ml contain: Phenobarbitone sodium……200mg	28-11-1998	Dy. No. 43813 dated 24-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 19-07-2019,details are as under: i. Valid DML. ii. Section approval letter for injectable dosage form issued by Licensing Division iii. Section approval letter for psychotropic injectable iv. dosage form issued by Licensing Division v. Brief reports of last batch manufactured. vi. Allocation of last quota for Phenobarbitone by Controlled Drug Division vii. Latest GMP Inspection report iii. Evidence of approval of formulation in reference agencies. ix. Renewal application has submitted late but within 60 days prescribed fee required.
441.	022187	Phenylbutazone Injection Each 1ml contain: Phenylbutazone..200mg	28-11-1998	Dy. No. 43813 dated 24-12-2018 10000/-		-do-

442.	022188	Lignocaine Injection contains: Lignocaine HCL…2% Sodium Chloride…0.6% Methyl hydroxybenzoate B.P 10%	28-11-1998	Dy. No. 43813 dated 24-12-2018 10000/-		-do-
xv.	**M/s. Opal Laboratories (Pvt) Ltd., Lc-41, L.I.T.E. Landhi Karachi**					
443.	032021	Venrith Dry Suspension 125mg Each 5ml Contain: Clarithromycin…125mg	15-01-2004	Dy. No. 44034 dated 27-12-2018 10000/-		Deferred for confirmation source of coated granules of Clarithromycin and in case of imported source fee is required.
xvi.	**M/s.Candid Pharmaceuticals, Opp. Pasrur Sugar Mills Sialkot Road, Pasrur**					
444.	022333	Pepdis Tablets Each Tablet contain: Famotidine USP…40mg	11-09-1998	Dy. No. 43814 24-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 19-07-2019,details are as under: a. Latest GMP inspection report. b. Valid DML.
445.	022336	Napex Tablet Each Tablet contain: Naproxen Sodium..550mg	11-09-1998	Dy. No. 43814 dated 24-12-2018 10000/-		-do-
446.	022337	Flexar Tablets Each Tablet Contain: Orphenadrine Citrate…35mg Paracetamol….450mg	11-09-1998	Dy. No. 43814 dated 24-12-2018 10000/-		-do-
xvii.	**M/s. Munawar Pharma (Pvt) Ltd., 31-Km, Ferozepur Road, Lahore**					
447.	022934	Chloroquine Phosphate 150mg tablet Each tablet contains: Chloroquine Base 150mg	21-12-1998	Dy. No. 42661 dated 13-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 22-07-2019,details are as under: i. Latest cGMP Inspection Report. ii. Undertakings as mentioned in SOP of renewal. iii. Last Renewal iv. Valid DML/evidence of renewal application for renewal of license submitted in DRAP
xviii.	**M/s. Pacific Pharmaceuticals Ltd., 30-Km, Multan Road, Lahore**					
448.	021649	Levopraid Tablet 25mg Each tablet contain: L-Sulpiride… 25.0mg	19-12-1998	Dy. No. 43273 dated 19-12-2018 10000/-		Deferred for following: Differential fee is not submitted by the firm as the application is submitted after due date but within sixty days.
449.	021650	Levopraid tablets 100mg	19-12-1998	Dy. No.		Deferred for following:

		Each talet contain: L-Sulpiride..…100mg		43273 dated 19-12-2018 10000/-		Differential fee is not submitted by the firm as the application is submitted after due date but within sixty days.
450.	001136 -EX	Flamotase Tablet Each Tablet Contain: Trypsin…..1mg Bromelain..…40mg	16-12-2008	Dy. No. 42983 dated 17-12-2018 10000/-		Deferred for following: Differential fee is not submitted by the firm as the application is submitted after due date but within sixty days. The COA submitted by the firm states the source of API is pancreas. Therefore the evaluation of drug substance with respect to its manufacturing requirements and quality control is required.
xix.	**M/s. Lahore Chemical & Pharmaceutical Works Pvt Limited, 137 Ferozpur Road Lahore.**					
451.	022888	Vefradin Capsules 250mg Each capsule contain: Cephradine B.P …. 250mg	18-12-2018	Dy. No. 40481 dated 5-12-2018 10000/-		Deferred for following: As per inspection report dated 26-06-2018 w.r.t. decision of CLB in its 256th meeting the panel has recommended that the production will remain stop in Cephalosporin Capsules and Dry Powder Suspension till the development of Self contained and Segregated facilities.
xx.	**M/s. Medicaids, Plot No. 10, Sector 27, Korangi Industrial Area, Karachi**					
452.	053454	Mediamin Injection Each ml contain: Mecobalamin ….500mcg	17-01-2009	Dy. No. 44432 dated 31-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 11-07-2019,details are as under: a) Section approval letter issued by Licensing Division. b) Latest cGMP Inspection Report. c) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. 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 **(on Stamp Papar)**. e) Brief report of last batch manufactured.

453.	053455	Arteblax Injection Each ml contain: Artemether….80mg	17-01-2009	Dy. No. 44430 31-12-2018 10000/-		-do-
454.	053456	Dart Injection Each 2ml contain: Ranitidine…..50mg	17-01-2009	Dy. No. 44431 31-12-2018 10000/-		-do-
xxi.	**M/s. Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar**					
455.	078437	Invocet 5mg Tablet Each film coated tablet Contain: Levocetirizine……5mg	05-03-2014	Dy. No. 42777 14-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 22-07-2019,details are as under: a) Evidence of approval of formulation in reference drug agencies for products having reg. no. 078437,056124,054524,054525,054526. b) Approval of source of pellets for product at sr.no.259-263 c) Evidence of submission of last renewal for product having reg.no. 056124,054524,054525
456.	056124	Volfenac SR 100mg Capsules Each Capsules Contain: Diclofenac Sodium……..100mg Source: M/s Spansule formulations India.	07-03-2009	Dy. No. 42778 dated 14-12-2018 10000/-		-do-
457.	054524	Volfenac 50mg Capsules Each capsule contain: Diclofenac sodium….50mg Source: M/s Vision Pharma Islamabad.	17-12-2008	Dy. No. 40470 dated 5-12-2018 10000/-		-do-
458.	054525	Volfenac 75mg Capsules Each Capsules contain: Diclofenac Sodium….75mg Source: M/s Spansule formulations India.	17-12-2008	Dy. No. 40471 dated 5-12-2018 20000/-		-do-
459.	054526	Ariflam 50mg Capsules Each capsule contains: Diclofenac Potassium….50mg Source: M/s Vision Pharma Islamabad.	17-12-2008 Change of brand name dated: 01-11-2012	Dy. No. 40466 dated 5-12-2018 10000/-		-do-
460.	054527	Ariflam 75mg Capsules Each Capsules contain: Diclofenac	17-12-2008 Change of	Dy. No. 40467 dated 5-12-		-do-

		Potassium…..75mg Source: M/s Spansule formulations India.	brand name dated: 01-11-2012	2018 20000/-		
461.	054528	Esox 20mg Capsules Each capsule contain: Esomeprazole….20mg	17-12-2008	Dy. No. 40468 5-12-2018 20000/-		-do-
462.	054529	Esox 40mg Tablet Each capsules contain: Esomeprazole….40mg	17-12-2008	Dy. No. 40469 5-12-2018 20000/-		-do-
463.	054530	Omec 20mg Capsules Each capsules contain: Omeprazole Delayed Released Enteric Coated Pellets eq. to Omeprazole…20mg	17-12-2008	Dy. No. 40464 5-12-2018 20000/-		-do-
464.	054531	Losin 30mg Capsules Each capsule contain: Lansoprazole ….30mg	17-12-2008	Dy. No. 40465 5-12-2018 20000/-		-do-
465.	054532	Aptec 40mg Capsules Each Capsule contain: Pantoprazole coated pellets equivalent to Pantoprazole ….40mg	17-12-2008	Dy. No. 40461 dated 5-12-2018 20000/-		-do-
466.	054845	Flutix 20mg Capsule Each Capsule Contain: Fluoxetine hydrochloride equivalent to Fluoxetine…..20mg	23-01-2009	Dy. No. 42776 dated 14-12-2018 10000/-		-do-
467.	053795	Acifix 20mg Tablet Each Enteric Coated Tablet contain: Rabeprazole Sodium….20mg	17-12-2008	Dy. No. 40462 dated 5-12-2018 10000/-		-do-
468.	053796	Trican 150mg Capsules Each capsules contain: Fluconazole….150mg	17-12-2008	Dy. No. 40463 5-12-2018 10000/-		-do-
xxii.	**M/s. English Pharmaceutical Industries, Link Kattar Bund Road, ThokarNiazBaig, Multan Road, Lahore**					
469.	022926	Cartac 50mg tablet Each tablet contains: Atenolol ..50mg	19-12-1998	Dy. No. 42569 dated 13-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 22-07-2019,details are as under: a) Latest GMP inspection report b) 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
470.	022927	Cartac 100mg tablet Each tablet contains: Atenolol…...100mg	19-12-1998	Dy. No. 42569 13-12-2018 10000/-		-do-
471.	022928	Ardi-75 Tablet Each tablet contains: Diclofenac Sodium 75mg	19-12-1998	Dy. No. 42569 13-12-2018 10000/-		-do-
472.	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 13-12-2018 10000/-		-do-
473.	022930	Cezen Tablets Each tablet contains: Cetrizine Dihydrochloride 10mg	19-12-1998	Dy. No. 42569 13-12-2018 10000/-		-do-
474.	022931	F-100 Tablet Each tablet contains: Flurbiprofen 100mg	19-12-1998 Change of brand name dated 06-07-1999	Dy. No. 42569 13-12-2018 10000/-		-do-
xxiii.	**M/s. Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi**					
475.	032201	Fosoril Capsules Each Capsules contain: Fosfomycin (as calcium salt….500mg)	27-02-2004 Change of brand name dated 29-06-2004	Dy. No. 43815 dated 24-12-2018 10000/-		Deferred for following: Evidence of formulation provided is not traceable.
476.	032202	Fosoril suspension Each 5ml contain: Fosfomycin (as calcium salt….250mg	27-02-2004 Change of brand name dated 29-06-2004	Dy. No. 43815 dated 24-12-2018 10000/-		Deferred for following: Evidence of formulation provided is not traceable.
477.	032205	Pericort Skin Ointment Each gram contain: Polymyxin B sulphate.8000I.U Bacitracin Zinc…..500I.U Neomycin (as neomycin sulphate)..3.0mg Lidocaine (As lidocaine HCL)….40mg	27-02-2004	Dy. No. 43815 dated 24-12-2018 10000/-		Deferred for following: Evidence of approved formulation in same strength is required as the evidence submitted does not indicate the same
478.	032210	Hyocort Cream Each 100gm contain: Hydrocortisone Acetate….1.0mg	27-02-2004	Dy. No. 43815 dated 24-12-2018		Deferred for following: Evidence of approved formulation in same strength is required as the evidence

				10000/-		submitted does not indicate the same
xxiv. **M/s. Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, ThokarNiazBaig, Multan Road, Lahore**						
479.	054564	Festpram 10mg Tablet Each Tablet contain: Escitalopram (as HBr)……10mg	16-12-2008	Dy. No. 42278 dated 10-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 22-07-2019,details are as under: a) Latest GMP inspection report
480.	054565	Moxifest 400mg Tablet Each Tablet contain: Moxifloxacin (as HCL)…..400mg	16-12-2008	Dy. No. 42278 dated 10-12-2018 10000/-		-do-
481.	054566	Asthlu 10mg Tablet Each Tablet contain: Montelukast (as Sodium)…10mg	16-12-2008	Dy. No. 42278 10-12-2018 10000/-		-do-
482.	054567	Feflam 50mg Tablet Each Tablet contain: Diclofenac Potassium….50mg	16-12-2008	Dy. No. 42278 10-12-2018 10000/-		-do-
483.	054568	Sulpril 25mg Tablet Each Tablet contain: Levosulpride…25mg	16-12-2008 Change of brand name dated: 13-07-2015	Dy. No. 42278 dated 10-12-2018 10000/-		-do-
xxv. **M/s. Bio Fine Pharmaceuticals 74 Industrial Estate , Multan**						
484.	031952	Fruit Fawar Sachet Each Sachet (5gm) contain: Sod. Bicarbonate…2.8gm Tartaric Acid…1.33gm Citric Acid….0.82gm	Nil	Dy. No. 42259 10-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 22-07-2019,details are as under: a) Latest GMP inspection report. b) Valid DML c) Section approval letter issued by Licensing Division. d) Brief report of last batch manufactured. e) Undertakings as required under SOP of renewal of registration.
485.	031951	Povisol Vaginal Douches Each 100ml Contains: Povidone Iodine (10%)..10gm	Nil	Dy. No. 42258 dated 10-12-2018 10000/-		-do-
486.	031949	Povisol Solution Each 100ml contain: Povidone –Iodine (10%)…10gm	Nil	Dy. No. 42257 10-12-2018 10000/-		-do-

487.	031950	Povisol Surgical Scrub Each 100ml contain: Povidone-Iodine (7.5%)…7.5mg	Nil	Dy. No. 42260 10-12-2018 10000/-		-do-
xxvi.	**M/s. Medisure Laboratories Pakistan (Pvt) Ltd., A-115, S.I.T.E, Super Highway, Karachi**					
488.	076193	Trankilium 250mg Injection Each 5ml contain: Tranexamic Acid…250mg	29-01-2014	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: Evidence of approval of formulation in reference agencies.
489.	076194	Trankilium 500mg Injection Each 5ml contain: Tranexamic Acid…500mg	29-01-2014	Dy. No. 44594 31-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Evidence of approval of formulation in reference agencies.
490.	076147	Suregine Oral Solution Each ml contain: Co-degrocrine mesylate……1mg	06-01-2014	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: Evidence of approval of formulation in reference agencies.
491.	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.
492.	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.
493.	031747	Sulvo Tablet 25mg Each Tablet Contain: Levosulpiride….25mg	13-11-2003	Dy. No. 42662 dated 13-		Deferred for rectification/ clarification of shortcomings communicated vide letter

				12-2018 10000/-		dated 23-07-2019,details are as under: i. Differential fee required as renewal application is submitted after due date. ii. Section approval letter issued by Licensing Division.
494.	031748	Sulvo Tablet 50mg Each Tablet Contain: Levosulpiride….50mg	13-11-2003	Dy. No. 42662 13-12-2018 10000/-		-do-
495.	031749	Sulvo Tablet 100mg Each Tablet Contain: Levosulpiride…..100mg	13-11-2003	Dy. No. 42662 13-12-2018 10000/-		-do-
496.	031750	Faclo Tablet 135mg Each Tablet Contain: Mebeverine HCL BP…..135mg	13-11-2003	Dy. No. 42662 13-12-2018 10000/-		-do-
497.	022547	Nidol Granules 100mg Sachet Each 100mg Sachet contain: Nimesulide….100gm	28-11-1998	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: Approval of formulation in RRA. Differential fee Legible and complete copy of registration letter
498.	022546	Nidol Tablet 0.100g Each Tablet contain: Nimesulide ….0.100gm	28-11-1998	Dy. No. 42662 13-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Approval of formulation in RRA. Differential fee Legible and complete copy of registration letter
xxvii.	**M/s. Zephyr Pharmatec (Pvt) Ltd., A-39, S.I.T.E. II, Super Highway, Karachi**					
499.	055013	Nyloz 20mg Capsule Each Capsules contain: Esomeprazole (as pellets)…20mg M.s Meenaxy Pharma Pvt limited, 5 Phase TLE Balanagar Hyderabad.	13-01-2009	Dy. No. 44593 dated 31-12-2018 20000/-		Deferred for following: Evidence of submission of renewal fee of imported pellets for year 2014.
500.	055014	Nyloz 40mg Capsules Each Capsules contain: Esomeprazole (as pellets)…40mg	13-01-2009	Dy. No. 44593 dated 31-12-2018		Deferred for following: Evidence of submission of renewal fee of imported pellets for year 2014.

		M.s Meenaxy Pharma Pvt limited, 5 Phase TLE Balanagar Hyderabad.		20000/-		
xxviii.	**M/s. Neomedix, Plot No. 05, N/5, National Industrial Zone, Islamabad**					
501.	054629	E-Therol 200mg Capsules Each Capsules Contain: Alpha Tocopherol acetate (Vitamin E)….200mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Evidence of approval of formulation in reference drug agencies.
502.	054630	E-Therol 400mg Capsules Each Capsules Contain: Alpha Tocopherol acetate (Vitamin E)….400mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Evidence of approval of formulation in reference drug agencies.
503.	054631	E-Therol 600mg Capsules Each Capsules Contain: Alpha Tocopherol acetate (Vitamin E)….600mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Evidence of approval of formulation in reference drug agencies.
504.	054632	Azifine 250mg Capsules Each Capsules Contain: Azithromycin (as dehydrate)…250mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Evidence of approval of formulation in reference drug agencies.
505.	054633	Transadix 250mg Capsules Each Capsules Contain: Tranexamic Acid….250mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Evidence of approval of formulation in reference drug agencies.
506.	054634	Transadix 500mg Capsules Each Capsules Contain: Tranexamic Acid….500mg	24-12-2008	Dy. No. 42987 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Evidence of approval of formulation in reference drug agencies.
507.	054781	Neomep 20mg Capsule Each Capsules Contain:	02-01-2009	Dy. No. 44163		Deferred for rectification/ clarification of shortcomings

		Omeprazole (Pellets)…..20mg		dated 28-12-2018 10000/-		communicated vide letter dated 23-07-2019,details are as under: Approval of source of pellets and in case of imported pellets differential fee for the year 2014 and 2019.
508.	054782	Neomep 40mg Capsule Each Capsules contain: Omeprazole (Pellets)..40mg	02-01-2009	Dy. No. 44163 28-12-2018 10000/-		-do-
509.	054783	Esofix 20mg Capsule Each Capsules Contain: Esomeprazole as Magnesium trihydrate (Pellets) equivalent to Esomeprazole…20mg	02-01-2009	Dy. No. 44163 28-12-2018 10000/-		-do-
510.	054784	Esofix 40mg Capsule Each Capsules contain: Esomeprazole as Magnesium trihydrate (Pellets) equivalent to Esomeprazole…40mg	02-01-2009	Dy. No. 44163 28-12-2018 10000/-		-do-
511.	054785	Neolans 30mg Capsule Each Capsules contain: Lansoprazole as enteric coated pellets equivalent to Lansoprazole…30mg	02-01-2009	Dy. No. 44163 dated 28-12-2018 10000/-		-do-
xxix.	**M/s. Scotmann Pharmaceuticals, Plot No. 05-D, Sector I-10/3, Industrial Area, Islamabad**					
512.	054751	Dostax Capsules 30mg Each Capsules Contain: Duloxetine (as HCL) Enteric Coated Pellets…30mg M/s Mack & Co., GmbH Bahnhofstrasse Rotenburg Germany	01-01-2009	Dy. No. 39825 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 23-07-2019,details are as under: Differential fee is required for the year 2014 & 2019 as the product is imported pellets.
513.	054752	Dostax Capsules 60mg Each Capsules Contain: Duloxetine (as HCL) Enteric Coated Pellets…60mg M/s Mack & Co., GmbH Bahnhofstrasse Rotenburg Germany	01-01-2009	Dy. No. 39825 3-12-2018 10000/-		-do-
514.	054750	Dune Sachet 4mg Each Tablet contain: Montelukast as sodium…..4mg	01-01-2009	Dy. No. 39825 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: Section approval letter issued by Licensing Division.
xxx.	**M/s. Micko Industrial Chemicals Co. (Pvt) Ltd., 28-Km Ferozepur Road, Lahore**					
515.	022935	Povidin Scrub Each 100ml Contains:	01-12-1998	Dy. No. 39824		Deferred for rectification/ clarification of shortcomings

		PovidoneLodine 7.5gm eq 0.75%		dated 3-12-2018 10000/-		communicated vide letter dated 24-07-2019,details are as under: i. Copy of registration letter submitted does not bear the date of issuance. ii. Valid DML iii. Latest GMP report iv. Section approval letter issued by Licensing Division v. Brief details of last batch manufactured vi. Evidence of approval of formulation in reference drug agencies.
516.	022936	Lactinex HC Lotion Each HC Lotion: Hydrocortisone…25gm	01-12-1998	Dy. No. 39824 3-12-2018 10000/-		-do-
517.	022937	Veracort Cream Contains: Econazole nitrate…1%	01-12-1998	Dy. No. 39824 3-12-2018 10000/-		-do-
518.	022938	Fongifix Solutoin . Shampoo Contains: Tarextract in Archis oil. 1%w/w Pyrithione Zinc…1%w/w Oleyl alcohol…1%w/w	01-12-1998	Dy. No. 39824 3-12-2018 10000/-		-do-
519.	022939	Oxytal Emollient Contains: Tarext in Archis oil..25% light liquid Paraffin B.P.35%	01-12-1998	Dy. No. 39824 dated 3-12-2018 10000/-		-do-
520.	022940	Nixdermal Cram Contains: Permethrin…5%w/w	01-12-1998	Dy. No. 39824 3-12-2018 10000/-		-do-
xxxi. **M/s. Mass Pharma (Pvt) Ltd., 17-Km, Ferozpur Road, Lahore**						
521.	022392	Maclexin Drops 125mg Each 1.25ml Contains: Cephalexin Micronized B.P…..125mg	18-12-1998	Dy. No. 42986 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division.
522.	022868	Clintol Tablet 10mg Each Tablet Contain: Loratadine……10mg	18-12-1998	Dy.# 42986 17-12-2018 10000/-		-do-

523.	022869	Bioplus-C Tablet Each Tablet contain: Betacarotone….9mg Vitamin E…..100mg Vitamin C…500mg Zinc…..10mg Selenium…….0.02mg	18-12-1998	Dy. No. 42986 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Evidence of approval of formulation in reference drug agencies.
524.	022870	Flute Capsule 20mg Each Capsule Contain: Fluoxetine HCL….20mg	18-12-1998	Dy. No. 42986 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division.
525.	046362	Enclot Tablet 75mg Each Tablet Contain: Clopidogrel (as hydrogen sulphate)……75mg	13-06-2007 Change of brand name dated: 04-01-2010	Dy. No. 42986 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division.
526.	030869	Lotrigen Cream Contain: Clotrimazole……1%	16-08-2003 Change of brand name dated: 11-01-2004	Dy. No. 42986 dated 17-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division.
527.	030867	Mecare-C Cream Contain: Isoconzaole Nitrate….1%	16-08-2003	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee

						required under SRO 1005 (I)/ 2017 as the application received after 60 days.
528.	030868	Mecare Pessaries 300mg Each Pessaries contains: Isoconazole Nitrate…300mg	16-08-2003	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. ii. Differential fee required under SRO 1005 (I)/ 2017 as the application received after 60 days.
529.	030874	Azelaxin Cream Contain: Azelaic Acid..20%	16-08-2003	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee required under SRO 1005 (I)/ 2017 as the application received after 60 days.
530.	035720	Xamogine Tablet 50mg Each Tablet Contain: Lamotrigine….50mg	31-12-2004 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.
531.	035739	Xaslexx Tablet SR 75mg Each Tablet contain: Bupropion HCL…75mg	31-12-2004 Change of brand name	Dy. No. 39828 dated 3-12-2018		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are

			dated: 26-08-2013	10000/-		as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.
532.	035740	Xaslexx Tablet SR 150mg Each Tablet Contain: Bupropion HCL…150mg	31-12-2004 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.
533.	035741	XprodineInjeciton 10mg Each 2ml ampoule contain.: Procyclidine HCL…10mg	31-12-2004 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.
534.	036190	Xaspine Tablet 100mg Each film coated tablet contain: Quetiapime (as Furnarate)…100mg	31-12-2004 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance

						with initial registration date.
535.	040700	Xantol Tablet 10mg Each Tablet Contain: Memantine HCL…10mg	08-07-2005 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.
536.	041646	Xaspine Tablet 25mg Each Tablet Contain: Quetiapine (as Fumarate)…..25mg	21-11-2005 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.
537.	041647	Xexor SR Tablet 75mg Each Tablet Contain: Venlafaxine (as Hydrochloride)…..75mg	21-11-2005 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.

538.	041648	Xastrin Tablet 100mg Each Tablet Contain: Sertraline (as HCL)….100mg	21-11-2005 Change of brand name dated: 26-08-2013	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. Differential fee required under SRO 1005 (I)/ 2017 **OR** evidence of submission of renewal of 2014 in accordance with initial registration date.
539.	051155	Letirizine Tablet 5mg Each film coated tablet contain: Levocetirizine Dihydrochloride…5mg	01-09-2008	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee required under SRO 1005 (I)/ 2017 as the application received after 60 days.
540.	051156	Xaspine Tablet 300mg Each Tablet contain: Quetiapine (as Fumarate)….300mg	01-09-2008 Change of brand name dated: 13-06-2014.	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division. iii. Differential fee required under SRO 1005 (I)/ 2017 as the application received after 60 days.
541.	051158	Zilify Tablet 10mg Each Tablet contain: Aripiprazole….10mg	01-09-2008	Dy. No. 39828 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report. ii. Section approval letter issued by Licensing Division.

						iii. Differential fee required under SRO 1005 (I)/ 2017 as the application received after 60 days.
xxxii. **M/s. EPLA Laboratories (Pvt) Ltd., D-12, Estate Avenue, S.I.T.E., Karachi**						
542.	053408	Gliguard M1 Tablet Each tablet contain: Metformin HCL…500mg Glimepiride….1.0mg	22-12-2008	Dy. No. 43282 dated 19-12-2018 10000/-		Deferred for statsus of show cause notice has been issued by the concerned section regarding cancellation of registration of said formulation to M/s Sanofi Aventis Karachi.
543.	053409	Gliguard 3mg Tablet Each Tablet contain: Glimepiride…3mg	22-12-2008	Dy. No. 43283 dated 19-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report.
544.	053410	Gliguard 4mg Tablet Each Tablet contain: Glimepiride….4mg	22-12-2008	Dy. No. 43284 dated 19-12-2018 10000/-		-do-
545.	053411	Azocin 250mg Capsules Each Capsule contain: Azithromycin (as Dihydrate)	22-12-2008	Dy. No. 43285 dated 19-12-2018 10000/-		-do-
546.	053412	Azocin 200mg/5ml Dry Suspension Each 5ml contain: Azithromycin (as Dihydrate)…..200mg	22-12-2008	Dy. No. 43286 dated 19-12-2018 10000/-		-do-
xxxiii. **M/s. Dyson Research Laboratories (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore**						
547.	078837	Apollo Tablet 10mg Each film coated tablet contains: Rosuvastatin (as calcium)….10mg	31-12-2013	Dy. No. 39839 dated 4-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: i. Latest GMP inspection report ii. You are also advised produce Original Registration Letter through your authorized representative which shall be returned after verification.
548.	078840	Timzi Tablet 4mg Each Tablet contain: Tizanidine (as HCL)…..4mg	31-12-2013	Dy.# 39839 4-12-2018 10000/-		-do-

549.	078839	Gencox Tablet 60mg Each film coated tablet contain: Etoricoxib…..60mg	31-12-2013	Dy. No. 39839 4-12-2018 10000/-		-do-
550.	078841	Limi Tablet 2/500mg Each film coated tablet contain: Glimepride…..2mg Metformin Hydrochloride…500mg	31-12-2013	Dy. No. 39839 dated 4-12-2018 10000/-		-do-
551.	078843	Limi Tablet 1/500mg Each film coated tablet contain: Glimepride…..1mg Metformin Hydrochloride…500mg	31-12-2013	Dy. No. 39839 4-12-2018 10000/-		-do-
552.	078847	Apollo Tablet 20mg Each film coated tablet contain: Rosuvastatin (as Calcium)..…20mg	31-12-2013	Dy. No. 39839 4-12-2018 10000/-		-do-
553.	078848	Rabicol Tablet 20mg Each enteric coated tablet contains: Rabeprazole as sodium……20mg	31-12-2013	Dy. No. 39839 dated 4-12-2018 10000/-		-do-
554.	078845	Apollo Tablet 5mg Each film coated tablet contain: Rosuvastatin (as Calcium)..…5mg	31-12-2013	Dy. No. 39839 dated 4-12-2018 10000/-		-do-
555.	078851	Duodil Tablet 20mg Each Tablet contain: Nicorandil…..20mg	31-12-2013	Dy. No. 39839 4-12-2018 10000/-		-do-
556.	078849	Gluchk Tablet 850mg Each film coated tablet contain: Metformin HCL….850mg	31-12-2013	Dy. No. 39839 dated 4-12-2018 10000/-		-do-
557.	078844	Bacnor Tablet 400mg Each film coated tablet contain: Norfloxacin….400mg	31-12-2013	Dy. No. 39839 4-12-2018 10000/-		-do-
558.	078838	Atorex-E Tablet Each Tablet contain: Atorvastatin (as calcium)…10mg	31-12-2013	Dy. No. 39839 4-12-2018 10000/-		-do-
xxxiv.	**M/s. Hilton Pharma (Pvt) Ltd., Plot No. 13-14, Sector 15, Korangi Industrial Area, Karachi**					
559.	015103	Enterocin Dry suspension Each gm contain: Colistin Sulphate….1 M.U	27-02-1994	Dy. No. 39829 dated 3-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 24-07-2019,details are as under: Evidence of approval of

						formulation of formulation in reference drug agencies.
xxxv.	**M/s. Karachi Pharmaceutical Laboratories, S-54 Maripur Road, S.I.T.E., Karachi**					
560.	007034	Chlorpheniramine Maleate Syrup 2mg/ 5ml	09-01-1984	Dy. No. 41223 dated 6-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: a) Valid DML. b) Evidence of submission of last renewal. c) Section approval letter issued by Licensing Division esp. for product at Sr. No. 5 being steroidal dosage form. d) Latest cGMP Inspection Report. e) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. f) 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)**. g) Brief report of last batch manufactured. h) Differential fee for the product at Sr. No.480 due to imported source of pellets. i) Evidence of approval of formulation in reference agencies.
561.	007035	Methagan Elixir Promethazine Elixir 5mg/ 5ml	09-01-1984 Change of brand name 17-5-1993	Dy.# 41218 6-12-2018 10000/-		-do-
562.	007050	Pexocitral Syrup Sodium Acid Citrate Syrup 1.25gm/ 5ml	09-01-1984 Change of brand name 25-10-1984	Dy. No. 41220 6-12-2018 10000/-		-do-
563.	007051	Sulphatran Tablet Each tablet contains: Sulphamethoxazole ….400mg Trimethoprim…..80mg	09-01-1984	Dy. No. 41224 6-12-2018 10000/-		-do-

564.	007091	Prednisolone Tablet 5mg	16-01-1984	Dy. No. 41222 6-12-2018 10000/-		-do-
565.	007253	Hydrogen Peroxide Solution 6% w/v	15-02-1984	Dy. No. 41219 6-12-2018 10000/-		-do-
566.	055016	Pastrazole Capsules Each Tablet contain: Lansoprazole (as Pellets) ….30mg **Source**: M/s Titan Laboratories Pvt Limited, Mumbai India	15-01-2009	Dy. No. 41221 6-12-2018 10000/-		-do-
xxxvi.	**M/s. Shaheen Pharmaceuticals, 3-Km Murghzar Road, Saidu Sharif , Swat (KPK)**					
567.	054626	Shavozin 5mg Tablet Each Tablet contain: Levocetirizine Dihydrochloride….5mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		Deferred for following: Differential fee for the year 2013 has not been submitted as the renewal application of year 2013 has been received but within 60 days.
568.	054617	Flucosh capsules Each Capsules Contain: Fluconazole…150mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
569.	054618	Clarish 500mg tablet Each Tablet contain: Clarithromycin…500mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
570.	054621	Olox Tablets Each Tablet contain: Ofloxacin….200mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
571.	054619	Batin 100mg Tablet Each Tablet Contain: Gabapentin….100mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
572.	054620	Batin 300mg Tablet Each Tablet contain: Gabapentin….300mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
573.	054622	Alfadal Tablet Each Tablet contain: Alfacalcidol (Vitamin D analogue)…0.5mcg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
574.	054623	Tapzol Tablets Each Tablet contain: Pantoprazole sodium sesquihydrate equivalent to Pantoprazole…40mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
575.	054624	Shoride 50mg Tablets Each Tablet contain: Itopride HCL eq. to Itopride…50mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-

576.	054625	Lacenac 100mg Tablet Each Tablet contain: Aceclofenac….100mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
577.	054627	Depgo 10mg Each Tablet contain: Escitalopram Oxalate equivalent to Escitalopram…10mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
578.	054628	Spanor 80mg Tablets Each Tablet contain: Drotaverine HCL……80mg	24-12-2008	Dy. No. 41231 6-12-2018 10000/-		-do-
579.	054852	Persolon 60ml Syrup Prednisolone….15mg/5 ml	Nil	Dy. No. 1252 dated 10-1-2019 10000/-		Deferred for following: Section approval letter is not submitted for steroid oral liquid formulation. Inspection report submitted does not indicate aforesaid manufacturing facility. The registration may be suspended till clarification from the firm.
xxxvii.	**M/s. PharmaWise Labs. (Pvt) Ltd., 25-M Industrial Estate KotLakhpat, Lahore**					
580.	022808	Rifacin 300mgs Each tablet contain: Rifampicin….300mg	08-12-1998	Dy. No. 41228 dated 6-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: a) Valid DML. b) Evidence of submission of last renewal. c) Section approval letter issued by Licensing Division d) Latest cGMP Inspection Report. e) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. f) 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)**. g) Brief report of last batch manufactured. h) Transfer of registration in name of M/s PharmaWise

						Labs to M/s Fakma Pharma Lahore.
xxxviii.	**M/s. Pliva Pakistan (Pvt) Ltd., Plot No. B-77, Hub Industrial Trading Estate Hub, Balochistan**					
581.	050380	Plimaltos Tablet Each Tablet Contain: Iron(III) Hydroxide Polymaltose Complex eq.to Elemental Iron…100mg	23-12-2008	Dy. No. 42980 dated 17-12-2018 10000/-		Deferred for confirmation of submission of last renewal as last Renewal application was submitted through TCS.
582.	050381	Plimaltos-F Tablets Each Tablet Contain: Iron(III) Hydroxide Polymaltose Complex eq.to Elemental Iron…100mg Folic Acid……0.35mg	23-12-2008	Dy. No. 42980 dated 17-12-2018 10000/-		-do-
583.	050382	Plimaltos Syrup Each 5ml Contain: Iron(III) Hydroxide Polymaltose Complex eq.to Elemental Iron…50mg	23-12-2008	Dy. No. 42980 dated 17-12-2018 10000/-		-do-
xxxix.	**M/s. MBL Pharma, Plot No. B-77/A, Hub Industrial Trading Estate, Balochistan**					
584.	053457	Betamethasone Eye Ear Drops Each ml contain: Betamethasone sodium Phosphate…….0.1%	17-01-2009	Dy. No. 44437 dated 31-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: Latest GMP inspection report Valid DML
585.	053458	Betamethasone N Eye Ear Drops Each ml contain: Betamethasone Sodium Phosphate……0.1%w/v Neomycin Sulphate…….0.5% w/v	17-01-2009	Dy. No. 44437 dated 31-12-2018 10000/-		-do-
586.	055083	Justopain 10mg Tablet Each Tablet contain: Hyoscine-N-Butyl bromide….10mg	14-02-2009	Dy. No. 44436 31-12-2018 10000/-		-do-
587.	055084	Justopain 20mg/ml Injection Each ml contain: Hyoscine-N-Butyl bromide…20mg	14-02-2009	Dy. No. 44436 dated 31-12-2018 10000/-		-do-
xl.	**M/s. Novins International (Pvt) Ltd., Plot No. E-37&38, Port Qasim Authority, Karachi**					
588.	053360	Alfuprozin SR 5mg Tablet Each Tablet Contains: Alfuzosin HCL……5mg	16-12-2008	Dy. No. 42515 dated 12-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: a) Evidence of submission of last renewal.

						b) Section approval letter issued by Licensing Division for product at Sr. No. 589 being steroidal dosage form. c) Latest cGMP Inspection Report. d) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. e) 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)**. f) Brief report of last batch manufactured. g) Evidence of approval of formulation in reference drug agencies.
589.	053361	Prostryl Tablet 5mg Each Tablet Contain: Finasteride …..5mg	16-12-2008	Dy.#42515 12-12-2018 10000/-		-do-
xli.	**M/s. Hizat Pharmaceutical Industry, 170 Industrial Estate Hayatabad, Peshawar**					
590.	022862	Oprazole Capsules Each Capsule Contain: Omeprazole….20mg	16-12-1998	Dy. No. 42346 dated 11-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: a) Source fixation approval for pellets/ b) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. c) An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws **(on Stamp Papar)**. d) Brief report of last batch manufactured.

xlii. **M/s. Zafa Pharmaceutical Laboratories (Pvt) Ltd., L-4/1, A&B, Block-21, Federal-B Industrial Area, Karachi**						
591.	055546	Vofloza Tablet 500mg Each Tablet contain: Levofloxacin as Hemihydrate…500mg	27-03-2009	Dy. No. 44427 31-12-2018 10000/-		Deferred for following: Evidence of submission of renewal in DRAP having endorsement of R&I has not been submitted.
xliii. **M/s. Bloom Pharmaceuticals (Pvt) Ltd., Plot No. 30, Phase-I & II Industrial Estate, Hattar**						
592.	022577	Cyten 10mg Tablet Each tAblet contain: Cetirizine Dihydrochloride BP.10mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: i. Differential fee required as renewal of year 2013 was submitted after due date but within sixty days. ii. Evidence of approval of formulation in reference drug agencies.
593.	022576	Piroc-20mg Capsules Each capsule contain: Piroxicam BP…20mg	08-12-1998	Dy. No. 40460 5-12-2018 10000/-		-do-
594.	022578	Zonid 400mg Tablet Each tablet contain: Metronidazole BP…400mg	08-12-1998	Dy. No. 40460 5-12-2018 10000/-		-do-
595.	022579	Zonid Suspension 60ml Each 5ml contain: Metronidazole BP….200mg	08-12-1998	Dy. No. 40460 dated 5-12-2018 10000/-		-do-
596.	022580	Zyvit Syrup 120mg Each 5ml contain: Eiastase.....135mg Pepsin……..50mg Papine…….50mg Vitamin B1... 5mg Vitamin B2... 2mg Vitamin B6... 2mg Vitamin B12. 5mcg Nicotinamide… 20mg Cal. Pantothenate…..1mg	08-12-1998	Dy. No. 40460 5-12-2018 10000/-		-do-
xliv. **M/s. Meditech Pharmaceuticals, 15-D Industrial Estate, Jamrud Road, Peshawar**						
597.	54616	Benzil emulsion Each contains: Benzyl Bezoate..25% w/v (USP Specification)	24-12-2008	Dy. No. 4288 dated 13-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: a) Valid DML. b) Notarized copy of initial registration letter. c) Evidence of submission

						of last renewal. d) Section approval letter issued by Licensing Division e) Latest cGMP Inspection Report. f) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. g) 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)**. h) Brief report of last batch manufactured. i) Evidence of approval of formulation in reference drug agencies.
598.	54614	Betzil suspension Each 5ml contains: Metronidazole Bernzoateeq to Metronidazole ..200mg (B.P Specification)	24-12-2008	Dy. No. 4288 dated 13-12-2018 10000/-		-do-
xlv. **M/s. Nawabsons Laboratories (Pvt) Ltd., Jia Bagga Off Raiwind Road, Lahore**						
599.	014793	Dexamethasone Tablet Each tablet contain: Dexamethasone ….0.5mg	06-12-1993	Dy. No. 40458 5-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: a) Evidence of submission of last renewal. b) Section approval letter issued by Licensing Division for steroidal dosage form at Sr. No. 537. c) Latest cGMP Inspection Report. d) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. e) 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)**. f) Brief report of last batch manufactured. g) Evidence of approval of formulation in reference drug agencies.
600.	014794	Furazolidone Susp Each 5ml contain: Furazolidone….25mg	06-12-1993	Dy. No. 40458 5-12-2018 10000/-		-do-
601.	014795	Cimetidine Tablets Each tablet contain: Cimetidine…..200mg	06-12-1993	Dy. No. 40458 5-12-2018 10000/-		-do-
xlvi.	**M/s. Wnsfeild Pharmaceuticals, Plot No. 122, Block-A, Phase-V, Industrial Estate, Hattar**					
602.	078427	Haglox CR 12.5mg Tablet Each controlled release coated tablet contains: Paroxetine HCL Hemihydrate Paroxetine…..12.5mg	02-01-2014	Dy. No. 43810 dated 24-12-2018 10000/-		Deferred for rectification/ clarification of shortcomings communicated vide letter dated 30-07-2019,details are as under: a) Latest cGMP Inspection Report. b) An undertaking that the applied products have never been de-registered **(on Stamp Papar)**. c) An undertaking that submitted documents are true copy of the originals and that, if at any stage any discrepancy / misinformation is detected / observed the firm/company will be held responsible as per relevant laws **(on Stamp Papar)**. d) Evidence of approval of formulation in reference drug agencies.
xlvii.	**M/s. Z.Jans Pharmaceuticals (Pvt) Ltd., 148-A Industrial Area Hayatabad, Peshawar**					
603.	054569	Oxa-Z Tablets 500mg Each Tablet contain: Levofloxacin (as hemihydrate)…500mg	22-12-2008	Dy. No. 43167 18-12-2018 10000/-		Deferred for following: Evidence of submission of last renewal is not submitted by the firm.
604.	054570	Oxa-Z Tablets 250mg Each Tablet contain: Levofloxacin (as hemihydrate)…250mg	22-12-2008	Dy. No. 43167 18-12-2018 10000/-		-do-

605.	054571	Ibo-Z Suspension Each 5ml Contain: Ibuprofen……100mg	22-12-2008	Dy.#43167 18-12-2018 10000/-		-do-
606.	054572	Girest Suspension Each 5ml contain: Simethicone….50mg Dicyclomine HCL……5mg	22-12-2008	Dy. No. 43167 18-12-2018 10000/-		-do-
607.	054573	Cim-Z Susp Each 5ml contain: Cimetidine……100mg	22-12-2008	Dy. No. 43167 18-12-2018 10000/-		-do-

VI. CASES DEFERRED IN PREVIOUS MEETINGS

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Remarks (if any)
i.	**M/s Medera Pharmaceuticals (Pvt) Ltd, 249/A, Industrial Triangle, Kahuta Road, Islamabad**				
608.	024750	Amazole Capsule 20mg Each Capsule Contains: Omeprazole Pellets 235mg eq. to Omeprazole…20mg Source: M/s Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	Transfer of registration dated: 31-7-2003	Dy. No. 25523 dated 23-07-2018 10000/-	Deferred for issuance of final reminder for following: Differential fee for the year 2013 and 2018 because the source was changed from import to local on 17-06-2019.
M/s. Remington Pharmaceutical Industries (Pvt) Ltd., 18-Km Multan Road Lahore					
609.	051021	Myodip 5/10mg Tablets Each film coated tablet contains: Amlodipine besylate eq. to amlodipine…….5mg Atorvastatin calcium eq. to Atorvastin……..10mg	13-08-2008	Dy. No. 26383 01-08-2018 10000/-	w.e.f. 13-08-2018-12-08-2023
610.	051022	Myodip 5/20 Tablets Each film coated tablet contains: Amlodipine besylate eq. to amlodipine…….5mg Atorvastatin calcium eq. to Atorvastatin……..20mg	13-08-2008	Dy. No. 26383 01-08-2018 10000/-	-do-
611.	051023	Myodip10/10 Tablet Each film coated tablet contains: Amlodipine besylate eq. to amlodipine……..10mg Atorvastatin calcium eq. to Atorvastatin ……10mg	13-08-2008	Dy. No. 26383 01-08-2018 10000/-	-do-
612.	051030	Rapril 5mg Tablets Each tablet contains: Ramipril…….5mg	13-08-2008	Dy. No. 26377 01-08-2018 10000/-	-do-
613.	051031	Rheumid 10mg Tablets Each film coated tablet	13-08-2008	Dy. No. 26377 01-08-2018	-do-

		contains: Leflunomide…10mg		10000/-	
614.	051032	Rheumid 20mg Tablets Each film coated tablet contains: Leflunomide…20mg	13-08-2008	Dy. No. 26377 01-08-2018 10000/-	-do-
615.	051015	Diarid 3mg Tablet Each tablet contains: Glimepiride ….3mg	13-08-2008	Dy. No. 26381 01-08-2018 10000/-	-do-
616.	051016	Diarid 4mg Tablets Each tablets contains: Glimepiride…….4mg	13-08-2008	Dy. No. 26381 01-08-2018 10000/-	-do-
617.	051017	Diarid-M 2mg Tablet Each tablet contains: Glimepiride….2mg (USP Specs)	13-08-2008	Dy. No. 26381 01-08-2018 10000/-	-do-
618.	051011	Cegrel –A 75/75 Tablets Each film coated tablet contains: Clopidogrel Hydrogen sulfate eq. to clopidogrel ……..75mg Aspirin…….75mg	13-08-2008	Dy. No. 26370 01-08-2018 10000/-	-do-
619.	051012	Cegrel-A 75/150 Tablets Each tablets contains: Clopidogrel Hydrogen sulfate equivalent to clopidogrel ….75mg Aspirin……150mg	13-08-2008	Dy. No. 26370 dated 01-08-2018 10000/-	-do-
620.	051027	Rapril 1.25mg Tablets. Each table Contains: Ramipril……1.25mg. (B.P Specs)	13-08-2008	Dy. No. 26386 01-08-2018 10000/-	-do-
621.	051029	Rapril 2.5mg Tablets. Each Table Contains: Ramipril…….2.5mg. (B.P Specs)	13-08-2008	Dy. No. 26386 01-08-2018 10000/-	-do-
622.	051028	Rapril 10mg Tablets Each tablet contains: Ramipril……10mg (BP Specs)	13-08-2008	Dy. No. 26386 01-08-2018 10000/-	-do-
623.	051024	Neurogab 200mg Tablets Each film coated tablet contains: Gabapentin….200mg	13-08-2008	Dy. No. 26382 01-08-2018 10000/-	-do-
624.	051025	Neurogab 400mg Tablets. Each film Coated tablet Contains: Gabapentin…..400mg.	13-08-2008	Dy. No. 26382 01-08-2018 10000/-	-do-
625.	051026	Neurogab 600mg Tablets. Each film Coated tablet Contains: Gabapentin…..600mg.	13-08-2008	Dy. No. 26382 01-08-2018 10000/-	-do-
626.	051018	Dolbon 0.25mcg Tablets. Each tablet Contains:	13-08-2008	Dy. No. 26376 01-08-2018	-do-

		Alfacalcidol…0.25mcg.		10000/-	
627.	051019	Dolbon 0.5mcg Tablets. Each tablet Contains: Alfacalcidol…….0.5mcg.	13-08-2008	Dy. No. 26376 01-08-2018 10000/-	-do-
628.	051020	Dolbon 1mcg Tablets. Each tablet Contains: Alfacalcidol…….1mcg.	13-08-2008	Dy. No. 26376 01-08-2018 10000/-	-do-
629.	050900	Valzar Plus 160/25 Each film coated tablet contains: Valsartan……..160mg Hydrochlorothiazide.25mg (USP Specs)	02-08-2008	Dy. No. 26371 01-08-2018 10000/-	w.e.f. 02-08-2018 to 01-08-2023
630.	050901	Valzar Plus 80/12.5 Tablets Each film coated tablet contains: Valsartan……..80mg Hydrochlorothiazide …..12.5mg (USP Specs)	02-08-2008	Dy. No. 26371 01-08-2018 10000/-	-do-
631.	050910	Q-Lox 100mg Tablets Each film coated tablet contains: Sparfloxacin…….100mg	02-08-2008	Dy. No. 26369 01-08-2018 10000/-	-do-
632.	050911	Q-Lox 200mg Each film coated tablet contains: Sparfloxacin…….200mg	02-08-2008	Dy. No. 26369 01-08-2018 10000/-	-do-
633.	050878	Flutex Nasal Spray Each ml contains: Fluticasone propionate …..0.50mg Each actuation delivers 50mcg of fluticasone propionate from the nasal actuator. (BP Specs)	02-08-2008	Dy. No. 26368 01-08-2018 10000/-	-do-
634.	050877	Dozypress –T Eye Drops Each ml contains: Dorzolamide HCl eq.to Dorzolamide……. 20mg Timolol maleate eq. to timolol……..5.00mg	02-08-2008	Dy. No. 26368 01-08-2018 10000/-	-do-
635.	051033	Zoride Tablet 50mg Each film coated tablet contains: Itopride HCl…….50mg.	13-08-2008	Dy. No. 26374 01-08-2018 10000/-	-do-
636.	052653	Esler 20mg Capsules. Each Capsule Contains: Esomeprazole as Mgnesium Trihydrate….20mg.	13-10-2008	Dy. No. 26374 01-08-2018 10000/-	Deferred for following: Differential Fee is required as the product is imported pellets for renewal of year 2013 & 2018.
637.	052654	Esler 40mg Capsules. Each Capsule Contains: Esomeprazole as Mgnesium	13-10-2008	Dy. No. 26374 01-08-2018 10000/-	Deferred for following: Differential Fee is required as the product is imported pellets

		Trihydrate…….40mg.			for the renewal of year 2013 & 2018.
638.	076962	Remisole Neo Syrup Each 5ml contains: Chlorpheniramine maleate…2.5mg, Ammonium chloride…..125mg, Sodium citrate…..55mg, Glycerine…….150mg	23-09-2013	Dy. No. 26379 01-08-2018 10000/-	w.e.f. 23-09-2018 to 22-09-2023
639.	076963	Eyclear Eye Drops Each ml contains: Naphazoline HCl..0.25mg	23-09-2013	Dy. No. 26379 01-08-2018 10000/-	w.e.f. 23-09-2018 to 22-09-2023
640.	050892	Rosulip 10mg Tablets Each film coated tablet contains: Rosuvastatin calcium eq. to rosuvastatin ……10mg	02-08-2008	Dy. No. 26379 01-08-2018 10000/-	w.e.f. 02-08-2018 to 01-08-2023
641.	050884	Loxiget Eye drops Each ml contains: Gatifloxacin……3.0mg	02-08-2008	Dy. No. 26378 01-08-2018 10000/-	-do-
642.	050886	Prostilet-T Eye Drops Each ml contains: Latanoprost…….50mcg Timolol maleate eq. to timolol……..…..5.00mg	02-08-2008	Dy. No. 26378 01-08-2018 10000/-	-do-
643.	050890	Remikair 5mg Tablets Each chewable tablet contains: Montelukast sodium eq. to montelukast acid …5.0mg	02-08-2008	Dy. No. 26378 01-08-2018 10000/-	-do-
644.	500905	Xoglit-M 15/500 Tablets. Each Film Coated Tablet Contains: Pioglitazone Hydrochloride eq. to piogltazone…15mg Metformin HCl……500mg.	02-08-2008	Dy. No. 26373 01-08-2018 10000/-	-do-
645.	050906	Xoglit-M 15/850 Tablets. Each Film Coated Tablet Contains: Pioglitazone Hydrochloride eq. to piogltazone…15mg Metformin HCl…850mg.	02-08-2008	Dy. No. 26373 01-08-2018 10000/-	-do-
646.	050891	Remilak Eye drops Each ml contains: Ketorolac tromethamine……5mg	02-08-2008	Dy. No. 26373 01-08-2018 10000/-	-do-
647.	050879	Kanpress 16mg Tablets Each tablets contains: Candesartan cilexetil…….16mg	02-08-2008	Dy. No. 26388 01-08-2018 10000/-	-do-
648.	050880	Kanpress 8mg Tablets Each tablets contains: Candesartan cilexetil……8mg	02-08-2008	Dy. No. 26388 01-08-2018 10000/-	-do-

649.	050881	Kanpress Plus Tablets Each tablets contains: Candesartan cilexetil……16mg Hydrochlorothiazide12.5mg	02-08-2008	Dy. No. 26388 01-08-2018 10000/-	-do-
650.	050887	Remikair 10mg Tablets Each film coated tablet contains: Montelukast sodium eq. to montelukast acid ……10mg	02-08-2008	Dy. No. 26384 01-08-2018 10000/-	-do-
651.	050888	Remikair 4mg Sachet Each sachet contains: Montelukast sodium eq. to montelukast…….4mg	02-08-2008	Dy. No. 26384 dated 01-08-2018 10000/-	-do-
652.	050889	Remikair 4mg Tablets Each chewable tablet contains: Montelukast sodium eq. to montelukast acid…..4mg	02-08-2008	Dy. No. 26384 dated 01-08-2018 10000/-	-do-
653.	050895	Timvast plus 20/10 Tablets Each film coated tablet contains: Simvastatin……20mg Ezetimibe……..10mg	02-08-2008	Dy. No. 26385 dated 01-08-2018 10000/-	-do-
654.	050896	Timvast Plus 40/10 Tablets Each film coated tablets contains: Simvastatin……40mg Ezetimibe……..10mg	02-08-2008	Dy. No. 26385 01-08-2018 10000/-	-do-
655.	050897	Timvast Plus Tablets 10/10 Each Film Coated Tablet Contains: Simvastatin…..10mg. Ezetimibe…….10mg.	02-08-2008	Dy. No. 26385 01-08-2018 10000/-	-do-
656.	050898	Valzar 160mg Tablets Each film coated tablet contains: Valsartan…….160mg	02-08-2008	Dy. No. 26375 01-08-2018 10000/-	-do-
657.	050899	Valzar 80mg Tablets Each film coated tablet contains: Valsartan …….80mg	02-08-2008	Dy. No. 26375 01-08-2018 10000/-	-do-
658.	050907	Zidopril Tablets Each tablets contains: Lisinopril As dihydrate……..20mg Hydrochlorothiazide12.5mg	02-08-2008	Dy. No. 26375 01-08-2018 10000/-	-do-
659.	050908	Dexcip Ear Suspension Each ml contains: Ciprofloxacin Hydrochloride eq. to ciprofloxacin base…..3.0mg Dexamethasone……..1.0mg	02-08-2008	Dy. No. 26372 01-08-2018 10000/-	-do-

660.	050909	Ocumox Tablets Each film coated tablets contains: Moxifloxacin HCl eq. to Moxifloxacin …400mg	02-08-2008	Dy. No. 26372 01-08-2018 10000/-	-do-
661.	050893	Rosulip 20mg Tablets. Each Tablet Contains: Rosuvastatin Calcium eq. to rosuvastatin .20mg	02-08-2008	Dy. No. 26372 01-08-2018 10000/-	-do-
662.	050902	Xoglit 15mg Tablets Each tablet contains: Pioglitazone Hydrochloride eq. to pioglitazone….15mg	02-08-2008	Dy. No. 26387 01-08-2018 10000/-	-do-
663.	050903	Xoglit 30mg Tablets Each tablets contains: Pioglitazone Hydrochloride eq. to pioglitazone….30mg	02-08-2008	Dy. No. 26387 01-08-2018 10000/-	-do-
664.	050904	Xoglit 45mg Tablet Each tablet contains: Pioglitazone Hydrochloride eq. to pioglitazone.45mg	02-08-2008	Dy. No. 26387 01-08-2018 10000/-	-do-
665.	050894	Rosulip 5mg Tablets Each film coated tablet contains: Rosuvastatin calcium eq. to rosuvastatin……..5mg	02-08-2008	Dy. No. 26380 01-08-2018 10000/-	-do-
666.	051013	Diarid 1/500 Tablets. Each film Coated tablet Contains: Glimepiride……1 mg. Metformin HCl…..500 mg.	13-08-2008	Dy. No. 26380 01-08-2018 10000/-	Defered for status of showcause issued by the concerned section for same formulation.
667.	051014	Diarid 1mg Tablets Each tablet contains: Glimepiride……..1mg	13-08-2008	Dy. No. 26380 01-08-2018 10000/-	w.e.f. 13-08-2018 to 12-08-2023
ii.	**M/s. Shaheen Pharmaceuticals, 3-Km Murghzar Road, Saidu Sharif, Sawat**				
668.	49330	Lanosh Capsules. Each Enteric Coated Capsule Contains: Lansoprazole Pellets eq. to Lansoprazole …30mg M/s Smilex Laboratories Ltd Hyderabad India	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023 subject to submission of differential fee
669.	49331	Zoger Capsules. Each Enteric Coated Capsule Contains: Omeprazole Pellets eq. to Omeprazole…20mg M/s Smilex Laboratories Ltd Hyderabad India	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023 subject to submission of differential fee
670.	49367	Dequit 25mg Tablets. Each Tablet Contains: Quetiapine Fumarate eq. to Quetiapine……..25mg.	11-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 11-07-2018 to 10-07-2023

671.	49368	Dequit 200mg Tablets. Each Tablet Contains: Quetiapine Fumarate eq. to Quetiapine…..200mg.	11-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 11-07-2018 to 10-07-2023
672.	49332	Pepnor 20mg Tablets. Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate ……..20mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
673.	49333	Pepnor 40mg Tablets. Each Enteric Coated Tablet Contains: Esomeprazole as Magnesium Trihydrate …….40mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
674.	49334	Shalox Tablets. Each Tablet Contains: Moxifloxacin HCl..400mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
675.	49335	Rager Tablets. Each Enteric Coated tablet Contains: Rabeprazole Sodium..20mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
676.	49336	Alenat Tablets. Each Tablet Contains: Alendronate as Sodium…..70mg (USP Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
677.	49337	Cyclodor Tablets. Each Tablet Contains: Piroxicam B-Cyclodextrine eq. to Piroxicam…20mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
678.	49338	Ocedep 50mg Tablets. Each Tablet Contains: Fluvoxamine Maleate BP……50mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
679.	49339	Ocedep 100mg Tablets. Each Tablet Contains: Fluvoxamine Maleate ……100mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
680.	49340	Preston 250mg Tablets. Each Tablet Contains: Mefenamic Acid..250mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
681.	49341	Preston Forte 500mg Tablets. Each Tablet Contains: Mefenamic Acid..500mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
682.	49342	Butral 10mg Tablets. Each Tablet Contains: Bambuterol……10mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023

683.	49343	Butral 20mg Tablets. Each Tablet Contains: Bambuterol ……20mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
684.	49344	Normidol Tablets. Each Tablet Contains: Paracetamol …..500mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
685.	49345	Curedol Extra Tablets. Each Tablet Contains: Paracetamol …..500mg. Caffeine …….65mg. (B.P Specs)	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
686.	49346	Dequit 100mg Tablets. Each Tablet Contains: Quetiapine Fumarate eq. to Quetiapine……..100mg.	10-07-2008	Dy. No. 23230 05-07-2018 10000/-	w.e.f. 10-07-2018 to 09-07-2023
iii.	**M/s. Helix Pharma (Pvt.) Ltd., A/56,S.I.T.E., Karachi**				
687.	031232	Tobracin-D Eye Drops Each ml contains: Tobramycin….3.0mg Dexamethasone….1mg	26-09-2003	Dy. No. 28376 20-08-2018	w.e.f 26-09-2018 to 25-09-2023
M/s. High-Q Pharmaceuticals, Plot No. 244, Sector No. 23, Korangi Industrial Area, Karachi					
688.	076105	Pytex 20mg Tablet Each tablet contains: Piroxicam Betacyclodextrin eq. to Piroxicam……20 mg	24-10-2013	Dy. No. 28847 29-08-2018 10000/-	w.e.f 24-10-2018 to 23-10-2023
iv.	**M/s. Jaens Pharmaceuticals Industries (Pvt.) Ltd. 28-Km,Lahore Sheikhupura Road, Sheikhupura**				
689.	051186	Pinadex Ear Drops Each ml contains: Ciprofloxacin HCl eq. to Ciprofloxacin…..3mg Dexamethasone….1mg	11-09-2008	Dy. No. 29261 31-08-2018	w.e.f. 11-09-2013 to 10-09-2023 subject to submission of differential fee for the year 2013.
690.	051187	Ligcy Ear Drops Each ml contains: Ciprofloxacin HCl eq. to Ciprofloxacin…3mg Lignocaine….50mg	11-09-2008	Dy. No. 29261 31-08-2018	w.e.f. 11-09-2013 to 10-09-2023 subject to submission of differential fee for the year 2013.
v.	**M/s. Wise Pharmaceuticals, Plot No. 3-A,s-1,RCCI Industrial Estate, Rawat ,Rawalpindi**				
691.	EX-003066	Piroxi 20mg Tablet Each Film coated Tablet contains: Piroxicam as Beta Cyclodextrin….20mg	27-08-2013	Dy. No. 28565 31-08-2018	w.e.f. 27-08-2018 to 26-08-2023 subject to the submission of differential fee for the year 2013.
692.	EX-003067	Dothine 25mg Tablet Each tablet contains: Dothiepin (as HCl)….25mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-

693.	EX-003068	Cepzon 2gm Injection Each vial Contains: Sterile Cefoperazone(as sodium + Sulbactum (as sodium) (1:1)…2gm	27-08-2013	Dy. No. 28565 31-08-2018	-do-
694.	EX-003069	Cepzon 1gm Injection Each vial Contains: Sterile Cefoperazone(as sodium + Sulbactum (as sodium) (1:1)…1gm	27-08-2013	Dy. No. 28565 31-08-2018	-do-
695.	EX-003070	Lpride 50mg Tablet Each tablet contains: Levosulpride….50mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
696.	EX-003071	Lpride 25mg Tablet Each tablet contains: Levosulpride….25mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
697.	EX-003072	Cirta 50mg Each film coated tablet contains: Sertraline (as HCl)…50mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
698.	EX-003073	Cirta 25mg Each film coated tablet contains: Sertraline (as HCl)…25mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
699.	EX-003074	Nepro 550mg Tablet Each tablet contains: Naproxen Sodium…550mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
700.	EX-003075	Lozapin 10mg Tablet Each Film coated Tablet contains: Olanzapine as (citrate).10mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
701.	EX-003076	Resp 1mg Tablet Each film coated tablet contains: Risperidone…1mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
702.	EX-003077	Vepim 1gm Injection Each vial contains: Cefepime as HCl with L-Arginine ….1gm	27-08-2013	Dy. No. 28565 31-08-2018	-do-
703.	EX-003078	Vepim 500mg Injection Each vial contains: Cefepime as HCl with L-Arginine ….500mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
704.	EX-003079	Esta 10mg Tablet Each film coated tablet contains: Escitalopram (as oxalate)…..10mg	27-08-2013	Dy. No. 28565 31-08-2018	-do-
vi.	**M/s. Pharmix Laboratories (Pvt.) Ltd., 21-KM,Ferozpur Road, Lahore**				
705.	Ex-001806	Kwatadin Tablet 10mg Each tablet contains: Loratadine….10mg	24-06-2013	Dy. No. 28378 28-08-2018	w.e.f 24-06-2018 to 23-06-2023

706.	Ex-001805	Metfodi Tablet 300mg Each tablet contains: Tenofovir Disoproxil Fumarate 300mg equivalent to Tenofovir Disoproxil	24-06-2013	Dy. No. 28378 28-08-2018	-do-
707.	Ex-001804	Zidetin Suspension 5mg Each 5ml contains: Loratadine….5mg	24-06-2013	Dy. No. 28378 28-08-2018	-do-
vii.	**M/s. Frontier Dextrose Ltd., Plot No. 18/3, Phase-I, Hattar Industrial Estate, Haripur**				
708.	049285	Sterifluid-DS 1/2 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose…5gm Sodium Chloride…0.45gm	09-07-2008 Change of brand name dated 24-09-2008	Dy. No. 23685 09-07-2018 10000/-	w.e.f. 09-07-2013 to 08-07-2023 subject to submission of differential fee for the year 2013.
709.	049286	Sterifluid-Pead's Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose…4.3gm Sodium Chloride…0.18gm	09-07-2008 Change of brand name dated 24-09-2008	Dy. No. 23685 dated 09-07-2018 10000/-	w.e.f. 09-07-2013 to 08-07-2023 subject to submission of differential fee for the year 2013.
710.	049818	Sterifluid-5 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose …..……..……5gm. (B.P Specs)	16-07-2008 Change of brand name dated 24-09-2008	Dy. No. 24515 dated 16-07-2018 10000/-	w.e.f. 16-07-2013 to 15-07-2023 subject to submission of differential fee for the year 2013.
711.	049819	Sterifluid-10 Infusion Each 100ml Contains: Dextrose Monohydrate eq. to Anhydrous Dextrose …..……..……10gm. (B.P Specs)	16-07-2008 Change of brand name dated 24-09-2008	Dy. No. 24515 dated 16-07-2018 10000/-	w.e.f. 16-07-2013 to 15-07-2023 subject to submission of differential fee for the year 2013.
viii.	**M/s. Venus Pharma, 23-Km Multan Road, Lahore**				
712.	13993	Xylex 2% Injection with Adrenaline Contains: Lignocaine HCl…2%w/v Adrenaline…0.001%w/v	28-07-1993	Dy. No. 24679 dated 16-07-2018 10000/-	w.e.f. 28-07-2018 to 27-07-2023.
ix.	**M/s. Saffron Pharmaceuticals (Pvt) Ltd., 19-Km Sheikhupura Road, Faisalabad**				
713.	052953	Locus 500mg/100ml Infusion Each 100ml Vial Contains: Levofloxacin (as Hemihydrate)…500mg	28-11-2008	Dy. No. 25139 dated 19-07-2018 10000/-	w.e.f 28-11-2018 to 27-11-2023.
714.	052954	Doplet-3 5mg/ml Injection Each ml Contains: Cholecalciferol…5mg	28-11-2008 Change of brand name dated: 26-07-2011	Dy. No. 25139 dated 19-07-2018 10000/-	-do-
715.	052955	Cetrix 5mg/5ml Syrup Each 5ml Contains: Cetirizine Dihydrochloride…5mg	28-11-2008	Dy. No. 25139 dated 19-07-2018 10000/-	-do-

716.	052958	Terbisil 250mg Tablet Each Tablet Contains: Terbinafine (as HCl)…250mg	28-11-2008	Dy. No. 25139 dated 19-07-2018 10000/-	-do-
717.	052959	Provate 0.05% w/w Cream Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
718.	052961	Provate 0.05% w/w Ointment Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
719.	052962	Cosmin 0.05% w/w Gel Each gm Contains: Isotretinoin…0.50mg	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
720.	052963	Provate-G Cream Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg Gentamycin Sulphate…1.00mg	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
721.	052964	Provate-S Ointment Each gm Contains: Betamethasone (as Dipropionate)…0.50mg Salicylic Acid…30mg	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
722.	052965	Provate Lotion Each ml Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
723.	052966	Provate-G Ointment Each gm Contains: Betamethasone Dipropionate 0.64mg eq. to Betamethasone…0.50mg Gentamycin Sulphate…1.00mg	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
724.	052968	Water for Injection 5ml Ampoule Each Injection Contains: Water for Injection…5ml	28-11-2008	Dy. No. 25139 19-07-2018 10000/-	-do-
725.	052969	Noctis 20mg Capsule Each Capsule Contains: Omeprazole (Omeprazole Pellets)…20mg M/s Metrochem API Pvt Limited India	28-11-2008	Dy. No. 25139 19-07-2018 10000/- 10000/- dated 23-07-2018	-do-
726.	052988	Gatron Injection Each ml Contains:	29-11-2008	Dy. No. 25139 19-07-2018	w.e.f 29-11-2018 to 28-11-2023

		Granisetron (as HCl)…1.0mg		10000/-	
727.	052990	Amorob 500mg/100ml Injection Each 100ml Vial Contains: Metronidazole…500mg	29-11-2008	Dy. No. 25139 dated 19-07-2018 10000/-	-do-
728.	077026	Noctis 40mg Capsule Each Capsule Contains: Omeprazole (Pellets)…40mg Source: M/s Amoli Organics Limited India	19-11-2013	Dy. No. 25139 dated 19-07-2018 10000/- 10000/- 13-05-2019	-do-
x.	**M/s. ATCO Laboratories Ltd., B-18, S.I.T.E., Karachi**				
729.	050519	Trimalor Adult Tablet Each co-blister contains: Each six small tablets contains:- Artesunate……..100mg Each three large tablets contains:- Sulfadoxine……500mg Pyrimethamine……25mg	29-08-2008	Dy. No. 25929 dated 27-07-2018 10000/-	w.e.f. 29-08-2018 to 28-08-2023
xi.	**M/s. Brookes Pharma Private Limited,58-59 Sector 15,Korangi Industrial Area, Karachi**				
730.	009128	Phlogin-50 Capsules Each capsules contains: Diclofenac Sodium…50mg	11-10-1988	Dy. No. 27474 09-08-2018	Deferred for confirmation of transfer of registration from M/s Brooks Laboratories to M/s Broks Pharma Pvt Limited from the concerned section.
731.	009129	Phlogin-SR-100 Capsule Each capsule contains: Diclofenac Sodium….100mg	11-10-1988	Dy. No. 27474 09-08-2018	-do-
732.	009529	Pyodine Gargle & Mouth Wash Each 100ml contains: Polyvinylpyrolidine I odine	11-10-1988	Dy. No. 27474 09-08-2018	-do-
733.	009528	Pyodine Solution Each 100ml contains: Polyvinylpyrrolidine Iodine	21-10-1988	Dy. No. 27474 09-08-2018	-do-
734.	009031	Hepa-Merz Syrup Each ml contains: Ornithine Asparate….60mg Nicotinamide….4.8mg Riboflavin-5-Phosphate Sodium….0.153mg Sodium Benzoate…1.2mg Potassium Sorbate…1.2mg Citric Acid…6.0mg	15-09-1988	Dy. No. 27473 09-08-2018	-do-
735.	009939	Sterile Water for Injection Contains: Water for Injection…5ml	15-09-1988	Dy. No. 27473 09-08-2018	-do-

736.	022304	Ponsac Tablets Each tablet contains: Mefenamic Acid….250mg	29-09-1998	Dy. No. 27473 09-08-2018	-do-
xii.	**M/s. Reliance Pharma, Plot No. 8, Street No. S-8 , RCCI Industrial Estate, Rawat.**				
737.	072164	Genbet Cream 30gm Contains: Betamethasone as DP 0.05% Gentamycin as Sulphate		Dy. No. 27339 09-08-2018	Deferred for final reminder for rectification of following shortcomings: Initial registration and evidence of last renewal.
738.	075076	Religent-B Ointment Each gm contains: Gentamycin (as sulphate)…0.1%, Betamethasone (as dipropionate) … 0.05%		Dy. No. 27339 09-08-2018	-do-
739.	075077	Religent-SB Ointment Each gm contains Betamethasone (as dipropionate)…0.5 mg, Salicylic acid … 30 mg		Dy. No. 27339 09-08-2018	-do-
740.	072951	Relaxipain 20mg Capsule Each capsule contains: Piroxicam…20mg		Dy. No. 27339 09-08-2018	-do-
xiii.	**M/s Medisure Laboratories Pakistan Pvt. Limited, A-115, S.I.T.E., Super Highway, Karachi.**				
741.	031149	Clarocin Tablets 500mg Each tablet contains: Clarithromycin ….500mg	20-08-2003	Dy. No. 26920 06-08-2018 10000/-	w.e.f 20-08-2018 to 19-08-2023
742.	004222 -EX	Rumatidine Tablet 300mg Contains: Ranitidine HCl eq. to Ranitidine…300mg	22-08-2013	Dy. No. 26920 06-08-2018 10000/-	w.e.f 22-08-2018 to 21-08-2023
xiv.	**M/s. Akhai Pharmaceuticals (Pvt) Ltd., A-248, A-256 to A-259, H.I.T.E., Lasbela, Baluchistan**				
743.	75995	Sulpy 100mg Tablet Each Tablet Contains: Levosulpiride…100mg	19-09-2013	Dy. No. 23889 10-07-2018 10000/-	w.e.f 19-09-2018 to 18-09-2023
744.	75996	Togal 200mg Tablet Each Tablet Contains: Quetiapine as Fumarate…200mg	19-09-2013	Dy. No. 23888 10-07-2018 10000/-	-do-
xv.	**M/s. International Pharma Lab's,Raiwind Road, Bhohtain Chowk, Defense Road,1-Km Toward Kahna, Lahore**				
745.	53982	ANTI-BECTER INJECTION Each ml contains:: Sulphamerazine…100MG Sulphadiazine…60MG Sulphathiazole….40MG TRIMETHOPRIM….40MG	30-03-2009	Dy. No. 26762 dated 03-08-2018 10000/-	w.e.f 30-03-2019 to 29-03-2024
746.	53980	DR-FLOX-10 INJECTION Each ml contains:: Enrofloxacin…….10GM	30-03-2009	Dy. No. 26763 03-08-2018 10000/-	-do-

747.	53983	ENROCK INJECTION Each ml contains:: Enrofloxacin…..20GM	30-03-2009	Dy. No. 26764 03-08-2018 10000/-	-do-
748.	53979	JEXINEL INJECTION Each ml contains:: Ceftiofur HCL…..5GM	30-03-2009	Dy. No. 26765 03-08-2018 10000/-	-do-
749.	53981	ITOSIN INJECTION Each ml contains:: Tylosin Tartrate…..200MG	30-03-2009	Dy. No. 26766 03-08-2018 10000/-	-do-
750.	53984	I-VIT SUPER INJECTION Each ml contains:: CALCIUM GLUCONATE….20.83GM MAGNESIUM HYPOPHOSPHITE….5.33 GM MAGNESIUM CHLORIDE….2GM CALCIUM D SACCHARATE….1GM BORIC ACID….4.33GM DEXTROSE….20GM VITAMIN B-1….10MG VITAMIN B-6…70MG VITAMIN B-12…..3MG	30-03-2009	Dy. No. 26767 dated 03-08-2018 10000/-	-do-
751.	53987	ITOFEN INJECTION Each ml contains:: KETOPROFEN….10GM	30-03-2009	Dy. No. 26768 03-08-2018 10000/-	-do-
752.	53986	DR-OXY-LA INJECTION Each ml contains:: OXYTETRACYCLINE HCL B.P…..21.60GM	30-03-2009	Dy. No. 26769 03-08-2018 10000/-	-do-
753.	53985	I-FENAC INJECTION Each ml contains:: MELOXICAM…..1GM	30-03-2009	Dy. No. 26770 03-08-2018 10000/-	-do-
xvi.	**M/s Nawabsons Laboratories, Jia Bagga Off Raiwind Road, Lahore**				
754.	030320	Hemasol Syrup Each 5ml Contains: Ferrous Sulphate…100mg Ascorbic Acid…5mg	30-06-2003	Dy. No. 20289 dated 05-06-2018 10000/-	Deferred for The product was deferred in 288th meeting of Registration Board clarification of following: i. Reference formulation of BPC is provided which is 30g/1000ml i.e. 150mg/5ml. ii. Section approval letter. Now the has informed that the formulation approved by then MOH was in reference BPC 1973.This is brand of firm and concentration of ferrous is reduced fron 150mg to 100mg due to astringent property of API. In light of above, Registration Board deferred for further deliberation

xvii.	**M/s. Saydon Pharmaceutical Industries (Pvt) Ltd, 77-A, hayatabad Industrial Estate, Peshawar**				
755.	022381	Baby-S Sachet Each Sachet Contains:- Sodium chloride …. 3.5 gm Sodium Citrate …… 2.9gm Potassium Chloride …. 1.5gm Dextrose Anhydrous ….. 20gm	20-10-1998	Dy. No. 34417 dated 17-10-2018 10000	w.e.f 20-10-2018 to 19-10-2023
756.	022380	ORA-C Sachet Each Sachet Contains Calcium Lactate Gluconate …. 1000mg Calcium Carbonate …. 0.327mg Vitamin C …. 500mg	20-10-1998	Dy. No. 34417 dated 17-10-2018 10000	-do-
757.	022484	Ostefen 50mg Tablets Each tablet Contains Diclofenac Potassium.50mg	05-11-1998	Dy. No. 34417 17-10-2018 10000	w.e.f 05-11-2018 to 04-11-2023
758.	022485	Ostefen 75mg Tablets Each tablet Contains Diclofenac Potassium …. 75mg	05-11-1998	Dy. No. 34417 17-10-2018 10000	-do-
759.	022486	Arcam 20mg Talets Each tablet Contains Piroxicam …. 20mg	05-11-1998	Dy. No. 34417 17-10-2018 10000	-do-
xviii.	**M/s Elko Organization, Plot No. 27 & 28, Sector 12/B, North Karachi, Industrial Area, Karachi.**				
760.	028600	LEOX Bolus Each Bolus Contains: Levamisole HCl…1.125gm Oxyclozanide…2.250gm	02-07-2003	Dy. No. 20016 04-06-2018 10000/-	w.e.f. 02-07-2018 to 01-07-2023
xix.	**M/s. Alfalah Pharma (Pvt.) Ltd. 12 Km,Sheikhupura Road,Lahore**				
761.	051110	Limperide Tablet 1mg Each tablet contains: Glimepiride….1mg	23-08-2008	Dy. No. 28063 16-08-2018	Deferred for issuance of final reminder for rectification of following shortcomings: Latest GMP report and evidence of submission of last renewal.
762.	051111	Limperide Tablet 2mg Each tablet contains: Glimepiride….2mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
763.	051112	Methoxine Tablet Each tablet contains: Sulfadoxine….500mg Pyrimethamine…25mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
764.	051113	Benbit Tablet 5mg Each tablet contains: Glibenclamide….5mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
765.	051114	Pyomic Tablet 25mg Each tablet contains: Glibenclamide….5mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
766.	051115	Alfakalium Tablet 50mg Each Tablet contains: Diclofenac Potassium…50mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-

767.	051116	Mczole Tablets 400mg Each tablet contains: Metronidazole….400mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
768.	051117	Vasit Tablet 20mg Each tablet contains: Atorvastatin….20mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
769.	051118	Vasit Tablet 10mg Each tablet contains: Atorvastatin….10mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
770.	051119	Zolo Tablets Each tablet contains: Pantoprazole (as Sodium Sesquihydrate)….40mg	23-08-2008	Dy. No. 28063 16-08-2018	-do-
xx.	**M/s. MBL Pharma, Plot No. B-77/A, Hub Industrial Trading Estate, Baluchistan**				
771.	050384	MB Stine Tablet 10mg Each Tablet Contains: Ebastine…10mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	Deferred for issuance of final reminder for rectification of following shortcomings: Evidence of submission of last renewal.
772.	050385	MB Cobal Tablet 500mcg Each Tablet Contains: Mecobalamin…500mcg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	-do-
773.	050386	MB Cobal Injection 500mcg Each 1ml Contains: Mecobalamin…500mcg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	-do-
774.	050387	Anbox Capsule 10mg Each Capsule Contains: Piroxicam…10mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	-do-
775.	050388	Anbox Capsule 20mg Each Capsule Contains: Piroxicam…20mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	-do-
776.	050389	Anbox 0.5% Gel Each gm Contains: Piroxicam…5mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	-do-
777.	050390	Xaser Tablet 10mg Each Tablet Contains: Cetirizine Dihydrochloride…10mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	-do-
778.	050391	Xaser 1mg/ml Syrup Each ml Contains: Cetirizine Dihydrochloride…1mg	05-08-2008	Dy. No. 26193 30-07-2018 10000/-	-do-
xxi.	**M/s. Usawa Pharmaceuticals, 146-Special Zone, (Export Processing Zone) Risalpur**				
779.	50826	Quinspar Tablet Each Tablet Contains: Sparfloxacin…100mg	30-07-2008	Dy. No. 24772 dated 16-07-2018 10000/-	Deferred for issuance of final reminder for submission of evidence of formulation in reference drug agencies.
xxii.	**M/s. Otsuka Pakistan Ltd., F/4-9, Hub Industrial Trading Estate, Distt. Lasbella, Balochistan**				
780.	22318	Pan-Amin SG Injection Each 100ml Contains: D-Sorbitol…5gm L-Arginine HCl…0.8gm L-Histidine HCl…0.4gm	17-11-1998	Dy. No. 25221 19-07-2018 10000/-	w.e.f. 17-11-2018 to 16-11-2023

		L-Isoleucine…0.55gm L-Leucine…1.23gm L-Lysine HCl…1.86gm L-Methionine…0.71gm L-Phenylalanine…0.87gm L-Threonine…0.54gm L-Tryptophan…0.18gm L-Valine…0.61gm Glycine (Amino Acetic Acid)…1gm Water for Injection qs			
781.	31125	Neodexsal Injection Each 1000ml Contains: Dextrose Monohydrate…100gm Sodium Chloride…1.8gm Water for Injection qs to make 1000ml	03-12-2003	Dy. No. 25223 dated 19-07-2018 10000/-	w.e.f 03-12-2018 to 02-12-2023
782.	31126	Plabolyte-40 Injection Each 1000ml Contains: Dextrose Monohydrate…50gm Potassium Chloride…3gm Water for Injection qs to make 1000ml	03-12-2003	Dy. No. 25222 dated 19-07-2018 10000/-	-do-
xxiii.	**M/s. Wilson's Pharmaceuticals, 387-388, I-9, Industrial Area, Islamabad**				
783.	030922	Herr-C 1000 Tablet (Effervescent) Each tablet contains: Calcium Carbonate.....550mg Calcium Lactate Gluconate..250mg Vitamin C.....500mg Folic Acid.....1mg Vitamin B12.....250mcg	28-07-2003	Dy. No. 25530 dated 23-07-2018 10000/-	w.e.f. 28-07-2018 to 27-08-2023
784.	030923	Strength Sachets Each sachet contains: Calcium Glycerophosphate…..400mg Vitamin C.....150mg Thiamine.....5mg Pyridoxine.....5mg Riboflavin……..5mg Nicotinamide.....15mg	28-07-2003	Dy. No. 25530 dated 23-07-2018 10000/-	-do-
785.	014237	Epirate Tablet Each Tablet Contains: Sodium Valporate…200mg	05-08-1993	Dy. No. 25530 23-07-2018 10000/-	w.e.f 05-08-2018 to 04-08-2023
786.	014240	Normacid Suspension Each 5ml Contains: Cimetidine…100mg	05-08-1993	Dy. No. 25530 23-07-2018 10000/-	-do-
787.	014239	Normacid Tablet Each Tablet Contains: Cimetidine…400mg	05-08-1993	Dy. No. 25530 23-07-2018 10000/-	-do-

788.	014241	Scabiderm Cream Contains: Permethrin…5%w/w	05-08-1993	Dy. No. 25530 23-07-2018 10000/-	-do-
789.	010011	Duodopa Forte Tablet Each tablet contains: CARBIDOPA 25MG LEVODOPA 250MG	31-10-1988	Dy. No. 25530 23-07-2018 10000/-	w.e.f 31-10-2018 to 30-10-2023.
790.	010021	CALCEE-500 SACHETS Each sachet contains: CALCIUM LACTATE GLUCONATE 1000MG (CALCIUM GLUCONATE 578MG, CALCIUM LACTATE 422MG) VITAMIN C 500MG CALCIUM CARBONATE 327MG	29-11-1988	Dy. No. 25530 dated 23-07-2018 10000/-	w.e.f 29-11-2018 to 28-11-2023
791.	022555	A2A Tablet 25mg Each Tablet Contains: Losartan Potassium…25mg	26-11-1998	Dy. No. 25530 23-07-2018 10000/-	w.e.f. 26-11-2018 to 25-11-2023
792.	022556	A2A Tablet 50mg Each Tablet Contains: Losartan Potassium…50mg	26-11-1998	Dy. No. 25530 23-07-2018 10000/-	-do-
793.	022593	Promethazine Syrup Each 5ml Contains: Promethazine HCl…25mg	14-12-1998	Dy. No. 25530 23-07-2018 10000/-	w.e.f. 14-12-2018 to 13-12-2023
794.	022590	Talergin-F Capsule Each Capsule contains: Fexofenadine as HCl….60mg	14-12-1998	Dy. No. 25530 23-07-2018 10000/-	-do-
795.	054800	Season Sachet 4mg Each sachet contains: Montelukast Sodium eq. to Montelukast……4mg	31-12-2008	Dy. No. 25530 23-07-2018 10000/-	w.e.f 31-12-2018 to 30-12-2023
796.	053799	Teli-H Tablets Each tablet contains: Telmisartan……..80mg Hydrochlorothiazide.25mg	31-12-2008	Dy. No. 25530 23-07-2018 10000/-	-do-
797.	031083	Gem-SR Tablet Each tablet contains: Pantoprazole (as Sodium Sesquihydrate)……40mg	05-10-2003 Change of brand name dated: 12-05-2005	Dy. No. 25530 23-07-2018 10000/-	Deferred for clarification required that last renewal of 2015 is submitted and renewal is applied in 2018 as per initial letter
798.	031082	Reset-SR Tablet Each tablet contains: Lansoprazole…….30mg	05-10-2003 Change of brand name dated: 12-05-2005	Dy. No. 25530 dated 23-07-2018 10000/-	Deferred for clarification required that last renewal of 2015 is submitted and renewal is applied in 2018 as per initial letter
799.	010029	Slepam Capsule 15mg Each tablet contains: Tenazepam.....15mg	29-11-1988	Dy. No. 25530 23-07-2018 10000/-	Deferred for confirmation of section from Licensing Division.

xxiv.	**M/s. Wise Pharmaceuticals, Plot No. 3-A, Street No. S-1, RCCI Industrial Estate, Rawat, Rawalpindi**				
800.	001016-EX	Levise Tablet Each Film Coated Tablet Contains: Levocetirizine 2HCl...5mg	28-07-2008	Dy. No. 25928 27-07-2018 10000/-	w.e.f. 28-07-2018 to 27-08-2023
801.	001017-EX	Rumak Tablet Each Film Coated Tablet Contains: Diclofenac Potassium…75mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
802.	001018-EX	Lovin Tablet 250mg Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…250mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
803.	1019-EX	Lovin Tablet 500mg Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…500mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
804.	1021-EX	Ciprise 250mg Tablet Each Film Coated Tablet Contains: Ciprofloxacin as HCl…250mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
805.	1022-EX	Ciprise 500mg Tablet Each Film Coated Tablet Contains: Ciprofloxacin as HCl…500mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
806.	1026-EX	Wizol 20mg Capsule Each Capsule Contains: Omeprazole Enteric Coated Pellets eq. to Omeprazole…20mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 20000/-	-do-
807.	1027-EX	Hexim 400mg Capsule Each Capsule Contains: Cefixime as (Trihydrate)…400mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
808.	1028-EX	Hexime Dry Suspension 100mg/5ml Each 5ml Contains: Cefixime as (Trihydrate)…100mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
809.	1029-EX	Hexime Dry Suspension 200mg/5ml Each 5ml Contains: Cefixime as (Trihydrate)…200mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
810.	1030-EX	Sofenac Capsule 500mg Each Capsule Contains: Cephradine as Monohydrate…500mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-

811.	1031-EX	Sofenac Capsule 250mg Each Capsule Contains: Cephradine as Monohydrate…250mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
812.	1032-EX	Sofenac Dry Suspension 125mg/5ml Each 5ml Contains: Cephradine as Monohydrate…125mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
813.	1033-EX	Sofenac Dry Suspension 250mg/5ml Each 5ml Contains: Cephradine as Monohydrate…250mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
814.	1034-EX	Tarson Injection 250mg Each vial contains: Ceftriaxone as Sodium…250mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
815.	1035-EX	Tarson Injection 1gm Each vial contains: Ceftriaxone as Sodium…1gm	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
816.	1036-EX	Sefox Injection 1gm Each vial contains: Cefotaxime as Sodium…1gm	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
817.	1037-EX	Sefox Injection 250mg Each vial contains: Cefotaxime as Sodium…250mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 10000/-	-do-
818.	1023-EX	Wisest 20mg Capsule Each Capsule Contains: Esomeprazole Enteric Coated Pellets eq. to Esomeprazole…20mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 20000/-	Deferred for submission of source fixation approval for pellets.
819.	1024-EX	Wisest 40mg Capsule Each Capsule Contains: Esomeprazole Enteric Coated Pellets eq. to Esomeprazole…40mg	28-07-2008	Dy. No. 25928 dated 27-07-2018 20000/-	Deferred for submission of source fixation approval for pellets.
xxv.	**M/s. Friends Pharma (Pvt) Ltd., 31-Km, Ferozepur Road, Lahore**				
820.	050136	Intelect Tablet Each Tablet Contains: Citalopram as HBr…20mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	w.e.f 23-07-2018 to 22-07-2023
821.	50137	Regainol Tablet Each Tablet Contains: Tizanidine as HCl…2mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
822.	50139	Rounder Capsule Each Capsule Contains: Cefdinir…100mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
823.	50140	Rounder Suspension Each 5ml Contains: Cefdinir…50mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-

824.	50141	Bactirol Tablet Each Tablet Contains: Moxifloxacin HCl…400mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
825.	50142	Trendone Tablet 1mg Each Tablet Contains: Risperidone…1mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
826.	50143	Trendone Tablet 2mg Each Tablet Contains: Risperidone…2mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
827.	50144	Brainagol Tablet Each Tablet Contains: Olanzapine…5mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
828.	50145	Loctal Capsule Each Capsule Contains: Gabapentin…300mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
829.	50146	Fledonil Capsule Each Capsule Contains: Tranexamic Acid…500mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
830.	50147	Ritopar Tablet Each Tablet Contains: Ritodrine HCl…10mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
831.	50148	Loctal Capsule Each Capsule Contains: Gabapentin…100mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
832.	50149	Peprozol Tablet Each Tablet Contains: Pantoprazole as Sodium Sesquihydrate…40mg	23-07-2008	Dy. No. 25307 20-07-2018 10000/-	-do-
xxvi.	**M/s. Sharex Laboratories Ltd., K.L.P. Road, Sharex Colony Sadiqabad, Distt. Rahim Yar Khan.**				
833.	14209	Anaren Tablet Each Tablet Contains: Diclofenac Sodium…50mg	05-08-1993	Dy. No. 25634 24-07-2018 10000/-	w.e.f 05-08-2018 to 04-08-2023
834.	14210	Anaren Injection Each 3ml Contains: Diclofenac Sodium…75mg	05-08-1993	Dy. No. 25635 24-07-2018 10000/-	-do-
835.	22259	Bibcol Drops Each ml Contains: Activated Dimethicone…10mg Xanthun Gum…2.5mg	31-08-1998	Dy. No. 25636 24-07-2018 10000/-	w.e.f. 31-08-2018 to 30-08-2023

Decision: Registration Board considered cases pf aforementioned firms and decision is mentioned in the last column above.

VII. DEFERRED CASES OF PREVIOUS MEETINGS

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. Synchro Pharmaceuticals, 77-Industrial Estate, Kot Lakhpat, Lahore							
836.	076945	Solanz Capsule 30mg Each capsule contains: Lansoprazole …30mg	25-06-2013	Dy. No. 21752 dated 21-06-2018 10,000/-	Deferred for approval of source of pellets as the firm has submitted a copy of request for change of their approved i.e. M/s Spansule India to new source i.e. M/s Vision Pharmaceuticals Islamabad.	The firm has now submitted the approval of pellets issued vide DRAP Letter F. No. 14-4/2019-AD PR-II (PRVC-28) dated 11-06-2019 wherein the approved source is M/s Vision Pharmaceuticals Plot No. 22-23 Industrial Triangle Kahuta Road Islamabad.	w.e.f. 25-06-2018 to 24-06-2023
837.	076946	Proset Capsule 0.4mg Each capsule contains: Tamsulosin HCl…0.4mg	25-06-2013	Dy. No. 21752 dated 21-06-2018 10,000/-	Deferred for approval of source of pellets as the firm has submitted a copy of request for change of their approved i.e. M/s Spansule India to new source i.e. M/s Vision Pharmaceuticals Islamabad.	-do-	-do-
i.	**M/s Unexolabs, 9.5-Km, Sheikhupura Road, Lahore.**						
838.	022035	Dipotil Tablet Each tablet contains: Diphenoxylate HCl…2.5mg Atropine Sulphate…0.025mg	20-05-1998	Dy. No. 21605 dated 20-06-2018 10000/- 10000/- dated 21-1-2019.	Deferred for GMP status from QA&LT Division as the submitted GMP report is of 2016.	Inspection of the firm was carried out on 27-05-2019 wherein it is concluded that Firm has shown positive approach towards compliance of GMP advises given for further up gradation. With reference to check the improvement made by the firm vide letter dated14-09-2018,the panel	w.e.f. 20-05-2018 to 19-05-2023.

						concluded that the firm has made improvement and rectification .The firm was advised to rectify the further observation noted on the same day and submit compliance report to the competent authority re-inspection will be conducted accordingly,	
839.	014271	Methacid Capsule 25mg Each capsule contains: Indomethacin …25mg	05-08-1993	Dy. No. 20441 dated 06-06-2018 10000/-	Deferred for GMP status from QA&LT Division as the submitted GMP report is of 2016	-do-	w.e.f 05-08-2018 to 04-08-2023
840.	009910	Semidine 400mg Tablet Each tablet contains: Cimetidine 400mg	15-09-1988	Dy. No. 20441 dated 06-06-2018 10000/-	Deferred for GMP status from QA&LT Division as the submitted GMP report is of 2016	-do-	w.e.f 15-09-2018 to 14-09-2023
841.	009911	Empicil Capsule 250mg Each capsule contains: Ampicillin as Trihydrate …250mg	15-09-1988	Dy. No. 20441 dated 06-06-2018 10000/-	Deferred for GMP status from QA&LT Division as the submitted GMP report is of 2016	-do-	w.e.f 15-09-2018 to 14-09-2023
M/s. AGP Limited, B-23-C, S.I.T.E., Karachi.							
842.	024881	Novafol 250mg Capsules Each capsule contains: Cephradine……250mg	23-06-1999 Transfer of registration dated 17-07-2008	Dy. No. 21874 dated 22.6.2018 10000/-	Registration Board decided to defer the case for the opinion from legal Affair Division and clarification from the firm regarding the matter related to dedicated section of Cephalosporin under Schedule B Section I (5.2).**Dedicated Facilities for Production of** Drug Act 1976. Whether firm is legally authorize to hold the registration of such product for	The firm now submitted that at the time of registration of this product they had approved area for the production of cephalosporin products. Now the firm has applied for transfer of registration vide letter dated 14-03-2019.	Deferred for confirmation of transfer of registration from concerned section.

					which they do not have dedicated section currently. According to the firm, they have approved area for the production of Cephalosporin at the time of Registration later the firm discontinued the production of Cephalosporin and the firm do not have approval of Cephalosporin section vide letter no. F.2-3/92-Lic (Vol-II) Dated 28th April, 2016 of Licensing Division.		
843.	024882	Novafol 500mg Capsules Each capsule contains: Cephradine.500mg	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21875 dated 22.6.2018 10000/-	-do-	-do-	-do-
844.	024883	Novafol Suspension Each 5ml Contains: Cephradine.125mg	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21872 dated 22-6-2008 10000/-	-do-	-do-	-do-
845.	024884	Novafol 250mg Suspension Each 5ml contains: Cephradine 250mg	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21873 dated 22.6.2018 10000/-	-do-	-do-	-do-
846.	024878	Novafol 250mg Injection (IM/IV) Each vial contains: Cephradine…..250 mg	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21876 dated 22.6.2018 10000/-	-do-	The firm now submitted that at the time of registration of this product they had approved area for the production of cephalosporin products. Now the firm stated they are planning to extend their facility for the manufacturing/ filling of Cephalosporin Injectable in future and facility will be ready till	Defferred for issuance of showcause under and section 42 of Drug Act 1976 read with Schedule B-I (5.2) of Drug (LRA) Rules 1976 to the firm regarding manufacturing facility for Cephalosporins.

						next renewal of this product. Therefore the request for giving time for suitable period for establishment of facility. As the firm has not approved manufacturing facility therefore registration may be suspended and show cause may be issued.	
847.	024879	Novafol Injection IM/IV Each vial contains: Cephradine.500mg	23-06-1999 Transfer of registration dated 17-07-2008	Dy. No. 21877 dated 22-6-2008 10000/-	-do-	-do-	-do-
848.	024880	Novafol Injection IM/IV Each vial contains: Cephradine..1gm	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21878 dated 22-6-2008 10000/-	-do-	-do-	-do-
849.	024949	Tecadin Injection 250mg IM/IV Each vial contains: Cefoperazone …..250mg	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21863 dated 22-6-2008 10000/-	-do-	-do-	-do-
850.	024950	Tecadin Injection 500mg IM/IV Each vial contains: Cefoperazone …..500mg	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21864 dated 22-6-2008 10000/-	-do-	-do-	-do-
-do-	-do-	Tecadin Injection 1gm IM/IV Each vial contains: Cefoperazone.1gm	23-06-1999 Transfer of registration dated 17-7-2008	Dy. No. 21865 dated 22-6-2008 10000/-	-do-	-do-	-do-
851.	018070	Kefadim 1gm Injection Each vial contains: Ceftazidime Sterile…..1.00gm	24-09-1995 Transfer of registration dated 13-10-2003	Dy. No. 21868 dated 22.6.2018 10000/-	Registration Board decided to defer the case for the clarification of status of Application of year 2011 for the extension in contract manufacturing from the concerned section. As the firm submitted permission dated 15-7-2008 of contract	The firm stated that they had applied for contract extension in 2011 which is pending. Now the firm stated they are planning to extend their facility for the manufacturing/ filling of Cephalosporin Injectable in future and	-do-

					manufacturing from M/s PharmEvo Pvt Limited Karachi for three years. The firm also informed that they had applied for extension in 2011 from same facility for five years but no evidence of approval of extension is provided. They further stated that product is discontinued.	facility will be ready till next renewal of this product. Therefore the request for giving time for suitable period for establishment of facility.	
852.	018069	Kefadim 500mg Injection Each vial contains: Ceftazidime Sterile…….500mg	24-09-1995 Transfer of registration dated 13-10-2003	Dy. No. 21868 dated 22.6.2018 10000/-	-do-	-do-	-do-
853.	036178	Kefadim 250mg Injection Each vial contains: Ceftazidime Pentahydrate eq. to Ceftazidime …..250mg	10-01-2005	Dy. No. 21866 dated 22-6-2008 10000/-	-do-	-do-	-do-
854.	021640	Phyllocontin 100mg Tablet Each tablet contains: Aminophylline Hydrate…100mg	20-05-1998 Transfer of registration dated 17-7-2008	Dy. No. 21852 dated 22.6.2018 10000/-	As the product was initially registered with the brand name Phyllocontin Continus Tablet. The transfer of registration also bears the same name. However the transfer letter dated 17-7-2008 bears only "Phyllocontin" when the was inquired about the evidence of change of brand name, they informed that: "*The full brand name is Phyllocontin Continus Tablet, sometimes it is mentioned in short form as Phyllocontin 100mg Tablet"*	The firm submitted that they had not changed brand name and however the reply is again submitted in name of Phyllocontin Tablets	Deferred for final clarifaction regarding Brand name from the firm.

					Registration Board decided to defer the case for the clarification from the firm regarding the change of brand name if any.		
855.	016418	Nebcin Injection 80mg Each vial contains: Tobramycin Sulphate….. 80mg	21-11-1994 Change of brand name dated 30-8-2003	Dy. No. 21857 dated 22-6-2008 10000/-	Registration Board decided to defer the case for the clarification of transfer of registration in the name of M/s. AGP Limited, Karachi from the concerned section.	The change of brand name dated 30-08-2003 is issued to M?s AGP Pvt Limited B-23 Karachi.	w.e.f 30-08-2018 to 29-08-2023
856.	016908	Tojina 6.0mg Tablet Each tablet contains: Bromazepam…..6 mg	Transfer of registration dated: 02-07-1999 Change of brand name 30-08-2003	Dy. No. 21862 dated 22-6-2008 10000/-	Deferred for following: i. Opinion from Legal Affair Division regarding those firms where at the time of registration there is no requirement for approval of Psychotropic section but later on it is mandatory to do so, in the light of decision of Central Licensing Board in its 233rd meeting i.e. as follows: After thorough deliberations and keeping in view the directions of Policy Board, recommendations of DRAP Authority, recommendations of Committee for Allocation of Controlled Substances / Drugs (Inter-Ministerial Committee), views of honorable members, previous decisions of Central Licensing Board on the said issue, and ensuring adequate	The firm stated that at the time of registration of this product there is no requirement for approval of psychotropic section. The requirement of section becomes mandatory in 233rd meeting of CLB held on 30-31st December, 2013. . Now the firm stated they are planning to extend their facility for the manufacturing/ filling psychotropic drugs in future and facility will be ready till next renewal of this product. Therefore the request for giving time for suitable period for establishment of facility. As the firm has not approved manufacturing facility therefore registration may be suspended and show cause may be issued.	Deferred for issuance of reminder for opinion from Legal Affairs division

					availability of narcotic drugs and psychotropic substances for medical and scientific purposes as highlighted by INCB, the Central Licensing Board decided: - □ To continue the previous policy / decisions of Central Licensing Board of segregated facility for manufacturing of Psychotropic / Narcotic Drugs. □ To process all pending layout plans / applications accordingly in the light of above decision. □ To carryout fresh panel inspections of sections / areas of Psychotropic / Narcotic Drugs considered and deferred in 227th meeting of CLB. ii. Clarification from the firm regarding transfer of registration in name of M/s AGP Pvt Limited from the firm.		
857.	016907	Tojina 3.0mg Tablet Each tablet contains: Bromazepam..3mg	Transfer of registration dated: 02-07-1999 Change of brand name : 30-8-2003	Dy. No. 21861 dated 22-6-2008 10000/-	-do-	-do-	-do-
ii.	**M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi**						
858.	039557	Nettle Capsules 250mg Each capsule contains: Cefaclor..250mg	31-08-2005	Dy. No. dated 28-06-2018 10,000/-	Deferred for clarification of following from concerned section: The product was initially registered	The firm submitted that they had applied for transfer of registration on concerned section	Deferred for confirmation of transfer of registration from M/s Pride Pharmaceutical

					in name of M/s Pride Pharmaceuticals Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi. The title/ name of the firm was changed from aforesaid name to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi vide approval dated 22-10-2008 by Licensing Division. However the product was not transferred on the new title. It further to mention that Brand Name of this product was changed from Noor Capsule 250mg to Nettle Capsules 250mg vide approval dated 8-11-2008 by Registration Division in name of M/s Nexus Pvt Limited.	on 16-12-2016 and waiting for approval.	s Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi to M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi from concerned section.
859.	039558	Nettle capsules 500mg Each capsule contains: Cefaclor…500mg	31-08-2005	Dy. No. dated 28-06-2018 10,000/-	-do-	-do-	-do-
860.	039555	Nettle Suspension 125mg/5ml Each 5ml contains: Cefaclor….125mg	31-08-2005	Dy. No. dated 28-06-2018 10,000/-	-do-	-do-	-do-
861.	039561	Nitaxim 250mg Injection Each vial contains: Cefotaxime (as Sodium)….250mg	31-08-2005	Dy. No. dated 28-06-2018 ,000/-	-do-	-do-	-do-
862.	039563	Nitaxim Injection 1gm Each powder vial contains: Cefotaxime (as Sodium)….1gm	31-08-2005	Dy. No. dated 28-06-2018 10,000/-	-do-	-do-	-do-

863.	039562	Nitaxim Injection 500mg Each powder vial contains: Cefotaxime (as Sodium)…500mg	04-07-2013	Dy. No. dated 28-06-2018 10,000/-	-do-	-do-	-do-
864.	039529	Flur Tablet 100mg Each tablet contains: Flurbiprofen …..100mg	31-08-2005	Dy. No. dated 28-06-2018 10,000/-	-do-	-do-	-do-
865.	039633	Coozip Capsules 20mg Each capsule contains: Omeprazole.20mg	24-10-2005	Dy. No. dated 28-06-2018 10,000/-	-do-	-do-	-do-
M/s. GlaxoSmithKline Pakistan Limited F-268, S.I.T.E. ,Karachi							
866.	021770	Calpol Plus Tablet Each Tablet Contains: Paracetamol…500 mg Caffeine…65mg	20-05-1998 30-08-2003	Dy. No. 25292 dated 20-07-2018 10000/-	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 06-05-2019 which has not yet been responded by the firm. 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. Valid Drug Manufacturing License.	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.
867.	012427	Calpol 6 Plus Suspension Each 5ml Contains: Paracetamol …250mg	14-03-1991	Dy. No. 25292 dated 20-07-2018 10000/-	-do-	-do-	-do-
868.	000354	Calpol Suspension Each 5ml Contains: Paracetamol …120mg	17-04-1976	Dy. No. 25292 dated 20-07-2018 10000/-	-do-	-do-	-do-
869.	001612	Calpol Tablet Each Tablet Contains: Paracetamol …500mg	15-08-1976	Dy. No. 25292 dated 20-07-2018 10000/-	-do-	-do-	-do-
870.	000355	Cicatrin Powder Each gm Contains: Neomycin	17-04-1976	Dy. No. 25298 dated 20-07-2018	-do-	-do-	-do-

		Sulphate…3300 Units Bacitracin Zinc…250 Units		10000/-			
871.	000301	Cytacon Liquid Each 5ml Contains: Cyanocobalamin …25mcg	20-04-1976	Dy. No. 25298 dated 20-07-2018 10000/-	-do-	-do-	-do-
872.	008382	Marzine Syrup Each 5ml Contains: Cyclizine HCl…12.5mg	18-06-1985	Dy. No. 25293 dated 20-07-2018 10000/-	-do-	-do-	-do-
873.	000179	Maxolon Syrup Each 5ml Contains: Metoclopramide HCl eq. to Anhydrous Sustance…5mg	16-04-1976	Dy. No. 25293 dated 20-07-2018 10000/-	-do-	-do-	-do-
874.	013321	Nemazole Suspension Each 5ml Contains: Mebendazole …100mg	25-05-1992	Dy. No. 25299 dated 20-07-2018 10000/-	-do-	-do-	-do-
875.	013320	Nemazole Tablet Each Tablet Contains: Mebendazole …100mg	25-05-1992	Dy. No. 25299 dated 20-07-2018 10000/-	-do-	-do-	-do-
876.	017306	Nemazole-500 Chewable Tablet Each Tablet Contains: Mebendazole …500mg	21-06-1995	Dy. No. 25299 dated 20-07-2018 10000/-	-do-	-do-	-do-
M/s. GlaxoSmithKline Pakistan Limited,35- Dockyard Road, West Wharf, Karachi							
877.	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	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	Deferred for clalrifcation from the firm for complete details regarding transfer of registration and sections since initial regsitation.

					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). 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.	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.	
878.	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-
879.	003139	Dermovate Ointment Contains: Clobetasol	10-12-1977	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-

		Propionate…0.05 %w/w					
880.	003100	Dermovate Cream Contains: Clobetasol Propionate…0.05 %w/w	10-12-1977	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
881.	000401	Fefol Spansule 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-
882.	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-
883.	020543	Fefol Z Spansule Pellets Each Capsule Contains: Dried Ferrous Sulphate…150mg Zinc Sulphate Monohydrate (eq. to 22.5mg Elemental Zinc)…61.8mg Folic Acid …0.5mg	12-11-1997	Dy. No. 25294 dated 20-07-2018 10000/-	-do-	-do-	-do-
884.	089275	Maxolon Injection Each 2ml Contains: Metoclopramide… 10mg	28-08-1977	Dy. No. 25293 dated 20-07-2018 10000/-	-do-	-do-	-do-
885.	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-
886.	000178	Maxolon Injection Each 2ml Contains:	28-08-1977	Dy. No. 25293 dated 20-07-2018	-do-	-do-	-do-

		Metoclopramide …10mg		10000/-			
887.	001608	Lanoxin Injection Each 2ml Ampoul Contains: Digoxin…0.5mg	15-08-1976	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
888.	000365	Lidosporin Ear Drops Each ml Contains: Polymyxin B Sulphate …10,000IU Lignocaine HCl …50mg Propylene Glycol…0.92ml	17-04-1976	Dy. No. 25295 dated 20-07-2018 10000/-	-do-	-do-	-do-
889.	000370	Otosporin Ear Drops Each ml Contains: Polymyxin B Sulphate.10,000IU Neomycin Sulphate …3,400Units Hydrocortisone Acetate…10mg	17-04-1976	Dy. No. 25291 dated 20-07-2018 10000/-	-do-	-do-	-do-
890.	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-
M/s. GlaxoSmithKline Pakistan Limited,Plot 5,Sector 21,Korangi Industrial Area, Karachi							
891.	003375	Ceporex Capsule 250mg Each Capsule Contains: Cephalexin Anhydrous (as Cephalexin)…250 mg	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 Manufactu	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.

					ring License. c) Approval of products in reference regulatory agencies.		
892.	005641	Ceporex Capsule 500mg Each Capsule Contains: Cephalexin Anhydrous (as Cephalexin) …500mg	16-11-1980	Dy. No. 25296 dated 20-07-2018 10000/-	-do-	-do-	-do-
893.	010806	Ceporex Paediatric Drops Each 1.25ml Contains: Cephalexin …125mg	24-03-1990	Dy. No. 25296 dated 20-07-2018 10000/-	-do-	-do-	-do-
894.	003374	Ceporex Syrup 125mg/5ml Each 5ml Contains: Cephalexin Anhydrous (as Cephalexin) …125mg	04-01-1978	Dy. No. 25296 dated 20-07-2018 10000/-	-do-	-do-	-do-
895.	006408	Ceporex Syrup 250mg/5ml Each 5ml Contains: Cephalexin Anhydrous (as Cephalexin) …250mg	07-08-1982	Dy. No. 25296 dated 20-07-2018 10000/-	-do-	-do-	-do-
M/s. GlaxoSmithKline Pakistan Limited							
896.	68	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.

VIII. DEFERRED IMPORTED CASES OF PREVIOUS MEETINGS

Sr. No	Reg. No.	Manufacturer	Brand Name and Composition	Initial date of Registration	Date of application (R&I) Fee submitted	Remarks (if any)
i.	**M/s Pantex Pharmaceutica 26 Abbot Road Lahore**					
897.	049736	M/s Pantex Holland B.V., Holland	Doxycyclin 500 Water Solube Powder Each gm contains: Doxycycline Hyclate….500mg	24-09-2008	Dy. No. 27669 dated 13-08-2018 20000/-	Deferred for issuance of final reminder for submission of CoPP.
898.	049735	M/s Pantex Holland B.V., Holland	Amoxy C Water Soluble Powder Each gm contains: Colistin as base (as sulphate)…50mg Amoxicillin base as trihydrate….200mg	24-09-2008	Dy. No. 27669 dated 13-08-2018 20000/-	-do-
ii.	**M/s. Ghazi Brothers,Ghazi House D-35,K.D.A Scheme # 1,Miran Muhammad Shah Road, Karachi**					
899.	049607	M/s. Distributors Processing Incorporated,USA	Cocci-Guard Powder Each dose of Cocci-Guard Contains: Steroidal Sapoginins 13600ppm	06-09-2008	Dy. No. 28555 24-08-2018	Deferred for issuance of final reminder for submission of CoPP.
900.	049606	Manufactured by M/s. Laboratories Pfizer Ltd.,Brazil	Terramycin Soluble Powder with Anti-germ 77 Each 100gm contains: Terramycin(Oxytetyracycline Chlorhydrate) 5.6gm Anti-germ 77 (benzetonium chloride)5.5gm	06-09-2008	Dy. No. 28560 24-08-2018	-do-
iii.	**M/s Prix Pharmaceutica 26 Abbot Road Lahore.**					
901.	049578	M/s Fatro S.p.A Italy.	Oxtra Effervescent Tablets Each pessary contains: Oxytetracycline hydrochloride eq. to Oxytetracycline …..1gm	02-09-2008	Dy. No. 27823 dated 13-08-2018 20000/-	Deferred for issuance of final reminder for submission of CoPP.
902.	021492	M/s Fatro S.p.A Italy.	Aminolife Poultry W/S Powder	16-09-1998	Dy. No. 27823 13-08-2018 20000/-	-do-
903.	049579	M/s Fatro S.p.A Italy.	Micospectone Each ml contains: Lincomycin 50mg as Lincomycin HCL 56070mg Spectinomycin 100mg as Spectinimycin HCl 150mg	02-09-2008	Dy. No. 27823 dated 13-08-2018 20000/-	-do-

iv.	**M/s. Atco Pharma International (Pvt) Ltd., B-18, S.I.T.E., Karachi**					
904.	047676		Femizet Tablets 1mg Each film coated tablets contains: Anastrozole IH*…1mg (In House)	05-08-2008 Change: 04-01-2010	Dy. No. 25638 dated 24-07-2018 20000/-	Deferred for further evaluation.
v.	**M/s. Vet Line International, Flat No. 55/5, First Floor, Shadman Market, Lahore**					
905.	049749	M/s Bela-Pharm GmnH & Co., KG Lohner Str. 19 49377 Vechta Germany.	Tylo-Suscit Powder Each gm Contains: Tylosin Tartrate…250mg	25-09-2008	Dy. No. 23134 dated 04-07-2018 20000/-	w.e.f. 25-09-2018 to 24-09-2023
906.	049750	M/s Bela-Pharm GmnH & Co., KG Lohner Str. 19 49377 Vechta Germany.	Sulfaclozin Na 60% Powder Each gm Contains: Sulfaclozin Sodium…600mg	25-09-2008	Dy. No. 23134 dated 04-07-2018 20000/-	w.e.f. 25-09-2018 to 24-09-2023
vi.	**M/s. Medinet Pharmaceuticals Building No.601, Lane. No. 5, Main Peshawar Road, Rawalpindi**					
907.	028482	M/s Dae Han New Pharm. Co., Ltd. 66-Jeyakgongdan 1-gil, Hyangnam-eup, Hwaseog-si, Gyeonggi-do, Republic of Korea.	Hydra Capsule Each capsule contains: Hydroxyurea……. 500mg	26-08-2003	Dy. No. 28380 20-08-2018	Deferred for issuance of final reminder for submission of following: i. Valid Legalized CoPP
	028482	M/s Dae Han New Pharm. Co., Ltd. 904-3 Shangshin- ri, Hyangnam-myun, Hwasung-si, Kyunggi-do Republic of Korea.	DAC Injection Each vial contain: Dacarbazine…200mg	26-08-2003	Dy. No. 28381 20-08-2018	Deferred for issuance of final reminder for submission of following: i. Valid Legalized CoPP
908.	028491	M/s. Laboratorio Varifarma S.A. Argentina	Etoside Injection Each ampoule contains: Etoposide….100mg	01-09-2003	Dy. No. 28383 20-08-2018	Deferred for issuance of final reminder for submission of following: i. Valid Legalized CoPP
909.	028489	M/s. Laboratorio Varifarma S.A. Argentina	Tamodex Tablets Each tablet contains: Tamoxifen Citrate equivalent to 10mg Tamoxifen base	01-09-2003	Dy. No. 28385 20-08-2018	Deferred for issuance of final reminder for submission of following: i. Valid Legalized CoPP

910.	028490	M/s. Laboratorio Varifarma S.A. Argentina	Tamodex Tablets Each tablet contains: Tamoxifen Citrate equivalent to 20mg Tamoxifen base	01-09-2003	Dy. No. 28385 20-08-2018	Deferred for issuance of final reminder for submission of following: i. Valid Legalized CoPP	
911.	028493	M/s. Laboratorio Varifarma S.A. Argentina	Progace Tablet Each tablet contains: Megestrol Acetate…160mg	01-09-2003	Dy. No. 28384 20-08-2018	Deferred for issuance of final reminder for submission of following: i. Valid Legalized CoPP	

IX. MISCELLANEOUS CASES

A. M/s Biocare Pharmaceutica Lahore

Sr. No	Reg. No.	Manufacturer	Brand Name & Composition	Initial date of Reg.	Date of application (R&I) Fee submitted	Decision of RB in 288th meeting	Remarks
912.	028469	M/s Suzhou Dawnrays Pharmaceuticals Co., Ltd, No.22 Tianling Road, Wuzhongu Economic Development District Suzhou, Giangsu, China	Sulzone 2.0Gm Injection. Each Vial Contains: Cefoperazone as sodium salt 1.0gm. Sulbactam as sodium salt 1.0gm	06-08-2003	Dy. No. 25892 dated 27-07-2018 20000/-	Deferred for following: 1. Deferred for evaluation as per Import Policy for Finished Drugs. 2. Address of DSL varies from address on registration letter. 3. Clarification required because the clearance of the consignments was obtained from DRAP Karachi on the address M/s Biocare Pharmaceutica 705, Progressive Square , Block 6- PECHS Karachi whereas the registration holder is M/s. Biocare Pharmaceutica, 807 Shadman-1, Lahore	The firm submitted following documents: 1. The firm submitted letter dated 10-02-2016 received in DRAP on 19-02-2016 regarding change of address and Tel. Number. "M/s Biocare Pharmaceutica 807-Shadman Colony-1 Lahore." 2. The firm has submitted the copies of indents/ authorization to their Karachi office for clearance of consignments . The firm submitted copy of DSL having address M/s Biocare Pharmaceutic

						4. Legalized FSC submitted by the firm was expired on 30-3-2019, however valid at time of submission.	a 705, Progressive Square , Block 6-PECHS Karachi 3. The firm has now submitted new Legalized CoPP bearing No. JS20190097 dated 28-03-2019 and validity upto 17-09-2020.
913.	028468	-do-	Sulzone 1.0Gm Injection Each Vial Contains: Cefoperazone as sodium salt 500mg. Sulbactam as sodium salt 500mg	06-08-2003	Dy. No. 25888 dated 27-07-2018 20000/-	-do-	-do-
Decision: Registration Board acceded to the request of the firm and confirms the receipt of renewal application of above products subject to prevailing Import Policy for Finished Drugs.							

B. M/s Alina Combine Pharmaceuticals Pvt Limited Karachi.

Sr. No	Reg. No.	Manufacturer	Brand Name & Composition	Initial date of Registration	Date of application (R&I) Fee submitted	Decision of RB in 289th meeting
914.	48183	M/s Alfasan International BV The Netherlands	Oxytetracycline 10% Injectable Solution Each ml Contains: Oxytetracycline HCl…100mg	17-07-2008	Dy. No. 23435 dated 06-07-2018 10000/-	Letter of shortcomings was issued to the firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 and 09-04-2019 which has not yet been responded by the firm.
915.	48184	M/s Alfasan International BV The Netherlands	Tylosin 20% Injectable Solution Each ml Contains: Tylosin (as Tartrate)…200mg	17-07-2008	Dy. No. 23435 dated 06-07-2018 10000/-	-do-
916.	48180	M/s Alfasan International BV The Netherlands	Alfamec 1% Injectable Solution Each ml Contains: Ivermectin…10mg	12-07-2008	Dy. No. 22816 dated 02-07-2018 10000/-	-do-
917.	48181	M/s Alfasan International BV The Netherlands	Xylazine 2% Injectable Solution Each ml Contains: Xylazine (as HCl)…20mg	12-07-2008	Dy. No. 22816 dated 02-07-2018 10000/-	-do-

918.	48182	M/s Alfasan International BV The Netherlands	Lincomycine-Spectinomycin 5/10 Injectable Solution Each ml Contains: Lincomycin (as HCl)…50mg Spectinomycin (as HCl)…100mg	12-07-2008	Dy. No. 22816 dated 02-07-2018 10000/-	-do-
919.	48185	M/s Alfasan International BV The Netherlands	Multivitamin Injectable Solution Each ml Contains: Vitamin A (as Synthetic Concentrate Oily Form)…15,000IU Cholecalciferol (as Concentrate Oily Form)…1000IU Alpha tocopheryl Acetate…20mg Thiamine HCl…10mg Riboflavine Sodium Phosphate …6.85mg Pyridoxine HCl…3mg Cyanocobalamin …50mcg Nicotinamide …35mg Dexpanthenol...25 mg	12-07-2008	Dy. No. 22815 dated 02-07-2018 10000/-	

It is submitted that M/s Alfasan International BV The Netherlands have submitted letter dated 10-07-2019 wherein they have informed that they terminated the sole distribution agreement with Alina Combine Pharmaceuticals Pvt Limited Karachi from 26-01-2010. No exports have been made after cancellation of distribution agreement and they have aslo not been permitted to manufacture products locally. The firm futher informed that they have appointed M/s Chakwal Pharma International Lahore as their sole agents for above mentioned and other products.M/s Alfasan International BV The Netherlands has also submitted copy of legalized Sole Authorization letter in name of M/s Chakwal Pharma International Lahore.

It is to mention that Form-5B submitted in renewal application of indicates that they manufacturing the products locally however the authorization letter from import to local has not been submitted. The aforementioned letter of shortcomings communicated to firm vide letter No. F.1-65/ 2018 (RRR) dated 5-3-2019 and 09-04-2019 has also not been responded by the firm.

Decision: Registration Board deferred the case for confirmation of transfer of registration of M/s Alina Combine from import to local from concerned section.

C. **M/s. Legacy Pharmaceuticals (Pvt) Limited, 111-A Industrial Estate Hayatabad, Peshawar**

Following products of M/s M/s. Legacy Pharmaceuticals (Pvt) Limited, 111-A Industrial Estate Hayatabad, Peshawar were deferred in the 289th meeting of Registration Board due to following shortcomings communicated to the firm vide letter No. F.1-65/ 2018 (RRR) dated 10-04-2019

i. Latest c GMP inspection report
ii. Section approval letter issued by Licensing Division
iii. Valid DML
iv. Differential fee for products containing imported pellets.
v. Approval of formulation for Legofen P 50mg Capsules (Reg. No. 050098)
vi. Notarized copy of initial registration letter of all applied products.

Now the firm has submitted the above documents. Details of the products are as under:

Sr. No	Reg. No.	Brand Name & Composition	Initial date of Registration	Date of application (R&I) Fee submitted	Remarks
920.	50092	Lesozol 20mg Capsule Each Capsule Contains: Esomeprazole as Magnesium Trihydrate…20mg	21-07-2008	Dy. No. 24171 12-07-2018 10000/-	Deferred for confirmation of source fixation letter.
921.	50093	Lesozol 40mg Capsule Each Capsule Contains: Esomeprazole as Magnesium Trihydrate…40mg	21-07-2008	Dy. No. 24171 12-07-2018 10000/-	Deferred for confirmation of source fixation letter.
922.	50094	Ompecid Capsule 20mg Each Capsule Contains: Omeprazole Pellets…20mg	21-07-2008 Brand name change dated: 16-1-2014	Dy. No. 24171 12-07-2018 10000/-	Deferred for confirmation of source fixation letter.
923.	50095	Ompecid Capsule 40mg Each Capsule Contains: Omeprazole Pellets…40mg	21-07-2008 Brand name change: 16-1-2014	Dy. No. 24171 12-07-2018 10000/-	Deferred for confirmation of source fixation letter.
924.	50096	Lanso Capsule Each Capsule Contains: Lansoprazole…30mg	21-07-2008	Dy. No. 24171 12-07-2018 10000/-	Deferred for confirmation of source fixation letter.
925.	50097	Legofen Capsule Each Capsule Contains: Diclofenac Sodium Pellets…50mg	21-07-2008	Dy. No. 24171 12-07-2018 10000/-	Deferred for confirmation of source fixation letter.
926.	49854	Urinac Tablet Each Tablet Contains: Norfloxacin…400mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
927.	49855	Legamox 400mg Tablet Each Tablet Contains: Moxifloxacin…400mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
928.	49856	Lepracit10mg Tablet Each Tablet Contains: Escitalopram as Oxalate…10mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023

929.	49857	Ribena-F Tablet Each Chewable Tablet Contains: Iron III Hydroxide Polymaltose Complex eq. to Elemental Iron …100mg Folic Acid…0.35mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
930.	49858	Ciprat 20mg Tablet Each Film Coated Tablet Contains: Citalopram as HBr…20mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
931.	49859	Emitilium 10mg Tablet Each Tablet Contains: Domperidone…10mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
932.	49860	Napxen 250mg Tablet Each Film Coated Tablet Contains: Naproxen…250mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
933.	49861	Napxen 500mg Tablet Each Film Coated Tablet Contains: Naproxen…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
934.	49862	Acetamol 500mg Tablet Each Tablet Contains: Paracetamol…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
935.	49863	Acetamol Extra Tablet Each Tablet Contains: Paracetamol…500mg Caffeine…65mg Chlorpheniramine Maleate…2mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
936.	49864	Levobac 250mg Tablet Each Film Coated Tablet Contains: Levofloxacin as Hemihydrate…250mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
937.	49865	Levobac 500mg Tablet Each Film Coated Tablet Contains: Levofloxacin as Hemidydrate…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
938.	49866	Olax 200mg Tablet Each Film Coated Tablet Contains: Ofloxacin…200mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
939.	49867	Olax 400mg Tablet Each Film Coated Tablet Contains: Ofloxacin…400mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
940.	49868	Leganil 500mg Tablet Each Tablet Contains: Nalidixic Acid…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
941.	49869	Leganil 1000mg Tablet Each Tablet Contains: Nalidixic Acid…1000mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
942.	49870	Legocip 250mg Tablet Each Film Coated Tablet Contains: Ciprofloxacin as HCl…250mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
943.	49871	Legocip 500mg Tablet Each Film Coated Tablet Contains: Ciprofloxacin as HCl…500mg	16-07-2008	Dy. No. 24316 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
944.	49872	Lexime 400mg Capsule Each Capsule Contains: Cefixime…400mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023

945.	49873	Roxif 500mg Capsule Each Capsule Contains: Cefadroxil as Monohydrate…500mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
946.	49874	Fluzox 150mg Capsule Each Capsule Contains: Fluconazole…150mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
947.	49875	Depox 20mg Capsule Each Capsule Contains: Fluoxetine as HCl…20mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
948.	49876	Legicam 20mg Capsule Each Capsule Contains: Piroxicam…20mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
949.	49877	Legaceph 250mg Capsule Each Capsule Contains: Cephradine…250mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
950.	49878	Legaceph 500mg Capsule Each Capsule Contains: Cephradine…500mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
951.	49879	Efaclor 250mg Capsule Each Capsule Contains: Cefaclor…250mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
952.	49880	Efaclor 500mg Capsule Each Capsule Contains: Cefaclor…500mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
953.	49881	Lexina 250mg Capsule Each Capsule Contains: Cephalexin as Monohydrate…250mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
954.	49882	Lexina 500mg Capsule Each Capsule Contains: Cephalexin as Monohydrate…500mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
955.	49883	Fusidax Cream Each gm Contains: Fusidic Acid…20mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
956.	49884	Fusidax-H Cream Each gm Contains: Fusidic Acid…20mg Hydrocortisone Acetate…10mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
957.	49885	Polybac Skin Ointment Each gm Contains: Polymyxin B Sulphate…10,000Units Bacitracin Zinc…500Units	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
958.	49886	Clozam Cream Each gm Contains: Clotrimazole…10%	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
959.	49887	Legicam Cream Each gm Contains: Piroxicam…0.5%	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
960.	49888	Hydrol ORS Sachet Each Sachet Contains: Sodium Chloride…2.6gm Trisodium Citrate Dihydrate…2.9gm Potassium Chloride…1.5gm Dextrose Anhydrous…13.05gm	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023

961.	49889	Airin Syrup Each 5ml Contains: Salbutamol as Sulphate…2mg	16-07-2008	Dy. No. 24317 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
962.	49890	Doxip Dry Suspension Each 5ml Contains: Cefpodoxime as Proxetil…40mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
963.	49891	Leganil Suspension Each 5ml Contains: Nalidixic Acid…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
964.	49892	Leriton Syrup Each 5ml Contains: Chlorpheniramine Maleate…2mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
965.	49893	Acetamol Suspension Each 5ml Contains: Paracetamol…120mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
966.	49894	Metrol Suspension Each 5ml Contains: Metronidazole as Benzoate…200mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
967.	49895	Lexime Dry Suspension Each 5ml Contains: Cefixime…100mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
968.	49896	Emitilium Suspension Each ml Contains: Domperidone…1mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
969.	49897	Roxif 125mg Dry Suspension Each 5ml Contains: Cefadroxil as Monohydrate…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
970.	49898	Roxif 250mg Dry Suspension Each 5ml Contains: Cefadroxil as Monohydrate…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
971.	49899	Legaceph 125mg Dry Suspension Each 5ml Contains: Cephradine…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
972.	49900	Legaceph 250mg Dry Suspension Each 5ml Contains: Cephradine…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
973.	49901	Laxina 125mg Dry Suspension Each 5ml Contains: Cephalexin as Monohydrate…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
974.	49902	Laxina 250mg Dry Suspension Each 5ml Contains: Cephalexin as Monohydrate…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
975.	49903	Efaclor 125 Dry Suspension Each 5ml Contains: Cefaclor…125mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
976.	49904	Efaclor 250 Dry Suspension Each 5ml Contains: Cefaclor…250mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
977.	49905	Cofnol-E Syrup Each 5ml Contains: Aminophylline…32mg Diphenhydramine HCl…8mg Ammonium Chloride…30mg Menthol…0.98mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023

978.	49906	Montekast Sachet Each Sachet Contains: Montelukast as Sodium…4.0mg	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
979.	49907	Noscab Cream Contains: Lindane…1%	16-07-2008	Dy. No. 24318 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
980.	49908	Skinazin Cream Contains: Silver Sulphadiazine ..1%	16-07-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
981.	49909	Remistate Cream Contains: Miconazole Nitrate…2%	16-07-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f. 16-07-2018 to 15-07-2023
982.	50098	Legofen-P Capsule Each Capsule Contains: Diclofenac Potassium Pellets…50mg	21-07-2008	Dy. No. 24319 12-07-2018 10000/-	Defered for confirmation of evidence of approval of formulation in reference drug agencies.
983.	52832	Hireez 10mg Tablet Each Film Coated Tablet Contains: Cetirizine 2HCl…10mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f 20-11-2018 to 19-11-2023
984.	52833	Legofen Gel Each 100gm Contains: Diclofenac as Diethyl Ammonium Salt…1gm	20-11-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f 20-11-2018 to 19-11-2023
985.	52834	Hireez Syrup Each ml Contains: Cetirizine 2HCl…1mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f 20-11-2018 to 19-11-2023
986.	52835	Ribena-F Syrup Each 5ml Contains: Iron-III Hydroxide Polymaltose Complex eq. to Elemental Iron…50mg Folic Acid…0.35mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f 20-11-2018 to 19-11-2023
987.	52836	Lebon Sachet Each Sachet Contains: Calcium Lactate Gluconate…3.24g Calcium Carbonate…0.30g	20-11-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f 20-11-2018 to 19-11-2023
988.	52837	Ener-Cee Sachet Each Sachet Contains: Calcium Lactate Gluconate…1000mg Vitamin C…500mg Calcium Carbonate…327mg	20-11-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f 20-11-2018 to 19-11-2023
989.	52838	Remistate-HC Cream Each Tube Contains: Miconazole Nitrate…2% Hydrocortisone…1%	20-11-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f 20-11-2018 to 19-11-2023
990.	53622	Spasmorin Tablet Each Tablet Contains: Mebeverine as HCl…135mg	04-12-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f. 04-12-2018 to 03-12-2023
991.	53623	Ascorbic-500 Sachet Each Sachet Contains: Vitamin C…500mg	04-12-2008	Dy. No. 24319 12-07-2018 10000/-	w.e.f. 04-12-2018 to 03-12-2023

Decision: **Registration Board considered the case of aforementioned firms and decision is recorded in the last column.**

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	Remarks
M/s Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore.						
992.	52660	**Lipirex-Z Tablets.** Each tablet contains: Ezetimibe……10mg. Atorvastatin as Calcium Trihydrate…..10mg.	16/10/2008	Dy. No. 31721 dated 24-09-2018 10,000/-	15-10-2023	w.e.f. 16-10-2018 to 15-10-2023 Also applied for renewal on 18-09-2013.
993.	14490	**Minalfene 150mg Tablet** Each Tablet Contains Alminoprofen… 150mg	21/10/1993	Dy. No. 31721 dated 24-09-2018 10,000/-	20-10-2023	w.e.f. 21-10-2018 to 20-10-2023 Also applied for renewal on 18-09-2013.
994.	14491	**Minalfene 300mg Tablet** Each Tablet Contains Alminoprofen …300mg	21/10/1993	Dy. No. 31721 dated 24-09-2018 10,000/-	20-10-2023	w.e.f. 21-10-2018 to 20-10-2023 Also applied for renewal on 18-09-2013.
995.	77004	**Mucostin Capsule300mg** Each capsule contains:- Erdosteine…..300mg	07/10/2013	Dy. No. 31721 dated 24-09-2018 10,000/-	06-10-2023	w.e.f. 07-10-2018 to 06-10-2023
996.	77000	**Triforge 10/160/12.5 Tablets** Each film coated tablet contains:- Amlodipine (as besylate)…….10mg Valsartan……160mg Hydrochlorthiazide……12.5mg	07/10/2013	Dy. No. 31721 dated 24-09-2018 10,000/-	06-10-2023	w.e.f. 07-10-2018 to 06-10-2023
997.	76999	**Triforge 10/160/25 Tablets** Each film coated tablet contains:- Amlodipine (as besylate)….10mg Valsartan…160mg Hydrochlorthiazide……25mg	07/10/2013	Dy. No. 31721 dated 24-09-2018 10,000/-	06-10-2023	w.e.f. 07-10-2018 to 06-10-2023
M/s Tabros Pharma Pvt. Limited, Plot No. L-20/B, Sector 22, Federal B Area, Karachi.						
998.	22832	**Pectus Cough Syrup** Each 5ml Contains:- DexatramethorphanHydrobromide 10mg Chloropheniramine Maleate3.75mg PhynylPropanolamine …6mg Guaiphenesin 100mg Sodium Citrate …150mg"	16-12-1998	Dy.No. 31858 dated 24-09-2018 10,000/-		w.e.f 16-12-2018 to 15-12-2023. Also applied for renewal on 20-10-2013.
999.	14782	**Hemsamic Injection 500mg/5ml** Each 5ml Contains Tranexamic Acid…500mg	05-12-1993	Dy.No. 31857 dated 24-09-2018 10,000/-		w.e.f. 15-12-2018 to 14-12-2023 Also applied for renewal on 12-07-2013. Complete

M/s. Barrett Hodgson Pakistan, F/423, S.I.T.E., Karachi						
1000.	30948	Diabold 1mg Tablets Each tablet contains:- Glimepride……..1mg	17/10/2003	Dy.No. 32056 26.09.2018 Rs.10000/-		w.e.f 17-10-2018 to 16-10-2023
1001.	30949	Diabold 2mg Tablets Each tablet contains:- Glimepride……..2mg	17/10/2003	Dy.No.32057 26.09.2018 Rs.10000/-		w.e.f 17-10-2018 to 16-10-2023
1002.	30951	Diabold 4mg Tablets Each tablet contains:- Glimepride……..4mg	17/10/2003	Dy.No.32058 dated 26.09.2018 Rs.10000/-		w.e.f 17-10-2018 to 16-10-2023
1003.	30953	Cefstar Injection 500mg Each vial contains:- Cefepime Arginine Sterile eq. to Cefepime……..500mg	06/10/2003	Dy.No.32054 dated 26.09.2018 Rs.10000/-		w.e.f. 06-10-2018 to 05-10-2023
1004.	30954	Cefstar Injection 1gm Each vial contains:- Cefepime Arginine Sterile eq. to Cefepime……..1gm	06/10/2003	Dy.No.32055 dated 26.09.2018 Rs.10000/-		w.e.f. 06-10-2018 to 05-10-2023
M/s. Life Pharmaceutical Company, 24-III Industrial Estate, Multan						
1005.	52721	Albonix Suspension. Each 5ml contains:- Mebendazole……100mg. (USP Specs)	25/10/2008	Dy.No.32047 dated 26.09.2018 Rs.10000/-		w.e.f 25-10-2018 to 24-10-2023
1006.	52722	Azgard Suspension Each 5ml contains:- Albendazole……..200mg. (USP Specs)	25/10/2008	Dy.No.32048 dated 26.09.2018 Rs.10000/-		w.e.f 25-10-2018 to 24-10-2023
1007.	001887-EX	Wikisure 500mg Tablet Each tablet contains Ciprofloxacin (as HCl)……50mg	11/12/2013	Dy.No. 38225 dated 20.11.2018 Rs.10000/-		
M/s. Genix Pharma Pvt Limited, 44-45-B, Korangi Creek Road, Karachi						
1008.	4336-EX	Novom Tablet 10mg Each Delayed Release Tablet Contains Doxylamine Succinate…10mg Pyridoxine HCl…10mg	25/11/2013	Dy.No.32046 dated 26.09.2018 Rs.10000/-		w.e.f 25-11-2018 to 24-11-2023
1009.	4337-EX	Folat Tablet 400mcg Each Film Coated Tablet Contains L-Methylfolate…400mcg	25/11/2013	Dy.No.32046 dated 26.09.2018 Rs.10000/-		w.e.f 25-11-2018 to 24-11-2023
1010.	53285	Gen-M 15/ 90 Dry Suspension Each 5ml contains: Artemether …..15mg Lumefantrine …90mg	03/12/2008	Dy.No.29396 dated 03.09.2018 Rs.10000/-		w.e.f 03-12-2018 to 02-12-2023
M/s. CCL Pharmaceuticals, 62 Industrial Estate KotLakhpat Lahore.						
1011.	1848-EX	Gablin Capsule 50mg Each Capsule Contains Pregabalin…50mg	17/09/2013	Dy. No 30944 13/09/2018 Rs.10000		w.e.f. 17-09-2018 to 16-09-2023
M/s. Barrett Hodgson Pakistan, F/423 SITE Karachi.						
1012.	76010	Vedicar 3.125mg Tablet Each Film Coated Tablet Contains Carvedilol……..….3.125mg	19/09/2013	Dy. No 30943 dated 13/09/2018 Rs.10000		w.e.f 19-09-2018 to 18-09-2023

M/s. Ferozsons Laboratories Limited, PO Ferozsons Nowshera, KPK						
1013.	022501	Xolox Cream Each 100gm contains Ribavirin USP…..7.50gm	26/11/1998	Dy.No. 37938 dated 16.11.2018 Rs.10000/-		w.e.f. 26-11-2018 to 26-11-2023
1014.	022502	Xolox Syrup Each 100gm contains Ribavirin USP…..0.05gm	26/11/1998	Dy.No. 37938 dated 16.11.2018 Rs.10000/-		w.e.f. 26-11-2018 to 26-11-2023
1015.	052840	Centaurus 1mg Tablet Each tablet contains Entecavir as monohydrate….1mg	20/11/2008	Dy.No. 37988 dated 16.11.2018 Rs.10000/-		w.e.f 20-11-2018 to 19-11-2023
1016.	052841	Centaurus 0.5mg Tablet Each tablet contains Entecavir as monohydrate….0.5mg	20/11/2008	Dy.No. 37988 dated 16.11.2018 Rs.10000/-		w.e.f 20-11-2018 to 19-11-2023
M/s. Highnoon Laboratories Ltd, 17.5 Km, Multan Road, Lahore						
1017.	014743	**Aria Syrup 60ml** Each ml contains Ketotifen (as fumarate)…….0.2mg	5/12/1993	Dy.No. 37981 dated 16.11.2018 Rs.10000/-		w.e.f 5-12-2018 to 4-12-2023
1018.	014742	**Aria Tablet 1mg** Each ml contains Ketotifen (as fumarate)…….1mg	5/12/1993	Dy.No. 37981 dated 16.11.2018 Rs.10000/-		w.e.f 5-12-2018 to 4-12-2023
1019.	000149 -Ex	**TresOrix Forte Capsule** Each capsule contains Cyproheptadineorotate…..0.0015g, Carnitine CIH…..0.150g, Lysine CIH……0.150g, Coenzyme B12…..0.001g	09/12/2003	Dy.No. 37981 dated 16.11.2018 Rs.10000/-		w.e.f 9-12-2018 to 8-12-2023
1020.	000034 -Ex	**Meprobamate 200mg Tablet** Each tablet contains Meprobamate…….200mg	31/12/1998	Dy.No. 37981 dated 16.11.2018 Rs.10000/-		w.e.f 31-12-2018 to 30-12-2023
1021.	047739	**Higem Tablet** Each tablet contains Gemifloxacinmesylateeq to Gemifloxacin…. 320mg	16/12/2008	Dy.No. 37981 dated 16.11.2018 Rs.10000/-		w.e.f 16-12-2018 to 15-12-2023
M/s. Pacific Pharmaceuticals Limited, 30 Km Multan Road, Lahore.						
1022.	052822	Uric Low Tablet Each film coated tablet contains Allopurinol .. 300 mg	18/11/2008	Dy.No. 37534 dated 13.11.2018 Rs.10000/-		w.e.f 18-11-2018 to 17-11-2023
1023.	022895	Rifin 300mg Tablet Each tablet contains Rifampicin B.P…300mg, Isoniazid B.P……150mg	18/12/1998	Dy.No. 37534 dated 13.11.2018 Rs.10000/-		w.e.f 18-12-2018 to 17-12-2023
M/S. Platinum Pharmaceuticals (Pvt) Ltd, A-20, North Western Industrial Zone, Bin Qasim, Karachi						
1024.	053283	Hi-Servin DS Tablet Each tablet contains Artemether…….40mg, Lumefantrine……..240mg	3/12/2008	Dy.No. 37536 dated 13.11.2018 Rs.10000/-		w.e.f. 3-12-2018 to 2-12-2023

1025.	053284	Hi-Servin Dry Suspension Each 5ml contains Artemether…….15mg, Lumefantrine……..90mg	3/12/2008	Dy.No. 37536 dated 13.11.2018 Rs.10000/-		w.e.f. 3-12-2018 to 2-12-2023
1026.	022482	Inrox Tablet 150mg Each film coated tablet contains Roxithromycin…150mg	8/12/1998	Dy.No. 37536 dated 13.11.2018 Rs.10000/-		w.e.f 8-12-2018 to 7-12-2023
1027.	022482	Prevent Tablet 500mg Each film coated tablet contains Tinidazole 500mg	8/12/1998	Dy.No. 37536 dated 13.11.2018 Rs.10000/-		w.e.f 8-12-2018 to 7-12-2023
1028.	022383	Tormax Tablet 550mg Each tablet contains Naproxen sodium…550mg	8/12/1998	Dy.No. 37536 dated 13.11.2018 Rs.10000/-		w.e.f 8-12- 2018 to 7-12- 2023
M/s. Genome Pharmaceuticals (Pvt) Ltd, Plot No. 16/1, Phase-IV, Industrial Estate, Hattar, Haripur, KPK						
1029.	004377 -Ex	Gecomin Tablet Each film coated tablet contains Mecobalamine…….500mcg	23/11/2013	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f 23-11-2018 to 22-11-2023
1030.	052916	Cipvax 250mg Tablets Each tablet contains Ciprofloxacin as HCl…..250mg	01-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 01-12-2018 to 30-11-2023
1031.	052917	Intercirin Capsule Each capsule contains Ribavirin…….400mg	01-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 01-12-2018 to 30-11-2023
1032.	053543	Gemox Tablet Each tablet contains Gemifloxacinmesylate (as mesylate)……..320mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1033.	053544	Ceclofin Tablet Each tablet contains Aceclofenac……..100mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1034.	053545	Levetram tablet 250mg Each tablet contains Levetiracetam……250mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1035.	053546	Mirton-15 Tablet Each tablet contains Mirtazapine……..15mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1036.	053547	Mirton-30 Tablet Each tablet contains Mirtazapine……..30mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1037.	053548	Mekast-Chewable Tablet Each tablet contains Montelukast (as sodium)…..5mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1038.	053549	Mekast-5 Tablet Each tablet contains Montelukast (as sodium)…..5mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12- 2018 to 02- 12-2023

1039.	053550	Mekast-10 Tablet Each tablet contains Montelukast (as sodium)…..10mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1040.	053551	Venlor 37.5 Tablet Each tablet contians Venlafaxine (as HCl)……37.5mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1041.	053552	Venlor 75 Tablet Each tablet contians Venlafaxine (as HCl)……75mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1042.	053553	Esonom-20 Tablet Each tablet contians Esomeprazole (as Magnesium Trihydrate)….20mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1043.	053554	Esonom-40 Tablet Each tablet contians Esomeprazole (as Magnesium Trihydrate)….40mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1044.	053555	Levetram Tablet 500mg Each tablet contians Levetiracetam……500mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1045.	053556	Oleanz-5 Tablet Each tablet contians Olanzapine Citrate eq.to Olanzapine……..5mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1046.	053557	Oleanz-10 Tablet Each tablet contians Olanzapine Citrate eq.to Olanzapine……..10mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1047.	053558	Zydex-25 Tablet Each tablet contians Clozapine……25mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1048.	053559	Zydex-100 Tablet Each tablet contians Clozapine……100mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1049.	053560	Riperidone-1 tablet Each tablet contians Risperidone……1mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1050.	053561	Riperidone-2 tablet Each tablet contians Risperidone……2mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1051.	053562	Riperidone-3 tablet Each tablet contians Risperidone……3mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1052.	053563	Qupin-25 Tablet Each tablet contians Quetiapine……25mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1053.	053564	Qupin-100 Tablet Each tablet contians Quetiapine……100mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023

1054.	053565	Dulin Tablet Each tablet contians Desloratadine……5mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1055.	053566	Alciron Tablet Each tablet contians Alfacalcidol……0.5mcg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1056.	053567	Flonid-10 tablet Each tablet contians Leflunomide (as HCl)……10mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1057.	053568	Flonid-20 tablet Each capsule contains Leflunomide (as HCl)……20mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1058.	053569	Mosether Capsule Each capsule contains Artemether……..20mg, Lumefantrine……..120mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1059.	053570	Zipsyde-60 Capsule Each capsule contains Ziprasidone (as HCL)……..60mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1060.	053571	Zipsyde-80 Capsule Each capsule contains Ziprasidone (as HCL)……..80mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1061.	053572	Brexidol Capsule Each capsule contains Piroxicam Beta cyclodextrin eq. to Piroxicam……20mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1062.	053573	Gabril 100 capsule Each capsule contains Gabapentin……100mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1063.	053574	Gabril 300 capsule Each capsule contains Gabapentin……300mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1064.	053575	Gabril 400 capsule Each capsule contains Gabapentin……400mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1065.	053576	Atractin-10 capsule Each capsule contains Isotretinoin……..10mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		Deferred for clarification of type of capsule (Soft or Hard gelatin)
1066.	053577	Atractin-20 capsule Each capsule contains Isotretinoin……..20mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		Deferred for clarification of type of capsule (Soft or Hard gelatin)
1067.	053578	Zipsyde-20 Capsule Each capsule contains Ziprasidone (as HCL)……..20mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1068.	053579	Omina-20 tablet Each tablet contains Omeprazole……20mg	03-12-2008	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023
1069.	053580	Zinom Tablet Each capsule contains Domperidone Maleate….19.10mg, Cinnarizine…….25mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 03-12-2018 to 02-12-2023

1070.	078423	Dazod-150 tablet Each film coated tablet contains Trazodonr HCl……150mg	16-12-2013	Dy.No. 38335 22.11.2018 Rs.10000/-		w.e.f. 16-12-2018 to 15-12-2023
1071.	078424	Dazod-300 tablet Each film coated tablet contains Trazodonr HCl……300mg	16-12-2013	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		w.e.f. 16-12-2018 to 15-12-2023
1072.	078425	Osicap-D Capsule Each capsule contains Vitamin D……200IU, Hydroxyapatite compound….830mg, Ossein mineral complex eqto.177.6mg, Phosphorus…….82.2mg, Residual minerals salts….24.9mg, collagen……224mg, other rotein 66.4mg	16-12-2013	Dy.No. 38335 dated 22.11.2018 Rs.10000/-		Deferred for confirmation of Atomic Absorption in Quality Control.
1073.	053581	Esim-40 capsule Each capsule contains Esomeprazole (as magnesium trihydrate) pellets……..40mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.20000/-		w.e.f. 03-12-2018 to 02-12-2023
1074.	053582	Renom-20 Capsule Each capsule contains Rabeprazole (as sodium) pellets…..20mg	03-12-2008	Dy.No. 38335 dated 22.11.2018 Rs.20000/-		w.e.f. 03-12-2018 to 02-12-2023
M/s Davis Pharmaceuticals Laboratories, 121 Industrial Triangle Area, Kahuta Road, Islamabad						
1075.	022467	Cafiper Tablet Each tablet contains Caffeine Anhydrous…65mg Paracetamol 500mg	20/11/1998	Dy.No. 38009 dated 19.11.2018 Rs.10000/-		W.e.f 20-11-2018 to 19-11-2023
M/s. Abbott Laboratories Pakistan, Opp. Radio Pakistan Transmission Centre, Hyderabad Road, Landhi, Karachi						
1076.	076148	Klaricid DS Granules Each 5ml contain Clarithromycin…250mg	7/1/2014	Dy.No. 37635 13.11.2018 Rs.10000/-		w.e.f 07-01-2019 to 06-01-2024.
1077.	006894	Tronolane Cream Each gm contains:-Promoxine HCl……10mg	29/01/1984	Dy.No. 37635 dated 13.11.2018 Rs.10000/-		A letter of shortcoming was sent to clarify their address at P.O Box 7229, Karachi. Firm replied that this is their mailing address and still mentioned on their letterhead.
1078.	006979	Entamizole Suspension Each 10ml contains DilexanideFuroate B.P…….250mg, Metronidazole Benzoate…320mg eq to Metronidazole B.P…200mg	08/01/1984	Dy.No. 37635 dated 13.11.2018 Rs.10000/-		A letter of shortcoming was sent to clarify their address at P.O Box 7229,

						Karachi. Firm replied that this is their mailing address and still mentioned on their letterhead.
1079.	004595	Brufen Suspension Each 5ml contains Ibuprofen…100mg	14/01/1979	Dy.No. 37635 dated 13.11.2018 Rs.10000/-		w.e.f 14-01-2019 to 13-01-2024.
M/s. Albro Pharmaceuticals Pvt ltd, 340-S, Kotlakh Pat Industrial Area, Lahore						
1080.	013146	Promet suspension Each 5ml contains Metronidazole Benzoate eq to 200mg Metronidazole BP	12-12-1991 Change of brand name on 20-11-1998	Dy.No. 37637 dated 13.11.2018 Rs.10000/-	19-11-2018	w.e.f 20-11-2018 to 19-11-2023
1081.	022816	OrthoxenTabet 500mg Each tablet contains Naproxen B.P……..500mg	12-12-1998	Dy.No. 37638 dated 13.11.2018 Rs.10000/-	11-12-2018	w.e.f. 12-12-2018 to 11-12-2023
1082.	013145	Promet Tablet Each tablet contains Metronidazole BP……200mg	12-12-1991 Change of brand name on 20-11-1998	Dy.No. 37636 dated 13.11.2018 Rs.10000/-	19-11-2018	w.e.f 20-11-2018 to 19-11-2023
M/s. Helix Pharma, Hakimsons House, A/56, S.I.T.E. Mangopir Road, Karachi						
1083.	053334	Co-Mether Dry Suspension Each 5ml containsArtemether15mg, Lumefantrine……..90mg	31/12/2008	Dy.No. 38097 19.11.2018 Rs.10000/-		w.e.f. 31-12-2018 to 30-12-2023
1084.	053463	Tegex 67mg Capsule Each capsule contains Fenofibrate…67mg	31/12/2008	Dy.No. 38097 19.11.2018 Rs.10000/-		w.e.f. 31-12-2018 to 30-12-2023
1085.	053333	Tegex 200mg Capsule Each capsule contains Fenofibrate200mg	31/12/2008	Dy.No. 38097 19.11.2018 Rs.10000/-		w.e.f. 31-12-2018 to 30-12-2023
M/s. Maple Pharmaceuticals (Pvt) Ltd, Karachi						
1086.	004371 -Ex	Moximap 400mg tablet Each film coated tablet contains Moxifloxacin…….400mg	25/11/2013	Dy.No. 38239 dated 20.11.2018 Rs.10000/-		w.e.f 25-11-2018 to 24-11-2023
1087.	004372 -Ex	Mapkast 4mg Sachet Each film coated tablet contains Montelukast soiumeq to. Montelukast acid……..40mg	25/11/2013	Dy.No. 38239 dated 20.11.2018 Rs.10000/-		w.e.f 25-11-2018 to 24-11-2023
M/s. Barrett Hodgson Pakistan, F/423, S.I.T.E., Karachi						
1088.	3098 0	Megaklar Suspension 125mg Each 5ml contains:- Clarithromycin .125mg Source of granules: M/s Surge Laboratories, Lahore	17/10/2003	Dy.No.32053 dated 26.09.2018 Rs.10000/-		w.e.f. 17-10-2018- to 16-10-2023

M/s. Danas Pharmaceuticals (Pvt) Ltd,Plot No .312-Industrial Triangle Kahuta Road Islamabad.						
1089.	077697	Cyclofen injection Each 3ml contains diclofenac sodium ……75mg	9/12/2013	Dy.No.39204 Dated.28/11/2018 Rs.10000		w.e.f 09-12-2018 to 08-12-2023
M/s. Bosch Pharmaceuticals, Plot No. 209 Sector 23 Korangi Industrial Area Karachi.						
1090.	057750	Calamox 300mg Injection Each vail contains Amoxycillin as doium…….250mg, Clavulanic acid as potassium….50mg	17/06/2009	Dy.No.39042 Dated.28/11/2018 Rs.10000		w.e.f 17-06-2019 to 16-06-2024
Pakistan Pharmaceutical Products (Pvt) Ltd,D-122 SITE Karachi.						
1091.	014759	Arcofloxin Tablet 250mg Each tablet contains Ciprofloxacin…….250mg	5/12/1993	Dy.No.39040 Dated.28/11/2018 Rs.10000		W.e.f. 05-12-2018 to 04-12-2023
1092.	014761	Acomin capsule 250mg Each capsule contains Tranaxamic acid…….250mg	5/12/1993	Dy.No.39040 28/11/2018 Rs.10000		W.e.f. 05-12-2018 to 04-12-2023
1093.	014762	Acomin injection 250mg/5ml Each ampoule contains Tranaxamic acid…….250mg	5/12/1993	Dy.No.39040 Dated.28/11/2018 Rs.10000		W.e.f. 05-12-2018 to 04-12-2023
1094.	014764	Felcam Injection 20mg/ml Each ampoule contains Pirexicam…….20mg	5/12/1993	Dy.No.39040 Dated.28/11/2018 Rs.10000		W.e.f. 05-12-2018 to 04-12-2023
1095.	014765	Cepadin Dry Syrup Each 5ml contains Cephradine USP……..250mg	5/12/1993	Dy.No.39040 28/11/2018 Rs.10000		W.e.f. 05-12-2018 to 04-12-2023
1096.	014760	Arcofloxin Tablet 500mg Each tablet contains Ciprofloxacin…….500mg	5/12/1993	Dy.No.39040 28/11/2018 Rs.10000		W.e.f. 05-12-2018 to 04-12-2023

Incomplete cases

X. 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
M/s Metro Pharmaceuticals, Plot No. 14, Street No. SS-2, National Industiral Zone, Rawat, Rawalpindi.						
1097.	75470	**Pebtrin 20mg Tablet** Each Film Coated Tablet Contains Piroxicam as Beta Cyclodextrin…20mg	26/08/2013	Dy. No. 31878 Dated 24-09-2018 20,000/-	25-08-2023	Deferred for following shortcomings.
Shortcoming communicated on 1st July, 2019 a) **Notarized copy** of last submitted renewal application along with fee or renewal certificate. b) **Notarized copy** of valid Drug Manufacturing License. c) **Notarized copy** of last inspection report conducted by DRAP. d) **Notarized copy** of registration letter for confirmation of brand name and strength. e) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. f) 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**. Last batch manufactured record.						
M/s Highnoon Laboratories Limited, 17.5 Km, Multan Road, Lahore.						
1098.	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	Deferred for Shortcoming communicated on 1st July, 2019 a) Registration letters were issued on 71-B, C/2 Gulberg-III, Lahore whereas, your manufacturing site is at 17.5 Km, Multan Road, Lahore. Please clarify. In case of change of address, Please provide **Notarized Copy** of approval of change of address. b) Record of last manufactured batch
1099.	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	Deferred for Shortcoming communicated on 1st July, 2019

						a) Registration letters were issued on 71-B, C/2 Gulberg-III, Lahore whereas, your manufacturing site is at 17.5 Km, Multan Road, Lahore. Please clarify. In case of change of address, Please provide **Notarized Copy** of approval of change of address. b) Record of last manufactured batch
1100.	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	Deferred for Shortcoming communicated on 1st July, 2019 a) Registration letters were issued on 71-B, C/2 Gulberg-III, Lahore whereas, your manufacturing site is at 17.5 Km, Multan Road, Lahore. Please clarify. In case of change of address, Please provide **Notarized Copy** of approval of change of address. b) Record of last manufactured batch
1101.	4496	**Hi-Togan Drops (For Ear)**	30/10/1978	Dy. No. 31721 dated 24-09-2018	29-10-2023	Deferred for Shortcoming

		Contains Benzocaine…1% Phenazone…5% Glycerin qs to 100%"		10,000/-		communicated on 1st July, 2019 a) Registration letters were issued on 38-M, Gulberg-III, Lahore whereas, your manufacturing site is at 17.5 Km, Multan Road, Lahore. Please clarify. In case of change of address, Please provide **Notarized Copy** of approval of change of address. b) Record of last manufactured batch
1102.	14348	**Xamig Capsule 250mg** Each Capsule Contains Tranexamic Acid…250mg	14/10/1993	Dy. No. 31721 dated 24-09-2018 10,000/-		Deferred for Shortcoming communicated on 1st July, 2019 **Notarized copy** of registration letter for confirmation of brand name and strength.
1103.	14349	**Xamig Capsule 500mg** Each Capsule Contains Tranexamic Acid…500mg	14/10/1993	Dy. No. 31721 dated 24-09-2018 10,000/-		Shortcoming communicated on 1st July, 2019 **Notarized copy** of registration letter for confirmation of brand name and strength.
M/s Akhai Pharmaceuticals Pvt. Limited, Plot No. A-248 & A-256 to A-259, Hub Industrial Trading Estate, Lasbela, Balochistan.						
1104.	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	Deferred for Shortcoming communicated on 3rd July, 2019 a) **Notarized copy** of last submitted renewal application along with fee or renewal
1105.	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	
1106.	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	

1107.	50797	**Sursyp Syrup** Each 5ml contains: Cetirizine Dihydrochloride 5mg	09/10/2008	Dy.No. 32041 dated 25-09-2018 10,000/-	08-10-2023	certificate. b) **Notarized copy** of valid Drug Manufacturing License. c) **Notarized copy** of last inspection report conducted by DRAP. d) **Notarized copy** of registration letter for confirmation of brand name and strength. e) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. f) 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**. g) Last batch manufactured record.
1108.	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	
1109.	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	
1110.	50800	**Enalbin Syrup** Each 5ml contains: Ibuprofen…..100mg	09/10/2008	Dy. No. 32039 dated 25-09-2018 10,000/-	08-10-2023	
M/s Spencer & Company Pvt.Limited, D-105, SITE, Karachi.						
1111.	75987	**Levos 500mg Infusion** Each 100ml contains:- Levofloxacin ……500 mg	26/07/2013	Dy. No. 32034 Dated 25-09-2018 20,000/-		Deferred for following shortcomings

1112.	75988	**Moxilox 400mg Infusion** Each 250ml contains:- Moxifloxacin HCl BP ….400 mg	26/07/2013	Dy. No. 32033 Dated 25-09-2018 20,000/-		

Shortcoming communicated on 3rd July, 2019

a) **Notarized copy** of valid Drug Manufacturing License.
b) **Notarized copy** of last inspection report conducted by DRAP.
c) **Notarized copy** of registration letter for confirmation of brand name and strength.
d) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**.
e) 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**.

Last batch manufactured record.

M/s. Semos Pharmaceuticals Pvt. Limited, Plot No. 11, Sector 12-A, North Karachi industrial Area, Karachi

1113.	14377	Mefalgic Tablet Each Tablet Contains Mefenamic Acid…250mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		Deferred for Shortcoming communicated on 22-07-2019 reply not yet received. a) **Notarized** copy of last inspection report conducted by DRAP. b) Notarized copy of last submitted renewal application along with fee challan or renewal certificate. c) An undertaking on stamp paper that the applied products has never been de-registered duly notarized. d) An undertaking on stamp paper that submitted documents are true copy of the originals and that, if at any stage any discrepancy
1114.	14379	Pyrol Suspension Each 5ml Contains Paracetamol…120mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1115.	14381	Semotox Tablet Each Tablet Contains Attapulgite…500mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1116.	14382	Semo-C Tablet Each Tablet Contains Ascorbic Acid…100mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1117.	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/-		
1118.	14387	Semoquine Tablet Each Tablet Contains Amodiaquine…150mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1119.	14389	Semorfen Suspension Each 5ml Contains Ibuprofen…100mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1120.	14390	Semozol Tablet Each Tablet Contains Trimethoprim…80mg Sulphamethoxazole…400mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1121.	14391	Semozol Suspension Each 5ml Contains Sulphamethoxazole…200mg Trimethoprim…40mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1122.	14393	Neocin Skin Ointment Each gm Contains Neomycin Sulphate…5mg	14/10/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		
1123.	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/-		
1124.	14386	Semodazol Tablet 400mg Each Tablet Contains Metronidazole…400mg	27/12/1993	Dy.No.32221 dated 26.09.2018 Rs.10000/-		

						/ misinformation is detected / observed the firm/company will be held responsible as per relevant laws duly notarized. e) Status of products availability in reference regulatory authority.
M/s. Akhai Pharmaceuticals Pvt. Limited, Plot No. A-248 & A-256 to A-259, Hub Industrial Trading Estate, Lasbela, Balochistan.						
1125.	53001	Ebrantil Syrup Each 5ml contains: Acefyllin……..125mg	09/10/2008	Dy.No.32214 dated 26.09.2018 Rs.10000/-		Deferred for Shortcoming communicated on 22-07-2019 reply not yet received. a) **Notarized copy** of last submitted renewal application along with fee or renewal certificate. b) **Notarized copy** of valid Drug Manufacturing License. c) **Notarized copy** of last inspection report conducted by DRAP. d) **Notarized copy** of registration letter for confirmation of brand name and strength. e) An
1126.	53002	Ebrantil EXP Syrup Each 5ml contains: AcefyllinPiprazine……..45mg Diphenhydramine…….8mg	09/10/2008	Dy.No.32215 dated 26.09.2018 Rs.10000/-		
1127.	53003	Comitril Cream Each gram contains: Clotrimazole……..1%w/w(BP Specification)	09/10/2008	Dy.No.32216 dated 26.09.2018 Rs.10000/-		
1128.	53004	Ademac Cream Each gram contains: Terbinafine (as HCl)……1%w/w	09/10/2008	Dy.No.32217 dated 26.09.2018 Rs.10000/-		
1129.	53005	Antiburn Cream Each gram contains: Silver Sulphadiazine(as HCl)…….....1%w/w(USP Specification)	09/10/2008	Dy.No.32218 dated 26.09.2018 Rs.10000/-		
1130.	53006	Aprical Cream Each gram contains: Mupirocin……2%w/w(BP Specification)	09/10/2008	Dy.No.32219 dated 26.09.2018 Rs.10000/-		
1131.	53007	Xesity Capsule Each Capsule Contains: Orlistat……..120mg	09/10/2008	Dy.No.32213 dated 26.09.2018 Rs.10000/-		

						undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. f) 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**. g) Last batch manufactured record.
M/s. Hicon Pharmaceuticals, 131 Industrial Estate Hayatabad, Peshawar						
1132.	77433	Artil Dry Powder Suspension Each 5ml contains: Artemether……15 mg Lumefantrine….90 mg	24/09/2013	Dy.No.32212 dated 26.09.2018 Rs.10000/-		Deferred for following shortcomings.
Shortcoming communicated on 22-07-2019 reply not yet received. a) Application for renewal is applied after due date, please deposit differential fee b) Please provide approval of dry powder suspension section. c) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. d) 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**. e) Last batch manufactured record.						
M/s. Helix Pharma, A/56, S.I.T.E., Monghopir Road, Karachi						
1133.	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/-		Deferred for Shortcoming communicated on 22-07-2019 reply not received yet. a) Signature on the covering letter and undertaking
1134.	53012	Lowseiz 25mg Tablets Each film coated tablet contains Topiramate….25mg	16/10/2008	Dy.No.32220 dated 26.09.2018 Rs.10000/-		
1135.	53013	Lowseiz 50mg Tablets Each film coated tablet contains Topiramate….50mg	16/10/2008	Dy.No.32220 dated 26.09.2018 Rs.10000/-		

1136.	76128	Nurosa 200mg Tablet Each film coated tablet contains:- Lacosamide…….200 mg	29/10/2013	Dy.No.32220 dated 26.09.2018 Rs.10000/-		on Form 5-B should be from 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. b) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. c) 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**.
1137.	76129	Nurosa 100mg Tablet Each film coated tablet contains:- Lacosamide…….100 mg	29/10/2013	Dy.No.32220 dated 26.09.2018 Rs.10000/-		
1138.	76130	Nurosa 50mg Tablet Each film coated tablet contains:- Lacosamide……..50 mg	29/10/2013	Dy.No.32220 dated 26.09.2018 Rs.10000/-		

M/s. Epla Laboratories, D-12, Estate Evenue, S.I.T.E, Karachi, 75700						
1139.	76082	**Pregrose-F Tablet** Each chewable Tablet contains:- Iron (lll) Hydroidepolymaltose 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 Shortcoming communicated on 22-07-2019 a) Application for renewal is applied after due date 25-09-2018, please deposit differential fee for each product mentioned b) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. c) 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**. d) Notarized Last Inspection Report
1140.	76083	**Pregrose Syrup** Each 5ml contains:- Iron (lll) Hydroidepolymaltose complex eq. to Elemental Iron……..…..50 mg	26/09/2013	Dy.No.32049 dated 26.09.2018 Rs.10000/-		
1141.	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/-		
1142.	76085	**Ulcez 40mg Tablet** Each enteric coated tablet contains:- Esomeprazole as Magnesium Trihydrate ……40 mg	26/09/2013	Dy.No.32052 dated 26.09.2018 Rs.10000/-		
1143.	22048	**Mecol Injection** Each ml Contains Mecobalamin…500mcg imported in bulk vials from Panbiotic Taiwan and	10/09/1998	Dy.No.29395 dated 03.09.2018 Rs.20000/-		Deferred for Shortcoming communicated on 22-07-2019 reply

		repacked locally.				not received yet. a) Please Clarify source of vials along with pack size imported. b) Please Clarify that imported vial is labelled or not. **c)** Please provide approval of section for repacking. d) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. e) 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**. f) Notarized Last Inspection Report

M/s. Genix Pharma Pvt Limited, 44-45-B, Korangi Creek Road, Karachi						
1144.	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/-		Shortcoming communicated on 22-07-2019 reply not received yet. a) Please clarify the dosage form description of formulation (each tablet contains). b) Please provide evidence of formulation in reference regulatory authority.
M/s. Macter International Limited, E-40 SITE Karachi.						
1145.	037769	Benza L-A 0.6MIU Injection Each vial contains Benzathine Penicillin G….600,000units	19/03/2005 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		Deferred for Shortcoming communicated reply not received yet. Confirmation is required regarding penicillin manufacturing facility.
1146.	037770	Benza L-A 1.2MIU Injection Each vial contains Benzathine Penicillin G..1,200,000units	19/03/2005 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1147.	010133	Maccillin capsule 250mg Each capsule contains Ampicillin (as trihydrate)……250mg	5/7/1989 Transfer of registration to this site 06-12-18	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1148.	010530	Maccillinforte 250mg/5ml dry susp Each 1.25ml contains Amoxycillin (as trihydrate)…..125mg	17-03-1990 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.8/11/2018 Rs.10000		
1149.	026275	Maccillin Injection 250mg Each vial contains Ampicillin sodium eq to Ampicillin..250mg	19-09-2000 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1150.	026276	Maccillin Injection 500mg Each vial contains Ampicillin sodium eq to Ampicillin..500mg	19/9/2000 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		

1151.	010528	Maciclox capsule 500mg Each capsule contains Ampicillin (as trihydrate).....250mg, Cloxacillin (as Sodium).....250mg	7/3/1990 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1152.	009766	Maciclox 60mg+125mg/5ml drops Each 0.6ml Contains Ampicillin (as trihydrate).....60mg Cloxacillin (as sodium).....30mg	8/5/1988 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1153.	007906	Maciclox 125mg+125mg/5ml dry susp Each 5ml contains Ampicillin.....125mg	5/2/1985 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		

XI. **Deferred Cases of Previous Meeting**

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Remarks
M/s. Zafa Pharmaceuticals Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi						
1154.	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/-		Deferred for Clarification of specification either Following BP or USP. Undertakings are not notarized.
1155.	006926	Naptrol 250mg Tablet Each tablet contains Naproxen B.P.....250mg	25/02/1984	Dy.No. 37977 dated 16.11.2018 Rs.10000/-		Deferred for Proof of formulation in RRA Last inspection report Undertakings are not notarized.
1156.	007153	Furatop Powder Contains Nitrofurazone USP/BP.0.2%w/w	25/02/1984	Dy.No. 37978 dated 16.11.2018 Rs.10000/		Deferred for Clarification of specification either Following BP or USP. Undertakings are not notarized.
M/s. Zafa Pharmaceuticals Laboratories (Pvt) Ltd, L-1/B, A&B, Block 22, Federal B Industrial Area, Karachi						
1157.	007130	Adicos-M Syrup Each 5ml contains DextrometherphanHdrobromide B.P.....6.5mg, Diphenhydramine Hydrochloride B.P.....14mg Pseudoephedrine Hydrochloride B.P.....22.5mg, Menthol B.P.1.75mg	25/02/1984	Dy.No. 37980 dated 16.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 22-07-2019 reply not received yet. Proof of formulation in RRA Last Inspection Report Undertakings are not notarized.

M/s. Safe Pharmaceuticals (Pvt) Ltd, Plot No. C-I-20, Sector 6-B, North Karachi Industrial Area, Karachi						
1158.	053051	Neboross 400mg Each tablet contains Norfloxacin…….400mg	19/11/2008	Dy.No. 37985 dated 16.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 23-07-2019 reply not received yet. i. 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 case of authorized person, authority letter shall be submitted along with application. ii. **Notarized copy** of any change in particulars of registration of these products. iii. An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. iv. 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**. v. Notarized copy of approval of change of brand name of safedime 500 mg and 1 g injections..
1159.	053052	Muzelus 400mg Each tablet contains Moxifloxacin…….400mg	19/11/2008	Dy.No. 37985 dated 16.11.2018 Rs.10000/-		
1160.	053053	Hynidate 10mg Each tablet contains Methylphenidate HCl….10mg	19/11/2008	Dy.No. 37985 dated 16.11.2018 Rs.10000/-		
1161.	053054	Ploxen 400mg Each tablet contains PefloxacinMesylate Dihydrate……..400mg	19/11/2008	Dy.No. 37985 dated 16.11.2018 Rs.10000/-		
1162.	053055	Soxacin 400mg Each tablet contains Enoxacin……..400mg	19/11/2008	Dy.No. 37985 dated 16.11.2018 Rs.10000/-		
1163.	053056	Nebedox 500mg Each tablet contains Nalidixic Acid……..500mg	19/11/2008	Dy.No. 37985 16.11.2018 Rs.10000/-		
1164.	053057	Xanker 500mg Each tablet contains Naproxen……..500mg	19/11/2008	Dy.No. 37985 16.11.2018 Rs.10000/-		
1165.	053058	Xanthma 10mg Each tablet contains Zafirlukast……..10mg	19/11/2008	Dy.No. 37985 16.11.2018 Rs.10000/-		
1166.	053059	Xanthma 20mg Each tablet contains Zafirlukast……..20mg	19/11/2008	Dy.No. 37985 16.11.2018 Rs.10000/-		
1167.	053060	Monte-safe 4mg Each tablet contains Montelukast (as Sodium)…….4mg	19/11/2008	Dy.No. 37985 dated 16.11.2018 Rs.10000/-		
1168.	053061	Monte-safe 5mg Each tablet contains Montelukast (as Sodium)…….5mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1169.	053062	Monte-safe 10mg Each tablet contains Montelukast (as Sodium)…….10mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1170.	053063	Risdon 1mg Each tablet contains Risperidone…….1mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1171.	053064	Risdon 2mg Each tablet contains Risperidone…….2mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1172.	053065	Risdon 3mg Each tablet contains Risperidone…….3mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1173.	053066	Risdon 4mg Each tablet contains Risperidone…….4mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		

1174.	053067	Lomef 200mg Each tablet contains Lomefloxacin HCl…200mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1175.	053068	Saferol 120mg Each capsule contains: Orlistat…….120mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1176.	053069	Lymocin 500mg Each capsule contains: Lincomycin (as HCl Monohydrate) ….500mg	19/11/2008	Dy.No. 37984 dated 16.11.2018 Rs.10000/-		
1177.	053070	Phynoline 250mg Each 10ml contains Aminophylline…..250mg	19/11/2008	Dy.No. 37984 16.11.2018 Rs.10000/-		
1178.	053071	Ostig 0.5mg/ml Each ml contains Neostigmine..……0.5mg	19/11/2008	Dy.No. 37983 16.11.2018 Rs.10000/-		
1179.	053072	Ostig 2.5mg/ml Each ml contains Neostigmine..……2.5mg	19/11/2008	Dy.No. 37983 16.11.2018 Rs.10000/-		
1180.	053073	Escape 25mg/ml Each ml contains Promethazine HCl…….25mg	19/11/2008	Dy.No. 37983 16.11.2018 Rs.10000/-		
1181.	053074	Safedime 250mg Each vial contains Ceftazidime (as Pentahydrate)…..250mg	19/11/2008	Dy.No. 37983 16.11.2018 Rs.10000/-		
1182.	053075	Safedime 500mg Each vial contains Ceftazidime (as Pentahydrate)…..500mg	19/11/2008	Dy.No. 37983 16.11.2018 Rs.10000/-		
1183.	053076	Safedime 1mg Each vial contains Ceftazidime (as Pentahydrate)…..1gm	19/11/2008	Dy.No. 37983 16.11.2018 Rs.10000/-		
1184.	053077	Tixac 250mg Each vial contains Ceftizoxime (as Sodium)……250mg	19/11/2008	Dy.No. 37983 dated 16.11.2018 Rs.10000/-		
1185.	053078	Tixac 500mg Each vial contains Ceftizoxime (as Sodium)……500mg	19/11/2008	Dy.No. 37983 dated 16.11.2018 Rs.10000/-		
1186.	053079	Tixac 1g Each vial contains Ceftizoxime (as Sodium)..……1gm	19/11/2008	Dy.No. 37983 dated 16.11.2018 Rs.10000/-		
1187.	053080	Safoper 250mg Each vial contains Cefoperazone (as Sodium)..…250mg	19/11/2008	Dy.No. 37983 dated 16.11.2018 Rs.10000/-		
1188.	053081	Safoper 500mg Each vial contains Cefoperazone (as Sodium)..…500mg	19/11/2008	Dy.No. 37982 16.11.2018 Rs.10000/-		
1189.	053082	Safoper 1g Each vial contains	19/11/2008	Dy.No. 37982 16.11.2018		

		Cefoperazone (as Sodium)……1gm		Rs.10000/-		
1190.	053083	Safoper 2g Each vial contains Cefoperazone (as Sodium)……2gm	19/11/2008	Dy.No. 37982 16.11.2018 Rs.10000/-		
1191.	053084	Opirocef 500mg Each vial contains Cefpirome (as Sulphate)…….500mg	19/11/2008	Dy.No. 37982 16.11.2018 Rs.10000/-		
1192.	053085	Opirocef 1g Each vial contains Cefpirome (as Sulphate)…….1gm	19/11/2008	Dy.No. 37982 16.11.2018 Rs.10000/-		
1193.	053086	Zolpro 20mg Each capsule contains: Omeprazole enteric coated pellets…….20mg	19/11/2008	Dy.No. 37986 16.11.2018 Rs.10000/-		
1194.	053087	Lanspro 15mg Each capsule contains: Lansoprazole……15mg	19/11/2008	Dy.No. 37986 16.11.2018 Rs.10000/-		
1195.	053088	Lanspro 30mg Each capsule contains: Lansoprazole Pellets……30mg	19/11/2008	Dy.No. 37986 16.11.2018 Rs.10000/-		
1196.	053089	Pep-Ease 20mg Each capsule contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate).....20mg	19/11/2008	Dy.No. 37986 16.11.2018 Rs.10000/-		
1197.	053090	Pep-Ease 40mg Each capsule contains: Esomeprazole enteric coated pellets (as Magnesium Trihydrate).....40mg	19/11/2008	Dy.No. 37986 16.11.2018 Rs.10000/-		
1198.	053392	Bunex 0.3mg Each ml contains Buprenorphine (as HCl)…....0.30mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		
1199.	053393	Laxum 3mg Each tablet contains Bromazepam…...3mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		
1200.	053394	Pantasafe 25mg Each tablet contains Pentazocine……25mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		
1201.	053395	Bunex 0.2mg Each tablet contains Buprenorphine HCl……0.2mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		
1202.	053396	Ambien 10mg Each tablet contains Zolpidem Tartrate…10mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		
1203.	053397	Pantasafe 30mg Each ml contains Pentazocine (as Lactate).....30mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		

1204.	053398	Nubagesic 10mg Each ml contains Nalbuphine (as HCl Dihydrate)…10mg	19/12/2008	Dy.No. 37987 dated 16.11.2018 Rs.10000/-		
1205.	053399	Nubagesic 20mg Each ml contains Nalbuphine (as HCl Dihydrate)...20mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		
1206.	053407	Daz 10mg/2ml Each 2ml ampoule contains Diazepam……..…10mg	19/12/2008	Dy.No. 37987 16.11.2018 Rs.10000/-		
M/s. English Pharmaceuticals, Link Kattar Bund Road, ThokarNiazBaig, Multan Road, Lahore						
1207.	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/-		Deferred for Shortcoming communicated on 23-07-2019 reply not received yet. a) 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 case of authorized person, authority letter shall be submitted along with application. Form-5B should not be printed on company letterhead. b) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. c) 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**. d) Please provide evidence of availability of formulation in reference regulatory authority. e) Last Inspection Report f) Record of Last Batch manufactured.
1208.	052922	Enxamin 250mg Capsule Each capsule contains Tranexamic Acid…….250mg	26/11/2008	Dy.No. 37992 dated 16.11.2018 Rs.10000/-		
1209.	052923	Enxamin 500mg Capsule Each capsule contains Tranexamic Acid…….500mg	26/11/2008	Dy.No. 37992 dated 16.11.2018 Rs.10000/-		
1210.	052924	Enxamin 250mg Injection Each 5ml contains Tranexamic Acid…….250mg	26/11/2008	Dy.No. 37992 dated 16.11.2018 Rs.10000/-		
1211.	052925	Enxamin 500mg Injection Each 5ml contains Tranexamic Acid…….500mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-		
1212.	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/-		
1213.	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/-		
1214.	052928	Medex 20mg tablet Each tablet contains Piroxicam Beta cyclodextrin eq. to Piroxicam…20mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-		
1215.	001875-Ex	Amborox 150mg Tablet Each tablet contains Roxithromycin USP…..150mg	20/11/2013	Dy.No. 37992 16.11.2018 Rs.10000/-		
1216.	001876-EX	Hoxidal 200mg Tablet Each film coated tablet contains Ofloxacin…200mg	20/11/2013	Dy.No. 37992 16.11.2018 Rs.10000/-		

1217.	077034	Jeta 15mg Tablet Each tablet contains Mirtazapin.15mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-		
1218.	077035	Jeta 30mg Tablet Each tablet contains Mirtazapin.30mg	26/11/2008	Dy.No. 37992 16.11.2018 Rs.10000/-		
1219.	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/-		
M/s. PDH Laboratories (Pvt) Ltd, 9.5 Km, Sheikhupura Road, Lahore						
1220.	022560	Silvin Cream Contains Silver sulphadiazineUsp……1%	28/11/1998	Dy.No. 37532 dated 13.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 24-07-2019 reply not received yet. Firm has approval of Cream Ointment section for pharmacological category of Steroidal preparations. However, this formulation is non-steroidal. Please clarify?
M/s Opal Laboratories Pvt. Limited LC-41, L.I.T.E, Landhi Karachi						
1221.	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/-		Deferred for Shortcoming communicated on 29-07-2019 reply not received yet. a) 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 case of authorized person, authority letter shall be submitted along with application. b) Please provide evidence of availability of formulation in reference regulatory authority.
1222.	053372	Malther DS Tablet Each tablet contains Artemether…40mg Lumefantrine….240mg	17/12/2008	Dy.No. 37639 dated 13.11.2018 Rs.10000/-		
M/s. Searle Company Limited, F-319, S.I.T.E, Karachi						
1223.	053340	Alpent 20mg Injection Each 2ml contains FlupentixolDecanoate….20 mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 29-07-2019 reply not received yet. i. 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
1224.	053341	Alpent 100mg Injection Each ml contains Flupentixol Decanoate.100mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1225.	053342	Atrium Injection 10mg Each ml contains Atracurium Besylate….10mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		

1226.	053338	Defnac 75mg/3ml Injection Each 3ml contains Diclofenac sodium…….75mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		manager level. In case of authorized person, authority letter shall be submitted along with application.
1227.	053344	Relispa 40mg/2ml Injection Each 2ml contains Drotaverine HCl…40mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		ii. Approval of sections for manufacturing of these drugs.
1228.	053327	Rotec-50mg Tablet Each tablet contains Diclofenac sodum…50mg, Misoprostol 200mcg	4/12/2008	Dy.No. 38099 19.11.2018 Rs.10000/-		
1229.	076184	Ropion 100mg Tablets Each tablet contains Bupropion HCl…100mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1230.	076185	Ropin SR 150mg Tablet Each sustained lealease tablet contains Bupropion HCl…..150mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1231.	076186	Ropin SR 300mg Tablet Each sustained lealease tablet contains Bupropion HCl …..300mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1232.	076187	Olesta-AM 5/20mg Tablet Each film coated tablet contains Amlodipine as besylate….5mg, Olmesartan Medoxomil20mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1233.	076188	Olesta-AM 5/40mg Tablet Each film coated tablet contains Amlodipine as besylate….5mg, Olmesartan Medoxomil40mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1234.	076189	Olesta-AM 10/20mg Tablet Each film coated tablet contains Amlodipine as besylate….10mg, Olmesartan Medoxomil20mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1235.	076190	Olesta-AM 10/40mg Tablet Each film coated tablet contains Amlodipine as besylate….10mg, Olmesartan Medoxomil40mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1236.	076191	Beslol 2.5mg Tablet Each film coated tablet contains Bisoprolol Fumarate….2.5mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		

1237.	076192	Beslol 10mg Tablet Each film coated tablet contains Bisoprolol Fumarate….10mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
1238.	053340	Alpent 20mg Injection Each 2ml contains Flupentixol Decanoate….20mg	29/01/2014	Dy.No. 38099 19.11.2018 Rs.10000/-		
M/s. Mediceena Pharma Pvt, Limited, 27 Km Raiwind Road, Lahore						
1239.	052855	Amlanic Tablets 1gm Each vial contains Amoxycillin (as Sodium salt)…..875mg, Clavulanic Acid (as Potassium salt)……125mg	22/11/2008	Dy.No. 38090 19.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 29-07-2019 reply not received yet. a) 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 case of authorized person, authority letter shall be submitted along with application. Form-5B should not be printed on company letterhead. b) Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division c) **Notarized copy** of last submitted renewal application along with fee or renewal certificate. d) **Notarized copy** of valid Drug Manufacturing License. e) **Notarized copy** of approval of sections for manufacturing of said drugs. f) **Notarized copy** of last inspection report conducted by DRAP. g) **Notarized copy** of registration letter for confirmation of brand name and strength. h) **Notarized copy** of any change in particulars of registration of these products. i) An undertaking **on stamp paper** that the applied products has never been de-registered
1240.	052856	Medioxil-F Capsules 500mg Each capsule contains Amoxycillin (as sodium) ….250mg, Flucloxacillin (as Sodium) …250mg	22/11/2008	Dy.No. 38091 dated 19.11.2018 Rs.10000/-		
1241.	052857	Medioxil-F Syrup 250mg Each 5ml contains Amoxycillin (as sodium) ….125mg, Flucloxacillin (as Sodium) …125mg	22/11/2008	Dy.No. 38092 dated 19.11.2018 Rs.10000/-		

						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**.
M/s. Mass Pharma (Private) Limited ,17 Km Ferozpur Road, Lahore						
1242.	022460	Mazivit Injection Each 3ml ampoule contains Thiamine Hcl……100mg, Pyridoxine HCl….100mg, Cyanocobalamine..1000mcg	13/11/1998	Dy.No. 38098 19.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 29-07-2019 reply not received yet. a) 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 case of authorized person, authority letter shall be submitted along with application. b) Application for renewal of drug registration of Mazivit Injection is submitted late. Please deposit differential Fee. c) **Notarized copy** of last submitted renewal application along with fee or renewal certificate. d) **Notarized copy** of valid Drug Manufacturing License. e) **Notarized copy** of approval of sections for manufacturing of said drugs. f) **Notarized copy** of last inspection report conducted by DRAP. g) **Notarized copy** of registration letter for confirmation of brand name and strength. h) **Notarized copy** of any change in particulars of registration of these
1243.	030871	Clobetrex Ointment Contains Cloobetazole Propionate….0.05%	16/08/2003 Change of brand name on 22-11-2003	Dy.No. 38098 dated 19.11.2018 Rs.10000/-		
1244.	030872	Clobetrex cream Contains Cloobetazole Propionate….0.05%	16/08/2003 Change of brand name on 22-11-2003	Dy.No. 38098 dated 19.11.2018 Rs.10000/-		
1245.	030873	Lotricot Cream Contains Betamethasone Dipropionate…..0.05% Clotrimazole…..1%	16/08/2003 Change of brand name on 22-11-2003	Dy.No. 38098 dated 19.11.2018 Rs.10000/-		

						products. i) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. j) 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**.
M/s Alina Combine Pharmaceuticals (Pvt) Ltd, A-127, S.I.T.E., Super Highway, Karachi.						
1246.	022529	Vitamin E Capsule Each capsule contains Alphatocopheryl Acid succinate…..400IU Imported in bulk from M/s Amco Pharmaceuticals Inc. Canada and repacked	23/11/1998	Dy.No. 38013 dated 19.11.2018 Rs.20000 /-		Deferred for Shortcoming communicated on 31-07-2019 reply not received yet. i. **Notarized** copy of last submitted renewal application along with fee or renewal certificate. ii. **Notarized** copy of valid Drug Manufacturing License. iii. **Notarized** copy of last inspection report conducted by DRAP. iv. An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. v. 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**. vi. Legalized CoPP as per WHO's Format or Legalized free sale certificate and GMP certificate vii. Notarized Copy of
1247.	022530	EpilonaGelcap Capsule Each capsule contains Evening prime rose oil……..500mg (9.5% Gamma Linolenic acid) Vitamin E … 15 IU Imported in bulk from M/s Amco Pharmaceuticals Inc. Canada and repacked	23/11/1998	Dy.No. 38013 dated 19.11.2018 Rs.20000/-		

						Approval of sections for repacking.
1248.	022526	Pizofen Syrup Each 5ml contains Pizotifen (as hydrogen maleate)…….0.25mg	23/11/1998	Dy.No. 38013 dated 19.11.2018 Rs.10000/-		i. **Notarized** copy of last submitted renewal application along with fee or renewal certificate. ii. **Notarized** copy of valid Drug Manufacturing License. iii. **Notarized** copy of last inspection report conducted by DRAP. iv. An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. v. 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**. vi. Availability of formulations in reference regulatory authority. vii. Notarized Copy of Approval of sections.
1249.	022527	PiZofen Tablet Each tablet contains Pizotifen (as hydrogen maleate)…….0.5mg	23/11/1998	Dy.No. 38014 dated 19.11.2018 Rs.10000/-		
1250.	022528	Pizofen V Syrup Each 5ml contains Pizotifen (as hydrogen maleate)…….0.25mg, ` Thiamine HCl……0.875mg, Riboflavin 5 phosphate sodium 1.31mg, Pyridoxine HCl….0.77mg, Nicotinamde.5.25mg	23/11/1998	Dy.No. 38014 dated 19.11.2018 Rs.10000/-		
1251.	004338-EX	Salgicef Suspension Each 5ml contains Cefixime Trihydrate eq to Cefixime anhydrous……..100 mg	25/11/2008	Dy.No. 38014 dated 19.11.2018 Rs.10000/-		
M/s Friends Pharma Pvt. Limited,31-Km, Ferozpur Road, Lahore.						
1252.	052842	Nomilex Tablets 0.5mg Each tablet contains Alprazolam.0.5mg	22/11/2008	Dy.No. 38002 dated 19.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 31-07-2019 reply not received yet. a) 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 case of authorized person, authority letter shall be submitted along with application. b) Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division c) **Notarized** copy of valid Drug Manufacturing
1253.	052843	Tanil Tablet 3mg Each tablet contains Bromazepam...3mg	22/11/2008	Dy.No. 38002 dated 19.11.2018 Rs.10000/-		

						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. d) **Notarized** copy of last inspection report conducted by DRAP. e) **Notarized** copy of registration letter for confirmation of brand name. f) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. g) 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**.
M/s. Helicon Pharmaceuticals Pakistan Pvt. Limited, Model Town Road, Faisalabad						
1254.	031294	Hepasil Suspension Each 5ml contains Simlmarin..100mg	21/11/2018	Dy.No. 38008 dated 19.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 01-08-2019 reply not received yet. a) Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division b) **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. c) **Notarized** copy of last inspection report conducted by DRAP. d) **Notarized** copy of registration letter for confirmation of brand name. e) An undertaking on

						stamp paper that the applied products has never been de-registered **duly notarized**. f) 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**. g) Proof of availability of these medicines in reference regulatory authority
M/s. Sanofi-aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi						
1255.	053206	lignocaine 1% Injection Each ml contains Lignocaine HCl……1% (2 ml)	25/11/2008	Dy.No. 38010 dated 19.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 01-08-2019 reply not received yet. a) Please provide recent inspection report based on GMP Certificate. b) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. c) 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**. d) Proof of availability of these medicines in reference regulatory authority
1256.	053205	lignocaine 1% Injection Each ml contains Lignocaine HCl……1% (3.5 ml)	25/11/2008	Dy.No. 38011 dated 19.11.2018 Rs.10000/-		
M/s. Hizat Pharmaceuticals Industries Pvt Limited, 170 Industrial Estate, Jamrud Road, Peshawar						
1257.	078410	Hizedol CF Tablet Each tablet contains Paracetamol…… 500mg, Caffeine….65mg, Chlorpheniramine Maleate…..2mg	25/11/2013	Dy.No. 38340 dated 22.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 01-08-2019 reply not received yet. a) **Notarized** copy of valid Drug Manufacturing License along with letter of approved sections.in

1258.	078408	lanzprazole capsule Each delayed release capsule contains lansoprazole enteric coated pellets 8.5% Lansoprazole… 30mg	25/11/2013	Dy.No. 38338 dated 22.11.2018 Rs.10000/-		case of renewal, notarized copy of receipt of application for renewal of licence along with fee challan. b) **Notarized** copy of last inspection report conducted by DRAP. c) Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division. d) **Notarized** copy of registration letter for confirmation of brand name. e) Source of Pallets, in case of imported source, please deposit differential fee**.** f) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. g) 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**. h) Proof of availability of these medicines in reference regulatory authority.
1259.	014711	Surfadine Syrup Each 5ml contains Ammonium chloride…..100mg, Ephedrine HCl…….7mg, Diphenhydramine HCl……8mg	24/11/93	Dy.No. 38336 dated 22.11.2018 Rs.10000/-		
1260.	078407	Essozat Capsule Each delayed release capsule contains Esomeprazole eneric coated pellets 22.5% Esomeprazole….. 40mg	25/11/2013	Dy.No. 38337 dated 22.11.2018 Rs.10000/-		
1261.	078410	Disenite Tablet Each film coated tablet contains Diloxanidefurate….500mg, Metronidazole ….400mg	25/11/2013	Dy.No. 38340 dated 22.11.2018 Rs.10000/-		
M/s. Rehmat Pharma, 10.5 Km, Sheikhupura Road, Lahore						
1262.	032040	Gentian Violet Solution Each 100ml contains:- Gentian violet…….1gm	24/01/2004	Dy.No. 38611 dated 22.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 01-08-2019 reply not received yet. a) **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. b) **Notarized** copy of last inspection report conducted by DRAP.
1263.	032042	Benzyl Benzoate lotion Each 100ml contains:- Benzyl Benzoate….25gm	24/01/2004	Dy.No. 38611 dated 22.11.2018 Rs.10000/-		
1264.	032043	Ichthammol Glycerin BPC Each 100ml contains:- Icthammol….10gm, Glycerin….90gm	24/01/2004	Dy.No. 38611 dated 22.11.2018 Rs.10000/-		

						c) Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division. d) Notarized Copy of Last Renewal Application Receipt along with Fee challan. e) **Notarized** copy of registration letter for confirmation of brand name. f) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. g) 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**. h) Proof of availability of these medicines in reference regulatory authority
M/s. Aptcure Pvt. Ltd, 8- Pharma City, 30 km, Multan Road, Lahore						
1265.	053583	Neuripen 100mg Capsule Each capsule contains Gabapentin……..100mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 01-08-2019 reply not received yet. a) 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 case of authorized person, authority letter shall be submitted along with application. b) **Notarized** copy of registration letter for confirmation of brand name. c) An undertaking on stamp paper that the applied products has
1266.	053584	Neuripen 300mg Capsule Each capsule contains Gabapentin……..300mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1267.	053585	Aptimac Capsule 250mg Each capsule contains Azithromycin as dihydrate USP……250mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1268.	053586	Prelap Capsule 5mg Each capsule contains Olanzapine Citrate eq to. Olanzapine…….5mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1269.	053587	Prelap Capsule 10mg Each capsule contains Olanzapine Citrate eq to. Olanzapine…….5mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1270.	053588	Aptex 120mg Capsule Each capsule contains Orlistat…….120mg	3/12/2008	Dy.No. 38240 20.11.2018 Rs.10000/-		

1271.	053589	Celmatic 200mg Capsule Each capsule contains Celecoxib…….200mg	3/12/2008	Dy.No. 38240 20.11.2018 Rs.10000/-		never been de-registered **duly notarized**. d) 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**. e) Proof of availability of these medicines in reference regulatory authority. f) Record of last batch manufactuered.
1272.	053590	Oxidex 20mg Tablet Each film coated tablet contains Piroxicam-beta-cyclodextrin 191.2mg eq.to Piroxicam…..20mg	3/12/2008	Dy.No. 38240 20.11.2018 Rs.10000/-		
1273.	053592	Thymin 10mg Tablet Each film coated tablet contains Escitalopram as oxalate……10mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1274.	053594	Aptizid 80mg Tablet Each un-coated tablet contains Gliclazide……..80mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1275.	053595	Artimal 20/120mg Tablet Each film coated tablet contains Artemether…….20mg, Lumefantrine……120mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1276.	053596	Apticip 250mg Tablet Each film coated tablet contains Ciprofloxacin (as hydrochloride monohydrate)……250mg	3/12/2008	Dy.No. 38240 dated 20.11.2018 Rs.10000/-		
1277.	053597	Apticip 500mg Tablet each film coated tablet contains Ciprofloxacin (as hydrochloride monohydrate)……500mg	3/12/2008	Dy.No. 38240 20.11.2018 Rs.10000/-		
1278.	053598	Apticlar 250mg Tablet Each film coated tablet contains Clarithromycin…..250mg	3/12/2008	Dy.No. 38240 20.11.2018 Rs.10000/-		
1279.	053599	Cinax 200mg Tablet Each film coated tablet contains Ofloxacin……..200mg	3/12/2008	Dy.No. 38240 20.11.2018 Rs.10000/-		
M/s. Caraway Pharmaceuticals, Plot No. 12, Street No. N-3, National Industrial Zone RCCI, Rawat, Islamabad						
1280.	052845	Fexicame capsule 120mg Each capsule contains Fexofenadine as HCL……..120mg	22/11/2008	Dy.No. 38238 dated 20.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 19-08-2019 reply not received yet. a) **Notarized** copy of valid Drug Manufacturing License b) **Notarized** copy of last inspection report conducted by DRAP. c) Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts
1281.	053706	Modivid Injection Each capsule contains Piroxicam ….20mg	11/12/2008	Dy.No. 38244 dated 20.11.2018 Rs.10000/-		

						Division. d) Notarized Copy of Last Renewal Application Receipt along with Fee challan. e) **Notarized** copy of registration letter for confirmation of brand name. f) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. g) 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**. h) Proof of availability of these medicines in reference regulatory authority.
M/s. Wise Pharmaceuticals, Plot No. 3-A, Street S-1, RCCI Industrial Area, Rawat, Rawalpindi						
1282.	052851	Feltose Capsule Each capsule contains Iron as (Iron III Hydroxy Polymaltose complex)…100mg, Folic acid……..0.35mg	23/11/2008	Dy.No. 38644 dated 23.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 19-08-2019 reply not received yet. a) **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. b) **Notarized** copy of last inspection report conducted by DRAP. c) Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division. d) Notarized Copy of Last Renewal Application Receipt along with Fee challan. e) **Notarized** copy of registration letter for confirmation of brand
1283.	052852	Betoxi 20mg Capsule Each capsule contains Piroxicam as beta cyclodextrin…..20mg	23/11/2008	Dy.No. 38644 dated 23.11.2018 Rs.10000/-		
1284.	052853	E-Rest 10mg Tablet Each tablet contains Escitalopram as oxalate……10mg	23/11/2008	Dy.No. 38644 dated 23.11.2018 Rs.10000/-		
1285.	052854	Saliar 200mg Capsule Each capsule contains Cefixime as trihydrate…200mg	23/11/2008	Dy.No. 38644 dated 23.11.2018 Rs.10000/-		

						name. f) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. g) 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**. h) Proof of availability of these medicines in reference regulatory authority.
M/s. Novamed Pharmaceuticals (Pvt) Ltd, 28 Km, Ferozpur Road, Lahore						
1286.	052929	Diabryl Tablet 1mg Each tablet contains Glimepiride 1mg	27/11/2008	Dy.No. 38473 23.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 19-08-2019 reply not received yet. a) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. b) Proof of availability of these medicines in reference regulatory authority.
1287.	052930	Diabryl Tablet 2mg Each tablet contains Glimepiride 2mg	27/11/2008	Dy.No. 38473 23.11.2018 Rs.10000/-		
1288.	052931	Diabryl Tablet 3mg Each tablet contains Glimepiride 3mg	27/11/2008	Dy.No. 38473 23.11.2018 Rs.10000/-		
1289.	052932	Diabryl Tablet 4mg Each tablet contains Glimepiride 4mg	27/11/2008	Dy.No. 38473 23.11.2018 Rs.10000/-		
M/s. Indus Pharma (Pvt) Ltd, Plot No. 65, Sector 27, Korangi Industrial Area, Karachi						
1290.	004339-Ex	Bioran Injection Each 3ml contains Diclofenac Sodium..75mg	25/11/2013	Dy.No. 38475 23.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 19-08-2019 reply not received yet. a) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. b) 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
1291.	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/-		
1292.	053450	Indomal Tablet 20mg+120mg Each tablet contains Ondaserton (as HCL)…….4mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
1293.	053451	Indomal Tablet 40mg+240mg Each tablet contains Artemether……..40mg, Lumefantrine…..240mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		

1294.	014823	Oflox Tablet 200mg Each tablet contains Ofloxacin……..200mg	5/12/1993	Dy.No. 38475 23.11.2018 Rs.10000/-		relevant laws **duly notarized**.
1295.	053448	Onseron 4mg Tablet Each tablet contains Ondaserton (as HCL)…….4mg	24/12/2008	Dy.No. 38475 dated 23.11.2018 Rs.10000/-		
1296.	053449	Onseron 8mg Tablet Each tablet contains Ondaserton (as HCL)…….8mg	24/12/2008	Dy.No. 38475 23.11.2018 Rs.10000/-		
1297.	053452	Onseron Injection 2ml Each 2ml contains Ondaserton (as HCL)…….4mg	24/12/2008	Dy.No. 38475 23.11.2018 Rs.10000/-		
M/S. High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi						
1298.	053318	Brexxel 3mg Tablet Each tablet contains Bromazepam...3mg	30/12/2008	Dy.No. 38474 23.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 19-08-2019 reply not received yet. a) Please provide approval of section for manufacturing of said drugs. b) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. c) 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**. d) Proof of availability of these medicines in reference regulatory authority
1299.	053319	Shenlax 0.25mg Tabet Each tablet contains Alprazolam……0.25mg	30/12/2008	Dy.No. 38474 23.11.2018 Rs.10000/-		
1300.	053320	Shenlax 0.5mg Tabet Each tablet contains Alprazolam……0.5mg	30/12/2008	Dy.No. 38474 23.11.2018 Rs.10000/-		
1301.	053328	Brendel 0.2mg Tablet Each tablet contains Buprenorphine…..0.2mg	30/12/2008	Dy.No. 38474 23.11.2018 Rs.10000/-		
1302.	053329	Dormex 7.5mg Tablet Each tablet contains Midazolam…….7.5mg	30/12/2008	Dy.No. 38474 23.11.2018 Rs.10000/-		
1303.	053330	Pentagin 25mg Tablet Each tablet contains Pentazocin……..25mg	30/12/2008	Dy.No. 38474 23.11.2018 Rs.10000/-		
1304.	053331	Klotril 0.5mg tablet Each tablet contains Clonazepam….0.25mg	30/12/2008	Dy.No. 38474 23.11.2018 Rs.10000/-		
1305.	053332	Klotril 2mg tablet Each tablet contains Clonazepam….2mg	30/12/2008	Dy.No. 38474 *23.11*.2018 Rs.10000/-		
1306.	052291	Alphaferon 3MIU Injection Each vial contains Human Recombinant Interferon Appha 2b 3MIU	2/12/2008	Dy.No. 38474 23.11.2018 Rs.20000/-		
M/s. Mediate Pharmaceuticals (Pvt) Ltd. 150-151, Sector 24, Korangi Industrial Area, Karachi						
1307.	053244	Water for Injection Each 5ml contains water for injection	1/12/2008	Dy.No. 38484 dated 23.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 19th August, 2019. a) **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
	053241	Lignocaine 2% Injection Each 10ml contains Lignocaine HCl……20mg	1/12/2008	Dy.No. 38485 dated 23.11.2018 Rs.10000/-		
1308.	053240	Tramorhage 500mg Injection Each 5ml contains	1/12/2008	Dy.No. 38486 dated 23.11.2018		

		Tranexamic Acid …. 500 mg		Rs.10000/-		with fee challan. b) **Notarized** copy of last inspection report conducted by DRAP. c) **Notarized** Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division. d) **Notarized** Copy of Last Renewal Application Receipt along with Fee challan. e) **Notarized** copy of registration letter for confirmation of brand name. f) An undertaking on stamp paper that the applied products have never been de-registered **duly notarized**. g) 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.
1309.	053237	Medifenac 75mg Injection Each 3ml contains Diclofenac Sodium…75mg	1/12/2008	Dy.No. 38487 dated 23.11.2018 Rs.10000/-		
M/s. Macter International Limited, E-40 SITE Karachi.						
1310.	010367	Maccillin capsule 500mg Ampicillin (as trihydrate)…500mg	19-02-1990 Transfer of registration to this site on 06-12-2018	Dy.No.39208 28/11/2018 Rs.10000		Deferred for Shortcoming communicated on 22-08-2019 reply not received yet. **Notarized** copy of initial registration letter for confirmation of brand name and strength.
1311.	007699	Maccillin 125mg/5ml dry susp Ampicillin (as trihydrate)…125mg	18-04-1985 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1312.	010132	Maciclox capsule 250mg Each capsule contains Ampicillin (as Trihydrate)……125mg, Cloxacillin (as sodium)….125mg	5/7/1989 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1313.	010131	Maxil capsule 250mg Each capsule contains	5/7/1989 Transfer of	Dy.No.39208 Dated.28/11/2		

		Amoxycillin (as trihydrate).250mg	registration to this site on 06-12-2018	018 Rs.10000		
1314.	010527	Maxil capsule 500mg Each capsule contains Amoxycillin (as Trihydrate .500mg	17/03/1990 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1315.	010130	Maxil drops 125mg/1.25ml Each 5ml contains Ampicillin (as trihydrate).250mg	5/7/1989 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1316.	007829	Maxil 125mg/1.25ml dry susp Each 5ml contains Amoxycillin …125mg	5/2/1985 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1317.	010529	MaxilFotre 250mg/5ml dry susp Each 5ml contains Amoxyxillin (as trihydrate)….250mg	17/03/1990 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1318.	026273	Maxil Injection 250mg Each vail contains Amoxycillin sodium eq to Amoxyxillin…….250mg	19/9/2018 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		
1319.	026274	Maxil Injection 500mg Each vail contains Amoxycillin sodium eq to Amoxyxillin…….500mg	19/9/2018 Transfer of registration to this site on 06-12-2018	Dy.No.39208 Dated.28/11/2018 Rs.10000		

Sr. No	**Reg. No.**	**Brand Name, Composition & Specification**	**Initial date of Registration**	**Date of application (R&I) Fee submitted**	**Renewal validity**	**Remarks**
M/s Bio-Labs Pvt. Limited, Plot No. 145, Industrial Triangle, Kahuta Road, Islamabad.						
1320.	14535	**U-Vit Forte Soluble Powder** Each 100gm Contains: Vitamin A…5,050,000IU Vitamin B1…550mg Vitamin B2 2,500mg Vitamin B6 1,500mg Vitamin B12…7mg Vitamin C 22,000mg Vitamin D3…1,200,000IU	22/04/1994 Re-register on 04-11-2008	Dy. No. 31926 dated 25-09-2018 10,000/-	03-11-2023	Deferred for Shortcoming communicated on 03-07-2019 reply not received yet. Also applied for renewal on 01-11-2013 a) **Notarized copy** of last inspection report conducted by DRAP. b) An undertaking **on**

		Vitamin E…7,300mg Vitamin K3 1,700mg Biotin 2%...80mg Choline Chloride 100,000mg"				**stamp paper**that the applied products has never been de-registered **duly notarized**.
1321.	23408	**Helminpipra Powder** Powder Contains: PiprazineAdipate 100% W/W	17/05/1999 Re-register on 04-11-2008	Dy. No. 31926 dated 25-09-2018 10,000/-		c) 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**.
1322.	23416	**Ciproxacin 20% Liquid** Each 100 ml contains: Ciprofloxacin 20gm	17/05/1999 Re-register on 04-11-2008	Dy. No. 31926 dated 25-09-2018 10,000/-		
1323.	25346	**U-Dek Powder** Each 1000gm contains: Vitamin A 30,000,000 IU, Vitamin D3 …25,00,000 I.U. Vitamin E 5000mg, Vitamin K3…6000mg	09/05/2000 Re-register on 04-11-2008	Dy. No. 31926 dated 25-09-2018 10,000/-		
1324.	25769	**Amoxacin-50 Powder** Each 100gm Contains: Amoxicillin Trihydrate Eq To 50gm Amoxicillin Base	04/10/2000 Re-register on 04-11-2008	Dy. No. 31926 dated 25-09-2018 10,000/-		Deferred for Shortcoming communicated on 03-07-2019 reply not received yet. Also applied for renewal on 01-11-2013 a) Letter for renewal of Drug Manufacturing Licence (DML) does not contain word "VET" against Penicillin oral powder section however, product is for veterinary use. Clarification seeks. b) **Notarized copy** of last inspection report conducted by DRAP. c) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. d) 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.**

M/s SB Pharma, Plot No. 5-E, Industrial Triangle, Kahuta Road, Islamabad.						
1325.	48220	**Sb Tiamulin 12.5% Oral Solution** Each 100 Ml Contains: Tiamulin Hydrogen Fumarate…12.5 g	25-09-2008	Dy. No. 31715 dated 24-09-2018 10,000/-		Deferred for Shortcoming communicated on 03-07-2019 reply not received yet. a) **Notarized copy** of last submitted renewal application along with fee or renewal certificate. b) **Notarized copy** of valid Drug Manufacturing License. c) **Notarized copy** of last inspection report conducted by DRAP. d) **Notarized copy** of registration letter for confirmation of brand name and strength. e) An undertaking **on stamp paper** that the applied products has never been de-registered **duly notarized**. f) 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**. g) Last batch manufactured record.
M/s Attabak Pharmaceuticals, 5-C I-10/3, Industrial Estate, Islamabad.						
1326.	049773	Oxyfen Injection Each ml contains Oxytetracycline HCl ……...50mg, Mepyramine Maleate …….25mg	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		Deferred for Shortcoming communicated on 03-07-2019 reply not received yet. a) 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 case of authorized person,
1327.	049774	Clozanide suspension Each ml contains Oxyclozanide BP…….46.875mg, Oxfendazole BP…….16.9875mg	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1328.	049775	Tylofenta Injection Each ml contains Tylosin Tartrate	22/11/2008	Dy.No. 38015 dated 19.11.2018		

		BP…….50mg, Gentamycin Sulphate BP……25mg		Rs.10000/-		authority letter shall be submitted along with application.
1329.	049776	Biotic Plus Powder Each 100g Contains Tylosin Tartrte BP…5gm, Doxycycline HCL BP……10gm, Gentamycin Sulphate BP…..25mg	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		b) Notarized Copy of NOC of Central Research Fund (CRF) as required by Budget & Accounts Division c) **Notarized** copy of valid Drug Manufacturing License. In case of renewal, notarized copy of receipt of application for renewal of licence along with fee challan. d) **Notarized** copy of last inspection report conducted by DRAP. e) **Notarized** copy of registration letter for confirmation of brand name. f) Notarized copy of approval of sections for manufacturing of these drugs. g) Proof of availability of these medicines in reference regulatory authority. h) An undertaking on stamp paper that the applied products has never been de-registered **duly notarized**. i) 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**.
1330.	049777	Tydox Gold Powder Each 1000gm contains Tylosine Tartrate BP…..100g, Doxyccline HCl BP…..200g, Bromohexine HCl (B.P)…….5g	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1331.	049779	Mexibak 8mg Injection Each ml contains Meloxicam BP…….8mg	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1332.	049780	Norbak 20mg Liquid Each 100ml contains:- Norfloxacin HCl…..20gm	22/11/2008	Dy.No. 38015 19.11.2018 Rs.10000/-		
1333.	049781	MexigoldInjecion Each ml contains Meloxicam BP….5mg	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1334.	049782	Claratin Powder Each 1000gm contains Chloretracycline HCl (BP)…..200gm	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1335.	049783	Coliser Water soluble powder Each 100g Contains Colistin Sulphate BP….400000000 IU	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1336.	049784	Colibak Forte Powder Each 100gm contains Colistin Sulphate BP….500000000 IU	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1337.	049785	ECA Mix Powder Each 100gm contains Enrofloxacin……20% Colistin Sulphate…3.5%, Amantadine……4%	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1338.	049786	Bromohexine 5% Solution Each ml contains Bromhexine HCl….50mg	22/11/2008	Dy.No. 38015 19.11.2018 Rs.10000/-		
1339.	049787	Doxycol Powder Each 100gm contains Doxycycline HCl BP…..10gm, Colistin Sulphate BP……20MIU	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1340.	049788	Bromodox Powder Each 1000gm contains Tylosin tartrate	22/11/2008	Dy.No. 38015 dated 19.11.2018		

		BP……100gm, Doxycycline HCL BP….200gm, Colistin Sulphate BP…..400IU, Bromhexine HCl…….3gm		Rs.10000/-		
1341.	049789	Darvicox Powder Each 100gm contains Sodium Sulphaquinoxaine BP….200mg, Sodium Sulphadimidine BP Vet……82.5gm, Diaveridine BP Vet…..50mg, Vitamin A……2.5MIU, Vitamin K3 BP, …2gm, Colistin Sulphate….500IU	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1342.	049790	Disulph D Powder Each 1000gm contains Sodium Sulphaquinoxaine BP….200mg, Sodium Sulphadimidine BP Vet……82.5gm, Diaveridine BP Vet…..50mg, Vitamin A……2.5MIU, Vitamin K3 BP, …2gm, Colistin Vitamin E BP….500mg	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1343.	049791	Oxyneomicina Powder Each 1000gm contains Oxytertracycline HCl…….190gm, Neomycin Sulphate….190gm	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1344.	049792	Flushbak Powder Each 1000gm contains Methenamine……955gm, Vitamin B2 (BP)…..10gm, Calcium Pantothenate….6gm, Nicotinamide BP…….25gm	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		
1345.	049793	Enrotin Solution Each 100ml contains:- Enrofloxacin……10gm, Colistin sulphate……50MIU	22/11/2008	Dy.No. 38015 dated 19.11.2018 Rs.10000/-		

COMPLETE CASES

a. Locally Manufactured Registered Drugs (Human).

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s. Innvotek Pharmaceuticals, Plot No. 35, Industrial Triangle, Kahuta Road, Islamabad.						
1.	52741	**Cromog-T EyeDrops** Each ml contains:- Sodium Cromoglycate …40mg Tetrahydrozoline Sodium …0.5mg	04/11/2008	Dy.No.36379 dated 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
2.	52742	**Invoflox-D Eye Drops** Each ml contains:- Ciprofloxacin …0.3%w/v Dexamethasone …0.1%w/v	04/11/2008	Dy.No.36381 dated 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
3.	52743	**Bromycin Onitment** Each gm contains:-Tobramycin …0.3%w/w	04/11/2008	Dy.No.36376 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
4.	52744	**Invoclor Ointment** Each gm contains:- Chloramphenicol …1%w/w	04/11/2008	Dy.No.36378 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
5.	52745	**Incot Tablets** Each tablet contains:- Co-trimoxazole Trimethoprim …80mg Sulphamethoxazole …400mg	04/11/2008	Dy.No.36382 dated 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
6.	52746	**Incot-DS Tablets** Each tablet contains:- Trimethoprim …160mg Sulphamethoxazole …800mg	04/11/2008	Dy.No.36385 dated 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
7.	52747	**Kutic Tablets** Each tablet contains:- Ketoconazole …200mg	04/11/2008	Dy.No.36377 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
8.	52748	**Inlef-10 Tablets** Each tablet contains:- Leflunomide …10mg	04/11/2008	Dy.No.36384 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
9.	52749	**Inlef -20 Tablets** Each tablet contains:- Leflunomide …20mg	04/11/2008	Dy.No.36385 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
10.	52750	**N-Pan Tablets** Each enteric coated tablet contains:- Pantoprazole as Pantoprazole Sodium …40mg	04/11/2008	Dy.No.36380 dated 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
11.	52751	**Inlod Eye Drops** Each ml contains:- Lodoxamide …0.1%w/v	04/11/2008	Dy.No.36385 02.11.2018 Rs.10000/-	03/11/2023	w.e.f. 04-11-2018 to 03-11-2023
Shortcomings:						
M/s.Bryon Pharmaceuticals (Pvt) Ltd, 48, Hayatabad Industrial Estate, Peshawar						
12.	22401	**Flucon 150 Capsules** Each Capsule Contains: Fluconazole …150mg	26/11/1998 Change of BN:	Dy.No.36460 05.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26-11-2018 to 25-11-2023

			22/08/2002			
13.	22402	**Azibect Capsule** Each Capsule Contains: Azithromycin …250mg	26/11/1998	Dy.No.36460 05.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26-11-2018 to 25-11-2023
14.	22403	**Ostrin Forte Suspension** Each 5ml contains Sulphamethoxazole …400mg Trimethoprim …80mg	26/11/1998	Dy.No.36460 dated 05.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26-11-2018 to 25-11-2023
15.	22404	**Loragix Tablet** Each tablet contains Loratadine …. 10mg	26/11/1998	Dy.No.36460 05.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26-11-2018 to 25-11-2023
16.	52811	**Corsafe AT 20 Tablet** Each film coated tablet contains:- Amlodipine (Besylate) … 5mg Atorvastatin (as Calcium Salt)….20mg	18/11/2008	Dy.No.36460 dated 05.11.2018 Rs.10000/-	17/11/2023	w.e.f. 18-11-2018 to 17-11-2023
17.	53625	**Enpress XR Capsules.** Each Capsule Contains: Venlafaxine HCl eq. To Venlafaxine …75mg.	04/12/2008	Dy.No.36460 dated 05.11.2018 Rs.10000/-	03/12/2023	w.e.f. 04-12-2018 to 03-12-2023
18.	54607	**Xyprin Tablet** Each film coated tablet contains: Oxaprozin …600mg	24/12/2008	Dy.No.36460 dated 05.11.2018 Rs.10000/-	23/12/2023	w.e.f. 24-12-2018 to 23-12-2023
19.	60888	**Nylosin Oral Suspension** Each ml contains: Nystatin …100,000Units	17/11/2008	Dy.No.36460 05.11.2018 Rs.10000/-	16/11/2023	w.e.f. 17-11-2018 to 16-11-2023
Shortcomings:						
M/s.Shaheen Pharmaceuticals, 3km Murghzar Road, Saidu Sharif, Swat						
20.	78402	**Finarid-M 1mg Tablets** Each film coated tablet contains: Finasteride …20 mg	19/11/2013	Dy.No.36618 dated 05.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19-11-2018 to 18-11-2023
21.	78403	**Dexet Plus 20 mg Tablets** Each film coated tablet contains: Paroxetin HCl ≡ Paroxetin …20 mg	19/11/2013	Dy.No.36618 dated 05.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19-11-2018 to 18-11-2023
22.	78404	**Eflun 20mg Tablets** Each film coated tablet contains Leflunomide …20mg	19/11/2013	Dy.No.36618 dated 05.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19-11-2018 to 18-11-2023
Shortcomings:						
M/s Davis Pharmaceutical Laboratories. 121, industrial triangle area, Kahuta road, Islamabad.						
23.	31708	**Eziklar 250mg Tablets** Each tablet contains:- Clarithromycin …250mg	08/11/2003	Dy.No.36469 05.11.2018 Rs.10000/- Late fee of 10000/- on 29/11/2018	07/11/2023	w.e.f. 08-11-2018 to 07-11-2023
24.	31709	**Eziklar 500mg Tablets** Each tablet contains:- Clarithromycin…500mg	08/11/2003	Dy.No.36469 05.11.2018 Rs.10000/- Late fee of 10000/- on 29/11/2018	07/11/2023	w.e.f. 08-11-2018 to 07-11-2023

25.	31712	**Derox 300mg Tablets** Each tablet contains:- Roxithromycin …300mg	08/11/2003	Dy.No.36469 05.11.2018 Rs.10000/- Late fee of 10000/- on 29/11/2018	07/11/2023	w.e.f. 08-11-2018 to 07-11-2023
26.	31711	**Derox 150mg Tablets** Each tablet contains:- Roxithromycin …150mg	08/11/2003	Dy.No.36469 05.11.2018 Rs.10000/- Late fee of 10000/- on 29/11/2018	07/11/2023	w.e.f. 08-11-2018 to 07-11-2023
27.	31710	**Derox 50mg Tablets** Each tablet contains:- Roxithromycin …50mg	08/11/2003	Dy.No.36469 05.11.2018 Rs.10000/- Late fee of 10000/- on 29/11/2018	07/11/2023	w.e.f. 08-11-2018 to 07-11-2023
Shortcomings:						
M/s. Pharmevo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi						
28.	53317	**Steplex FA Tablet** Each tablet contains Iron Protein Succinylate …400mg, Folic Acid …2.5mg	05/12/2008	Dy.No.37130 dated 09.11.2018 Rs.10000/-	04/12/2023	w.e.f. 05-12-2018 to 04-12-2023
Shortcomings:						
M/s Pharmedic Laboratories (Pvt) Ltd, 16-KM Multan Road, Lahore- Pakistan						
29.	52753	**Malafantrine Dry Suspension**Each 5ml contains Artemether …15mg, Lumefantrine …90mg	11/11/2008	Dy.No.37166 09.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023
Shortcomings:						
M/s Novamed Pharmaceuticals (Pvt) Ltd., 28 KM, Ferozepur Road, Lahore.						
30.	001868-EX	**Pharxone Injection 1 gm** Each vial contains:- Ceftriaxone (as Sodium) …… 1 gm	11/11/2013	Dy.No.37300 dated 12.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023
31.	001869-EX	**Pharxone Injection 500 mg** Each vial contains:- Ceftriaxone (as Sodium) …. 500 mg	11/11/2013	Dy.No.37300 dated 12.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023
32.	001870-EX	**Pharxone Injection 250 mg** Each vial contains:- Ceftriaxone (as Sodium) … 250 mg	11/11/2013	Dy.No.37300 dated 12.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023
33.	001871-EX	**Pharvirin 400 mg Tablet** Each tablet contains:- Ribavirin …400mg	11/11/2013	Dy.No.37300 12.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023
34.	001872-EX	**Pharlevo 500 mg Tablet** Each tablet contains:- Levofloxacin (as hemihydrate)….500 mg	11/11/2013	Dy.No.37300 dated 12.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023
35.	001873-EX	**Makcet 10mg Tablet** Each tablet contains:- Escitalopram (as oxalate) …10mg	11/11/2013	Dy.No.37300 12.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023

36.	001874-EX	**Pharmoxi 400mg Tablet** Each film coated tablet contains:- Moxifloxacin …400mg		11/11/2013	Dy.No.37300 dated 12.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10-11-2023
Shortcomings:							
M/s. Mass Pharma Pvt. Ltd.,17 Km Ferozepur Road Lahore							
37.	022391	**Mustex Tablet** Each tablet contains Cetirizine Dihydrochloride….10mg		13/11/1998	Dy.No.37299 dated 12.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13-11-2018 to 12-11-2023
38.	022393	**Veromin-T Tablet** Each tablet contains Zinc…22.5mg, Vitamin E…..30IU, Vitamin C…….500mg, Folic Acid…..150mcg, Vitamin B1……15mg, Vitamin B2….15mg, Nicotinamide…….100mg, Vitamin B6…….20mg, Vitamin B12…….12mcg, Pantothenic Acid …20mg		13/11/1998	Dy.No.37299 dated 12.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13-11-2018 to 12-11-2023
39.	022394	**Kaldic Tablet** Each tablet contains Diclofenac Potassium …50mg		13/11/1998	Dy.No.37299 12.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13-11-2018 to 12-11-2023
40.	022457	**Ectobal Injection** Each 1ml ampoule contains Mecobalamin …500mcg		13/11/1998	Dy.No.37299 12.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13-11-2018 to 12-11-2023
Shortcomings:							
M/s Akhai Pharmaceuticals (Pvt.) Ltd. Plot # A-248 & A-256 to A-259, HITE, Lasbela Balochistan, Pakistan							
41.	017423	M/s Vision pharmaceuticals, Islamabad.	**Ramezole Capsule** Each Capsule Contains Omeprazole …….20mg	13/07/1995 Transfer from import to local: 28/11/2007 Transfer from contract mfg to own: **12/12/2008** Change of pellet source from import to local: 03/06/2010	Dy.No.37453 dated 12.11.2018 Rs.10000/-	11/12/2023	w.e.f. 12-12-2018 to 11-12-2023
Shortcomings:							
M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad							
42.	54602	**Drotex Tablets 40mg.** Each tablet contains: Drotavarine……40mg.		23/12/2008	Dy.No.36351 01.11.2018 Rs.10000/-	22/12/2023	w.e.f. 23-12-2018 to 22-12-2023
43.	54733	**Aripaze Tablets 10mg** Each tablet contains: Aripiprazole…….10mg		01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
44.	54729	**Aripaze Tablets 20mg** Each tablet contains: Aripiprazole……20mg		01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023

45.	54918	**Artinil-K SR 100mg Tablets** Each sustained release tablet contains:-Diclofenac Potassium 100mg	24/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	23/01/2024	w.e.f. 24-01-2019 to 23/01/2024
46.	54745	**Epidobe Capsule** Each Capsule Contains: Calcium Dobesilate …500mg	01/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
47.	54746	**Gabapan 600mg Tablets** Each tablet contains: Gabapentin…….600mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
48.	54739	**Hepalam Tablets 100mg** Each tablet contains: Lamivudine……..100mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
49.	54740	**Isenza Tablets 25mg** Each tablet contains: Eplerenone…….25mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
50.	32038	**Glosil Tablet With Enzymes** Each Tablet Contains: Pancreatin … 210 FIP P.U. Bromelain …35000 P.U Dimethylpolysilaxane… 50mg. Sodium dehydrocholate …20mg Metoclopramide … .6mg.	26/01/2004	Dy.No.36744 dated 06.11.2018 Rs.10000/-	25/01/2024	Deferred for Confirmation of API Source.
51.	54741	**Lisnozide Tablets 20mg** Each tablet contains: Lisinopril…….20mg Hydrochlorothiazide….12.5mg	01/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
52.	54728	**Maxophine Plus Dry Suspension** Each 5ml contains: Cefixime (as trihydrate) ….200mg	01/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
53.	54742	**Vorizol Tablets 5mg** Each tablet contains: Donepezil …5mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
54.	54810	**Tamat Tablets 200mg** Each tablet contains: Topiramate …….200mg	13/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	12/01/2024	w.e.f. 13-01-2019 to 12/01/2024
55.	54732	**Sulprex Tablets 50mg** Each tablet contains: Levosulpride …50mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
56.	54744	**Sulprex tablets 100mg** Each tablet contains: Levosulpride……100mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
57.	54730	**Topnin Injection** Each Vial Conatins:- Teicoplanin ……..100mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
58.	32039	**Piractim Injection** Each 5ml Contains: Piracetam……1gm	26/01/2004	Dy.No.36744 06.11.2018 Rs.10000/-	25/01/2024	w.e.f. 26-01-2019 to 25/01/2024
59.	54598	**Olmesa Tablet 20mg** Each tablet contains: Olmesartan as Medoxamil…….20mg.	23/12/2008	Dy.No.36744 dated 06.11.2018 Rs.10000/-	22/12/2023	w.e.f. 23-12-2018 to 22/12/2023

60.	54743	**Olmesa Tablets 10mg** Each tablet contains: Olmesartan (as Medoxamil)…10mg	01/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
61.	54737	**Resinate Tablets 35mg** Each tablet contains: Risedronate ……35mg	01/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
62.	54735	**Rovast Tablets 20mg** Each tablet contains: Rosuvastatin (as Calcium) …20mg	01/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
63.	54731	**Rovast Tablets 10mg** Each tablet contains: Rosuvastatin (as Calcium) ……10mg	01/01/2009	Dy.No.36744 dated 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
64.	54736	**Resinate Tablets 5mg**Each tablet contains: Risedronate Sodium ……..5mg	01/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	31/12/2023	w.e.f. 01-01-2019 to 31/12/2023
65.	54808	**Rovast Tablet 5mg** Each tablet contains: Rosuvastatin (as Calcium)…….5mg	13/01/2009	Dy.No.36744 06.11.2018 Rs.10000/-	12/01/2024	w.e.f. 13-01-2019 to 12/01/2024
Shortcomings:						
M/s. Pharmatec Pakistan (Pvt) Ltd, D-86/A, S.I.T.E., Karachi						
66.	027210	**Maltofer-Fol Chewable Tablet** Each tablet contains: Iron (III) Hydroxide polymaltose complex corr to Iron (III) …100mg Folic acid …0.5350mg	01/09/2001 TOR from Getz on 24/11/2008	Dy.No.36865 dated 07.11.2018 Rs.10000/-	23/11/2023	w.e.f. 24-11-2018 to 23/11/2023
67.	001113-EX	**Lotek Tablet** Each tablet contains: Losartan potassium …50mg	11/11/2008	Dy.No.36865 07.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
Shortcomings:						
M/s.Genome Pharmaceuticals (Pvt) Ltd, 16/1-Phase IV Industrial Estate, Hattar						
68.	077444	**Oxcarb-600 Tablet** Each film coated tablet contains: Oxcarbazepine …600mg	11/11/2013	Dy.No.36743 dated 06.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
69.	077445	**Candesar-8 tablet** Each tablet contains Candesartan cilexetil …8mg	11/11/2013	Dy.No.36743 06.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
70.	077446	**Candesar-16 tablet** Each tablet contains Candesartan cilexetil …16mg	11/11/2013	Dy.No.36743 06.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
71.	077447	**Vimpex 50 tablet** Each film coated tablet contains: Lacosamide …50mg	11/11/2013	Dy.No.36743 06.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
72.	077448	**Vimpex 100 tablet** Each film coated tablet contains: Lacosamide …100mg	11/11/2013	Dy.No.36743 dated 06.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
73.	077449	**Vimpex 200 tablet** Each film coated tablet contains:	11/11/2013	Dy.No.36743 dated 06.11.2018	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023

		Lacosamide …200mg		Rs.10000/-		
74.	077489	**Febulus 40 Tablet** Each film coated tablet contains: Fexbuxostat …40mg	11/11/2013	Dy.No.36743 dated 06.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
75.	077490	**Febulus 80 Tablet** Each film coated tablet contains: Fexbuxostat …80mg	11/11/2013	Dy.No.36743 dated 06.11.2018 Rs.10000/-	10/11/2023	w.e.f. 11-11-2018 to 10/11/2023
Shortcomings:						
M/s. Le Mendoza Pharmaceuticals (Pvt.) Ltd., Plot No. 7, Sector 23, Korangi Industrial Area, Karachi						
76.	31850	**Kinfen Cream** Each gram contains:- Triamcinolone …1mg Neomycin …2.5mg Gramicidin …0.25mg Nystatin …100,000 units	22/11/2003 Change of formulation: 05/12/2007 Transfer on: 19/04/2018	Dy.No.36735 dated 06.11.2018 Rs.10000/-	21/11/2023	w.e.f. 22/11/2018 to 21/11/2023
Shortcomings:						
Maple Pharmaceuticals (Pvt) Ltd., 147/23, Korangi Industrial Area, Karachi						
77.	053122	**Loclog-AP 75mg Tablet** Each bi-layered tablet contains: Clopidogrel …75mg Aspirin …75mg	14/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	13/11/2023	w.e.f. 14/11/2018 to 13/11/2023
78.	053123	**Loclog-AP 150mg Tablet** Each bi-layered tablet contains Clopidogrel …75mg Aspirin …150mg	14/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	13/11/2023	w.e.f. 14/11/2018 to 13/11/2023
79.	053124	**T-Sartan 20mg Tablet** Each film coated tablet contains Telmisartan …20mg	14/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	13/11/2023	w.e.f. 14/11/2018 to 13/11/2023
80.	053125	**T-Sartan 40mg Tablet** Each film coated tablet contains Telmisartan …40mg	14/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	13/11/2023	w.e.f. 14/11/2018 to 13/11/2023
81.	053126	**T-Sartan 80mg Tablet** Each film coated tablet contains Telmisartan …80mg	14/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	13/11/2023	w.e.f. 14/11/2018 to 13/11/2023
82.	053127	**Rostatin 5mg Tablet** Each film coated tablet contains Rosuvastatin …5mg	14/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	13/11/2023	w.e.f. 14/11/2018 to 13/11/2023
83.	053128	**Rostatin 10mg Tablet** Each film coated tablet contains Rosuvastatin …10mg	14/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	13/11/2023	w.e.f. 14/11/2018 to 13/11/2023
84.	053158	**Curasoft-Eff 150mg Effervescent Tablets** Each tablet contains Ranitidine……150mg	15/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
85.	053159	**Curasoft-Eff 300mgEffervescent Tablets** Each tablet contains Ranitidine……300mg	15/11/2008	Dy.No.37694 dated 14.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
86.	053121	**Glibetic Plus Tablet** Each tablet contains	15/11/2008 Change of	Dy.No.37694 dated	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023

		Pioglitazone (as HCl)…30mg, Glimepriride …2mg	BN on 06/12/2008 Change of BN on 12/10/2010	14.11.2018 Rs.10000/-		
Shortcomings:						
M/s Valor Pharmaceuticals. 124/A Industrial Triangle, Kahuta Road Islamabad						
87.	077666	**Geodon 20mg Capsule** Each capsule contains Ziprasidone HCl Monohydrate eq to Ziprasidone…….20mg	20/11/2013	Dy.No.37692 dated 14.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
88.	077667	**Geodon 40mg Capsule** Each capsule contains Ziprasidone HCl Monohydrate eq to Ziprasidone…….40mg	20/11/2013	Dy.No.37692 dated 14.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
Shortcomings:						
M/s Dyson Research Laboratories (Pvt) Ltd. 28-km, Ferozpur Road, Lahore.						
89.	77051	**Bisfat Tablets 10mg** Each film coated tablet contains:- Bisoprolol fumarate …10mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
90.	77052	**Bisfat Tablets 5mg** Each film coated tablet contains:- Bisoprolol fumarate …5mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
91.	77053	**Zevro Syrup 20mg** Each 5ml contains:- Zinc sulphate monohydrate eq. to Elemental Zinc …20mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
92.	77054	**Bisfat Tablets 2.5mg** Each film coated tablet contains:- Bisoprolol fumarate …2.5mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
93.	77055	**Azigold Tablets 500mg** Each film coated tablet contains:- Azithromycin (as dihydrate) …500mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
94.	77056	**Azigold Tablets 250mg** Each film coated tablet contains:- Azithromycin (as dihydrate) …250mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
95.	77057	**Mevos Tablets 135mg** Each film coated tablet contains:- Mebeverine hydrochloride …135mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
96.	77058	**Zevro Syrup 10mg** Each 5ml contains:- Zinc sulphate monohydrate eq. to Elemental Zinc …10mg	06/12/2013	Dy.No.38334 dated 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
97.	77059	**Perimo Suspension** Each ml contains:- Domperidone …1mg	06/12/2013	Dy.No.38334 22.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
98.	77060	**Lowpix 20mg Tablets** Each film coated tablet	06/12/2013 Change of	Dy.No.38334 dated	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023

		contains:- Atorvastatin (as calcium) …20mg	BN: 30/01/2018	22.11.2018 Rs.10000/-		
Shortcomings:						
M/s. S.N.B Pharma (Pvt) Ltd, Plot No. 142, Industrial Estate, Hayatabad, Peshawar						
99.	077491	**S.N. Cip Dry Powder Suspension125mg/5ml** Each 5ml contains Ciprofloxacin (as HCl) …125mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
100.	077492	**S.N. Cip Dry Powder Suspension 250mg/5ml** Each 5ml contains Ciprofloxacin (as HCl) …250mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
101.	077493	**SN-Ceflor 50mg Drops** Each ml contains Cefaclor Monohydrate eq to Cefaclor …50mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
102.	077494	**SN-Ceflor Dry powder for suspension 125mg/5ml** Each 5ml contains Cefaclor Monohydrate eq to Cefaclor…125mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
103.	077495	**SN-Ceflor Dry powder for suspension 250mg/5ml** Each 5ml contains Cefaclor monohydrate eq to Cefaclor..250mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
104.	077496	**SN Xime Dry Powder for suspension 100mg/5ml** Each 5ml contains Cefixime trihydrate eq to.cefixime ……..100mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
105.	077497	**SN Sef Dry Powder Suspension 125mg/5ml** Each 5ml contains Cephradine monohydrate eq to. Cephradine...125mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
106.	077498	**SN Sef Dry Powder Suspension 250mg/5ml** Each 5ml contains Cephradine monohydrate eq to. Cephradine ...250mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
107.	077499	**SN Xime 400mg Capsule** Each capsule contains Cefixime trihydrate eq to.cefixime …….400mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
108.	077500	**SN Sef 250mg Capsule** Each capsule contains Cephradine monohydrate eq. to cephradine ..250mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023
109.	078401	**SN Sef 500mg Capsule** Each capsule contains Cephradine monohydrate eq. to cephradine..500mg	13/11/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	12/11/2023	w.e.f. 13/11/2018 to 12/11/2023

110.	078411	**SN Clar 125mg Drops** Each 5ml contains Clarithromycin…125mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	Deferred for Confirmation of granules source.
111.	078412	**SN Skelax 2mg Tablets** Each tablet contains Tizanidine as HCl eq to Tizanidine..... 2mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
112.	078413	**SN Skelax 4mg Tablets** Each tablet contains Tizanidine as HCl eq to Tizanidine..... 4mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
113.	078414	**SN Cip 250mg Tablets** Each film coated tablet contains: Ciprofloxacin HCl eq to.ciprofloxacin…..250mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
114.	078415	**SN Cip 500mg Tablets** Each film coated tablet contains: Ciprofloxacin HCl eq to.ciprofloxacin…500mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
115.	078416	**SN Clar 500mg Tablets** Each film coated tablet contains Clarithromycin…..500mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
116.	078417	**SN Zyr Syrup** Each 5ml contains Cetirizine Dihydrochloride eq to Cetirizine ….5mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
117.	078418	**SN Domp Syrup** Each 5ml contains Domperidone…….5mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
118.	078419	**SN Dol Suspension** Each 5ml contains Paracetamol…….120mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
119.	078420	**SN Planka Syrup** Each 5ml contains Iron (III) Hydroxide polymaltose complex eq to Iron (element)……50mg	11/12/2013	Dy.No.37042 dated 08.11.2018 Rs.10000/-	10/12/2023	w.e.f. 11/12/2018 to 10/12/2023
Shortcomings:						
M/s.Barrett Hodgson Pakistan (Pvt) Ltd, F/423, SITE, Karachi						
120.	076151	Irecon-H Tablet Each tablet contains Irbesartan …300mg, Hydrochlorothiazide …25mg	07/01/2014	Dy.37032 08.11.2018 Rs.10000/-	06/01/2024	w.e.f. 05/01/2019 to 06/01/2024
121.	076238	**PioBar Plus 15mg/500mg Tablet** Each film coated tablet contains Pioglitazone as HCl …15mg, Metformin HCl …500mg	31/01/2014	Dy.No.37030 dated 08.11.2018 Rs.10000/-	30/01/2024	w.e.f. 31/01/2019 to 30/01/2024

122.	076237	**Urobar 10mg Tablet** Each film coated tablet contains Alfuzosin hydrochloride …10mg	31/01/2014	Dy.No.37031 dated 08.11.2018 Rs.10000/-	30/01/2024	w.e.f. 31/01/2019 to 30/01/2024
Shortcomings:						
M/s Novamed Pharmaceuticals (Pvt) Ltd., 28 KM, Ferozepur Road, Lahore.						
123.	001877-Ex	**Vixa 500mg IV Injection** Each vial contains Ceftriaxone (as Sodium)……500mg	20/11/2013	Dy.No.37776 dated 15.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
124.	001878-Ex	**Vixa 500mg IM Injection** Each vial contains Ceftriaxone (as Sodium)……500mg	20/11/2013	Dy.No.37776 dated 15.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
125.	001879-Ex	**Vixa 1gm IV Injection** Each vial contains Ceftriaxone (as Sodium)……1gm	20/11/2013	Dy.No.37776 dated 15.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
126.	001880-Ex	**Vixa 1gm IV Injection** Each vial contains Ceftriaxone (as Sodium)……1gm	20/11/2013	Dy.No.37776 dated 15.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
127.	001881-Ex	**Vixa 250mg IV Injection** Each vial contains Ceftriaxone (as Sodium)……250mg	20/11/2013	Dy.No.37776 dated 15.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
128.	001882-Ex	**Vixa 250mg IM Injection** Each vial contains Ceftriaxone (as Sodium)……250mg	20/11/2013	Dy.No.37776 dated 15.11.2018 Rs.10000/-	19/11/2023	w.e.f. 20/11/2018 to 19/11/2023
Shortcomings:						
M/s Medipak limited 132/1,Industrial Estate, Kot Lakhpat, Lahore						
129.	022538	**Medisol Mannitol 20% Infusion** Each 1000ml contains Mannitol …200gm, Water for Injection …1000ml	26/11/1998	Dy.No.37772 dated 15.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26/11/2018 to 25/11/2023
130.	014774	**Gentamicin Injection** Each 2ml ampoule contains Gentamicin sulphate eq to 80mg Gentamicin base	06/12/1993	Dy.No.37775 dated 15.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
131.	014776	**Vitachlor Eye Drops** Each 100ml contains:- Chloramphenicol …0.5gm	06/12/1993	Dy.No.37775 15.11.2018 Rs.10000/-	05/12/2023	w.e.f. 06/12/2018 to 05/12/2023
132.	052878	**Myzone 45mg Tablet** Each tablet contains Pioglitazone HCl eq to Pioglitazone……..45mg	26/11/2008	Dy.No.37774 dated 15.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26/11/2018 to 25/11/2023
133.	052879	**Myzone 15mg Tablet** Each tablet contains Pioglitazone HCl eq to Pioglitazone……..15mg	26/11/2008	Dy.No.37774 dated 15.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26/11/2018 to 25/11/2023
134.	052880	**Myzone 30mg Tablet** Each tablet contains Pioglitazone HCl eq to Pioglitazone……..30mg	26/11/2008	Dy.No.37774 dated 15.11.2018 Rs.10000/-	25/11/2023	w.e.f. 26/11/2018 to 25/11/2023

135.	052881	M/s Vision pharmaceutical, Islamabad	**Acilox 40mg Capsule** Each capsule contain Esomeprazole Magnesium trihydrate eq to Esomeprazole…..40 mg	26/11/2008 Change of pellet source: 17/05/2019	Dy.No.37773 dated 15.11.2018 Rs.10000/-	25/11/ 2023	w.e.f. 26/11/2018 to 25/11/2023
136.	052882	M/s Vision pharmaceutical, Islamabad	**Acilox 20mg Capsule** Each capsule contain Esomeprazole Magnesium trihydrate eq to Esomeprazole…..20 mg	26/11/2008 Change of pellet source: 17/05/2019	Dy.No.37773 dated 15.11.2018 Rs.10000/-	25/11/ 2023	w.e.f. 26/11/2018 to 25/11/2023
Shortcomings:							
M/s. Shrooq Pharmaceuticals (Pvt.) Ltd., 21-km, Feroz Pur Road, Lahore							
137.	077024	**Maxlum-Forte Dispersible Tablets** Each tablet contains Artemether…….80mg, Lumefantrine……..480mg	19/11/2013	Dy.No.37822 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023	
Shortcomings:							
M/s. Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151 Sector 24 Korangi Industrial Area, Karachi.							
138.	053231	**Normacid Injection** Each 2ml contains Cimetidine …200mg	1/12/2008	Dy. No 38523 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	
139.	053232	**Lincomate Injection** Each 2ml contains Lincomycin (as HCl)…600mg	1/12/2008	Dy.No.38515 dated 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	
140.	053233	**M-Arthem Injection** Each ml contains Artemether …80mg	1/12/2008 Change of BN: 29/09/2009	Dy.No.38521 dated 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	
141.	053234	**Zaniate Injection** Each 2ml contains Ranitidine (as HCl) …50mg	1/12/2008	Dy.No.38519 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	
142.	053235	**Bigvin-M 500mcg/ml Injection** Each ml contains Mecobalamin …500mcg	1/12/2008 Change of BN: 24/12/2013	Dy.No.38490 dated 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	
143.	053236	**Feverol Injection I.M** Each 2ml contains Paracetamol …300mg Lignocaine HCl …20mg	1/12/2008	Dy.No.38522 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	
144.	053238	**M-Gravi Injection** Each ml contains Dimenhydrinate …50mg	1/12/2008	Dy.No.38489 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	
145.	053239	**Tramorhage Injection** Each 5ml contains Tranexamic Acid …250mg	1/12/2008	Dy.No.38488 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023	

146.	053242	**M-Neuro Injection** Each 3ml contains Vitamin B1 …100mg Vitamin B6 …100mg Vitamin B12 …1000mcg	1/12/2008	Dy.No.38493 dated 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
147.	053243	**Gentamed 80mg/2ml Injection** Each 2ml contains Gentamycin (as Sulphate) …80mg	1/12/2008	Dy.No.38494 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
148.	053245	**Metroate Infusion 500mg/100ml** Each ml contains Metronidazole …5mg	1/12/2008	Dy.No.38514 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
149.	053246	**Zywocid Infusion 400mg/200ml** Each vial contains Linezolid …400mg	1/12/2008	Dy.No.38513 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
150.	053247	**Zywocid Infusion 600mg/300ml** Each vial contains Linezolid …600mg	1/12/2008	Dy.No.38512 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
151.	053248	**Levoflomed Infusion 250mg/100ml** Each vial contains Levofloxacin (as Hemihydrate) …250mg	1/12/2008	Dy.No.38511 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
152.	053249	**Levoflomed Infusion 500mg/100ml** Each vial contains Levofloxacin (as Hemihydrate) …500mg	1/12/2008	Dy.No.38506 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
153.	053250	**C-Prox 100mg/50ml Infusion** Each vial contains Ciprofloxacin (as Lactate) …100mg	1/12/2008 Change of BN: 29/09/2009	Dy.No.38520 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
154.	053251	**C-Prox 200mg/100ml Infusion** Each vial contains Ciprofloxacin (as Lactate) …200mg	1/12/2008 Change of BN: 29/09/2009	Dy.No.38499 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
155.	053252	**C-Prox 400mg/100ml Infusion** Each vial contains Ciprofloxacin (as Lactate) …400mg	1/12/2008 Change of BN: 29/09/2009	Dy.No.38498 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
156.	053253	**Ezemox Infusion 400mg/250ml** Each vial contains Moxifloxacin HCl …400mg	1/12/2008	Dy.No.38497 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
157.	053254	**S-Vid Infusion 200mg/100ml** Each vial contains Ofloxacin …200mg	1/12/2008	Dy.No.38496 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
158.	053255	**Quin-Safe 250mg Injection**	1/12/2008	Dy.No.38495 Dated.23/11/20	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023

		Each vial contains Cephradine …250mg		18 Rs.10000		
159.	053256	**Quin-Safe 500mg Injection** Each vial contains Cephradine …500mg	1/12/2008	Dy.No.38525 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
160.	053257	**Quin-Safe 1000mg Injection** Each vial contains Cephradine …1000mg	1/12/2008	Dy.No.38491 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
161.	053258	**Hilexipim 500mg Injection** Each vial contains Cefepime (as HCl) ……...500mg with Arginine	1/12/2008 Change of BN: 04/12/2017	Dy.No.38492 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
162.	053259	**Hilexipim 1gm Injection** Each vial contains Cefepime (as HCl)..1gm with Arginine	1/12/2008	Dy.No.38518 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
163.	053260	**Defenac 100mg Tablet** Each tablet contains Diclofenac Potassium …100mg	1/12/2008 Change of BN: 29/09/2009	Dy.No.38524 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
164.	053261	**Mexodine 60mg Tablet** Each tablet contains Fexofenadine (as HCl) …60mg	1/12/2008	Dy.No.38505 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
165.	053262	**Cetrimate Syrup** Each 5ml contains Cetirizine Dihydrochloride …5mg	1/12/2008	Dy.No.38508 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
166.	053263	**C-Prox 750mg Tablet** Each tablet contains Ciprofloxacin (as HCl) …750mg	1/12/2008 Change of BN: 29/09/2009	Dy.No.38509 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
167.	053264	**Mezomed 250mg Tablet** Each tablet contains Azithromycin (as dihydrate) …250mg	1/12/2008	Dy.No.38510 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
168.	053265	**Mezomed 500mg Tablet** Each tablet contains Azithromycin (as dihydrate) …500mg	1/12/2008	Dy.No.38516 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
169.	053266	**Urticin 5mg Tablet** Each tablet contains Levocetirizine DiHCl …5mg	1/12/2008	Dy.No.38507 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
170.	053267	**Piro-H 10mg Capsule** Each capsule contains Piroxicam …10mg	1/12/2008 Change of BN: 11/01/2018	Dy.No.38504 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
171.	053268	**Piro-H 20mg Capsule** Each capsule contains Piroxicam …20mg	1/12/2008 Change of BN: 11/01/2018	Dy.No.38503 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
172.	053270	**Ewoxacin 400mg Tablet** Each tablet contains	1/12/2008	Dy.No.38517 Dated.23/11/20	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023

		Enoxacin …400mg		18 Rs.10000		
173.	053271	**Zywocid 600mg Tablet** Each tablet contains Linezolid …600mg	1/12/2008	Dy.No.38502 23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
174.	053272	**Para + CF Tablet** Each tablet contains Paracetamol …500mg Pseudoephedrine HCl …60mg Chlorpheniramine Maleate …4mg	1/12/2008	Dy.No.38501 Dated.23/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
Shortcomings:						
M/s. Atco Laboratories (Pvt) Ltd,B-18 S.I.T.E Karachi.						
	022464	**Capace 12.5mg Tablet** Each tablet contains Captopril …12.5mg	12/12/1998	Dy.No.38786 Dated.26/11/2018 Rs.10000	11/12/2023	w.e.f. 12/12/2018 to 11/12/2023
175.	022465	**Capace 25mg Tablet** Each tablet contains Captopril …25mg	12/12/1998	Dy.No.38786 Dated.26/11/2018 Rs.10000	11/12/2023	w.e.f. 12/12/2018 to 11/12/2023
176.	022466	**Cholescor Tablet** Each tablet contains Lovastatin …20mg	12/12/1998	Dy.No.38786 Dated.26/11/2018 Rs.10000	11/12/2023	w.e.f. 12/12/2018 to 11/12/2023
177.	053356	**IPNEB Inhalation solution** Each ml contains Ipratropium Bromide …0.25mg	15/12/2008 Change of BN: 08/03/2011	Dy.No.38786 Dated.26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023
178.	053357	**Nor Adrin injection** Each 4ml contains Norepinephrine …4mg	15/12/2008	Dy.No.38786 Dated.26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023
179.	001125-EX	**Betagenta Cream** Each gram contains:- Betamethasone as dipropionate …0.05% w/w, Gentamycin as sulphate ...0.1%w/w	19/12/2008	Dy.No.38788 Dated.26/11/2018 Rs.10000	18/12/2023	w.e.f. 19/12/2018 to 18/12/2023
180.	053358	**Pro-Eputin Injection** Each ml contains Fosphenytoin sodium (eq. to Phenytoin sodium 50mg/ml) ..75mg	15/12/2008	Dy.No.38787 Dated.26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023
181.	053354	**Norsaline-P Nasal Drops** Each ml contains Sodium Chloride …9mg	15/12/2008	Dy.No.38787 26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023
182.	053355	**Norsaline-P Nasal Spray** Each ml contains Sodium Chloride …9mg	15/12/2008	Dy.No.38787 26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023
183.	053345	**Dioplus 5mg/80mg Tablet** Each film coated tablet contains Amlodipine (as besylate) …5mg Valsartan …80mg	15/12/2008	Dy.No.38787 26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023

184.	053346	**Dioplus 5mg/160mg Tablet** Each film coated tablet contains Amlodipine (as besylate) …5mg Valsartan …160mg	15/12/2008	Dy.No.38787 26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023
185.	053347	**Dioplus 10mg/160mg Tablet** Each film coated tablet contains Amlodipine (as besylate) …10mg Valsartan …160mg	15/12/2008	Dy.No.38787 26/11/2018 Rs.10000	14/12/2023	w.e.f. 15/12/2018 to 14/12/2023
186.	053363	**Ascard Plus Tablet** Each tablet contains Aspirin …81mg, Clopidogrel …75mg	16/12/2008 Change of formulation 01/04/2010	Dy.No.38790 Dated.26/11/2018 Rs.10000	15/12/2023	w.e.f. 16/12/2018 to 15/12/2023
187.	053365	**Statobex 8mg tablet** Each tablet contains Betahistine dihydrochloride…8mg	16/12/2008	Dy.No.38790 Dated.26/11/2018 Rs.10000	15/12/2023	w.e.f. 16/12/2018 to 15/12/2023
188.	053366	**Statobex 16mg tablet** Each tablet contains Betahistine dihydrochloride…16mg	16/12/2008	Dy.No.38790 Dated.26/11/2018 Rs.10000	15/12/2023	w.e.f. 16/12/2018 to 15/12/2023
189.	053367	**Terbiderm Forte Tablet** Each tablet contains Terbinafine (as HCl)….250mg	16/12/2008	Dy.No.38790 Dated.26/11/2018 Rs.10000	15/12/2023	w.e.f. 16/12/2018 to 15/12/2023
190.	053368	**A-Fantrine DS Tablet** Each tablet contains Artemether…..40mg, Lumefantrine……240mg	16/12/2008	Dy.No.38790 Dated.26/11/2018 Rs.10000	15/12/2023	w.e.f. 16/12/2018 to 15/12/2023
Shortcomings:						
M/s. Noa Hemis Pharmaceuticals,Plot No. 154 Sector 23 Korangi Industrial Area Karachi.						
191.	032167	**Noadic-50 Tablet** Each tablet contains Diclofenac Sodium …50mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000	26/02/2024	w.e.f. 27/02/2019 to 26/02/2024
192.	032168	**Noadic SR-100 tablet** Each tablet contains Diclofenac Sodium …100mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000	26/02/2024	w.e.f. 27/02/2019 to 26/02/2024
193.	032169	**Noaflam-50 Tablet** Each tablet contains Diclofenac potassium …50mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000	26/02/2024	w.e.f. 27/02/2019 to 26/02/2024
194.	032170	**Nelsid Tablet** Each tablet contains Nimesulide …100mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000	26/02/2024	w.e.f. 27/02/2019 to 26/02/2024
195.	032171	**Propex tablet** Each tablet contains Naproxen sodium eq to naproxen …500mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000	26/02/2024	w.e.f. 27/02/2019 to 26/02/2024
196.	032174	**Orthoflex Tablet** Each tablet contains Orphenadrine citrate	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000	26/02/2024	w.e.f. 27/02/2019 to 26/02/2024

		…35mg, Pracetamol …450mg				
197.	032176	**Haemotyl Syrup** Each 5ml contains Iron (as Iron III Hydroxide polymaltose complex) …50mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000	26/02/2024	w.e.f. 27/02/2019 to 26/02/2024
Shortcomings:						
M/s Nabiqasim Industries Ltd, 17/24, Korangi Industrial Area, Korangi Highway, Korangi, Karachi.						
198.	053132	**Ordiab 2.5/500 tablet** Each tablet contains Glipizide …2.5mg Metformin Hydrochloride …500mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
199.	053133	**Ordiab 5/500 tablet** Each tablet contains Glipizide …5mg Metformin Hydrochloride …500mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
200.	053134	**Valset 500mg Tablet** Each tablet contains Valproic Acid (as Sodium) …500mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
201.	053135	**Lungair 4mg Tablet** Each chewable tablet contains Montelukast sodium eq to montelkust …4mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
202.	053136	**Lungair 4mg sachet** Each sachet contains Montelukast sodium eq to montelkust …4mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
203.	053137	**Valset syrup** Each 5ml contains Valproic Acid (as Sodium) …250mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
204.	053138	**Clarithro 125mg/5mg Oral Drops** Each 5ml contains Clarithromycin …125mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	Deferred for confirmation of Source of granules.
205.	053139	**Deplat-AP Tablet 75/75** Each tablet contains Clopidogrel (as bisuphate)….75mg, Aspirin BP….75mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
206.	053140	**Fanart Tablet** Each tablet contains Artemether…20mg, Lumefantrine …120mg	1/12/2008 Change of BN: 29/08/2009	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
207.	053141	**Dizon Plus 15/500 tablet** Each tablet contains Pioglitazone (as HCl) …15mg Metformin HCl …500mg	1/12/2008	Dy.No.38843 Dated.27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023
208.	053142	**Valset 250mg Tablet** Each tablet contains Valproic Acid (as Sodium)	1/12/2008	Dy.No.38843 27/11/2018 Rs.10000	30/11/2023	w.e.f. 01/12/2018 to 30/11/2023

		…250mg				
Shortcomings:						
M/s. Bio-Labs,Plot No.145 Kahuta Triangle Industrial Estate Islamabad.						
	054754	**Ignite 50mg Tablet** Each tablet contains Itopride hydrochloride …50mg	02/01/2009 Change of BN: 04/01/2018	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
209.	054755	**Tilva 25mg Tablet** Each tablet contains Levosulpiride …25mg	02/01/2009 Change of BN: 15/08/2016	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
210.	054756	**Tilva 50mg Tablet** Each tablet contains Levosulpiride …50mg	02/01/2009 Change of BN: 15/08/2016	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
211.	054757	**Evosol 100mg Tablet** Each tablet contains Levosulpiride …100mg	02/01/2009	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
212.	054758	**Biogaba 300mg Capsule** Each Capsule contains Gabapentin …300mg	02/01/2009	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
213.	054759	**Adacidol 0.5mcg Tablet** Each tablet contains Alfacalcidol …0.5mcg	02/01/2009 Change of BN: 23/02/2018	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
214.	054761	**Biogaba 100mg Capsule** Each Capsule contains Gabapentin …100mg	02/01/2009	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
215.	054762	**Afalor Dry Suspension 125mg** Each 5ml contains Cefaclor …125mg	02/01/2009	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
216.	054763	**Afalor Dry Suspension 250mg** Each 5ml contains Cefaclor …250mg	02/01/2009	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
217.	054764	**Afalor capsule 250mg** Each capsule contains Cefaclor …250mg	02/01/2009	Dy.No.39041 28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
218.	054765	**Afalor capsule 500mg** Each capsule contains Cefaclor …500mg	02/01/2009	Dy.No.39041 28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
219.	054766	**Bio-Oxil 125mg dry Suspension** Each 5ml contains Cefadroxil …125mg	02/01/2009	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
220.	054767	**Bio-Oxil 250mg dry Suspension** Each 5ml contains Cefadroxil …250mg	02/01/2009	Dy.No.39041 Dated.28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
221.	054768	**Bio-Oxil 500mg Capsule** Each Capsule contains	02/01/2009	Dy.No.39041 Dated.28/11/20	01/01/2024	w.e.f. 02/01/2019

		Cefadroxil …500mg		18 Rs.10000		to 01/01/2024
222.	054769	**Biozil Dry Suspension 100mg** Each 5ml contains Cefixime (as trihydrate) …100mg	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
223.	054770	**Biozil Dry Suspension 200mg** Each 5ml contains Cefixime (as trihydrate) …200mg	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
224.	054771	**Biozil Capsules 400mg** Each Capsule contains Cefixime (as trihydrate) …400mg	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
225.	054772	**Biotrim Cream** Contains Clorimazole …1%w/w	02/01/2009	Dy.No.39041 28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
226.	054773	**Bioscab cream** Each 1gm contains Permethrin …50mg	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
227.	054774	**Bioscab lotion** Contains Permethrin …5% w/v	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
228.	054775	**Poxicam gel** Each gm contains:- Piroxicam …5mg	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
229.	054776	**Miconit oral gel** Each gm contains:- Miconazole Nitrate …20mg	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
230.	054779	**Biodine Capsules 250mg** Each capsule contains Cephradine …250mg	02/01/2009	Dy.No.39041 Dated.28/11/20 18 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
231.	054780	**Biodine Capsules 500mg** Each capsule contains Cephradine …500mg	02/01/2009	Dy.No.39041 28/11/2018 Rs.10000	01/01/2024	w.e.f. 02/01/2019 to 01/01/2024
M/s Trigon Pharmaceuticals Pvt Limited. 8 km, Thoker Raiwind Road, Lahore						
232.	52756	**Testine Tablets** Each tablet contains:- Ebastine …10mg	05/11/2008	Dy.No.36404 dated 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
233.	52757	**Trinate Tablets 70mg** Each tablet contains:- Alendronate Sodium Eq. to Alendronate Acid …70mg	05/11/2008	Dy.No.36404 dated 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
234.	52758	**Trinate Tablets 10mg** Each tablet contains:- Alendronate Sodium Eq. to Alendronate Acid …10mg	05/11/2008	Dy.No.36404 dated 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
235.	52759	**Syndronil Tablets** Each tablet contains:- Tizanidine as HCl …2mg	05/11/2008	Dy.No.36404 dated 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023

236.	52760	**Tripofen Tablets** Each tablet contains:- Flurbiprofen … 100mg	05/11/2008	Dy.No.36404 dated 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
237.	52761	**Mounteez Chewable Tablets** Each tablet contains:- Montelukast …4mg	05/11/2008	Dy.No.36404 dated 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
238.	52762	**Tefloxin Tablets** Each tablet contains:- Pefloxacin …400mg	05/11/2008	Dy.No.36404 dated 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
239.	52763	**Fastin Tablets** Each tablet contains:- Famotidine…40mg	05/11/2008	Dy.No.36404 02.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
Shortcomings:						
M/s. Xenon Pharmaceuticals (Pvt) Ltd, 9.5km, Sheikhupura Road, Lahore.						
240.	32009	**Salinase Drops** Each 100ml contains:- Sodium Chloride …0.65%	08/01/2004	Dy.No.36616 05.11.2018 Rs.10000/-	07/01/2024	w.e.f. 08/01/2019 to 07/01/2024
Shortcomings:						
M/s. Focus &Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad						
241.	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
Shortcomings:						
M/s. Reko Pharmacal(Pvt) Ltd, 13Km Multan Road ,Lahore						
242.	001662	**Encore Ointment** Each gm contains:- Betamethasone Dipropionate…0.64mg	25/04/1998 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
243.	001663	**Encore Cream** Each gm contains:- Betamethasone Dipropionate…0.64mg	25/04/1998 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
244.	019105	**Loc-H Capsule** Each Capsule Contains: Omeprazole…….20mg	24/04/1996 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
245.	022011	**Encore-G Ointment** Each gm contains:- Betamethasone Dipropionate…0.64mg, Gentamicin sulphate …1.7mg	20/05/1998 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
246.	022012	**Encore-G Cream** Each gm contains:- Betamethasone Dipropionate…0.64mg, Gentamicin sulphate …1.7mg	20/05/1998 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
247.	024689	**Encore Lotion** Each 25ml contains	08/05/2002 Change of	Dy.No.37128 dated	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023

		Betamethasone dipropionate….16mg	BN 15/11/2008	09.11.2018 Rs.10000/-		
248.	024690	**Encore S Lotion** Each 25ml contains Betamethasone dipropionate….12.5mg, Salicylic Acid…….500mg	08/05/2002 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
249.	024691	**Trio Cream** Each gm contains:- Isotretinoin……..0.5mg	08/05/2002 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
250.	027190	**Encore-S Ointment** Each gm contains:- Betamethasone Dipropionate….0.64mg, Salicylic Acid……..30mg	3/7/2001 Change of BN 15/11/2008	Dy.No.37128 dated 09.11.2018 Rs.10000/-	14/11/2023	w.e.f. 15/11/2018 to 14/11/2023
251.	077033	**Vivox 50mg Tabet** Each tablet contains Naltrexone HCl …50mg	27/11/2013	Dy.No.37128 dated 09.11.2018 Rs.10000/-	26/11/2023	w.e.f. 27/11/2018 to 26/11/2023
Shortcomings:						
M/s Scotmann Pharmaceuticals. 5-D, I-10/3, Industrial Area, Islamabad						
252.	040678	**Dune Tablet 5mg** Each chewable tablet contains Montelukast (as sodium)…..5mg	08/07/2005 Change of BN: **11/06/2008**	Dy.No.37033 dated 08.11.2018 Rs.**70,000/-**	10/06/2023	w.e.f 11/06/2018 to 10/06/2023
Shortcomings:						

b. 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. Care Pharma International (Pvt) Ltd, 37/3, C.P & Berar Society, Karachi.							
253.	16148	M/s Hospira Australia Pty Ltd., Australia.	**Levcovorin Calcium Injection 100mg/10ml** Each 10ml vial contains Calcium Folinate eq. to folinic acid …100mg	07/02/1995 Transfer of Reg: 25/11/2008	Dy.No. 38236 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
254.	16149	M/s Hospira Australia Pty Ltd., Australia.	**Levcovorin Calcium Injection 300mg/30ml** Each 30ml vial contains Calcium Folinate eq. to folinic acid …300mg	07/02/1995 Transfer of Reg: 25/11/2008	Dy.No. 38236 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
255.	20426	M/s Hospira Australia Pty Ltd., Australia.	**Anzatax Concentrate 30mg/5ml Injection** Each 5ml vial contains Paclitaxel …30mg	01/12/1997 Transfer of Reg: 25/11/2008	Dy.No. 38235 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
256.	21091	M/s Hospira Australia Pty Ltd., Australia.	**Anzatax Concentrate 150mg/25ml Injection** Each 25ml vial contains Paclitaxel …150mg	09/05/1998 Transfer of Reg: 25/11/2008	Dy.No. 38235 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
257.	16106	M/s Hospira Australia Pty Ltd., Australia.	**DBL Cisplatin Injection 50mg/50ml** Each 50 ml vial contains Cisplatin …50mg	18/09/1994 Transfer of Reg: 25/11/2008	Dy.No. 38234 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
258.	16750	M/s Hospira Australia Pty Ltd., Australia.	**DBL Cisplatin Injection 100mg/100ml** Each 100ml vial contains Cisplatin …100mg	07/02/1995 Transfer of Reg: 25/11/2008	Dy.No. 38234 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
259.	18213	M/s Hospira Australia Pty Ltd., Australia.	**DBL Carboplatin Injection 150mg/15ml** Each 15ml vial contains Carboplatin …150mg	18/06/1996 Transfer of Reg: 25/11/2008	Dy.No. 38233 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
260.	18212	M/s Hospira Australia Pty Ltd., Australia.	**DBL Carboplatin Injection 450mg/45ml** Each 45ml vial contains Carboplatin …450mg	18/06/1996 Transfer of Reg: 25/11/2008	Dy.No. 38233 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
261.	21960	M/s Hospira Australia Pty Ltd., Australia.	**DBL Doxorubicin Hydrochloride Injection 10mg/5ml** Each 5ml vial contains Doxorubicin HCl …10mg	15/12/1998 Transfer of Reg: 25/11/2008	Dy.No. 38232 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
262.	20423	M/s Hospira Australia Pty Ltd., Australia.	**DBL Doxorubicin Hydrochloride Injection 50mg/25ml**	01/12/1997 Transfer of Reg:	Dy.No. 38232 dated	24/11/2023	w.e.f. 25/11/2018 to

			Each 25ml vial contains Doxorubicin HCl …50mg	25/11/2008	20.11.2018 Rs.20000/-		24/11/2023
263.	18205	M/s Hospira Australia Pty Ltd., Australia.	**DBL Cytarabine Injection 500mg/5ml** Each 5ml vial contains Cytarabine …500mg	18/06/1996 Transfer of Reg: 25/11/2008	Dy.No. 38231 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
264.	16152	M/s Hospira Australia Pty Ltd., Australia.	**DBL Methotrexate Injection 1g/10ml** Each 10ml vial contains Methotrexate …1gm	07/02/1995 Transfer of Reg: 25/11/2008	Dy.No. 38230 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
265.	16145	M/s Hospira Australia Pty Ltd., Australia.	**DBL Vincristine sulfate Injection 1mg/ml** Each 1ml vial contains Vinoristine sulfate …1mg Mannitol …100mg	27/11/1994 Transfer of Reg: 25/11/2008	Dy.No. 38229 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
266.	16150	M/s Hospira Australia Pty Ltd., Australia.	**DBL Levcovorin Calcium Injection 15mg/2ml** Each 2ml ampoule contains Folinic Acid 15mg as calcium slat Sodium chloride …0.8% w/v	27/11/1994 Transfer of Reg: 25/11/2008	Dy.No. 38228 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
267.	16147	M/s Hospira Australia Pty Ltd., Australia.	**DBL Levcovorin Calcium Injection 50mg/5ml** Each 5ml vial contains Folinic Acid 50mg as calcium slat	07/02/1995 Transfer of Reg: 25/11/2008	Dy.No. 38227 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
268.	27344	M/s Hospira Australia Pty Ltd., Australia.	**Pamisol 30mg/10ml Injection** Each 10ml vial contains Disodium Pamidronate …30mg	11/04/2002 Change of brand name: 03/02/2003 Transfer of Reg: 25/11/2008	Dy.No. 38226 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
Shortcomings:							
M/s. Angelini Pharmaceuticals (Pvt) Ltd, 221 Block CCA, Phase-4, DHA, Lahore							
269.	21929	Manufactured by: M/s Doppel FarmaceuticiS.R.l., Piacenza, Italy . Exported by and MA Holder: Scharper S.p.A. Milane, Italy.	**Spasmex 40mg Injection** Each 4ml vial contains 1,3,5 Trihydroxybenzene dihydrate (phloroglucinol dihydrate)51.43mg (equal to anhydrous phloroglucine 40mg)	04/09/1998 Change of company name & transfer of registration of products **25/11/2013**	Dy.No. 38224 dated 20.11.2018 Rs.20000/-	24/11/2023	w.e.f. 25/11/2018 to 24/11/2023
Shortcomings:							

c. 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 Sanna Laboratories, 1019-B, P.S.I.E Sargodha Road, Faisalabad.						
270.	021498	**Senrox-20 Liquid** Each 1000ml contains Enrofloxacin……..200mg	02/12/1998	Dy.No.37039 08.11.2018 Rs.10000/-	01/12/2023	w.e.f. 02/12/2018 to 01/12/2023
271.	021499	**Sancure Powder** Each kg contains Methenamin…..900gm, Riboflavin B2……..10mg, Calcium Pantothenate……..5gm, Nicotinamide……..25gm	02/12/1998	Dy.No.37039 dated 08.11.2018 Rs.10000/-	01/12/2023	w.e.f. 02/12/2018 to 01/12/2023
272.	001117-Ex	**Scoursan Oral Suspension** Each ml contains Sulphadimidine B.P…21.3mg, Sulphaguanidine B.P….21.3mg, Sulphadiazine B.P….28.4mg, Streptomycin sulphate B.P..7.6mg, Neomycin Sulphate B.P…..1.8mg, Hyoscine hydrobromide B.P…0.02mg, Sodium chloride B.P….11.33mg, Calcium gluconate B.P……2.2mg, Magnesium sulphate B.P.....0.6mg, Potassium Chloride B.P....3.6mg, Kaolin B.P...103mg, Pectin.....7.0mg, Glycine B.P.....20.8mg, Vitamin B1 B.P....0.15mg, Vitamin B2 B.P....0.22mg	27/11/2008	Dy.No.37038 dated 08.11.2018 Rs.10000/-	26/11/2023	w.e.f. 27/11/2018 to 26/11/2023
Shortcomings:						
M/s A&K Pharmaceuticals, 94-A, Punjab Small Industrial Estate, Sargodha Road, Faisalabad.						
273.	049794	**B-Cid Liquid** Each 100ml contains:- Lincomycin HCl…….3.33gm Spectinomycin HCl…..6.67gm	22/11/2008	Dy.No.37770 dated 15.11.2018 Rs.10000/-	21/11/2023	w.e.f. 22/11/2018 to 21/11/2023
274.	049795	**Toltracox Liquid** Each 100ml contains:- Toltrazuril …3gm	22/11/2008	Dy.No.37770 15.11.2018 Rs.10000/-	21/11/2023	w.e.f. 22/11/2018 to 21/11/2023
275.	049796	**Colak Powder** Each 1gm contains Colistin Sulfate…4.8MIU	22/11/2008	Dy.No.37770 15.11.2018 Rs.10000/-	21/11/2023	w.e.f. 22/11/2018 to 21/11/2023
276.	049797	**Xylostin Powder** Each 1kg contains	22/11/2008	Dy.No.37770 dated	21/11/2023	w.e.f. 22/11/2018 to 21/11/2023

		Tylosin Tartrate…100gm, Colistin Sulphate….240MIU		15.11.2018 Rs.10000/-		
277.	049798	**Sinoxy Liquid** Each 100ml contains:-Tylosin Tartrate….10gm, Doxycycline HCl…20gm	22/11/2008	Dy.No.37770 dated 15.11.2018 Rs.10000/-	21/11/2023	w.e.f. 22/11/2018 to 21/11/2023
278.	075792	**Adeka Injection** Each 1ml contains Vitamin A……100000IU, Vitamin D3…….40000IU, Vitamin E…..40mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
279.	075793	**Genin Injection** Each 1ml contains Tylosin Tartrate….100mg, Gentamycin Sulphate …50mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
280.	075794	**Genak-10 Injection** Each 1ml contains Gentamycin sulphate…100mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
281.	075795	**Ectin Injection** Each 1ml contains Ivermectin……..10mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
282.	075796	**Fenak Injection** Each 1ml contains Ketroprofen…….100mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
283.	075797	**Folak Injection** Each 1ml contains Florfenicol……..300mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
284.	075798	**Tine-20 Injection** Each 1ml contains Tylosin Tartrate…200mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
285.	075799	**Rofox-10 Injection** Each 1ml contains Enrofloxacin……..100mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
286.	075800	**FMO injection** Each 1ml contains Oxytetrcycline……300m Flunixine meglomine ...20mg	19/11/2013	Dy.No.37771 dated 15.11.2018 Rs.10000/-	18/11/2023	w.e.f. 19/11/2018 to 18/11/2023
Shortcomings:						
M/s Elko Organization, Plot# 27 & 28, Sector 12/B, North Karachi, Industrial Area, Karachi.						
287.	22155	**EL-OXANIL SUSPENSION** Each ml contains: Oxfendazole B.P...22.65mg	05/11/1998	Dy.No.36350 dated 01.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
288.	22156	**EL-LEVANIL SOLUTION** Each 100 ml contains: HCL B.P. 1.5% W/V	05/11/1998	Dy.No.36350 01.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
289.	22157	**El-Clozanil Suspension** Each 100 ml contains: Oxyclozanide B.P …3.4% W/V	05/11/1998	Dy.No.36350 dated 01.11.2018 Rs.10000/-	04/11/2023	w.e.f. 05/11/2018 to 04/11/2023
290.	22158	**El-Levaclozanil Suspension**	05/11/1998	Dy.No.36350	04/11/2023	w.e.f. 05/11/2018

		Each 100 ml contains: Levamisole HCL B.P.1.5% W/V, Oxyclozanide B.P.3.0% W/V		dated 01.11.2018 Rs.10000/-		to 04/11/2023
291.	22189	**Elvomec Injection** Each ml contains: IVERMECTIN 1.0% W/V	28/11/1998	Dy.No.36350 dated 01.11.2018 Rs.10000/-	27/11/2023	w.e.f. 28/11/2018 to 27/11/2023
292.	22190	**Elkosol Super Powder** Each 300gm contains Vitamin …. 6,000,000 IU, Vitamin D …. 1,200,000 IU, Vitamin E …. 480 IU, Vitamin K3 …. 2700mg, Vitamin B1 …. 375mg, Vitamin B2 …. 6000mg, Vitamin B12 …. 9000mg, Vitamin C …. 3000mg Folic Acid …. 600mg Nicotinic Acid .... 30,000mg Calcium Pantothenate 9000mg	28/11/1998	Dy.No.36350 dated 01.11.2018 Rs.10000/-	27/11/2023	w.e.f. 28/11/2018 to 27/11/2023
293.	31536	**Distilled Water for Injection** (Distilled Water for Inj for Poultry Vaccination)	06/11/2003	Dy.No.36350 dated 01.11.2018 Rs.10000/-	05/11/2023	w.e.f. 06/11/2018 to 05/11/2023
Shortcomings:						

d. 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

a. Locally manufactured registered drugs (Human)

Registration Board considered the applications of renewal of registration of following products of various firms and decision is mentioned in the last column below:

Sr. No	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s.Welwink Pharmaceuticals G.T Road, Industrial Estate, Gujranwala						
294.	77654	**Nektrol 1mcg Injection** Each 1ml ampoule contains:- Calcitriol ….. 1mcg	05/11/2013	Dy.No.36403 dated 02.11.2018 Rs.10000/-	04/11/2023	
Decision: Deferred for the rectification of following shortcomings: 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).						

Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s Ipram International, Plot # 26, S.S 3, National Industrial Zone Rawat, Islamabad.						
295.	52799	**D-Drop Injection** Each ml contains:- Cholecalciferol (Vitamin D3) eq to …5mg	13/11/2008	Dy.No.36617 dated 05.11.2018 Rs.10000/-	12/11/2023	
296.	49049	**Dekat Injection** Each ampoule contains:- Ketamine as HCI …50mg	06/03/2008	Dy.No.36617 dated 05.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following shortcomings: Late submission of last renewal fee for Dekat Injection (Reg#49049). Late submission of renewal fee Dekat Injection (Reg#49049). Undertakings not submitted. Latest GMP inspection report. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s Bio-Labs (Pvt) Ltd,Plot # 145, Industrial triangle, Islamabad.						
297.	Ex-003090	**Amwarm Syrup** Each 5ml contains Aminophylline …32mg, Diphenydramine HCl …8mg, Ammonium Chloride …30mg, Menthol …5mg	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
298.	Ex-003091	**Fexguard-180 Tablet** Each tablet contains Fexofenadine HCl …180mg	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
299.	Ex-003092	**PV-Koff Syrup** Each 5ml contains Diphenhydramine HCl …13.5mg Ammonium Chloride …131.5mg	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
300.	Ex-003093	**Esmepra Capsule** Each Capsule Contains: Esomeprazole Magnesium Dihydrate eq to Esomeprazole…..40mg (Enteric coated pellets)	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
301.	Ex-003094	**Esophil Capsule** Each Capsule Contains: Esomeprazole Magnesium Dihydrate eq to Esomeprazole…..40mg (Enteric coated pellets)	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
302.	Ex-003095	**Mersum Syrup** Each 5ml contains Calcium lactate gluconate …40mg, Vitamin A …1200IU, Vitamin D3…..100IU, Vitamin B1 Hydrochloride …1mg, Vitamin B2 5-sodium	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	

		Phosphate …1mg, Vitamin B6 hydrochloride …0.5mg, Nicotinamide …5mg, Dexpanthenol …2mg, Vitamin C…….50mg, Vitamin E Acetate.....1mg,				
303.	Ex-003096	**Himzian syrup** Each 5ml contains Aminophylline …32mg, Diphenhydramine HCl …8mg, Ammonium Chloride …30mg, Menthol …5mg	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
304.	Ex-003097	**Fexguard-120 Tablet** Each tablet contains Fexofenadine HCl …120mg	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
305.	Ex-003098	**Sulivit Syrup** Each 5ml contains Calcium lactate gluconate…..40mg, Vitamin A …1200IU, Vitamin D3 …100IU, Vitamin B1 Hydrochloride …1mg, Vitamin B2 5-sodium Phosphate …1mg, Vitamin B6 hydrochloride …0.5mg, Nicotinamide …5mg, Dexpanthenol …2mg, Vitamin C …50mg, Vitamin E Acetate …1mg,	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
306.	Ex-003099	**Esmezin Tablet** Each enteric coated tablet contains:- Esomeprazole Magnesium Dihydrate eq to Esomeprazole…..40mg	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	
307.	Ex-003100	**Nopitam Solution for Infusion** Each ml contains Paracetamol …10mg	09/12/2013	Dy.No.37301 dated 12.11.2018 Rs.10000/-	08/12/2023	

Decision:

Deferred for the rectification of following shortcomings:

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).

Source of pellets for Esmepra Capsule (Reg# Ex-003093) &Esophil Capsule (Reg# Ex-003094) and differential fee in case of imported pellets.

Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).

M/s Pliva Pakistan (Pvt) Ltd, B-77, Hub Industrial Trading Estate, Hub, Baluchistan.

308.	022180	**Gentamycin Injection** Each ml contains Gentamycin Sulphate eq. to 40mg Gentamycin base	24/11/1998	Dy.No.37454 dated 12.11.2018 Rs.10000/-		
309.	014717	**Vitamin B Compound Injection** Each 3ml contains Thiamine Hcl …100mg, Pyridoxine HCl…100mg, Cyanocobalamine …1000mcg	24/11/1993	Dy.No.37455 dated 12.11.2018 Rs.10000/-		
310.	014718	**Neoplex Super Injection** Each ml contains B1…….100mg, B2…….5mg, B6…….5mg, Nicotinamide…..75mg, Pantothenic Acid…….5mg	24/11/1993	Dy.No.37455 dated 12.11.2018 Rs.10000/-		
311.	014719	**Neoplex Plain Injection** Each ml contains B1 …10mg, B2 …2mg, B6 …5mg, Nicotinamide …75mg, Pantothenic Acid …5mg	24/11/1993	Dy.No.37455 dated 12.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following shortcomings: Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO. Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Notarized copy of Section approval letter issued by Licensing Division. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s Nexus Pharma Pvt Limited, Plot No. 4/19 Sector 21, Korangi Industrial Area Karachi						
312.	039530	**Nex Meco Tablet 500mcg** Each tablet contains Mecobalamin …500µg	31/08/2005 Transfer & Change of BN: 01/12/2008 Change of BN: 12/03/2014	Dy.No.37446 dated 12.11.2018 Rs.10000/-	11/03/2024	
313.	039531	**Nex Meco injection 500mcg/ml** Each ml contains Mecobalamin …500µg	31/08/2005 Transfer & Change of BN: 01/12/2008 Change of BN: 12/03/2014	Dy.No.37447 dated 12.11.2018 Rs.10000/-	11/03/2024	
314.	039332	**Nexbon Tablet 0.5mcg** Each tablet contains Alfacalcidol …0.5mcg	4/6/2005 Transfer &Change of BN: 01/12/2008	Dy.No.37445 dated 12.11.2018 Rs.10000/-	30/11/2023	
315.	039331	**Nexbon Tablet 0.25mcg** Each tablet contains Alfacalcidol …0.25mcg	4/6/2005 Transfer & Change of BN:	Dy.No.37445 dated 12.11.2018 Rs.10000/-	30/11/2023	

			01/12/2008			
316.	039554	**Nettle Suspension 250mg/5ml** Each 5ml contains Cefaclor …250mg	31/08/2005 Change of BN: 08/11/2008	Dy.No.37449 dated **12.11.2018** Rs.10000/-	07/11/2023	
317.	039543	**Nadium SR 100mg Capsule** Each Capsule contains Diclofenac Sodium …100mg	31/08/2005 Transfer & Change of BN: 01/12/2008	Dy.No.37442 dated 12.11.2018 Rs.10000/-	30/11/2023	
318.	039546	**Zefung Capsules 150mg** Each capsule contains Fluconazole …150mg	31/08/2005 Transfer on: 01/12/2008	Dy.No.37443 dated 12.11.2018 Rs.10000/-	30/11/2023	
319.	039556	**Nettle Drop 50mg/1ml** Each ml contain Cefaclor 50mg.	31/08/2005 Change of BN: 08/11/2008	Dy.No.37448 dated **12.11.2018** Rs.10000/-	07/11/2023	
320.	031945	**Eftax Injection 1gm** Each vial contains Ceftazidime (as Pentahydrate) …1g	13/12/2003 Transfer & Change of BN: 01/12/2008	Dy.No.37452 dated 12.11.2018 Rs.10000/-	30/11/2023	
321.	031947	**Eftax Injection 500mg** Each vial contains Ceftazidime (as Pentahydrate) …500mg	13/12/2003 Transfer & Change of BN: 01/12/2008	Dy.No.37451 dated 12.11.2018 Rs.10000/-	30/11/2023	
322.	031946	**Eftax Injection 250mg** Each vial contains Ceftazidime (as Pentahydrate) …250mg	13/12/2003 Transfer & Change of BN: 01/12/2008	Dy.No.37450 dated 12.11.2018 Rs.10000/-	30/11/2023	
Decision: Deferred for the rectification of following shortcomings: 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 have never been de-registered. **(on Stamp Papar)**. Renewal fee is submitted after the due date, therefore, differential fee is required for Nettle Suspension 250mg/5ml .(Reg#039554), Nettle Drop 50mg/1ml. (Reg#039556) Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Venus Pharma, 23 KM, Multan Road, Lahore						
323.	14721	**B complex Injection** Each 1ml contains B1 ….. 10mg B2 …. 2mg B6 ….. 5mg Nicotinamide …. 75mg Pantothenic Acid …. 5mg	24/11/1993	Dy.No.36349 dated 01.11.2018 Rs.10000/-	23/11/2023	
Decision: Deferred for the rectification of following shortcomings: 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 have never been de-registered. **(on Stamp Papar)**. Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO. Evidence of approval of formulation in Reference Drug Agencies.						

Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).

M/s Global Pharmaceuticals Pvt Ltd. Plot # 204-205, Industrial Triangle, Kahuta Road, Islamabad

324.	16831	**Fadiphine Tablet 40mg** Each tablet contains: Famotidine ...40mg		16/05/1997	Dy.No.36351 dated 01.11.2018 Rs.10000/-		
325.	25195	**Fericard 5mg Tablet** Each tablet contains: Warfarin Sodium …5mg		12/10/1999 Change of BN: 30/01/2002	Dy.No.36351 dated 01.11.2018 Rs.10000/-		
326.	52507	**Clopirine Tablet** Each tablet contains:- Clopidogrel ……. 75mg Aspirin …… 75mg		17/09/2008	Dy.No.36351 dated 01.11.2018 Rs.10000/-		
327.	30533	**Gloxil 250mg Injection** Each vial contains:- Amocycillin (as sodium) …250mg		17/05/2003	Dy.No.36351 dated 01.11.2018 Rs.10000/-		

Decision:

Deferred for the rectification of following shortcomings:

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.

Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).

M/s. Biorex Pharma, Plot No. 251-A, Industrial Triangle, Kahuta Road, Islamabad.

328.	75496	M/s Vision Pharmaceuticals, Islamabad.	**Neusec Forte Capsules 40 mg** Each Capsule Contains:Omeprazole Pellets (Enteric coated) eq. to Omeprazole ….. 40 mg.	22/10/2013	Dy.No.36734 dated 06.11.2018 Rs.10000/-	21/10/2023	

Decision:

Deferred for the rectification of following shortcomings:

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).

M/s. Hizat Pharmaceutical Industry, 170 Industrial Estate Hayatabad, Peshawar

329.	13877	**Zapex Syrup** Each 28.4ml contains Vit. A …14000 I.U Vit. D2 …1400 I.U Thiamine HCI …2.8mg Riboflavine …3.4mg Nicotinamide …28.4mg Ascorbic Acid …85.2mg	08/11/1993	Dy.No.36736 dated 06.11.2018 Rs.10000/-	07/11/2023	

330.	13878	**Zarsine Syrup** Each 30ml contains Thiamine HCI …. 2.5mg Riboflavine …. 10mg Pyridoxine HCI …. 6mg Cyanocobalamine ….. 50mcg Cal.D Pantothenate …. 15mg Lysine Monohydro Chloride …. 200mg Inositol …. 30mg Niacinamide ….. 108mg Ascorbic Acid …. 450mg	08/11/1993	Dy.No.36737 dated 06.11.2018 Rs.10000/-	07/11/2023	
Decision: Deferred for the rectification of following 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 approval of formulation in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Tagma Pharma (Pvt) Ltd, 12.5 Km Raiwind Road, Lahore						
331.	31787	**Metomet Tablets** Each tablet contains:- Metronidazole….250mg Di-Iodohydroxyquinolone … 325mg	13/11/2003	Dy.No.36738 dated 06.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following 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. Evidence of approval of formulation in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Pharmatec Pakistan (Pvt) Ltd, D-86/A, S.I.T.E., Karachi						
332.	009266	**Acetal Tablet** Each tablet contains: Spray dried sodium polyhydroxy aluminium monocarbonate hexitol complex 360mg (eq. to 216mg aluminium hydroxide)	11/06/1987 TOR from Sterling on 07/12/1993	Dy.No.36865 dated 07.11.2018 Rs.10000/-	06/12/2023	
333.	022468	**Isomon CR Capsule** Each capsule contains: Isosorbide-5-mononitrate …50mg	08/12/1998 Change of BN on 25/06/2003	Dy.No.36865 dated 07.11.2018 Rs.10000/-	07/12/2023	
334.	030732	**Nalacid 1g Caplet** Each tablet contains: Nalidixic acid …1000mg	11/12/2003 Corrigendum from capsule to caplet on 02/12/2008	Dy.No.36865 dated 07.11.2018 Rs.10000/-	10/12/2023	
335.	001122-EX	**Flu-Gone Cough expectorant Syrup** Each 5ml contains: Ammonium chloride	28/11/2008	Dy.No.36865 dated 07.11.2018 Rs.10000/-	27/11/2023	

		…100mg Guaiphensin …100mg Pseudoephedrine HCl …30mg Chlorpheniramine Maleate …2mg				
Decision: Deferred for the rectification of following shortcomings: For the product **Isomon CR Capsule** (Reg#022468) pellets are imported as per Initial registration letter. Firm is required to pay differential fee for last renewal and also for current renewal. Evidence of approval of formulations in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Indutrial Zone, Rawat, Islamabad						
336.	052800	**Monteser 5mg Chewable tablet** Each tablet contains Montelukast as sodium …5mg	15/11/2008	Dy.No.36742 dated 06.11.2018 Rs.10000/-	14/11/2023	
337.	052801	**Dewfer-F Chewable tablet** Each tablet contains Iron Polymaltose complex eq to. Elemental Iron……100mg, Folic acid…….0.35mg	15/11/2008	Dy.No.36742 dated 06.11.2018 Rs.10000/-	14/11/2023	
338.	052802	**Moads 10mg capsule** Each capsule contains Escitalopram oxalate …10mg	15/11/2008	Dy.No.36742 dated 06.11.2018 Rs.10000/-	14/11/2023	
339.	052803	M/s Spansules Pharma (Pvt) Ltd, Subash Nagar IDA Jeedimetla Hyderabad, India. (Pellets source)	**Tasium Capsule 75mg** Each capsule contains: Diclofenac Potassium (as enteric coated pellets)…….75mg	15/11/2008	Dy.No.36741 dated 06.11.2018 Rs.10000/-	14/11/2023	
Decision: Deferred for the rectification of following shortcomings: Form 5-B has not been submitted along with dossier. Form 5-B is required for consideration of renewal application. Differential fee for import of pellets for Tasium Capsule 75mg (Reg#052803) for last renewal as well as latest renewal application. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. MKB Pharmaceuticals (Pvt) Ltd, Plot# 66, Hayatabad Industrial Estate, Peshawar						
340.	052793	**Cetamol Oral Liquid** Each 5ml contains Paracetamol …160mg	11/11/2008	Dy.No.36740 dated 06.11.2018 Rs.10000/-	10/11/2023	Renewal submitted on 11/07/2017 with 20,000/- fee. And then on 09/11/2017 with 10,000/- additional fee.
341.	052794	**Rinsora Mouth Wash** Each 5ml contains	11/11/2008	Dy.No.36740 dated	10/11/2023	Renewal submitted on 29/09/2017 with

		Chlorhexidine Gluconate….0.2%, Benzydamine HCl…..0.15%		06.11.2018 Rs.10000/-		20,000/- fee. And then on 09/11/2017 with 10,000/- additional fee.
Shortcomings:						
M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore.						
342.	052771	**Nozin SR 100mg Tablet** Each tablet contains: Diclofenac Sodium ….100mg	11/08/2008	Dy.No.36739 dated 06.11.2018 Rs.10000/-	10/08/2023	
343.	052772	**Fentolin 2mg tablet** Each tablet contains: sulbutamol as sulphate…..2mg	11/08/2008	Dy.No.36739 dated 06.11.2018 Rs.10000/-	10/08/2023	
344.	052773	**Festofen 200mg tablet** Each tablet contains: Ibuprofen …200mg	11/08/2008	Dy.No.36739 dated 06.11.2018 Rs.10000/-	10/08/2023	
345.	052774	**Feridone 10mg tablet** Each tablet contains: Domperidone …10mg	11/08/2008	Dy.No.36739 dated 06.11.2018 Rs.10000/-	10/08/2023	
346.	046369	**Fesodamint 300mg tablet** Each tablet contains: Sodium Bicarbonate …300mg	17/12/2008	Dy.No.36739 dated 06.11.2018 Rs.10000/-	16/12/2023	
Decision: Deferred for the rectification of following shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s Sapient Pharma,123/S Industrial estate, Kot Lakhpat, Lahore						
347.	052826	**Sapizine Syrup** Each 5ml contains Cetirizine 2HCl …5mg	18/11/2008	Dy.No.37303 dated 12.11.2018 Rs.10000/-	17/11/2023	
348.	052827	**Alersap Suspension** Each 5ml contains Loratadine …5mg	18/11/2008	Dy.No.37304 dated 12.11.2018 Rs.10000/-	17/11/2023	
Decision: Deferred for the rectification of following 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. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Ahsons Drug Company, T/1, S.I.T.E., Tando Adam, Sindh						
349.	004420	**Vitamin B Complex Lysine Syrup** Each 5ml contains: Thiamine HCl …4.16mg, Riboflavin 5 phosphate Sodium …1.66mg, Pyridoxine HCl …1mg, Cynocobalamin …8.33mcg, Calcium D-Pantothenate	22/11/1978 Initial registration letter doesn't bear the composition	Dy.No.37691 dated 14.11.2018 Rs.10000/-		

		…2.5mg, Lysine Monohydrate …33.33mg, Ascorbic Acid ….75mg, Inositol …5mg, Nicotinamide ….18mg				
350.	004421	**Diphenhydramin cough syrup** Each 5ml contains: Diphenhydramin HCl …13.5mg, Ammonium Chloride B …131.5mg Sodium Citrate …55mg, Menthol …1.00mg	22/11/1978 Initial registration letter doesn't bear the composition	Dy.No.37690 dated 14.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following 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. Evidence of approval of formulation in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Star Laboratories (Pvt) Ltd., 23-Km Multan Road (Chung), Lahore						
351.	022536	**Anvil Injection** Each ml contains Pheniramine Maleate……..25mg	26/11/1998	Dy.No.37688 dated 14.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Imco Pharmaceuticals Laboratories, 73-Industrial Estate, Hayatabad, Peshawar						
352.	014821	**Imoquin Syrup** Each 5ml contains Chloroquin Phosphate eq to 50mg Chloroquine	05/12/1993	Dy.No.37693 dated 14.11.2018 Rs.10000/-	04/12/2023	
353.	014822	**Gargoral Solutin** Each 100ml contains:- Carbolic Acid…….0.4%, Menthol……0.035%, Thymol……..0.075%, Sod.Phenolate…..1%, Glycerine….10%, Apple Green….0.001%, Citric Acid….0.01%	5/12/1993	Dy.No.37693 dated 14.11.2018 Rs.10000/-	04/12/2023	
354.	014771	**Imco Tuss Syrup** Each 5ml contains Dextromethorphan HBr…6.25mg, Diphenhydramine HCl …5mg	17/02/1994 Change of formulation on: 19/07/2012	Dy.No.37693 dated 14.11.2018 Rs.10000/-	16/02/2024	
Decision: Deferred for the rectification of following 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 approval of formulation in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. CSH Pharmaceuticals-North (Pvt) Ltd, 38-A, Industrial Estate, Hayatabad, Peshawar						
355.	030733	**Heldex Suspension** Each 5ml contains:- Albendazole …..100mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
356.	030734	**Heldex Tablets 200mg** Each tablet contains:- Albendazole …..200mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
357.	030735	**Dopin Tablets** Each tablet contains:- Domperidone ……10mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
358.	030736	**Dopin Suspension** Each ml contains:- Domperidone ……1mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
359.	030737	**Molid Suspension** Each 5ml contains:- Paracetamol ……..120mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
360.	030738	**Molid Forte Suspension** Each 5ml contains:- Paracetamol ……..250mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
361.	030739	**Molid Drops** Each 5ml contains:- Paracetamol ……..60mg	August, 2003	Dy.No.37041 08.11.2018 Rs.10000/-		
362.	030740	**Molid Tablets** Each tablet contains:- Paracetamol ……..500mg	August, 2003	Dy.No.37041 08.11.2018 Rs.10000/-		
363.	030741	**Decos Syrup** Each 5 ml contains:- Diphenhydramine …8mg, Aminolphylline ….32mg, Ammonium Chloride ….30mg, Menthol ……0.98mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
364.	030744	**Zotrim DS Suspension** Each 5ml contains Sulphamethaxole …400mg, Trimethoprim …80mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
365.	030745	Trocodex Syrup Each 5ml contains:- Triclofos Sodium ..500mg	August, 2003	Dy.No.37041 08.11.2018 Rs.10000/-		
366.	030746	**Fured Tablets** Each tablet contains:- Diloxanide Furoate ...250mg, Metronidazole …200mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
367.	030747	**Fured Suspension** Each 10ml contains:- Diloxanide Furoate ……250mg,	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		

		Metronidazole (as benzoate)….200mg				
368.	030748	**Lyodex Syrup** Each 5ml contains:-Vitamin B1 ……..4.16mg, Vitamin B2..1.66mg, Vitamin B6 .. 1mg, Vitamin B12 .. 8.33mcg, Vitamin C ……. 75mg, Calcium D Pentothenate …..2.5mg, Inositol ….5mg, Niacinamide …18mg, Lysine Monohydrochloride.33.33mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
369.	030749	**Apidol Tablet** Each tablet contains:- Aspirin……..300mg,Paracetamol…….200mg,Caffeine…….30mg	August, 2003 Change of BN: 11/03/2009	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
370.	030752	**Napred Tablets** Each tablet contains:- Naproxen Sodium 550mg eq. to Naproxen…500mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
371.	030753	**Glucotrol Tablet** Each tablet contains Glibenclamide……..50mg	August, 2003	Dy.No.37041 08.11.2018 Rs.10000/-		
372.	030754	**Myzid Dry Suspension** Each 5ml contains:- Azithromycin (as dihydrate)…..200mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
373.	030755	**Zotrim Tablets** Each tablet contains:- Sulphamethoxazole.400mg, Trimethoprim……..80mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
374.	030756	**Zotrim DS Tablets** Each tablet contains:- Sulphamethoxazole..800mg Trimethoprim…..160mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
375.	030757	**Zotrim Suspension** Each 5ml contains:- Sulphamethoxazole..200mg Trimethoprim…..400mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
376.	030761	**Spired Tablet** Each tablet contains:- Spiramycin…….500mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
377.	030762	**Spired Forte Tablet** Each tablet contains:- Spiramycin…….1000mg	August, 2003	Dy.No.37041 08.11.2018 Rs.10000/-		
378.	030763	**Mycin Tablets 250mg** Each tablet contains:- Clarithromycin ……250mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
379.	030764	**Mycin Tablets 500mg** Each tablet contains:-	August, 2003	Dy.No.37041 dated		

		Clarithromycin ……500mg		08.11.2018 Rs.10000/-		
380.	030765	**Mycin Dry Suspension** Each 5ml contains:- Clarithromycin …125mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
381.	030766	**Mycin Drops** Each 5ml contains:- Clarithromycin …125mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
382.	030767	**Myzid Capsule** Each capsule contains:- Azithromycin (as dihydrate)….250mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
383.	030768	**Nagid Tablets 10mg** Each tablet contains:- Piroxicam …….10mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
384.	030769	**Nagid Tablets 20mg** Each tablet contains:- Piroxicam …….20mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
385.	030770	**Besipine Tablets** Each tablet contains:- Amlodipine Besylate …5mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
386.	030771	**Napred Tablets 250mg** Each tablet contains:- Naproxen Sodium 275mg eq. to Naproxen …250mg	August, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
387.	031754	**Spocef Capsule** Each capsule contains:- Cefadroxil …….500mg	November, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
388.	031755	**Spocef Dry Suspension** Each 5ml contains:- Cefadroxil …….125mg	November, 2003	Dy.No.37041 08.11.2018 Rs.10000/-		
389.	031756	**Spocef Forte Dry Suspension** Each 5ml contains:- Cefadroxil …250mg	November, 2003	Dy.No.37041 dated 08.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following shortcomings: Notarized copy of Initial Registration Letter. 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). Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s.Popular Chemical Works (Pvt) Ltd, 9-km, Sheikhupura Road, Lahore						
390.	031851	**Atronil 10mg Tablet** Each tablet contains Atorvastatin……10mg (as calcium trihydrate salt)	15/11/2003	Dy.No.37034 dated 08.11.2018 Rs.10000/-	14/11/2023	

391.	031852	**Atronil 20mg Tablet** Each tablet contains Atorvastatin……20mg (as calcium trihydrate salt)	15/11/2003	Dy.No.37035 dated 08.11.2018 Rs.10000/-	14/11/2023	
392.	031853	**Atronil 40mg Tablet** Each tablet contains Atorvastatin……40mg (as calcium trihydrate salt)	15/11/2003	Dy.No.37036 dated 08.11.2018 Rs.10000/-	14/11/2023	
Decision: Deferred for the rectification of following shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Brief report of last batch manufactured. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s W.Woodward Pakistan (Pvt) Ltd, F-275,S.I.T.E, Karachi						
393.	003540	**Doltee Drops** Each Drops contains Lignocaine HCl Monohydrate …0.37%, Methyl Salicylate …0.02% Phenyl Carbinol …0.20%, Menthol …0.06%	12/01/1977 Change of BN: 22/11/2003	Dy.No.37777 dated 15.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following shortcomings: Evidence of approval of formulation in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s Medipak limited 132/1,Industrial Estate, Kot Lakhpat, Lahore						
394.	014775	**Chloroquine Phosphate Injection** Each 5ml contains Chloroquin Phosphate eq to 200mg Chloroquine base	6/12/1993	Dy.No.37775 dated 15.11.2018 Rs.10000/-		
Shortcomings: Evidence of approval of formulation for Chloroquine Phosphate Injection (Reg. No. 014775) in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s Eros Pharmaceuticals Pvt Ltd 94-95/23, Korangi Industrial Area, Karachi.						
395.	004443	Eropyrin Tablet Each tablet contains Paracetamol …200mg, Aspirin …300mg, Caffeine …30mg, Phenobarbitone …15mg	26/11/1978	Dy.No. 38333 dated 22.11.2018 Rs.10000/-		
396.	004444	Paracetamol suspension Each 5ml contains Paracetamol …120mg	26/11/1978	Dy.No. 38333 22.11.2018 Rs.10000/-		
397.	014706	Pholtex Syrup Each 5ml contains Pholcodine ….10mg, Ephedrine HCl …7mg, Chlorpheniramine Maleate …2mg	24/11/1993	Dy.No. 38333 dated 22.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following shortcomings: Transfer of registration to new address for Eropyrin Tablet (Reg#004443) & Paracetamol suspension (Reg#004443). Evidence of approval of formulation in Reference Drug Agencies. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						

M/s Navegal Laboratories. 41/1-A2, Phase-1, Industrial Estate, Hattar							
398.	078405	M/s Vision Pharmaceuticals, Islamabad.	**Movez SR Capsule 100mg** Each Prolonged-release capsule contains Diclofenac sodium prolonged release pellets eq to Diclofenac sodium….100mg	21/11/2013	Dy.No. 37869 dated 15.11.2018 Rs.10000/-		
399.	052858	**Adevox 10mg Tablet** Each tablet contains Adefovir Dipivoxil …10mg		26/11/2008	Dy.No. 37868 15.11.2018 Rs.10000/-		

Decision: Deferred for the rectification of following shortcomings:

Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO for Adevox 10mg Tablet
(Reg#052858).

Brief report of last batch manufactured.

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)**.

Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).

M/s. Mediate Pharmaceuticals (Pvt) Ltd. Plot No. 150-151 Sector 24 Korangi Industrial Area, Karachi.							
400.	053273	M/s Spansulex Pharmatech Phase-I IDA (Pvt) Plot No. 153 gubhash Nagar Jeedimetla, Hderabad, India.	**Mediprzole 40mg Capsule** Each capsule contains Omeprazole (enteric coated pellets)...40mg	1/12/2008	Dy.No.38500 Dated.23/11/2018 Rs.10000	30/11/2023	

Decision: Deferred for the rectification of following shortcomings:

Differential fee is required as according to registration letter, pellets are imported.

Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).

M/s. Noa Hemis Pharmaceuticals,Plot No. 154 Sector 23 Korangi Industrial Area Karachi.						
401.	032165	**Flamar Tablet** Each tablet contains Mefenamic Acid …250mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000		
402.	032166	**Flamar Forte Tablet** Each tablet contains Mefenamic Acid …500mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000		
403.	032172	**Neporex Tablet 250mg** Each tablet contains Naproxen …250mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000		
404.	032173	**Neporex DS Tablet 500mg** Each tablet contains Naproxen …500mg	27/02/2004	Dy.No.38291 26/11/2018 Rs.10000		
405.	032175	**Fastmov cream** Contains Methl Salicylate …20.0%, Menthol …8.0%, Camphor …4.0%	27/02/2004	Dy.No.38291 Dated.26/11/2018 Rs.10000		

Decision: Deferred for the rectification of following shortcomings: Evidence of approval of formulation in Reference Drug Agencies. Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Amarant Pharmaceuticals Pvt, Ltd,158-D Den Toro Gadap Road Super Highway Karachi. Karachi						
406.	075883	**Limgit 50mg Tablet** Each film coated tablet contains Lamotrigine …50mg	08/05/2013	Dy.No.39016 27/11/2018 Rs.10000	07/05/2023	
407.	075885	**Limgit 25mg Tablet** Each tablet contains Lamotrigine …25mg	08/05/2013	Dy.No.39016 27/11/2018 Rs.10000		
408.	075886	**Limgit 100mg Tablet** Each film coated tablet contains Lamotrigine …100mg	08/05/2013	Dy.No.39016 27/11/2018 Rs.10000		
409.	075888	**Cilosta 100mg Tablet** Each film coated tablet contains Cilostazol …100mg	08/05/2013	Dy.No.39016 27/11/2018 Rs.10000		
410.	075889	**Amlepo 25mg Tablet** Each tablet contains Clozapine …25mg	08/05/2013	Dy.No.39016 27/11/2018 Rs.10000		
411.	075882	**Esorant 40mg Tablet** Each tablet contains Esomeprazole Magnesium eq to Esomeprazole …40mg	08/05/2013	Dy.No.39016 27/11/2018 Rs.10000		
412.	075884	**Esorant 20mg Tablet** Each film coated tablet contains Esomeprazole Magnesium eq to Esomeprazole …20mg	08/05/2013	Dy.No.39016 27/11/2018 Rs.10000		
413.	075887	**Peprant 40mg Tablet** Each tablet contains Pantoprazole as sodium …40mg	08/05/2013 Change of BN: 24/06/2015	Dy.No.39016 27/11/2018 Rs.10000		
414.	076127	**Amprexa-F 6mg/25mg Capsule** Each capsule contains Olanzapine …6mg, Fluoxetine HCl …25mg	29/10/2013	Dy.No.39016 27/11/2018 Rs.10000		
415.	076131	**Cyclorant 250mg Capsule** Each capsule contains Cycloserine …250mg	29/10/2013	Dy.No.39016 Dated.27/11/201 8 Rs.10000		
Decision: Deferred for the rectification of following shortcomings: Complete description of tablet dosage form i.e. Film Coated or Plain etc for Esorant 40mg Tablet (Reg#075882), Esorant 20mg Tablet (Reg#075884) &Peprant 40mg Tablet (Reg#075887) Renewal fee was submitted after the due date, therefore, differential fee is required. Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Bio-Labs,Plot No.145 Kahuta Triangle Industrial Estate Islamabad.						
416.	054777	**Biodine Dry Suspension 125mg** Each 5ml contains Cephradine …125mg	02/01/2009	Dy.No.39041 28/11/2018 Rs.10000	01/01/2024	
417.	054778	**Biodine Dry Suspension 250mg** Each 5ml contains Cephradine …250mg	02/01/2009	Dy.No.39041 28/11/2018 Rs.10000	01/01/2024	
418.	054760	**Biodol 0.5mcg Capsule** Each capsule contains Alfacalcidol …0.5mcg	02/01/2009	Dy.No.39041 28/11/2018 Rs.10000	01/01/2024	
Decision: Deferred for the rectification of following shortcomings: Evidence of approval of formulation in Reference Drug Agencies.						

Evidence of approval of Alfacalcidol 0.5mcg hard gelatin capsule in Reference Drug Agencies Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).

b. 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. Mehran International, JM-498/D, Hume Road, Quaideen Colony, Opposite: World Map, Near 3 Star Hall, Karachi.							
419.	052273	M/s Zhejiang Hisun Pharmaceutical Co. Ltd, China.	**Vinblastine Sulfate for injection 5mg** Each vial contains:- Vinblastine Sulfate …5mg	25/11/2008	Dy.No.37457 dated 12.11.2018 Rs.20000/-		
420.	052274	M/s Zhejiang Hisun Pharmaceutical Co. Ltd, China.	**Vinblastine Sulfate for injection 10mg** Each vial contains:- Vinblastine Sulfate …10mg	25/11/2008	Dy.No.37457 dated 12.11.2018 Rs.20000/-		
421.	052275	M/s Zhejiang Hisun Pharmaceutical Co. Ltd, China.	**Vincristine Sulfate for injection 2mg** Each vial contains:- Vincristine Sulfate …2mg	25/11/2008	Dy.No.37457 dated 12.11.2018 Rs.20000/-		
422.	052271	M/s Zhejiang Hisun Pharmaceutical Co. Ltd, China.	**Granisetron Hydrochloride Injection** Each 3ml vial contains Granisetron Hydrochloride….3mg	25/11/2008	Dy.No.37456 dated 12.11.2018 Rs.20000/-		
Decision: Deferred for the rectification of following shortcomings: Address of DSL varies from the address mentioned on registration letter. 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. DRAP's attested invoice of last import. Evidence of submission of last renewal duly endorsed by R&I, DRAP, Islamabad and STO. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							
M/s. Angelini Pharmaceuticals (Pvt) Ltd, 221 Block CCA, Phase-4, DHA, Lahore							
423.	022663	M/s Inpharzam SA, (Zambon Group), Switzerland	**Monurol Sachets** Each 3gm sachet contains Fosfomycin Tremethamol 5.631gm (eq to Fosfomycin ….3gm)	10/12/1998 Transfer of drug; 25-05-2009 Change of company Name: 25-11-2013	Dy.No.37040 dated 08.11.2018 Rs.20000/-		

424.	021174	M/s Inpharzam SA, (Zambon Group), Switzerland	**Fluimucil 200mg Sachet** Each 1gm sachet contains: Acetylcysteine ..200mg	04/09/1998 Transfer of registration: 25/11/2013	Dy.No.37040 dated 08.11.2018 Rs.20000/-		
Decision: Deferred for the rectification of following shortcomings: Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate. Shortcoming letter issued on 02/08/2019 vide letter F.No. 1-65/ 2018 (RRR).								
M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf Road, Karachi								
425.	04458	M/s Novartis Farmaceuutica S.A, Spain	**Ritalin Tablet 10mg** Each tablet contains: Methylphenidate HCl …10mg,	20/11/1978 Change of manufacturing site: 10/11/2004	Dy. No. 31920 25/09/2018 20,000	19/11/2023	
426.	31327	M/s Novartis Farma S.p.A, Torre Annunziata, Italy	**Co-Diovan Film Coated Tablets (160/12.5mg)** Each tablet contains: Valsartan …160mg. Hydrochlorothiazide …12.5mg.	03/12/2003 Change of manufacturing site: 15/06/2009	Dy. No. 31922 25/09/2018 20,000	02/12/2023	
427.	78105	**MA Holder:** M/s Novartis Europharm Limited, Wimblehurst Road, Horsham, West Sussex, RH12 5AB, UK. **Mfgd by:** M/s Novartis Pharma Stein AG, Schaffhauserstrasse 4332 Stein AG, Switzerland	**Afinitor 2.5 mg Tablets** Each tablet contains: Everolimus …2.5mg	12/12/2003	Dy. No. 31610 25/09/2018 20,000	11/12/2023	
428.	52256	M/s Novartis Pharma Stein AG, Switzerland.	**Tasigna 200mg Capsules.** Each hard gelatin capsule contains Nilotinib…..200mg**.**	13/11/2008	Dy. No. 31611 25/09/2018 20,000	15/11/2023	
429.	78106	**MA Holder:** M/s Novartis Pharma, GmbH, Roonstrasse 25, 90429 Nurnberg, Germany. **Mfgd by:** M/s Novartis Pharma Produktions GmbH, Oflinger Str.44, 79664 Wehr, Baden-	**Galvus Met 50/500mg Tablets** Each tablets contains: Vildagliptin …50mg. Metformin hydrochloride …500mg.	12/12/2013 Change of manufacturing site: 31/10/2014	Dy. No. 31921 25/09/2018 20,000	11/12/2023	

		Wurttemberg, Germany.					
430.	52230	M/s Novartis Pharma Stein AG, Switzerland.	**Diovan Film Coated Tablets 320mg** Each film coated tablet contains: Valsartan …320mg.	20/10/2008	Dy. No. 31923 25/09/2018 20,000	19/10/2023	
Decision: Deferred for the rectification of following shortcomings: 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 Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							
M/s AJM Pharma (Pvt) Ltd 1st Floor, Shafi Court, Merewether Road, Civil Lines, Karachi.							
431.	72596	M/s Cipla Limited (Unit-**V**), Verna Industrial Estate, Verna, Salcette, Goa, India	**Cytabine Injection 1000mg/10ml.** Each 10ml vial contains Cytarabine …1000mg.	08/10/2013	Dy. No. 31601 19/09/2018 20,000	07/10/2023	
432.	72595	M/s Cipla Limited (Unit-**V**), Verna Industrial Estate, Verna, Salcette, Goa, India	**Cytabine Injection 500mg/5ml.** Each 5ml vial contains Cytarabine …500mg.	08/10/2013	Dy. No. 31601 19/09/2018 20,000	07/10/2023	
433.	72594	M/s Cipla Limited (Unit-**V**), Verna Industrial Estate, Verna, Salcette, Goa, India	**Cytabine Injection 100mg/ml.** Each 1ml vial contains Cytarabine …100mg.	08/10/2013	Dy. No. 31601 19/09/2018 20,000	07/10/2023	
434.	72593	M/s Cipla Limited (Unit-**VI**), Verna Industrial Estate, Verna, Salcette, Goa, India	**Capegard-500mg Film Coated Tablets.** Each film coated tablets contains Capecitabine …500mg.	08/10/2013	Dy. No. 31601 19/09/2018 20,000	07/10/2023	
Decision: Deferred for the rectification of following shortcomings: 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). Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							
M/s Bayer Pakistan (Pvt) Limited, Bahria Complex II, 4th Floor, M.T. Khan Road, Karachi.							
435.	52224	**Manufactured by:** M/s Bayer Pharma AG, 51368, Leverkusen, Germany. **Product License Holder:** M/s Bayer Pharma AG, 13342, Berlin, 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	Dy. No. 32036 25/09/2018 20,000	24/09/2023	

Decision: Deferred for the rectification of following shortcomings:
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).
Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).

M/s. Al Habib Corporation, Abdullah House, 81 Block-B, S.M.C.H.S., Karachi.

436.	31334	M/s Korea United Pharm. Inc., Korea	**Ucetam Injection 1gm** Each 5ml ampoule contains Piracetam …1000mg	24/12/2003	Dy.No. 38470 dated 22.11.2018 Rs.20000/-	23/12/2023	
437.	22622	M/s Korea United Pharm. Inc., Korea	**Etopul Injection** Each ampoule 5ml contains Etoposide …100mg	04/12/1998	Dy.No. 38471 dated 22.11.2018 Rs.20000/-	03/12/2023	
438.	22623	M/s Korea United Pharm. Inc., Korea	**Vinracine Injection** Each 2ml vial contain Vincristine sulphate …2mg	04/12/1998	Dy.No. 38471 dated 22.11.2018 Rs.20000/-	03/12/2023	
439.	22624	M/s Korea United Pharm. Inc., Korea	**K.U Dactinomycin Injection** Each vial contain Dactinomycin …0.5mg	04/12/1998	Dy.No. 38471 dated 22.11.2018 Rs.20000/-	03/12/2023	
440.	22625	M/s Korea United Pharm. Inc., Korea	**Hydrine Capsule** Each capsule contains Hydroxyurea …500mg	04/12/1998	Dy.No. 38472 dated 22.11.2018 Rs.20000/-	03/12/2023	
441.	22626	M/s Korea United Pharm. Inc., Korea	**Unitexrate Injection 25mg/ml** Each 1ml contains Methorrexate …25mg	04/12/1998	Dy.No. 38472 dated 22.11.2018 Rs.20000/-	03/12/2023	
442.	22637	M/s Korea United Pharm. Inc., Korea	**K.U Thioguanine Tablet** Each tablet contains Thioguanine …40mg	04/12/1998	Dy.No. 38472 dated 22.11.2018 Rs.20000/-	03/12/2023	

Decision: Deferred for the rectification of following shortcomings:
Evidence required regarding the transfer of registration to new address of firm as the address on Initial Registration Letter is different from that of Drug Sale License.
Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate
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).

M/s. Pharmevo (Pvt) Ltd., A-29, North Western Industrial Zone, Port Qasim, Karachi

443.	78103	M/s Hetero Labs Limited, Unit-VI APIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboob Nagar (Dist) 509301, Andhra Pradesh, India.	**Anazole 1mg Tablet** Each tablet contains Anastrazole …1mg	11/12/2013	Dy.No. 38237 dated 20.11.2018 Rs.20000/-		
444.	78104	M/s Hetero Labs Limited, Unit-VI	**Letzole 2.5mg Tablet** Each tablet contains	11/12/2013	Dy.No. 38237 dated 20.11.2018		

		APIIC Formulation SEZ, Polepally Village, Jadcherla Mandal, Mahaboob Nagar (Dist) 509301, Andhra Pradesh, India.	Letrozole …2.5mg		Rs.20000/-		
Decision: Deferred for the rectification of following shortcomings: 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). Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							
M/s. Atco Laboratories (Pvt) Ltd,B-18 S.I.T.E Karachi.							
445.	31333	M/s Feering A/s Denmark	**Pentasa 500mg Tablet** Each tablet contains Mesalazine …500mg	16/12/2003	Dy.No.38789 Dated.26/11/2018 Rs.20000		
Decision: Deferred for the rectification of following shortcomings: 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 Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							
M/s. Angelini Pharmaceuticals (Pvt) Ltd, 221 Block CCA, Phase-4, DHA, Lahore							
446.	43074	M/s Bruschettini s.r.l., Italy.	**Brumixol Cream** Each 100gm contains Ciclopiroxolamine …1gm	12/09/2006 Change of company name & transfer of registration of products **25/11/2013**	Dy.No.39014 Dated.27/11/2018 Rs.10000		
447.	43075	M/s Bruschettini s.r.l., Italy.	**Brumixol Ovules** Each ovule contains Ciclopiroxolamine …0.1gm	12/09/2006 Change of company name & transfer of registration of products **25/11/2013**	Dy.No.39013 Dated.27/11/2018 Rs.10000		
Decision: Deferred for the rectification of following shortcomings: Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate. Renewal fee was submitted after the due date; therefore, differential fee is required. Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							

c. 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. Decent Pharma Plot No. 30, Street SS 3, National Industrial Zone, Rawat						
448.	75779	**Nortrim-s oral liquid** Each ml contains: Norfloxacin …10% Sulphamethoxypyridazine..15% Trimethoprim …03%	05/11/2013	Dy.No.36615dated 05.11.2018 Rs.10000/-	04/11/2023	
Decision: Deferred for the rectification of following shortcomings: Renewal fee was submitted after the due date, therefore, differential fee is required. Shortcoming letter issued on 02/08/2019vide letter F.No. 1-65/ 2018 (RRR).						
M/s. Star Laboratories (Pvt) Ltd., 23-Km Multan Road (Chung), Lahore						
449.	022185	**Thiaprin Injection** Each ml contains Vitamin B1 …5mg Vitamin B2 sodium …2.5mg, Vitamin B6 (HCl) …2.5mg, Nicotinamide …37.5mg	04/12/1998	Dy.No.37689 dated 14.11.2018 Rs.10000/-		
Decision: Deferred for the rectification of following shortcomings: Latest cGMP Inspection Report having conclusive recommendations regarding cGMP. Shortcoming letter issued on 02/08/2019vide letter F.No. 1-65/ 2018 (RRR).						

d. 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 Registration	Date of application (R&I) Fee submitted	Renewal validity	Decision
M/s International Chempharma (Pakistan), House #397, Block B-1, Johar Town, Lahore							
450.	14199	M/s Franklin Pharmaceuticals Irl Ltd, Meath, Ireland	**Amoxycillin 15% LA Injection** Each ml Contains Amoxycillin Trihydrate eq. to Amoxycillin …150mg	25/10/1993	Dy. No. 31918 25/09/2018 20,000		
Decision: Deferred for the rectification of following shortcomings: 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. Evidence of transfer of products from address on Registration Letter to new address. 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). Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							
M/s. Better Traders International, 23-Z, Saifullah Shaheed Road, Madina Town, Faisalabad							
451.	49737	M/s Kepro B.V., Holland.	**Kepro Amoxy-Col WSP** Each gm Contains Amoxycillin Trihydrate…200mg	24/09/2008	Dy. No. 31487 18/09/2018 20,000	23/09/2023	

			Colistin Sulphate…600,000IU				
452.	49738	M/s Kepro B.V., Holland.	**Kepro Colistin 4800 WSP** Each gm Contains Colistin (as Sulphate) …4,800,000IU	24/09/2008	Dy. No. 31486 18/09/2018 20,000	23/09/2023	
Decision: Deferred for the rectification of following shortcomings: Original, valid and legalized CoPP as per WHO's format or original, valid and legalized free sale certificate and GMP certificate 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). Shortcoming letter issued on 26/08/2019 vide letter F.No. 1-65/ 2018 (RRR).							

Miscellaneous Cases

a) Cases of Bulk Import and Local Repacking

It is submitted that case of the following products of M/s. Sanofi-Aventis Pakistan Limited,Karachi has been placed in 288th meeting of Registration Board and Board decided to *deferred the case for the clarification regarding the status of bulk import from the firm***.**

Sr. No.	Reg. No.	Product Name	Initial date of Registration	Application Receiving date
1.	019564	Tritace 2.5mg Tablets Each tablet contains: Ramipril…..2.5mg	**08-07-1997** Change of company name from M/s. Hoechst Marion Roussel to M/s. Aventis Pharma (Pakistan) Limited, Karachi dated **24-01-2002.** Change of registration from import in finished form to bulk import and local repacking dated **11-02-2005.** Change of manufacturing site abroad from Germany to Aventis S.p.A, scopptio (A.Q) Italy dated **02-06-2005.** Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated **28-07-2006.** Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy dated **20-01-2007.**	**Due date (27-07-2016)** Fee of Rs.10,000/- deposited on 09-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi- aventis S.p.A. Italy** So remaining Fee of Rs.10,000/- deposited on 25-06-2018.
2.	019565	Tritace 5mg Tablets Each tablet contains: Ramipril…..5mg	-do-	**Due date (27-07-2016)** Fee of Rs.10, 000/- deposited on 09-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi- aventis S.p.A. Italy**So remaining Fee of Rs.10, 000/- deposited on 25-06-2018.
3.	045390	Tritace 10 mg Tablets	**13-06-2007**	Due date (12-06-2017) Fee of Rs.10,000/- deposited on

		Each tablet contains: Ramipril…..10mg		17-06-2016. As it is bulk import and locally repacked product from **M/s. Sanofi- aventis S.p.A. Italy**.So remaining Fee of Rs.10,000/- deposited on 25-06-2018.
4.	019567	Amaryl 1 mg tablets Each tablets contains Glimepride…..1mg	**08-07-1997** Change of source from M/s. Hoechst Marion Roussel Germany to M/s. Hoechst Marion Roussel Italy for bulk import and local repacking dated **22-12-1997.** Change of company name from M/s. Hoechst Marion Roussel to M/s. Aventis Pharma (Pakistan) Limited, Karachi dated **24-01-2002.** Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated **28-07-2006.** Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy dated **20-01-2007.**	Due date (27-07-2016) Fee of Rs.10,000/- deposited on 04-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi- aventis S.p.A. Italy**.. So remaining Fee of Rs.10,000/- deposited on 25-06-2018.
5.	019568	Amaryl 2 mg tablets Each tablets contains Glimepride…..2mg	-do-	Due date (27-07-2016) Fee of Rs.10, 000/- deposited on 02-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi- aventis S.p.A. Italy**. So remaining Fee of Rs.10, 000/- deposited on 25-06-2018.
6.	021094	Amaryl 3 mg tablets Each tablets contains Glimepride…..3mg	**22-05-1998** Change of company name from M/s. Hoechst Marion Roussel (Pakistan),Karachi to M/s. Aventis Pharma (Pakistan) Ltd., Karachi dated **24-01-2002.** Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated **28-07-2006.** Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy dated **20-01-2007.**	Due date (27-07-2016) Fee of Rs.10, 000/- deposited on 04-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi- aventis S.p.A. Italy**. So remaining Fee of Rs.10, 000/- deposited on 25-06-2018.

7.	021095	Amaryl 4 mg tablets Each tablets contains Glimepride…..4mg	**22-05-1998** Change of company name from M/s. Hoechst Marion Roussel (Pakistan),Karachi to M/s. Aventis Pharma (Pakistan) Ltd., Karachi dated **24-01-2002.** Transfer of Registration in the name of M/s. Sanofi Aventis (Pakistan) Limited, Karachi dated **28-07-2006.** Change of name of Manufacturer from M/s. Aventis Pharma S.p.A Italy to M/s. Sanofi- aventis S.p.A. Italy dated **20-01-2007.**	Due date (27-07-2016) Fee of Rs.10, 000/- deposited on 04-05-2016. As it is bulk import and locally repacked product from **M/s. Sanofi- aventis S.p.A. Italy**. So remaining Fee of Rs.10, 000/- deposited on 25-06-2018.

The firm has submitted the clarification that both Amaryl and Tritace range tablets are imported in bulk from Italy and packed **(both primary and secondary)** at M/s. Sanofi-Aventis Pakistan Limited situated at Plot No. 23, Sector 22, Korangi Industrial Area, Karachi, having manufacturing license no. 000007.Sanofi-Aventis Pakistan Limited site is responsible **for quality and final release of the Finished product.**
Submitted for the consideration of the Board.

Decision: Registration Board acceded to the request of the firm and advised the section record the complete details regarding manufacturing, packaging, labelling and release sites of above mentioned drugs.

b) Renewal application of M/s Marvi Pharmaceuticals Pvt Limited Karachi of Pain Gay Ointment (012777)

It is submitted that M/s. Marvi Pharmaceuticals had applied for renewal of registration of year 2015 for their following product vide SRO 1005(I)/2017 dated 05th October, 2017. Details of products are as under:

Reg. No	Brand Name & Composition	Date of registration as per Form-5B
012777	Pain Gay Ointment Each gm contains: Methyl Salicylate ……150mg Menthol….100	15-12-1992

The Firm was advised to submit the evidence of initial registration letter and post registration variation (if any) for further 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."

Case is submitted for the consideration of Board.

Decision: Registration Board deferred above case for deliberations in next meeting.

c) <u>M/s. Vision Pharmaceuticals, Islamabad</u>

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
1.	037784	Cibrotam Injection 1gm Each 5ml contains:- Piracetam …1gm	22-03-2005	Regularized the renewal of 2010 till 2015 and grant the renewal from 22-03-2015 to 23-03-2020
2.	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
3.	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
4.	041736	Inflanil Tablet 250mg Each tablet contains:- Mefenamic Acid … 250mg	15-12-2005	-do-

5.	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
6.	037572	Epilax 200mg Tablet Each tablet contains:- Carbamazepine … 200mg	21-03-2005	-do-
7.	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
8.	056310	Fevonor Plus Suspension Each 5ml contains:- Paracetamol … 250mg	20-02-2009	-do-
9.	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
10.	037573	Epilax Syrup Each 5ml contains:- Carbamazepine … 100mg	21-03-2005	-do-
11.	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.

Decision: Registration Board deferred above case for deliberations in next meeting.

d) M/s Hoover Pharmaceuticals (Pvt.) Ltd.Plot # 16 Zain Park Industrial Area Saggian By Pass Road, Lahore

Sr. No.	Reg. No.	Brand Name, Composition & Specification	Initial date of Registration	Date of application (R&I) Free submitted	Decision
1.	062445	Lotriderm Vaginal Tablets 100mg Each tablet contains:- Clotrimazole 100mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
2.	062446	Estiram Tablets 10mg Each tablet contains:- Escitalopram (as Oxalate) 10 mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
3.	062448	Bonrite Tablets 0.5 mcg Each tablet contains:- Alfacalcidol 0.5 mcg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
4.	062449	Retag-D Tablets 5mg Each tablet contains:- Desloratadine 5 mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
5.	062450	Lotriderm Vaginal Cream 1% Each gram contains:- Clotrimzole….10mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
6.	062451	De-Artho Gel 1% Each 100gram contains:- Diclofenac Diethyl Ammonium 1.16gm eq.to Diclofenac 1.00gm	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
7.	062452	Daymac Gel 1% Each gram contains:- Clindamycin (as Phosphate)10mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
8.	062453	Lotriderm-BG Cream Each gram contains:- Clotrimazole 1%+Betamethasone (as Dipropionate) 0.05%+ Gentamycin(as Sulphate) 0.1%	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
9.	062454	Lotriderm-H Cream Each 100gram contains:- Clotrimazole 1% +Hydrocortisone 1%	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
10.	062455	Eloderm Ointment 0.1% Each tube contains:- MometasoneFuroate0.1%	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
11.	062456	Novaderm Cream Each tube contains:- Tretinoin 0.05%+Hydroquinone 4%+ FluocinoloneAcetonide 0.01%	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
12.	062457	Biforoben Gel 5% Each gram contains:- Flurbiprofen 5%	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
13.	062458	Elucider Cream 0.1% Each gram contains:- Adapalene 1mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
14.	062459	Cortigen Cream Each gram contains:- Isoconazole Nittrate 10mg + Diflucortolone Valerate 1mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020

15.	062460	Bevate-N Cream Each tube contains:- Betamethasone (as Valerate) 0.1% +Neomycin Sulphate 0.5%	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
16.	062461	Feldetrol Capsules 20mg Each capsule contains:- Piroxicam 20mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
17.	062462	Cytobion Capsules 500mcg Each capsule contains:- Mecobalamin 500mcg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
18.	062465	Roxibeta Tablets 20mg Each tablet contains:- Piroxicam as Beta Cyclodextrin 20 mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
19.	062466	Co-Arfentin DS Tablets Each tablet contains:- Artemether 40 mg + Lumefantrine 240 mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
20.	062467	Rapilox Tablets 400mg Each tablet contains:- Moxifloxacin ... 400mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
21.	062468	Trazacin Tablets 250mg Each tablet contains:- Azithromycin (as Dilhydrate) 250 mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
22.	062469	Hidrogent-M Cream Each gram contains:- Hydrocortisone (Acetate) 10mg+ Miconazole Nitrate 20mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
23.	062470	Fusiwin-B Cream Each gram contains:- Fusidic Acid 20mg+ Betamethasone as (Valerate) 1mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
24.	062471	Fusiwin-H Cream Each gram contains:- Fusidic Acid 20mg+ Hydrocortisone Acetate 10mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
25.	062472	Co-Arfentin Tablets Each tablet contains:- Artemether 20 mg + Lumefantrine 120 mg	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
26.	062473	Cycloderm Cream 5% Each tube contains:- Acyclovir 5%	16-02-2010	16-02-2015 10000/-	w.e.f. 16-02-2015 to 15-02-2020
27.	062474	Tretigen Capsules 20mg Each capsule contains:- Isotretinoin 20mg	16-02-2010	16-02-2015 10000/-	Deferred for confirmation of formulation is not approved in RRA.
28.	062475	Pantomax Capsules 40mg Each capsule contains:- Pantoprazole as Sodium Sesquihydrate Pellets 40mg	16-02-2010	16-02-2015 10000/-	Deferred for confirmation of source of pellets.
29.	062476	Kaynac Capsule Each capsule contains:-	16-02-2010	16-02-2015	Deferred for confirmation of

		Diclofenac Potassium Pellets eq.to Diclofenac Potassium 75mg		10000/-	source of pellets.
30.	062477	De-Artho Capsule Each capsule contains:- Diclofenac Sodium Enteric CoatedPellets eq. to Diclofenac Sodium…50mg	16-02-2010	16-02-2015 10000/-	Deferred for confirmation of source of pellets.
31.	062478	Fungex Capsule Each capsule contains:- Itraconazole Pellets eq. to Itraconazole 100mg	16-02-2010	16-02-2015 10000/-	Deferred for confirmation of source of pellets.
32.	062479	De-Artho Capsule Each capsule contains:- Diclofenac Sodium Enteric CoatedPellets eq. to Diclofenac Sodium…100mg	16-02-2010	16-02-2015 10000/-	Deferred for confirmation of source of pellets.
33.	062480	Peptomet Capsules 40mg Each capsule contains:- Esomeprazole Magnesium Trihydrate Pellets eq. to Esomeprazole ...40mg	16-02-2010	16-02-2015 10000/-	Deferred for confirmation of source of pellets.
34.	062481	Peptomet Capsules 20mg Each capsule contains:- Esomeprazole Magnesium Trihydrate Pellets eq. to Esomeprazole ...20mg	16-02-2010	16-02-2015 10000/-	Deferred for confirmation of source of pellets.

The firm submitted that the due date of renewal was 15-02-2015 i.e. Sunday, therefore the firm submitted the renewal application and fee on the next working day on 16-02-2015 i.e. Monday. The firm requested for the issuance of renewal.

Decision: Registration Board consided the above cases and decision is mentioned in last column above.

e) M/s Vetaria Pharmaceuticals 603 Q Block Johar Town Lahore.

Assistant Director (I&E) DRAP Lahore has informed that M/s Punjnad Pharma Pvt Limited Plot No. 13 Block C Ghalib Road Gulberg II Lahore has applied for the grant of clearance / NOC for the import of following finished drugs indented by M/s Vetaria Pharmaceuticals 603 Q Block Johar Town Lahore. The officer requested to verify the following:

i) The Registration and renewal status of above products.

ii) Any Post Registration Variations/changes in above products.

2. The details are as under:-

S. No.	Reg. No.	Name of Importer	Name of manufacturer	Product Name	Initial date of Registration	Due date	Application receiving date	Decision
1.	021484	M/s. Vetaria Pharmaceuticals, 128 A, G.O.R. V Faisal Town, Lahore	M/s Invesa International SA., Spain.	Tilosina Injectable solution 100ml	10-09-1998	09-09-2018	04-10-2018	W.e.f 10/09/2018 to 09/09/2023
2.	019982	M/s. Vetaria Pharmaceuticals, 128 A, G.O.R. V	M/s Invesa International SA., Spain.	Ganadexil 5% Injection 100ml	03-06-1997	02-06-2017	18-05-2017	W.e.f 03/06/2017 to 02/06/2022

		Faisal Town, Lahore						
3.	034515	M/s. Vetaria Pharmaceuticals, 603 Q Johar Town, Lahore	M/s Invesa International SA., Spain.	Rolenol Injectable solution 100ml	27-11-2004	26-11-2014 25-01-2015 (within sixty days with double fee)	26-01-2015	W.e.f 27-11-2014 to 26/11/2019
4.	034516	M/s. Vetaria Pharmaceuticals, 603 Q Johar Town, Lahore	M/s Invesa International SA., Spain.	Promectine Injectable solution 10ml, 50ml, 100ml, 250ml and 500ml	27-11-2004	26-11-2014 25-01-2015 (within sixty days with double fee)	26-01-2015	W.e.f 27-11-2014 to 26/11/2019

As per above mentioned details, it is submitted that renewal application for product at Sr. No. 1 was received after the due date but within sixty days which has been regularized by the Registration Board in its 290th meeting subject to prevailing Import Policy for Finished Drugs and Product at Sr. No.2 has been received within due date

However the product at Sr. No. 3 & 4 was also submitted after due date but within sixty days. The firm informed that due date was 25-01-2015 but due to public holiday (Sunday), the same was submitted on Monday i.e. 26-01-2015. The firm has also submitted differential fee in this regard. It is to mention that Registration Board has already considered and regularized various cases of renewal on same analogy. One of the example the regularization of case of M/s Ambrosia Pharmaceuticals Islamabad in 276th meeting of Registration Board. The firm further informed that they are facing huge demurrage charges on their above mentioned shipment and requested to consider their renewal application within time. The case was also referred to the Reg-I section for confirmation of Post Registration Variation (PRV) if any and they have informed that no PRV has been granted since the grant of registration, however transfer of registration application has been received.

Decision: Registration Board considered the above mentioned products and decision in mentioned in last column above.

f) <u>Cases of differetial fee for imported pellets</u>

i) M/s. Pharmedic Laboratories, (Pvt) Ltd., 16 Km Multan Road, Lahore

S. No.	Reg. No.	Product Name	Initial Reg. Date	Application Receiving Date
1.	**016744**	Lansor Capsule Each Capsule contains:- Lansoprazole … 30mg **Source of Pellets:-** (M/s. Spansules Formulations, Plot No. 154/A 41.D.A. Bollaram Medak Hyderabad -502325 Ahdhera Pradesh, India)	**27-08-1996**	**Due date** 26-08-2016 **Application receiving date** 17-08-201 with fee of Rs 10,000 as pellets are imported so the firm paid **Differential Fee of Source of Pelletsof Rs. 10,000/-** 02-07-2019 **Validity is w.e.f** **27-08-2016 to 26-08-2021**

ii) M/s. OBS Pharma Pakistan (Pvt) Ltd., Karachi.

S. No.	Reg. No.	Product Name	Initial Reg. Date	Application Receiving Date
1.	039680	Nexprazole 20mg Capsule Each capsule contains:- (Enteric coated pellets) of Esomeprazole Magnesium Trihydrate eq. to Esomeprazole …20mg **Source of Pellets:-** M/s. Trichem Bombay, India	28-11-2005 Transfer of Reg. 25-07-2009	**Due date** 24-07-2019 **Application Receiving date**26-03-2019 with a fee of Rs 10,000/- as pellets are imported so the firm paid the **Differential Fee of Source of Pellets of Rs. 10,000/-on** 05-07-2019
2.	039681	Nexprazole 40mg Capsule Each capsule contains:- (Enteric coated pellets) of Esomeprazole Magnesium Trihydrate eq. to Esomeprazole …40mg **Source of Pellets:-** M/s. Trichem Bombay, India	-do-	-do-

Decision: Registration Board consided the above cases and decision is mentioned in last column above.

g) <u>Regularization of cases received after expiry but within sixty days under Rule 27 of Drug (Licensing ,Registring&Advertising)Rule</u>

i) M/s. Genix Pharma (Pvt.) Ltd., Karachi

S. No.	Reg. No.	Product Name	Initial Reg. Date	Application Receiving Date
1.	061629	Movcol Sachet Each sachet contains:- Polyethylene Glycol 3350…13.125g Sodium Chloride … 0.3507g Sodium Bicarbonate … 0.1785g Potassium Chloride … 0.0466g	06-07-2010	**Due Date** 05-07-2015 **Application receiving date** 06-07-2015i.e after expiry but with sixty days with fee of Rs 10,000 now the firm submitted the **Differential fee of Rs.10,000/-on**15-07-2019 **Regularization from05-07-2015 to 04-07-2020**

ii) M/s. Selmore Pharmaceutical (Pvt) Ltd., Lahore

S. No.	Reg. No.	Product Name	Initial Reg. Date	Application Receiving Date
1.	**032206**	Punch Drench Each ml contains:- Oxyclozanide … 6.250gm Oxfendazole …. 2.265gm Cobalt … 0.167gm Selenium … 0.0050gm	**05-08-2004**	**Due date** 04-08-2014 **Application receiving Date**05-08-2014i.e after expiry but with sixty days with fee of Rs 10,000 now the firm submitted the **Differential fee of Rs. 10,000/-** 28-12-2018 **Regularization from 05-08-2014 to 04-08-2019**

Decision: Registration Board consided the above cases and decision is mentioned in last column above.

iii) M/s. Quaper (Pvt) Ltd., Sargodha

S. No.	Reg. No.	Product Name	Initial Reg. Date	Application Receiving Date
1.	048932	Neuromin Tablet Each tablet contains:- Mecobalamin … 500mcg	06-02-2008	**Due Date** 05-02-2018 **Application receiving date of year 2013 is** 06-02-2013i.e after expiry but with sixty days with fee of Rs 10,000 now the firm submitted theDifferential fee of Rs. 10,000/-on 11-01-2019(regularization of renwal of year 2013 is required **Regularization from 06-02-2013 till-05-02-2018**

Decision: Registration Board consided the above cases and decision is mentioned in last column above.

h) Case of M/s Berlex Lab International, Multan

M/s Berlex Lab international 10 Km Nangshah Chowk Karachi Road, Multan has applied for the renewal of year 2015&2016 of their following registered products.

S. No.	Reg. No.	Product Name	Date of Reg.	Application Receiving Date	Challan Amount
1.	062592	Acio Tablet 40mg	24-02-2010	Received through courier but evidence of courier is not provided by the firm however fee is submitted on 17-04-2015	20,000
2.	062599	Azelab 250mg	24-02-2010	-do-	20,000
3.	062600	Azelab 250mg capsule	06-06-2011	-do-	20,000
4.	062598	Beridal tablet 10mg	24-02-2010	-do-	20,000
5.	062608	BS Zole capsule 20mg	24-02-2010	-do-	20,000
6.	062606	BS Zole capsule 20mg	24-02-2010	-do-	20,000
7.	062594	Byrex Capsule 20mg	24-02-2010	-do-	20,000
8.	062607	Diclotal capsule 50mg	24-02-2010	-do-	20,000
9.	062609	Diclotal SR Capsule 100mg	24-02-2010	-do-	20,000
10.	062604	Diclotal SR Tablet 100mg	24-02-2010	-do-	20,000
11.	062593	Diclotal K Tablet 100mg	24-02-2010	-do-	20,000 Deregistered according to the concerned registration section
12.	062605	Lamizol Capsule 20mg	24-02-2010	-do-	20,000
13.	062601	Levobex tablet 500mg	24-02-2010	-do-	20,000
14.	062602	Levobex tablet 250mg	24-02-2010	-do-	20,000
15.	062597	Mosther Tablet	24-02-2010	-do-	20,000
16.	062589	Mosther Tablet	24-02-2010	-do-	20,000
17.	062603	Qubid Tablet 200mg	24-02-2010	-do-	20,000
18.	062590	Veoxy Tablet 250mg	24-02-2010	-do-	20,000
19.	062535	Veoxy Tablet 500mg	24-02-2010	-do-	20,000
20.	065979	Bexelex 30mg Tablet	18-10-2010	-do-	10,000
21.	071444	Bs-Pram 10mg Tablet	18-08-2011	-do-	10,000
22.	065981	Bercavir 0.5mg Tablet	18-10-2010	-do-	10,000
23.	071443	Para Tablet	18-08-2011	-do-	10,000
24.	065983	Diclotal 50mg Tablet	18-10-2010	-do-	10,000
25.	065984	Belex 5mg Tablet	18-10-2010	-do-	10,000

The case was referred to the concerned division and section for the confirmation of the licensing statusf, registration status, and verification of fee challan from Budget & Account Division and status of allocation of quota for their products containing controlled molecules the replies of these sections and Division are as under

i) Reply of Registration Section regarding status of registration:

Regarding registration status of the product R-V section replied that all the above mentioned products are found registered as per available record except product at **Sr. No. 11** which is **deregistered** upon request of the firm in M-231.Reference is unsigned copy provided by R-V Section.It is pertinent to mention here that no record regarding de-registration of said product is available in RRR-Section rather firm has also applied for its renewal of registration.

ii) Reply of Licensing Division:

Regarding status of license, Licensing Division informed that application of M/s. Berlex Labs International, Multan under renewal of DML No. 000678 (Formulation) for period of 18-12-2014 to 17-12-2019 is received as per Rule 6 of the Drugs (LR&A) Rules 1976 and License is valid till decision of the Central Licensing Board.

iii) Reply of Budget & Account Division:

Regarding verification of fee challan, Budget & Account Division requested to provide the duly endorsed/signed copy of performa and deposit slips by the office of undersigned to proceed the case. Moreover, M/s, Berlex Labs International, Multan may be asked to provide the dully signed performa/deposit slips duly attested by the firm,

However, Budget& Account Division has provided MIS report submitted by Allied Bank Limited, regarding products at Sr. No. 20-25

iv) Regarding verification of quota allocation of products at Sr. No. 23-25, reply of Controlled Drugs Division is still awaited.

The Original deposit slip (DRAP copy) verified by this office may please be provided, because the verification as per SOP only be done on original deposit slip/receipt. If original deposit slip (DRAP copy) is not traceable then please proceed in the light of 264th meeting of Registration Board. However detail from MIS report submitted by the Allied Bank Limited.

Original fee challans of products at **Sr. No. 01-19** have been retrieved from record submitted late but within 60 days with prescribed fee and need regularization from Registration Board. Products at **Sr. No. 05,06,08,09 & 12** are imported pellets. So, differential fee is required.

It is to mention that the fee challan does not bear name & registration number of products now the firm has submitted a request along with the under taking to consider the challan numbers against the products as mentioned below

Sr. No.	Reg. No.	Product Name	Date of Reg.	Challan Paid date	Challan Amount	Bank Challan Number	Decision
1.	062592	Acio Tablet 40mg	24-02-2010	17-04-2015	20,000	0046613	w.e.f 24-02-2015 to 23-02-2020
2.	062599	Azelab 250mg	24-02-2010	17-04-2015	20,000	0046614	w.e.f 24-02-2015 to 23-02-2020
3.	062600	Azelab 250mg capsule	06-06-2011	17-04-2015	20,000	0046615	w.e.f. 06-06-2016 to 05-06-2021
4.	062598	Beridal tablet 10mg	24-02-2010	17-04-2015	20,000	0046616	w.e.f 24-02-2015 to 23-02-2020
5.	062608	BS Zole capsule 20mg	24-02-2010	17-04-2015	20,000	0046617	Deferred for confirmation of

							source fixation letter
6.	062606	BS Zole capsule 20mg	24-02-2010	17-04-2015	20,000	0046618	Deferred for confirmation of source fixation letter
7.	062594	Byrex Capsule 20mg	24-02-2010	17-04-2015	20,000	0046619	w.e.f 24-02-2015 to 23-02-2020
8.	062607	Diclotal capsule 50mg	24-02-2010	17-04-2015	20,000	0046619	Deferred for confirmation of source fixation letter
9.	062609	Diclotal SR Capsule 100mg	24-02-2010	17-04-2015	20,000	0046620	Deferred for confirmation of source fixation letter
10.	062604	Diclotal SR Tablet 100mg	24-02-2010	17-04-2015	20,000	0046621	w.e.f 24-02-2015 to 23-02-2020
11.	062593	Diclotal K Tablet 75mg	24-02-2010	17-04-2015	20,000	0046622	Deregistred vide letter dated: 18-08-2011
12.	062605	Lamizol Capsule 20mg	24-02-2010	17-04-2015	20,000	0046623	Deferred for confirmation of source fixation letter
13.	062601	Levobex tablet 500mg	24-02-2010	17-04-2015	20,000	0046624	w.e.f 24-02-2015 to 23-02-2020
14.	062602	Levobex tablet 250mg	24-02-2010	17-04-2015	20,000	0046625	w.e.f 24-02-2015 to 23-02-2020
15.	062597	Mosther Tablet	24-02-2010	17-04-2015	20,000	0046626	w.e.f 24-02-2015 to 23-02-2020
16.	062589	Mosther Tablet	24-02-2010	17-04-2015	20,000	0046627	w.e.f 24-02-2015 to 23-02-2020
17.	062603	Qubid Tablet 200mg	24-02-2010	17-04-2015	20,000	0046628	w.e.f 24-02-2015 to 23-02-2020
18.	062590	Veoxy Tablet 250mg	24-02-2010	17-04-2015	20,000	0046630	w.e.f 24-02-2015 to 23-02-2020
19.	062535	Veoxy Tablet 500mg	24-02-2010	17-04-2015	20,000	0046631	w.e.f 24-02-2015 to 23-02-2020
20.	065979	Bexelex 30mg Tablet	18-10-2010	15-10-2015	10,000	0047208	w.e.f 18-10-2015 to 17-10-2020
21.	071444	Bs-Pram 10mg Tablet	18-08-2011	15-10-2015	10,000	0047209	w.e.f 18-08-2016 to 17-08-2021
22.	065981	Bercavir 0.5mg Tablet	18-10-2010	15-10-2015	10,000	0047210	w.e.f 18-10-2015 to 17-10-2020
23.	071443	Para Tablet	18-08-2011	15-10-2015	10,000	0047211	w.e.f 18-08-2016 to 17-08-2021
24.	065983	Diclotal 50mg Tablet	18-10-2010	15-10-2015	10,000	0047212	w.e.f 18-10-2015 to 17-10-2020
25.	065984	Belex 5mg Tablet	18-10-2010	15-10-2015	10,000	0047213	w.e.f 18-10-2015 to 17-10-2020

Decision: **Registration Board considered the renewal of above products and decisions are mentioned in the last column of above table.**

Item No. III Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A	Imported Human Biologicals from Reference Countries	2
B	Imported Human Biologicals from Non-Reference Countries	5
C	Imported Veterinary Biologicals from Reference Countries	2
D	Imported Veterinary Biologicals from Non Reference Countries	8
E	Local Veterinary Biologicals	1
F	Miscellaneous/ Deferred cases	83
Additional Agenda		31
Total		132

Sr. No.	Assistant Director	Designated No.	No. of Cases
a.	Mr. Khurram Khalid	AD-I	31
b.	Mr. Saadat Ali Khan	AD-II	49
c.	Mr. M. ZubairMasood	AD-III	52

A: Imported Human Biologicals from Reference Countries.

1.	**Name of Importer**	**Healthbee Projects (Pvt) Ltd** **65-S, Quaid-e-Azam Industrial Area Kot Lakhpat ,Distrct Lahore.**
	DSL details	License No.05-352-0065-036894D valid upto 5th September ,2020
	Name of Manufacturer	M/s Beijing Biological Products Institute Co., Ltd Beijing Economic and Technological Development Area,, Boxing 2 Road No.6,9. China
	Brand Name +Dosage Form + Strength	Bivalent Poliomyelitis (bOPV) Live Vaccine Type I Type III (Human Diploid Cell), Oral
	Composition	Active Ingredient (s) and Amount (s) per unit dose: Each dose (2 drops: 0.1mL) contains polio virus: Not less than $10^{6.0}CCID_{50}$ (or $6.01gCCID_{50}$), Type III: Not less than $10^{5.8}CCID_{50}$(or $5.81gCCID_{50}$)
	Finished product specifications	BP specifications/WHO specification
	Pharmacological Group	Human Oral Vaccine
	Shelf life	30 months when stored at -20 ^oC 15 months when stored at 2-8^oC
	International availability	
	Products already registered in Pakistan	Oral bivalent type 1 & 3 Poliomyelitis vaccine by Sanofi Pasture,Polio oral by Amson Vaccine & Pharma
	Type of Form Dy. No. Date of Application, Fee submitted	Dy.No.5021 (R&I) dated 2nd May, 2019 30th April, 2019 Fee Submitted: Rs.100,000/- dated 30th April, 2019
	Demanded Price / Pack size	As per DRAP policy/1's -2ml vial
	General documentation	• Legalized FSC issued by Beijing Food &Drug Administration 12-03-2019 valid for two years. • Legalized GMP Certificate issued by China Food & Drug Administration valid till 19-11-2020. • Legalized DMLNo.JING 20160276 dated 19-12-2018. • Legalized Marketing Authorization Letter dated 18-3-2019. • Legalized GMP Certificate No.CN20150191 dated 18-3-2019. • Legalized Explanation on the Change of Company Name dated 18-3-2019.
	Remarks of Evaluator	On the GMP Certificate the name of Manufacturer is mentioned as **BeiJing Bio-Institute Biological Products Co.,Ltd.** while all other documents including FSC and WHO prequalification website it is mentioned M/s Beijing Biological Products Institute Co., Ltd . The address is same in all the mentioned documents. And the firm has submitted explanation:

		"Due to the development needs, on December 6,2018, the company changed its name to M/s Beijing Biological Products Institute Co., Ltd. Since this change of name does not involve change in address and production process, with the approval of Beijing Drug Administration(Beijing FDA), ***M/s Beijing Biological Products Institute Co., Ltd*** *will continue to use the GMP certificate of* ***Beijing Bio-Institute Biological Products Co.,Ltd****until the certificate expires on November 19,2020.If the GMP certificate is required during such period, the "Notice of Name Change" issued by Beijing Administration for Industry and Commerce shall also be provided as evidence"* As evidence the firm has submitted the following Legalized documents; i. Notice for Name Change by Beijing Administration for Industry and Commerce
	Decision: Keeping in view the WHO Prequalification and valid legalized GMP & Free Sale Certificates 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 LDS pvt. Ltd. 111, Hali Road, Westridge 1, Rawalpindi, Pakistan
	DSL details	License No. 01-374-0176-041296D dated 07-03-2019 valid till 07-03-2021
	Name of Manufacturer	Manufacturer: M/s Lyocontract GMBH Pulverwiese, Trift, Ilsenburg, D-38871, Germany Marketing Authorization Holder: BiofactorGmbh Rudolf Huch Str 14, Bad Harzburg, D-38667, Germany
	Brand Name +Dosage Form + Strength	**Biofactor** Streptokinase 15,00,000 Powder for infusion
	Composition	Each vial contains: Streptokinase……15,00,000 IU
	Finished product specifications	BP specifications
	Pharmacological Group	Thrombolytic
	Shelf life	12 months when stored at 30 ^{0}C 36 Months Store below 25^{0}C (Stability study not provided as per Zone IV-A)
	International availability	Germany
	Products already registered in Pakistan	DURAKINASE INJECTION of M/s Medisure Karachi
	Type of Form Dy. No. Date of Application, Fee submitted	Form-5A Dy. No 6845 Dated 22-02-2018 Rs. 100,000/- Dated 22-02-2018
	Demanded Price / Pack size	Rs. 11,800/1's vial

	General documentation	**CoPP No.PP10138834**dated 23 July 2015 issued by MHRA UKdeclaring the free sale of applied product but does not conduct inspection of the facility. However it is mentioned in CoPP that the certifying regulatory has been satisfied by the applicant on all aspect of manufacture of the product including GMP. **GMP Certificate No.DE-ST-01-GMP-2017-0008 dated 3rd February,2017** issued by Landesverwaltungsamt Saxony-Anhalt Department of Public Health ,Pharmacy Ernst-Kamieth-Strabe 2 06112 Halle/ Saale Germany.
	Remarks of Evaluator	i. Submitted Letter of authorization to M/s LDS pvt. Ltd Pakistan from M/s Karma Pharmatech GmbH Germany, which is neither manufacturer nor Product license holder. The firm submitted a copy of letter indicating that the transfer of MAH is Already fixed by contract and the transfer is scheduled in 4th quarter in name of M/s Karma Pharmatech GmbH. ii. Clinical data is not provided and M/s LDS pvt. Ltd submitted that applied product is generic hence no need of clinical data.
	Decision: **Registration Board deferred the case for submission of following by the firm:** **a. Valid legalized CoPP issued by concerned regulatory authority** **b. Clarification of difference of product license holder on CoPP and letter of authorization** **c. Clinical trial data Or any legalized document from regulatory body of country of origin indicating that clinical trial is not necessary for Streptokinase.**	

B: Imported Human Biologicals from Non Reference Countries.

1.	**Name of Importer**	HAEMTECH MEDICA PRIVATE LIMITED Address: M-3, Data Centre, 125-U Block 2 PECHS,Karachi-75400, Pakistan
	DSL details	License No. 10799, Valid: 29th October 2020 Qualified Person: Saba Inayat Ali (D.Pharm**)**
	Name of Manufacturer	Boya Bio-pharmaceutical Group Co." Ltd. Address: No.333, Huiquan Road. Hi-tech lndustrial Park, Fuzhou, Jiangxi, China
	Brand Name +Dosage Form + Strength	BOYA IVIG-5% (5 gram /100 ml) Injection for Intravenous Use (IV) use
	Composition	Each vial of 100 ml Contains ……..5 gram of IVIG
	Finished product specifications	BP Specification
	Pharmacological Group	Normal Human Immunoglobulin
	Shelf life	36 months from the date of manufacturing Storage Condition: Store in between 2-8 degree Celsius
	International availability	Gamma Plex 5% -100ml (Bioproduct UK)
	Products already registered in Pakistan	
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 27526 (R&I) Dated 10th August 2018 Rs. 100,000/- 10th August, 2018
	Demanded Price / Pack size	PKR. 56,000/- for each pack containing IVIG 5% in 100 ml

	General documentation	i. Legalized Free Sale Certificate Valid upto 28/01/2020 issued by Jiangxi Province Food & Drug Administration. ii. Legalized GMP Certificate No. JX20170025 valid up to 10/07/2022 issued by China Food & Drug Administration. iii. Legalized Approval for Drug Re-registration No.2015R002316 dated 16/09/2015 issued by Jiangxi Province Food & Drug Administration. iv. Legalized Approval for Supplementary Drug Application No.G.B.201700249 dated 25/09/2017issued by Jiangxi Province Food &Drug Administration. v. Legalized CoPP no.2017004 Valid upto 02/11/2019 but issuing authority is not clear (Stamp in Chinese without Translation)
	Remarks of Evaluator	• Strength & Composition is not mentioned on Free Sale Certificate only Generic Name & Product No is mentioned but the submitted Legalized Approval for Drug Re-registration letter and approval for supplementary Drug Application issued by the concerned Regulatory Authority (by Jiangxi Province Food & Drug Administration.) the strength is mentioned.
	Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the productsubject to compliance of current Import Policy for finished drugs. Before issuance of registration letter, the firm will submit valid legalized CoPP indicating composition of the product; Chairman Registration Board is authorized for issuance of registration letter.	
2.	Name of Importer	HAEMTECH MEDICA PRIVATE LIMITED Address: M-3, Data Centre, 125-U Block 2 PECHS,Karachi-75400, Pakistan.
	DSL details	License No. 10799, Valid: 29th October 2020 Qualified Person: Saba Inayat Ali (D.Pharm)
	Name of Manufacturer	Boya Bio-pharmaceutical Group Co." Ltd. Address: No.333, Huiquan Road. Hi-tech lndustrial Park, Fuzhou, Jiangxi, China.
	Brand Name +Dosage Form + Strength	BOYA IVIG-5% (2.5 gram /50 ml) Injection for Intravenous
	Composition	Each vial of 50 ml Contains ……..2.5 gram of IVIG
	Finished product specifications	BP Specification
	Pharmacological Group	Normal Human Immunoglobulin
	Shelf life	36 months (2^0-8^0C)
	International availability	Gamma Plex 5% -50ml (Bioproduct UK)
	Products already registered in Pakistan	IV SN Globulin Injection of M/s Hi-Warble.
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 27527 (R&I) Dated 10th August 2018 Rs. 100,000/- 10th August, 2018.
	Demanded Price / Pack size	PKR. 28,000/- for each pack containing IVIG 5% in 50 ml
	General documentation	i. Legalized Free Sale Certificate Valid upto 28/01/2020 issued by Jiangxi Province Food & Drug Administration. ii. Legalized GMP Certificate No. JX20170025 valid up to 10/07/2022 issued by China Food & Drug Administration. iii. Legalized Approval for Drug Re-registration No.2015R002316 dated 16/09/2015 issued by Jiangxi Province Food & Drug Administration. iv. Legalized Approval for Supplementary Drug Application No.G.B.201700249 dated 25/09/2017 issued by Jiangxi Province Food &

		Drug Administration. v. Legalized CoPP no.2017004 Valid upto 02/11/2019 but issuing Authority is not clear (Stamp in Chinese without Translation).
	Remarks of Evaluator	Strength & Composition is not mentioned on Free Sale Certificate only Generic Name & Product No is mentioned but the submitted Legalized Approval for Drug Re-registration letter and approval for supplementary Drug Application issued by the concerned Regulatory Authority (by Jiangxi Province Food & Drug Administration.) the strength is mentioned.
	Decision: Keeping in view valid legalized CoPP indicating product availability in country of origin; Registration Board approved the productsubject to compliance of current Import Policy for finished drugs. Before issuance of registration letter, the firm will submit valid legalized CoPP indicating composition of the product; Chairman Registration Board is authorized for issuance of registration letter.	
3.	**Name of Importer**	**Nees International ,Office No.6, 3rd Floor Al-Hafeez View Sir Syed Road Gulberg-III, Lahore.**
	DSL details	License No. 171-A/GT/11/2017, Valid: 14 June, 2019 Qualified Person: Umair Ikram Dar
	Name of Manufacturer	Hugel, Inc. Address: 23 Geodudanji 1-gil, Dongnae-myeon,Chuncheon-si Gangwon-do, Republic of Korea
	Brand Name +Dosage Form + Strength	Botulax Inj (100 units/ /vial) Lyophilized powder for injection
	Composition	Each vial (100 units) Contains….Clostridium botulinum toxin type A (CBFC26 strain)-------100 units
	Finished product specifications	BP specification
	Pharmacological Group	Muscle relaxant, peripherally acting agent
	Shelf life	36 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Botox Injection
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. (R&I) Dated 6th February 2018 Rs. 100,000/-6th February, 2018
	Demanded Price / Pack size	$60+ 10%FOC /100 units Vial
	General documentation	Legalized CoPP No.2017-A1-2061 dated 16-10-2017 Legalized GMP No. 2017-B1-0313 dated 27-06-2017 Copy of distribution Agreement
	Remarks of Evaluator	
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Evidence of availability of formulation in reference regulatory authorities along with approved indications.** **b. Medical indication of the product as approved by regulatory authority of manufacturer.**	
4.	Name of Importer	Nees International ,Office No.6, 3rd Floor Al-Hafeez View Sir Syed Road Gulberg-III, Lahore.
	DSL details	License No. 171-A/GT/11/2017, Valid: 14 June, 2019 Qualified Person: Umair Ikram Dar
	Name of Manufacturer	Hugel, Inc. Address: 23 Geodudanji 1-gil, Dongnae-myeon,Chuncheon-si Gangwon-do,

		Republic of Korea
	Brand Name +Dosage Form + Strength	Botulaxinj (50 units/ /vial) Lyophilized powder for injection
	Composition	Each vial (50 units) Contains….Clostridium botulinum toxin type A (CBFC26 strain)-------50 units
	Finished product specifications	**BP specification**
	Pharmacological Group	Muscle relaxant, peripherally acting agent
	Shelf life	36 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 5615 (R&I) Dated 11thFebruary 2019 Rs. 100,000/- 7th February, 2019
	Demanded Price / Pack size	$37.5+ 10% FOC/100 units Vial
	General documentation	CoPP No.2017-A1-2062 dated 16th October,2017 Legalized GMP No. 2017-B1-0313 dated 27-06-2017 Copy of distribution Agreement
	Remarks of Evaluator	
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Evidence of availability of formulation in reference regulatory authorities along with approved indications.** **b. Evidence of availability of formulation in Pakistan.** **c. Medical indication of the product as approved by regulatory authority of manufacturer.**	
5.	**Name of Applicant**	M/s Genome Pharmaceuticals Pvt. Ltd House No.593-B, St # 10, Chakalala Scheme III.
	DSL details	DSL No.01-374-0176-035673D valid upto 28-08-2020.
	Name of Manufacturer	**BELMEDPREPARATY,** Republic Unitary Production Enterprise, 30, Fabritsius Str., 220007 Minsk, The Republic of Belarus.
	Brand Name +Dosage Form + Strength	**CEREBROLYZATE** Solution for Injection Hydrolyzate of cattle and pig brain, which contains peptides and amino acids (on basic of dry matter) total - 47-77 mg
	Composition	Content per one ml: Hydrolyzate of cattle and pig brain which contains peptides and amino acids(on basic of dry matter), total…… 47-77mg Total amino acids…….27-42mg Including each amino acids: L-Lysine……0.4-5.5 mg L-Histidine……0.3-4.5 mg L-Arginine…….0.8-5.4 mg L-Aspartic acid……..1.0-3.5 mg L-Threonine……...0.7-4.2 mg L-Serine…….0.4-3.5 mg L-Glutamic acid…….3.0-6.5 mg L-Alanine……...0.8-5.2 mg

		L-Proline……0.4-4.2 mg Glycine……...0.7-2.1 mg L-Valine……1.3-4.1 mg L-Methionine……0.4-2.0 mg L-Leucine……...2.0-6.0 mg L-Phenylalanine……0.4-2.0 mg L-Isoleucine……....0.8-3.6 mg L-Tyrosine……..0.2-0.7 mg
	Finished product specifications	
	Pharmacological Group	Other psychostimulants and nootropics
	Shelf life	3 Years (below 25ºC)
	International availability	
	Alternate Products already registered in Pakistan	Cerebrolysine of M/s BioLabs, Multan.
	Type of Form Dy. No. Date of Application, Fee submitted	Form 5-A. Dy.No.1467/(R&I) DRAP dated 14th Jan, 2019. NIL 100,000/-
	Demanded Price / Pack size	Not provided 5x5ml ampoule
	General documentation	1. Legalized CoPP no. 116-2016/CPP/PK issued May 17, 2016 2. Copy of GMP
	Remarks of Evaluator	1. It is hydrolysate of free amino acids extracted from porcine and cattle. 2. Periodicity of inspection mentioned in CoPP is 3 years and has been issued on May 17, 2016. 3. GMP is copy and expired. 4. As per information on form 5A, product is registered in following Muslim countries; i. Azerbaijan ii. Turkmenistan iii. Republic of Uzbekistan 5. Clinical data is not provided 6. Stability data protocol & accelerated stability data are not provided. Moreover, the provided data is below 25Cº±60 and not as per phase-4 requirement. 7. As per submitted documents the product is indicated for; Alzheimer disease, dementia syndrome of various genesis; chronic cerebrovascular failure; ischemic stroke and tis complications; brain injuries. 8. Typo error of "Solytion" instead of "Solution" on label. 9. Composition Difference of Cerebrolysin (Austria) Vs. Cerebrolyzate (Belarus) is as under:

Amino Acid	**Cerebrolysin**	**Cerebrolyzate**
Lysine	5.98	4.96
Histidine	1.16	0.92
Arginine	0.49	0.99
Aspartic acid	3.18	2.23
Threonine	0.33	1.82
Serine	0.33	1.11
Glutamic acid	4.14	4.96

			Alanine	3.11	2.93
			Proline	2.05	1.37
			Glycine	1.46	1.08
			Valine	3.11	2.11
			Methionine	0.49	0.99
			Leucine	6.15	3.10
		10. Soft documents not attached.			
	Decision: **Registration Board deferred the case for submission of following by the firm:** **a. Confirmation of source of active ingredient either porcine or cattle.** **b. Clinical trial data.** **c. Real time and accelerated stability studies data on Zone-IVA conditions.** **d. Evidence of availability of formulation in reference regulatory authorities.** **e. Evidence of availability of formulation in Pakistan.** **f. Soft copy of the registration application.**				

C: Imported Veterinary Biologicals from Reference Countries.

1.	Name of Importer	M/s. Hipra Pakistan (Private) Limited, Office no. 3&4, 5th floor, 105-B-II,Ali Tower, M.M Alam Road, Gulberg, Lahore
	DSL details	License to sell drug as Distributor No. 0011000 0001301 valid upto 30-01-2020
	Name of Manufacturer	M/S LABORATORIOS HIPRA, S.A. Carretera C-63, Km 48,300, poligono Industrial El Rieral, Amer, 17170 Gerona Espana (Spain) **Translation as per Google translator:** LaboratoriosHipra, S.A. road C-63,300, Poligono Industrial El Rieral, Amer, 17170 Gerona Espana. **Address as per Authorization Letter/Form-5A:** M/S LABORATORIOS HIPRA, S.A.de La Selva, 135, 17170 Gerona Espana (Spain)
	Brand Name +Dosage Form + Strength	**Gumbohatch**Suspension for injection,lyophilisate
	Composition	Each dose contains:- Live attenuated IBD Virus, strain 1052…….10exp.1.48- 10exp.2.80 PU
	Finished product specifications	BP Specification
	Pharmacological Group	Oily Emulsion Veterinary viral Vaccine
	Shelf life	24 months(2^0C-8^0C)
	International availability	Not Provided
	Products already registered in Pakistan	Transmune IBD (Ceva France) Bursaplex (Zoetis US)
	Type of Form Dy. No & Date of application, Fee submitted	Form-5A Dy. No. 37705 (R&I) Dated 14th November, 2018 Rs. 100,000/- Dated 14th November 2018
	Demanded Price / Pack size	Decontrolled/ 5,000 Doses (500mL Vial)
	General documentation	CoPP No.26015/2018 dated 17th May,2018

	Remarks of Evaluator	i. The product is not licensed to be placed in the country of origin as per CoPP. Reason mentioned on CoPP is Commercial reasons for lacking market authorization. ii. Address of Manufacturer on CoPP is different from Form-5A& Letter of Authorization.
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Evidence of availability of product in reference regulatory authorities.** **b. Clarification regarding the difference in address of manufacturer on CoPP from Form-5A & Letter of Authorization.**	
2.	**Name of Applicant**	**M/s Eli Lilly Pakistan (Private) Limited** 5-A, 5th Office Floor, Al-TijarahCenter, 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal, Karachi.
	DSL details	DSL Certificate No. 00501 valid up to2nd January 2020
	Name of Manufacturer	Lohmann Animal Health International 375 China Road, Winslow, ME04901, United States of America.
	Brand Name +Dosage Form + Strength	**AviPro ND-IB Polybanco** Newcastle–Bronchitis Vaccine, B1 Type, B1 Strain, Mass. and Conn. Types, Live Virus
	Composition	The minimum antigen content per dose of the above product at release is as follows: Newcastle disease virus…..……..$10^{6.0}$ EID_{50} B1 Type, B1 Strain Infectious Bronchitis Virus…....$10^{3.5}EID_{50}$ Mass. Type, M-48 Strain Conn. Type The minimum antigenic content per dose of the above product at expiration when stored according to label recommendations is as follows: Newcastle disease virus…..……..$10^{5.5}$ EID_{50} B1 Type, B1 Strain Infectious Bronchitis Virus…....$10^{3.1}EID_{50}$ Mass. Type, M-48 Strain Conn. Type EID_{50} = 50% Embryo Infectious Dose
	Finished product specifications	BP
	Pharmacological Group	Veterinary Vaccine
	Shelf life	21 Months (Store at 2°C to 7°C)
	International availability	USA, Argentina, Canada, Malaysia
	Products already registered in Pakistan	MEDIVAC ND-IB VACCINE
	Type of Form Dy. No. Date of Application, Fee submitted	Dy.No.721/AD(BD) dated 17thJuly, 2018 27th Feb, 2019
	Demanded Price / Pack size	10x 2500 doses/ De-Controlled.
	General documentation	Legalized Certificate of Licensing & Inspection issued by United States Department of Agriculture Animal & Plant Health Inspection dated 6-7-2017.

	Remarks of Evaluator	1. Accelerated stability data not provided. 2. Registration Board in its 286th meeting adopted theEuropean framework for stability testing of vaccines for veterinary use developed in the light of European Pharmacopoeia 9.5 (General Monograph (0062)and European Directive 2001/82/EC (II-Title) for all veterinary vaccines which states that the stability should be evaluated under the recommended storage conditions. As the storage conditions of vaccines is 2-8^{0}C (unless otherwise stated), the European Pharmacopoeia requires to perform the stability studies only at 2-8^{0}C. Moreover, the European Directive 2001/82/EC (II-Title) does not require performing accelerated stability studies for vaccines.
	Decision: Keeping in view valid legalized Certificate of Licensing & Inspection indicating product availability in country of origin; Registration Board approved the productsubject to compliance of current Import Policy for finished drugs.	

D: Imported Veterinary Biologicals From Non Reference Countries.

1.	**Name of Importer**	**M/s Uranus Biotech (Private) Limited, Office No. 112, First Floor, Arooj Arcade, Sector F-10 Markaz, Islamabad**
	DSL details	License No. DSL-839-ICT/2013 dated 26-02-2018 valid till 25-02-2018
	Name of Manufacturer	M/s Chongqing Auleon Biologicals Co. Ltd., The Fourth Branche Road, Banqiao Industrial Park, Rongchang District, Chongqing, P.R. China.
	Brand Name +Dosage Form + Strength	Echinococcosis Recombinant Subunit Vaccine (Sheep & goats)
	Composition	Each dose contains: Eg95 antigen……50µg
	Finished product specifications	Innovator Specifications
	Pharmacological Group	Veterinary Vaccine
	Shelf life	12 months (2^{0}C-8^{0}C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 10322, 29965, 7518& 3293 Dated: 20-03-2018, 06-09-2018, 20-02-2019&11-04-2019 Rs. 100000/- dated 14-03-2018
	Demanded Price / Pack size	1's Vial (40 doses)/ De-controlled.
	General documentation	Valid legalized GMP certificate No. (2016) GMP 23013 dated 21-12-2016 valid till 20-12-2021 Legalized Free Sale Certificate dated 23-11-2017 valid till 22-11-2018.
	Remarks of Evaluator	a. The provided FSC was valid at the time of submission but it is now expired. b. The firm submitted that it is the only commercial vaccine for the prevention of echinococcosis so it is not available in any pharmacopoeia.
	Decision: Registration Board deferred the case for submission of following by the firm: a. Valid legalized Free Sale Certificate. b. Evidence of availability of product in reference regulatory authorities &other countries.	
2.	**Name of Importer**	**M/s Uranus Biotech (Private) Limited, Office No. 112, First Floor, Arooj Arcade, Sector F-10 Markaz, Islamabad**
	DSL details	License No. DSL-839-ICT/2013 dated 26-02-2018 valid till 25-02-2018

	Name of Manufacturer	M/s Chongqing Auleon Biologicals Co. Ltd., The Fourth Branche Road, Banqiao Industrial Park, Rongchang District, Chongqing, P.R. China.
	Brand Name +Dosage Form + Strength	Brucellosis Vaccine, Live (Strain A19)
	Composition	Each dose contains: Brucella strain A19…… not less than $6.0x10^{10}$CFU
	Finished product specifications	Chinese Pharmacopoeia
	Pharmacological Group	Veterinary Vaccine
	Shelf life	12 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 10323, 29965, 7517 & 3295 Dated: 20-03-2018, 06-09-2018, 20-02-2019& 11-04-2019 Rs. 100000/- dated 14-03-2018
	Demanded Price / Pack size	1's Vial (5 doses)/ De-controlled.
	General documentation	Valid legalized GMP certificate No. (2016) GMP 23013 dated 21-12-2016 valid till 20-12-2021 Legalized Free Sale Certificate dated 23-11-2017 valid till 22-11-2018.
	Remarks of Evaluator	a. The provided FSC was valid at the time of submission but it is now expired. b. The firm submitted that they will follow Chinese Pharmacopoeia specifications for finished product. c. The firm has not provided the clinical trial data and submitted that clinical trial data is not required for pharmacopoial products in China.
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Valid legalized Free Sale Certificate.** **b. Evidence of availability of product in reference regulatory authorities &other countries.** **c. Clinical trial data Or any legalized document from regulatory body of country of origin indicating that clinical trial is not necessary for Pharmacopoeial vaccines.**	
3.	**Name of Importer**	**M/s Uranus Biotech (Private) Limited,** **Office No. 112, First Floor, Arooj Arcade, Sector F-10 Markaz, Islamabad**
	DSL details	License No. DSL-839-ICT/2013 dated 26-02-2018 valid till 25-02-2018
	Name of Manufacturer	M/s Chongqing Auleon Biologicals Co. Ltd., The Fourth Branche Road, Banqiao Industrial Park, Rongchang District, Chongqing, P.R. China.
	Brand Name +Dosage Form + Strength	Brucellosis Vaccine, Live (Strain S2)
	Composition	Each dose contains: Brucella strain S2…… not less than $1x10^{10}$CFU
	Finished product specifications	Chinese Pharmacopoeia
	Pharmacological Group	Veterinary Vaccine
	Shelf life	12 months (2^0C-8^0C)
	International availability	China

	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 10324, 29965, 7519 & 3294 Dated: 20-03-2018, 06-09-2018, 20-02-2019 & 11-04-2019 Rs. 100000/- dated 14-03-2018
	Demanded Price / Pack size	1's Vial (40 doses)/ De-controlled.
	General documentation	Valid legalized GMP certificate No. (2016) GMP 23013 dated 21-12-2016 valid till 20-12-2021 Legalized Free Sale Certificate dated 23-11-2017 valid till 22-11-2018.
	Remarks of Evaluator	a. The provided FSC was valid at the time of submission but it is now expired. b. The firm submitted that they will follow Chinese Pharmacopoeia specifications for finished product. c. The firm has not provided the clinical trial data and submitted that clinical trial data is not required for pharmacopoial products in China.
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Valid legalized Free Sale Certificate.** **b. Target animal for which the vaccine will be used.** **c. Evidence of availability of product in reference regulatory authorities & other countries.** **d. Clinical trial data Or any legalized document from regulatory body of country of origin indicating that clinical trial is not necessary for Pharmacopoeial vaccines.**	
4.	**Name of Importer**	**M/s Uranus Biotech (Private) Limited,** **Office No. 112, First Floor, Arooj Arcade, Sector F-10 Markaz, Islamabad**
	DSL details	License No. DSL-839-ICT/2013 dated 26-02-2018 valid till 25-02-2018
	Name of Manufacturer	M/s Chongqing Auleon Biologicals Co. Ltd., The Fourth Branche Road, Banqiao Industrial Park, Rongchang District, Chongqing, P.R. China.
	Brand Name +Dosage Form + Strength	Pseudorabies Vaccine, Live (Strain Bartha-K61)
	Composition	Each dose contains: Pseudorabies attenuated strain Bartha K-61…… not less than $5.0x10^{3.0}TCID_{50}$
	Finished product specifications	Chinese Pharmacopoeia
	Pharmacological Group	Veterinary Vaccine
	Shelf life	12 months (2^0C-8^0C)
	International availability	China
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 10325, 29965, 7520& 3293 Dated: 20-03-2018, 06-09-2018, 20-02-2019 & 11-04-2019 Rs. 100000/- dated 14-03-2018
	Demanded Price / Pack size	1's Vial (20 doses)/ De-controlled.
	General documentation	Valid legalized GMP certificate No. (2016) GMP 23013 dated 21-12-2016 valid till 20-12-2021 Legalized Free Sale Certificate dated 23-11-2017 valid till 22-11-2018.
	Remarks of Evaluator	a. The provided FSC was valid at the time of submission but it is now expired. b. The firm submitted that they will follow Chinese Pharmacopoeia specifications for finished product.

		c. The firm has not provided the clinical trial data and submitted that clinical trial data is not required for pharmacopoial products in China.
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Valid legalized Free Sale Certificate.** **b. Target animal for which the vaccine will be used.** **c. Evidence of availability of product in reference regulatory authorities & other countries.** **d. Clinical trial data Or any legalized document from regulatory body of country of origin indicating that clinical trial is not necessary for Pharmacopoeial vaccines.** **e. Prevalence of disease in Pakistan**	
5.	**Name of Importer**	**M/s ZS Biotech,** **22-A Hidayatullah Block Mustafa Town Wahdat Road, Lahore**
	DSL details	License No. 05-352-0066-027355D, isuued on 20-01-2018, valid till 20-01-2020
	Name of Manufacturer	M/s Zhaoqing Dahuanong Biology Medicine Co., Ltd., No. 5 Chuangye Road, High-tech Development District, Zhaoqing City, Guandong, China
	Brand Name +Dosage Form + Strength	Sinovac ND+H9 Inactivated
	Composition	Main Ingredient & Content: Inactivated Newcastle Disease virus La Sota strain……$\geq 10^{8.0}EID_{50}$/0.1ml Inactivated Avian Influenza virus H9 subtype SS/94 strain……..$10^{7.0}EID_{50}$/0.2ml
	Finished product specifications	As per Innovator Specs
	Pharmacological Group	Veterinary Vaccine
	Shelf life	12 months (2^0C-8^0C)
	International availability	Not Provided.
	Products already registered in Pakistan	New Castle Disease and Avian Influenza (H9N2 Subtype) Vaccine, Inactivated of M/s Vet line International, Lahore. GPVAC ND-FLU 9(A) Injection of M/s Grand Pharma, Rawalpindi
	Type of Form Dy No & Date of application, Fee submitted	Dy. No. 2703 & 7065 Dated 04-04-2019 & 23-05-2019 Rs. 10000/- Dated: 04-04-2019
	Demanded Price / Pack size	1's Vial (500ml)/ De-controlled
	General documentation	Valid legalized GMP Certificate No. (2016) GMP 19028 dated 14-07-2016 valid till 13-07-2021. Legalized Free Sale dated 20-07-2016.
	Remarks of Evaluator	
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Complete description of strain of Avian Influenza virus including N subtype.** **b. Legalized approval of concerned regulatory authority of said strain of Avian Influenza virus.**	
6.	**Name of Importer**	**M/s Hi-Tech Pharmaceuticals, 1-C Shadman Chowk, Jail Road, Lahore, Pakistan**
	DSL details	CDSL No: 05-352-0063-037052D Expiry Date: 11-Oct-2020 Place: Lahore
	Name of Manufacturer	Zoetis Industria De ProdutosVeterinarios Ltda. Estrada Luiz Fernando Rodriguez, 1701 Campinas,Sao Paulo, Brazil.

	Brand Name +Dosage Form + Strength	**Brand Name: Chick NK** Dosage Form: Subcutaneous Injection Strength: Inactivated Newcastle Viral Fluid GMT HI ≥1:16
	Composition	Each dose contains:- Inactivated Newcastle Viral Fluid…….GMT HI ≥ 1:16
	Finished product specifications	BP Specification
	Pharmacological Group	Oily Emulsion Veterinary viral Vaccine
	Shelf life	24 months from the date of manufacturing Storage Condition: Store in between 2-8 degree Celsius
	International availability	Not Provided
	Products already registered in Pakistan	Not Available
	Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No. 18537 (R&I) Dated 19th October 2017 Rs. 100,000/- Dated 19th October 2017
	Demanded Price / Pack size	Decontrolled/ 5,000 Doses (500mL Vial)
	General documentation	• Legalized Certificate: ExclusiveManufacturing Authorization for Export issued by Ministry of Agriculture, Livestock and Supply Livestock inputs Inspection (SFA-SP), Sao Paulo, BrazilDated 30-05-2017 & 17-10-2018 • GMP Declaration on the letter head of the company(Principle Manufacturer)
	Remarks of Evaluator	i. The Certificate provided by the firm it is clearly mentioned that the said product is not freely available and certificate is issued for Export Purpose only. **Justification submitted by the firm:** **The overseas principle (M/s Zoetis Brazil) submitted which is reproduced as under:** "Through its technical responsible, declares that the Chick NK is an oily vaccine against Newcastle disease that is used in the regions that suffers disease outbreak with severe challenges. Brazil has no commercial interest/does not have a license, due to has not had Newcastle disease outbreak for many years, however, we conduct the control and prevention of Newcastle disease in accordance with instruction normative 17 (April 7 2006), thus for disease control and prevention we perform the vaccination of chicks with Live soft Vaccines (lentogenic) and not with oily Vaccines." ii. No GMP certificate is provided instead GMP Declaration on the letter head of the company (Principle Manufacturer) is provided. iii. Clinical Trial Data is not provided
	Decision: Registration Board deferred the case for submission of following by the firm: **a. Evidence of availability of product in reference regulatory authorities.** **b. Newcastle disease virus type** **c. Data of prevalence of Newcastle disease in Pakistan.**	
7.	**Name of Importer**	M/s Forward Solutions (Animal Health Company) Plot No.19-B, Off Abdul Sattar Eidhi Road, Near Qazalbash Chowk, Lahore-Pakistan
	DSL details	DSL No. 05-352-0066-028137D valid till 10 Feb 2020
	Name of Manufacturer	**ATAFEN** Ata Fen VeterinerMalzemeleriHayvancilik Paz. San. Ve Tic. A.S. OSB Mah. 21 Sok. No.7/A 35735 Kemalpasa – Izmir / Turkey
	Brand Name +Dosage Form + Strength	**VBR COLI SERA + C COMBINED SERUM ANTIBODY**

<table>
<tr><td></td><td>Composition</td><td><u>Active Substance:</u>

Each 1 ml of vaccine contains:
Escherichia coli K99 …….…….≥ 1/640 AU
Clostridium perfringens Type C antibodies…….≥ 50 IU</td></tr>
<tr><td></td><td>Finished product specifications</td><td></td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Veterinary Biologicals (Antibody Serum)</td></tr>
<tr><td></td><td>Shelf life</td><td>24 Months (Store at 2°C -8°C)</td></tr>
<tr><td></td><td>International availability</td><td>Turkey, Azerbaijan.</td></tr>
<tr><td></td><td>Products already registered in Pakistan</td><td></td></tr>
<tr><td></td><td>Type of Form
Dy. No.
Date of Application, Fee submitted</td><td>Form 5-A
Dy.No.1377/AD(BD) dated 3rdDecember, 2018
30thNov, 2018
Fee Submitted: Rs.100,000/-</td></tr>
<tr><td></td><td>Demanded Price / Pack size</td><td>100 ml vial / decontrolled</td></tr>
<tr><td></td><td>General documentation</td><td>• Free Sale Certificate issued by Ministry of Food Agriculture and Livestock General Directorate of Food and Control, Turkey valid upto 26-12-2022.
• Copy of GMP Certificate having Certificate No.GMP/TR/V/Yi/S0065/2017 issued by Ministry of Food Agriculture and Livestock of Turkey dated 03-03-2017.</td></tr>
<tr><td></td><td>Remarks of Evaluator</td><td>1. GMP certificate was valid at the time of submission but it is expired now.
2. Free sale certificate is not legalized and notarized.
3. Stability data is of three trial batches
4. Addresses mentioned on GMP & FSC are as under;

<table><tr><th>GMP</th><th>Free Sale Certificate</th></tr><tr><td><u>Manufacturer:</u>
i. Ata Fen VeterinerMalz Hay Paz. San. Ve Tic. A.S.
<u>Site Address:</u>
ii. OSB Mah. 21 Sokak No.7/A UlucakKemalpasa – IZMIR</td><td><u>License Holder and Manufacturer address:</u>
i. Ata Fen VeterinerMalzemeleriHayvancilik Paz. San. Ve Tic. A.S.
ii. OSB Mah. 21 Sok. No.7/A 35735 Kemalpasa – Izmir / Turkey</td></tr></table></td></tr>
<tr><td></td><td colspan="2">Decision: Registration Board deferred the case for submission of following by the firm:
a. Valid legalized GMP and Free Sale Certificates.
b. Stability studies data of commercial batches
c.Clarification regarding two manufacturing sites mention on GMP.</td></tr>
<tr><td>8.</td><td>Name of Importer</td><td>M/s Forward Solutions
(Animal Health Company)
Plot No.19-B, Off Abdul Sattar Eidhi Road, Near Qazalbash Chowk, Lahore-Pakistan</td></tr>
<tr><td></td><td>DSL details</td><td>DSL No. 05-352-0066-028137D valid till 10 Feb 2020</td></tr>
<tr><td></td><td>Name of Manufacturer</td><td>ATAFEN
Ata Fen VeterinerMalzemeleriHayvancilik Paz. San. Ve Tic. A.S.
OSB Mah. 21 Sok. No.7/A 35735 Kemalpasa – Izmir / Turkey</td></tr>
<tr><td></td><td>Brand Name +Dosage Form + Strength</td><td>VBR COLIMIX 9
CombinedClostridium novyiType A, Clostridium septicum, Clostridium sordelli, Clostridium perfringernsType B, C, D, Clostridium chauvoei, Clostridium haemolyticumand Escherichia coli Bacterin& Toxoid.</td></tr>
</table>

<table>
<tr><td></td><td>Composition</td><td><u>(As per Marketing Authorization Letter dated 12-4-2010).</u>

<u>Active Ingredient:</u>
2ml of the vaccine provide 75% minimum immune response against Clostridumhaemolyticum antigen in guinea pigs,
> 1.0 IU / ml Clostridium soredellii,
> 10.0 IU / ml Clostridium perfringens Type B and Type C Beta Antitoxin,
> 5.0 IU / ml Clostridium perfringens Type D Epsilon Antitoxin,
> 3.5 IU / ml Clostridium novyii Alfa Antitoxin,
> 2.5 IU / ml Clostridium septicum Alfa Antotoxin,
it provides 90% minimum immune response against Clostridium chauvoei antigen in guinea pigs,
> 100 AU minimum immune response against Escherichia coli antigen K99/F41/F17(Fy),</td></tr>
<tr><td></td><td>Finished product specifications</td><td></td></tr>
<tr><td></td><td>Pharmacological Group</td><td>Veterinary Vaccine</td></tr>
<tr><td></td><td>Shelf life</td><td>24 Months [2 Years] (Store at 2°C -8°C)</td></tr>
<tr><td></td><td>International availability</td><td>Turkey, Azerbaijan.</td></tr>
<tr><td></td><td>Products already registered in Pakistan</td><td></td></tr>
<tr><td></td><td>Type of Form
Dy. No.
Date of Application,
Fee submitted</td><td>Form 5-A
Dy.No.1377/AD(BD) dated 3rdDecember, 2018
30thNov, 2018
Fee Submitted: Rs.100,000/-</td></tr>
<tr><td></td><td>Demanded Price / Pack size</td><td>250 ml vial (62 cattle dose or 125 sheep and goats dose) / decontrolled</td></tr>
<tr><td></td><td>General documentation</td><td>• Legalized Marketing Authorization issued by Ministry of Food, Agriculture and Livestock of Turkey valid upto 12-04-2020 (attached English Translation is not legalized).
• Legalized Free Sale permission certificate for veterinary biological products issued by Ministry of Food, Agriculture and Livestock of Turkey valid upto 20-12-2019 (attached English Translation is not legalized).
• Copy GMP Certificate having Certificate No.GMP/TR/V/Yi/S0065/2017 issued by Ministry of Food Agriculture and Livestock of Turkey dated 03-03-2017 and valid till 23rd Dec 2018</td></tr>
<tr><td></td><td>Remarks of Evaluator</td><td>1. GMP certificate was valid at the time of submission but it is expired now.
2. Market authorization and free sale permission certificate are in Turkish language and attached English Translation is stamped by Translator Company and not legalized.
3. Provided stability data is of trial batches.
4. Addresses mentioned on GMP & Marketing Authorization are as under;
<table>
<tr><th>GMP</th><th>Marketing Authorization</th></tr>
<tr><td><u>Manufacturer:</u>
i. Ata Fen VeterinerMalz Hay Paz. San. Ve Tic. A.S.
<u>Site Address:</u>
ii. OSB Mah. 21 Sokak No.7/A UlucakKemalpasa – IZMIR</td><td><u>License Holder and Manufacturer address:</u>
i. Ata Fen VeterinerMalzemeleriHayv Paz. San. Ve Tic. A.S.
OSB Mah. 21 Sok. No.7/A Kemalpasa – Izmir
ii. OSB Mah. 21 Sok. No.7/A Kemalpasa – Izmir / Turkey</td></tr>
</table></td></tr>
</table>

	Decision: Registration Board deferred the case for submission of following by the firm: **a. Valid legalized GMP certificate.** **b. Notarized English translation of Free Sale Certificate.** **c.Stability studies data of commercial batches.** **d. Clarification regarding two manufacturing sites as mentioned on GMP.**

E: Local Veterinary Biologicals

Name and Address of Manufacturers	Grand Pharma (Pvt) LTD, Plot No.5-A, Street No. N-5, National Industrial Zone, RCCI Estate, Rawat, Islamabad
Brand Name + Dosage Form + Strength	GPVAC ND+IB+IBD+EDS 1000 doses injection. Inactivated Emulsion Against Newcastle disease, Infectious bronchitis, infectious Bursal Disease & egg drop syndrome vaccine
Composition	Each dose of 0.5ml contains: Inactivated new castle disease virus ……. inducing ≥ 5log2 HI units Inactivated bronchitis virus (mass) ……. inducing ≥ 5log2 HI units Inactivated Bursal disease virus ……... inducing ≥ 3000 Elisa units Inactivated egg drop syndrome virus ……... inducing ≥ 5log2 HI units
Diary No. Date of R & I & Fee	Diary No. & date 4835 &**01-02-19** And 16614 date 7-03-2019 of R& I & fee challan.No.1900170; Rs.20,000/-(06-03-2019)
Pharmacological Group	Veterinary Vaccine
Type of Form	Form-5
Finished Product Specifications	Manufacturers specs
Pack size and Demand Price	500ml; Decontrolled
Approval Status of Product	Lohman animal health, Germany
Me-too status	Avipro 402 (ND/IB/IBD/EDS) manufactured by Lohman animal health, Germany
GMP Status	Last GMP inspection was conducted on 05.03.2019 the report concludes a satisfactory level of GMP compliance.
Remarks of Evaluator	Firm has registration of this product in 300ml packing, now firm applied for additional pack in 500ml packing with new fee as per rules
Decision: Keeping in view the GMP inspection report; Registration board approved the product.	

F: Miscellaneous/ Deferred Cases

1. Registration of Human Biologicals from M/s Zam Zam Corporation, Karachi to M/s Apex Pharmaceuticals (Pvt) Ltd, Karachi.

M/s Apex Pharmaceuticals (Pvt) Ltd., Karachi applied for the registration of following human biologicals in their name from M/s Zam Zam Corporation, Karachi as per following details:

Sr. No.	**Name and address of Importer**	M/s Apex Pharmaceuticals (Pvt) Ltd., D-21, A/1, S.I.T.E., Super Highway, Karachi
1.	Detail of DSL	License No. 0562 dated 09-04-2018 valid till 22-02-2020
	Reg. No.	059008
	Name and address of Manufacturer	**Product License Holder:** M/s IBSA Institut Biochimique S.A. Via al Ponte 13 6903 Lugano, Switzerland. **Manufacturer:** M/s IBSA Institut Biochimique S.A. Via Cantonale, Zona Serta 6814 Lamone, Switzerland.
	Brand Name +Dosage Form + Strength	Choriomon 5000IU, Injectable Preparation (vial with solvent)

	Diary No. Date of R& I & fee	Dy. No. 2230 & 7206 Dated: 17-01-2019 & 27-05-2019 Rs. 100000/- Dated: 16-01-2019
	Composition	Each dose contains: Chorionic Gonadotropin (HCG)…….5000IU
	Pharmacological Group	Gonadotropins
	Type of Form	Form-5A
	Finished Product Specification	Not Provided
	Shelf Life	36 months (<25^{0}C)
	Document Details	Legalized CoPP No. 18005441 dated 23-10-2018 issued by Swissmedic.
	Pack size/ Demanded Price	1's Vial (lyophilized) + 1's Ampoule (Solvent)/ Rs. 2500/-
	International Availability	Pregnyl 5000IU of M/s Merk Sharp & Dohme, UK
	Products already registered in Pakistan	GHC 5000 Injection of M/s Foray Pharmaceuticals, Rawalpindi.
2.	**Name and address of Importer**	M/s Apex Pharmaceuticals (Pvt) Ltd., D-21, A/1, S.I.T.E., Super Highway, Karachi
	Detail of DSL	License No. 0562 dated 09-04-2018 valid till 22-02-2020
	Reg. No.	059010
	Name and address of Manufacturer	**Product License Holder:** M/s IBSA Institut Biochimique S.A. Via al Ponte 13 6903 Lugano, Switzerland. **Manufacturer:** M/s IBSA Institut Biochimique S.A. Via Cantonale, Zona Serta 6814 Lamone, Switzerland.
	Brand Name +Dosage Form + Strength	Merional 75IU, Injectable Preparation I.M., S.C.
	Diary No. Date of R& I & fee	Dy. No. 2232 & 7207 Dated: 17-01-2019 & 27-05-2019 Rs. 100000/- Dated: 16-01-2019
	Composition	Each dose contains: Human Menopausal Gonadotropin (HMG) (Menotrophin)…….75IU Human Chorionic Gonadotropin……3.5-10.5IU
	Pharmacological Group	Gonadotropins
	Type of Form	Form-5A
	Finished Product Specification	Not Provided
	Shelf Life	24 months (<25^{0}C)
	Document Details	Legalized CoPP No. 18005444 dated 23-10-2018 issued by Swissmedic.
	Pack size/ Demanded Price	1's Vial (lyophilized) + 1's Ampoule (Solvent)/ Rs. 2500/-
	International Availability	Menopur 75IU of M/s Ferring Pharmaceuticals Ltd., UK
	Products already registered in Pakistan	GHM 75IU Injection of M/s Foray Pharmaceuticals, Rawalpindi.
3.	**Name and address of Importer**	M/s Apex Pharmaceuticals (Pvt) Ltd., D-21, A/1, S.I.T.E., Super Highway, Karachi
	Detail of DSL	License No. 0562 dated 09-04-2018 valid till 22-02-2020
	Reg. No.	059007
	Name and address of Manufacturer	**Product License Holder:** M/s IBSA Institut Biochimique S.A. Via al Ponte 13 6903 Lugano, Switzerland.

		Manufacturer: M/s IBSA Institut Biochimique S.A. Via Cantonale, Zona Serta 6814 Lamone, Switzerland.
	Brand Name +Dosage Form + Strength	Fostimon 75IU, Injectable Preparation I.M., S.C. (Vial with solvent)
	Diary No. Date of R& I & fee	Dy. No. 2231 & 7205 Dated: 17-01-2019 & 27-05-2019 Rs. 100000/- Dated: 16-01-2019
	Composition	Each dose contains: Follicle-stimulating hormone (FSH) (Urofollitrophin)…….75IU
	Pharmacological Group	Gonadotropins
	Type of Form	Form-5A
	Finished Product Specification	Not Provided
	Shelf Life	24 months (<25^{0}C). The firm has applied for storage conditions of less than 25^{0}C while in Zone IV-A storage conditions are 30^{0}C. However, the firm has submitted the long term stability data for all the products on 5^{0}C, 25^{0}C and 30^{0}C.
	Document Details	Legalized CoPP No. 18005443 dated 23-10-2018 issued by Swissmedic.
	Pack size/ Demanded Price	1's Vial (lyophilized) + 1's Ampoule (Solvent)/ Rs. 2500/-
	International Availability	Bravelle 75IU of M/s Ferring Pharmaceuticals Ltd., UK
	Products already registered in Pakistan	Bravelle 75IU Injection of M/s Atco Pharma, Karachi.

The firm has provided the following documents for each product:

a. Application of Form-5A
b. Fee Challan of Rs. 100000/-
c. Copy of initial registration letter
d. Copy of last renewal submission
e. Original legalized termination letter in name of previous importer
f. Original legalized Sole Agency letter in name of M/s Apex Pharmaceuticals (Pvt.) Ltd., Karachi.
g. Original NOC dated 30-08-2018 from M/s Zam Zam Corporation, Karachi.
h. An undertaking that the documents in the dossier are true and correct

Remarks of Evaluator:

a. Two manufacturing sites are mentioned on submitted CoPPs for each product as per following details:
   i. M/s IBSA Institut Biochimique S.A. Via Cantonale, Zona Serta 6814 Lamone, Switzerland.
   ii. M/s IBSA Farmaceutici Italia S.r.l.
   Via Martiri di Cefalonia 2 26900 Lodi, Italy.

The firm submitted a letter from their principal stating:

"We IBS Institut Biochimique S.A., in Lugano (Switzerland), manufacturers of the pharmaceutical products

Fostimon, Merional and Chorioman

Confirm that the above mentioned medicinal products (vials containing lyophilized powder) are manufactured at our plant in Via Cantonale, Zona Serta, 6814, Lamone, Switzerland.

The same address is also mentioned in CoPP, submitted in DRAP for the change of local agent from Zam Zam Corporation to Apex Pharmaceuticals (Pvt) Ltd.

We further undertake that our pharmaceutical products

Fostimon, Merional and Choriomon

Shall be continued to be manufactured at our plant in Via Cantonale, Zona Serta, 6814, Lamone, Switzerland, to be supplied to Pkaistan"

b. In all the applications, solvents are in combo pack but the firm has not provided the details of the solvents.
c. For products at sr. no. 2 & 3 firm has only provided phase-I clinical study data while Phase-III data is not provided. In some public assessment reports of products available in reference regulatory authorities only Phase-I clinical trial is submitted while in some Phase III clinical trial is also submitted.

Discussion:

Registration Board was apprised by Division of Biological Evaluation and Research that the firm has only provided Phase I bioequivalence study instead of phase III clinical studies of products at sr. no. 2 & 3. Moreover, as per Australian Public Assessment report of Pergoveris having follicle stimulating hormone and leutinizing hormone as active ingredient; the approval was granted on the basis of two bioequivalence studies and no new efficacy or safety studies were submitted by the applicant. DBER further apprised the Board that all the above products are in combopack while the details of the solvent are not provided in Form-5A.

Registration Board further deliberated that two manufacturing sites are mentioned on CoPP and the firm has already clarified that lyophilized part will be manufactured by M/s IBSA Institut Biochimique S.A. Via Cantonale, Zona Serta 6814 Lamone, Switzerland and diluents will be manufactured by M/s IBSA Farmaceutici Italia S.r.l. Via Martiri di Cefalonia 2 26900 Lodi, Italy while the finished product will be imported from Switzerland.

Decision: **Keeping in view the above discussion, valid legalized CoPPs indicating products availability in country of origin, above products being Pharmacopoial; Registration Board cancelled the registration of Choriomon 5000IU (Reg. No. 059008), Merional 75IU (Reg. No. 059010) and Fostimon (Reg. No. 059007) from M/s Zam Zam Corporation, Karachi and granted in name of M/s Apex Pharmaceuticals (Pvt.) Ltd., Karachi subject to the compliance of current Import Policy for Finished Drugs, verification of cold storage facility and comments on the price of the products from Pricing Division. Before issuance of registration letters, the firm will submit the revised Form-5A indicating details of diluents as combo pack. Chairman Registration Board has been authorized for issuance of registration letters.**

2. Registration of Human Biologicals from M/s AA Pharma, Karachi to M/s A.J. Mirza Pharma (Pvt) Ltd., Karachi.

M/s A.J. Mirza Pharma (Pvt) Ltd., Karachi applied for the registration of following human biologicals in their name from M/s AA Pharma, Karachi as per following details:

Sr. No.	**Name and address of Importer**	M/s A.J. Mirza Pharma (Pvt) Ltd., 1st Floor, Shafi Court, Civil Lines, Merewether Road, Karachi
1.	Detail of DSL	License No. 0838 dated 08-01-2019 valid till 23-12-2020
	Reg. No.	047578
	Name and address of Manufacturer	**Product License Holder &Manufacturer:** M/s Shenyang Sunshine Pharmaceutical Co. Ltd., No. 3 A1, Road 10, Econ & Tech Development Zone, Shenyang 110027, China.
	Brand Name +Dosage Form + Strength	EPIAO 2000IU Injection

	Diary No. Date of R& I & fee	Dy. No. 182, 42989, 3656, 5036 & 10162 Dated: 03-02-2017, 17-12-2018, 28-01-2019, 04-02-2019 & 01-07-2019 Rs. 100000/- Dated: 01-02-2017
	Composition	Each 1ml vial contains: Recombinant Human Erythropoietin…….2000IU
	Pharmacological Group	rDNA Therapeutic Protein
	Type of Form	Form-5A
	Finished Product Specification	Not Provided
	Shelf Life	03 years (2^0C-8^0C)
	Document Details	Legalized CoPP No. 2017.79 dated 26-12-2017.
	Pack size/ Demanded Price	1's Vial/ Rs. 1029.60/-
	International Availability	Epogen 2000IU of M/s Amgen Inc., USA
	Products already registered in Pakistan	Gerepo 2000IU of M/s Titlis Pharma, Lahore.
2.	**Name and address of Importer**	M/s A.J. Mirza Pharma (Pvt) Ltd., 1st Floor, Shafi Court, Civil Lines, Merewether Road, Karachi
	Detail of DSL	License No. 0838 dated 08-01-2019 valid till 23-12-2020
	Reg. No.	047579
	Name and address of Manufacturer	**Product License Holder &Manufacturer:** M/s Shenyang Sunshine Pharmaceutical Co. Ltd., No. 3 A1, Road 10, Econ & Tech Development Zone, Shenyang 110027, China.
	Brand Name +Dosage Form + Strength	EPIAO 4000IU Injection
	Diary No. Date of R& I & fee	Dy. No. 182, 42989, 3656, 5036 & 10162 Dated: 03-02-2017, 17-12-2018, 28-01-2019, 04-02-2019 & 01-07-2019 Rs. 100000/- Dated: 01-02-2017
	Composition	Each 1ml vial contains: Recombinant Human Erythropoietin…….4000IU
	Pharmacological Group	rDNA Therapeutic Protein
	Type of Form	Form-5A
	Finished Product Specification	Not Provided
	Shelf Life	03 years (2^0C-8^0C)
	Document Details	Legalized CoPP No. 2017.79 dated 26-12-2017.
	Pack size/ Demanded Price	1's Vial/ Rs. 1144/-
	International Availability	Epogen 4000IU of M/s Amgen Inc., USA
	Products already registered in Pakistan	Gerepo 4000IU of M/s Titlis Pharma, Lahore.
3.	**Name and address of Importer**	M/s A.J. Mirza Pharma (Pvt) Ltd., 1st Floor, Shafi Court, Civil Lines, Merewether Road, Karachi
	Detail of DSL	License No. 0838 dated 08-01-2019 valid till 23-12-2020
	Reg. No.	047580
	Name and address of Manufacturer	**Product License Holder &Manufacturer:** M/s Shenyang Sunshine Pharmaceutical Co. Ltd., No. 3 A1, Road 10, Econ & Tech Development Zone, Shenyang 110027, China.
	Brand Name +Dosage Form + Strength	EPIAO 10000IU Injection
	Diary No. Date of R& I & fee	Dy. No. 182, 42989, 3656, 5036 & 10162 Dated: 03-02-2017, 17-12-2018, 28-01-2019, 04-02-2019 & 01-07-2019

		Rs. 100000/- Dated: 01-02-2017
	Composition	Each 1ml vial contains: Recombinant Human Erythropoietin…….10000IU
	Pharmacological Group	rDNA Therapeutic Protein
	Type of Form	Form-5A
	Finished Product Specification	Not Provided
	Shelf Life	03 years (2^0C-8^0C)
	Document Details	Legalized CoPP No. 2017.79 dated 26-12-2017.
	Pack size/ Demanded Price	1's Vial/ Not Provided.
	International Availability	Epogen 10000IU of M/s Amgen Inc., USA
	Products already registered in Pakistan	Epocan 10000IU of M/s Macter International, Karachi.

The firm has provided the following documents for each product:

a. Application of Form-5A
b. Fee Challan of Rs. 100000/-
c. Copy of initial registration letter dated 15-02-2008.
d. Copy of last renewal submission dated 28-07-2015 with Rs. 40000/- fee.
e. Original termination letter in name of M/s AA Pharma, Karachi.
f. Original legalized letter of authorization in name of M/s AJ Mirza Pharma Private Limited, Karachi dated 17-12-2018.
g. Original NOC dated 24-08-2016 from M/s AA Pharma, Karachi.
h. Legalized CoPP No. 2017.79 dated 26-12-2017 issued by Liaoning Provincial Food and Drug Administration, China.
i. An undertaking that the given information is true and correct to best of their knowledge.
j. The firm has submitted the biosimilarity data as per following details:

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison 1. Physicochemical Characterization	Primary Structure i. Amino acid Sequence by LTQ (Thermo) and MALDI-TOFmass spectrograph (Non-comparative) ii. Sequence coverage Analysis by LC-MS (Comparative) iii. Amino acid constitution by HPLC (Non-comparative) iv. N-terminal Analysis (Non-comparative) v. C-terminal Analysis (Non-comparative) vi. Peptide Mapping by HPLC (Comparative) vii. Molecular Weight by MALDI-TOF MS (Non- Comparative) High order Structure i. Circular Dichroism (CD) (Comparative) ii. Disulphide-bond Analysis (Non- Comparative) Heterogenicity i. Capillary Zone Electrophoresis (Comparative) ii. Isoelectric focusing (Comparative) Glycosylation i. Sialic Acid Content (Comparative) ii. Native Carbohydrate Chain Analysis (Comparative) iii. Neutral Carbohydrate Chain Analysis (Comparative) iv. N-glycosylation sites identification and sites occupancy analysis (Comparative)

	v. O-glycosylation sites identification and sites occupancy analysis (Comparative) vi. N-glycan qualitative analysis (Comparative)
Biological Activity	In-Vitro Cell Proliferation Assay (Comparative)
Immunochemical properties	SDS-Page and Immunoblotting
Impurities	Dimers and related substances of higher molecular mass (Comparative) Host Cell and Vector derived DNA (Comparative) Host Cell derived proteins (Comparative) Bacterial Endotoxin
Stability Studies	Stability study is provided.
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	In-vitro Studies a. Cell proliferation assay (Comparative) In-vivo Studies a. Pharmocokinetic method The relationship of invivo effect and time under same administration in BalBc inbred strain mice (Comparative) The relationship of invivo effect and dosage under same sampling time in BalBc inbred strain mice (Comparative) b. Bioassay in normocythaemic mice The relationship of invivo effect and time under same administration in BalBc mice (Comparative) Toxicology The comparison of toxicological profile between EPIAO and Eprex in rats after subcutaneous injection for 28 days.
Clinical Comparison	A prospective, randomized, double-blind, parallel group study to establish the therapeutic equivalence of EPIAO with the standard treatment Eprex in subjects with Chronic Kidney Disease (CKD) related Anaemia not yet on dialysis **(Only Protocol)**.

Remarks of Evaluator:

i. The already approved shelf life as per initial registration letter is 3 years while the firm has provided the real time stability data of 30 months.

ii. In clinical comparison under biosimilarity studies, the firm has only provided the protocol instead of complete studies.

Decision: Registration Board deferred the case for submission of following by the firm:

a. Valid legalized approval of demanded shelf life from regulatory body of country of origin.

b. Complete clinical trial data under biosimilarity studies.

3. Change of address of importer for already registered veterinary vaccines applied by M/s Vety-Care (Pvt.) Ltd., Islamabad.

M/s Vety-Care (Pvt.) Ltd., Islamabad has applied for the change in address of importer of already registered veterinary vaccines as per following details:

Sr. No.	Reg. No. & Date of Reg.	Name of product	Last Renewal	Previous Address of Importer	New Address of Importer
1.	017143 23-07-1995	Nobilis Coryza+ND	14-07-2015	Plot # 81-B, Street # 06, I-10/3, Islamabad	Plot No. 77, Street No. 6, I-10/3, Islamabad
2.	017144 23-07-1995	Nobilis RT Inac	14-07-2015		

3.	017145 23-07-1995	Nobilis MG Inac	14-07-2015		
4.	017146 23-07-1995	Nobilis RTV 8544	14-07-2015		
5.	017147 23-07-1995	Noblis FC Inac	14-07-2015		
6.	017148 23-07-1995	Nobilis E.Coli Inac	14-07-2015		
7.	018456 07-12-1995	Nobilis Rismavac+ CA126	14-07-2015		
8.	018892 04-04-1996	Nobilis IB Multi	25-03-2016		
9.	018893 04-04-1996	Nobilis IB Multi+ G+ND	25-03-2016		
10.	018891 04-04-1996	Nobilis IB Multi+ ND	25-03-2016		
11.	018894 04-04-1996	Nobilis IB Multi +ND+ EDS	25-03-2016		
12.	018895 04-04-1996	Nobilis CAV P4	25-03-2016		
13.	021405 11-05-1998	Nobilis Ib 4-91	07-05-2018		
14.	044971 12-04-2007	Nobilis ND C2	24-03-2017		
15.	044970 12-04-2007	Nobivac Rabies	24-03-2017		
16.	044969 12-04-2007	Nobivac KC	24-03-2017		
17.	044968 12-04-2007	Nobilis Influenza H5N2	24-03-2017		
18.	044935 19-04-2007	Diluent FD Poultry Vaccine	24-03-2017		
19.	044990 25-05-2007	Diluvac Forte	24-03-2017		
20.	052395 13-01-2009	Nobilis Influenza H9N2+ND	11-01-2019		
21.	052396 13-01-2009	Nobilis Influenza H9N2	11-01-2019		
22.	052397 13-01-2009	Nobilis Influenza H7N1	11-01-2019		
23.	080183 07-03-2016	Innovax-ND	Not Applicable		
24.	081295 30-08-2016	Innovax-ND	Not Applicable		
25.	081294 03-10-2016	Nobilis Dilavia Diluent	Not Applicable		
26.	081293 03-10-2016	Nobilis Diluent CA	Not Applicable		
27.	083387 23-06-2017	Nobilis SG 9R	Not Applicable		
28.	089804 16-05-2018	Nobivac L4	Not Applicable		

The firm has submitted the following documents for each product:

a. Fee challan of Rs. 5000 for each product
b. Copy of valid Drug Sale License
c. Copies of initial registration letter
d. Copies of last renewal submission

The last renewal applications of above products 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 Vety-Care (Pvt.) Ltd.,Plot # 81-B, Street # 06, I-10/3, Islamabad to M/s Vety-Care (Pvt.) Ltd.,Plot No. 77, Street No. 6, I-10/3, Islamabadfor above products subject to storage facility verification report of new address.**

4. Information regarding difference of Product License Holder in CoPP and panel inspection report of already approved human biologicals of M/s The Searle Company Limited, Karachi.

Following products of M/s The Searle Company Limited, Karachi were approved in different meetings of Registration Board as per following details:

Sr. No.	Name of Manufacturer	Brand Name & Composition	Document Details	Decision of RB
1.	**Product License Holder:** M/s Laboratorio Elea S.A.C.I.F.y.A, Sanabria No 2353-C1417AZE Ciudad Autonoma de Buenos Aires- Republica Argentina. **Bulk Manufacturer:** M/s Pharmadn S.A. Carlos Villate No 5148-Munro- Vicente Lopez Prov. De Buenos Aires- Republica Argentina **Drug Product Manufacturer, Filling & secondary packaging:** M/s Sinergium Biotech S.A. Ruta 9 Km 38.7- Garin-Prov. de Buenos Aires Republica Argentina	TUXIMAB Injection 100mg/10ml Each vial contains: 100mg/10ml of Rituximab	Legalized CoPP No. 20132019 000707 dated 11-05-2017	*Keeping in view the biosimilarity data as per WHO format and submitted CoPPs indicating that the products are available for sale in the country of origin, Registration Board approved the above products as per valid legalized CoPPs subject to price fixation by Federal Government and compliance of current Import Policy for Finished drugs.*
2.		TUXIMAB Injection 500mg/50ml Each vial contains: 500mg/50ml of Rituximab	Legalized CoPP No. 20132019 000142 15 dated 17-4-2015	
3.		Cizumab100mg/4ml Concentrate for solution for infusion Each vial of 4ml contains: Bevacizumab…100mg	Legalized CoPP No. 20132019001 11917 dated 24-07-2017	*Keeping in view the biosimilarity data and submitted CoPPs; Registration Board approved the above products subject to price fixation by Federal Government and compliance of current Import Policy for finished drugs.*
4.		Cizumab400mg/16ml Concentrate for solution for infusion Each vial of 16ml contains: Bevacizumab…400mg	Legalized CoPP No. 20132019 00112017 dated 24-07-2017	

The firm then applied for the change in name of API manufacturer from M/s Pharmadn S.A. to M/s Mabxience S.A.U. The request of the firm was approved by Registration Board in its 287th meeting as per following details:

"Keeping in view the valid legalized GMP and legalized certificate of change in name of manufacturer; Registration Board approved the change in name from M/s Pharmadn S.A. to

M/s Mabxience S.A.U. as per current Import Policy for finished drugs. The firm will submit valid legalized CoPPs indicating new name of manufacturer for all the products and the same will be verified during inspection of manufacturer abroad. Registration Board has authorized its Chairman for issuance of registration letters after confirmation of name of manufacturer."

The panel inspection of manufacturer abroad was conducted by following panel of inspectors of DRAP on 06th-07th March, 2019:

a. Mr. Akhter Abbas Khan, Dy. Director, DRAP
b. Mr. Abdullah, Add. Director, DRAP

The panel recommended the facility and rated "Good". Moreover, the panel also verified the change in name of manufacturer as per the decision of Registration Board. Furthermore, the firm has also submitted valid legalized CoPPs of above products indicating new name of manufacturer.

In this context, it is submitted that product license holder is different in inspection report of panel of inspectors from that of minutes of meeting & initially submitted CoPPs as per following details:

Product License Holder as per initial CoPPs and Minutes of meetings	**Product License Holder as per Panel Inspection Report**
M/s Laboratorio Elea S.A.C.I.F.y.A, Sanabria No 2353- C1417AZE Ciudad Autonoma de Buenos Aires- Republica Argentina.	M/s Mabxience SAU (formerly PharmaDN), Carlos Villate 5148, Munro, Buenos Aires, Argentina.

Moreover, name of product license holder on initially submitted CoPPs and minutes of meetings is different from that of newly submitted CoPPs as per following details:

Name of Product License Holder as per initial CoPPs and Minutes of meetings	**Product License Holder as per Panel Inspection Report**
M/s Laboratorio Elea S.A.C.I.F.y A,	M/s Laboratorio Elea Phoenix S.A.

The firm was asked for clarification and the firm submitted that

"1) Mabxience is the legal owner of all rights, title and interest in the finished pharmaceutical products containing Rituximab or Bevacizumab as active drug ingredient (the "Product") and the related intellectual property rights.

Mabxience granted a license to the company Laboratorio ELEA Phoenix S.A. (formerly known as Laboratorio ELEA S.A.C.I.F.y.A) with legal address at Sanabria 2353, C1417AZE, Ciudad de Buenos Aires, Republice Argentina (hereinafter "Elea"), to apply for a market authorization and further commercialize the product in Argentina.

Based on the law of Argentina, Elea is the responsible of the quality control of the API and Drug Product to be marketed in the territory of Argentina and the marketing authorization holder of the product in Argentina.

Mabxience, through its affiliate manufacturing site Mabxience SAU, is responsible for Quality Control of the Drug Product to be marketed outside the territory of Argentina and product license holder with rights for the Product being commercialized outside the Argentinean territory.

Hence Elea is the Marketing Authorization Holder of the product in country of origin Argentina only, and not the product owner for Rituximab Injection and Bevacizumab Injection.

With these we would like to reconfirm that as th Marketing Authorization Holder in Argentina, Elea is thus mentioned as Product License Holder in the CoPP of the products from the exporting country per the ANMAT regulation.

2) *Elea changed its legal name from Laboratorio Elea S.A.C.I.F.y.A to Laboratorio ELEA Phoenix S.A. in March 2018. This modification was not communicated to the DRAP as Elea has no responsibilities with the product to be marketed outside Argentina, so no further change was needed in the dossier.*

Further to this, ANMAT (health authority of Argentina) did duly approve this name change in the MA of Rituximab (Novex in Argentina) on 18th May, 2018 and Bevacizumab (Bevax in Argentina) on 19th April, 2018. Both of these documents are provided along with this response letter for agency's kind reference.

Furthermore, the latest CPPs submitted to DRAP, also mention the new name of Elea i.e. ELEA Phoenix S.A. as the MA Holder in Argentina.

With these above clarifications, we request DRAP authority to please grant registration for Tuximab and Cizumab in Pakistan."

Decision: Registration Board acknowledged the above information and advised DBER to proceed in light of panel inspection report of manufacturer abroad.

5. Sterile diluent for Vexxitek vaccine deferred in 289th meeting of Registration Board.

Following product of M/s Saadat International, Lahore was approved in 267th meeting of Registration Board as per following details:

Sr. No.	Name of Manufacturer	Brand Name & Composition	Fee Status &Pack Size	Documents submitted	Decision of RB in 274th meeting
1.	Merial, Inc. facilities at 1168 Airport Parkway, SW, Gainesville, Georgia 30501, USA	Sterile Diluent for Vexxitek Each dose contains: Sucrose…0.01025g Potassium Phosphate, monobasic...0.00009g Potassium phosphate dibasic…0.0002g NZ Amine… 0.003g Phenol Red…. ……0.000002g Deionized water… 0.2ml Sodium hydroxide… qs pH Diluent Shelf Life: 36 months	Rs. 100000/- 07-12-2016 400ml	Legalized Free Sale Certificate dated 26-08-2016 Valid Legalized GMP certificate no. 1603314 dated 22-09-2016	*Approved as per Import Policy for Finished Drugs and as per valid legalized CoPP/ GMP and FSC only for Vaxxitek vaccine.*

During processing the case for issuance of registration letter, the firm submitted that the same diluent will be used for Newxxitek HVT+ND vaccine approved in 271st meeting of Registration Board. The firm has submitted revised Form-5A indicating both vaccines along with

valid legalized Certificate of Licensing and Inspection No. 18-01591 dated 29-05-2018 of Newxxitek HVT+ND indicating sterile diluent.

The case was taken up in 287th meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case for submission of clarification of following by the firm:

a. Why the sterile diluent is required separately for Vexxitek and Newxxitek HVT+ND vaccines instead of combo pack."

Then, the firm submitted that both vaccines Newxxitek &Vaxxitek are stored/ transported in liquid nitrogen cylinder. However, the diluent is stored/ transported below 30^0C. Therefore, both the vaccine & the diluent cannot be shipped / stored together. The firm requested to process the cases of vaccine & sterile diluents separately. The case was considered in 289th meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case for clarification, of import of Vexxitek and Newxxitek HVT+ND vaccines in liquid nitrogen cylinders, by the firm."

Now, the firm submitted the following:

"Newxxitek HVT+ND and Vaxxitek HVT+IBD are live vaccines prepared from a Marek's disease vectored Newcastle Disease and Infectious disease recombinant viruses respectively.

Both of these vaccines are presented in a frozen form in ampoules containing a suspension of Turkey Herpes virus (HVT) vectored Newcastle Disease/ Infectious Bursal recombinant viruses infected cells in tissue culture media.

As these are cell associated vaccines and are required to be kept frozen and therefore are stored and imported in liquid nitrogen cylinders at low temperature up to -196degree centigrade.

However these vaccines are thawed prior to administration in the day old chickens in water of temperature from 20-30 degree centigrade. After thawing the vaccine is mixed with the diluents of the vaccine.

The classical Mareks disease vaccines which are already registered are stored and imported in liquid nitrogen cylinder in low temperatures as mentioned above."

Decision: **Keeping in view the valid legalized Certificate of Licensing and Inspection issued by USDA (Reference Regulatory Authority) indicating product availability in country of origin; Registration Board approved the product with Brand Name Sterile Diluent for Vexxitek HVT+IBD & Newxxitek HVT+ND subject to compliance of current Import Policy for finished drugs.**

6. Sterile Diluent of Avipox vaccine applied by M/s Vet Line International, Lahore deferred in 288th meeting of Registration Board.

Following product of M/s Vet Line International, Lahore was deferred in 288th meeting of Registration Board as per following details:

Name of Importer	M/s Vet Line International, 55/S, 1st Floor Main Shadman Market, Lahore.
DSL details	No. 60-A/DGBT/11/2015 dated 12-02-2015 valid till 11-02-2019
Name of Manufacturer	**Product License Holder:** 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	Sterile Diluent of Avipox Vaccine
Composition	Each vial of 10ml contains: Glycerol…….1.5ml Water, highly purified……..ad10ml
Finished product specifications	As per Innovator.
Pharmacological Group	Diluent for veterinary vaccine
Shelf life	60 months (2^0C-8^0C)
International availability	Egypt, Bangladesh
Products already registered in Pakistan	Sterile Diluent to be used with already registered vaccine AviPox (Reg. No. 085010)
Type of Form Dy No & Date of application, Fee submitted	Form-5A Dy. No.033700(R&I) dated 11-10-2018 Rs. 100000/- 11-10-2018
Demanded Price / Pack size	20 Vials x 10ml
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. Contract manufacturing certificate No. 02.2/3281-2/2018 dated 13-06-2018 for Avipox Vaccine issued by Directorate of Veterinary Medicinal Products, Hungary. iii. Legalized FSC No. 02.2/3917-2/2018 dated 13-07-2018 issued by Directorate of Veterinary Medicinal Products, Hungary.
Decision of RB in 288th meeting	*Registration Board deferred the case for submission of clarification regarding not importing diluent in combo pack by the firm.*

The firm now submitted that the applied product is imported product and their manufacturer has same packing and it's difficult for them regarding its costing to import in combo pack, so it becomes too costly. They import this applied product in limited quantity and it's not possible that their manufacturer provide them the customized packing.

Decision: Keeping in view the valid legalized GMP and Free Sale Certificates indicating product availability in country of origin; Registration Board approved the product subject to compliance of current Import Policy for finished drugs.

7. Imported veterinary biological applied by M/s Vet Line International, Lahore deferred in 289th 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	**Product License Holder:**

Manufacturer	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*

The two experts Dr. Qurban Ali and Dr. Arshad Javed has 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 opinion of 3rd expert is still awaited. Moreover, now the firm has provided the accelerated stability data of 03 batches for 02 months indicating that the potency of vaccine becomes out of specification within 01st month. So they did not proceed for 06 months accelerated stability studies.

Registration Board in its 286th meeting adopted theEuropean framework for stability testing of vaccines for veterinary use developed in the light of European Pharmacopoeia 9.5 (General Monograph (0062)and European Directive 2001/82/EC (II-Title) for all veterinary vaccines which states that the stability should be evaluated under the recommended storage conditions. As the storage conditions of vaccines is 2-8^{0}C (unless otherwise stated), the European Pharmacopoeia requires to perform the stability studies only at 2-8^{0}C. Moreover, the European Directive 2001/82/EC (II-Title) does not require performing accelerated stability studies for vaccines.

Decision:

Registration Board deferred the case and advised DBER to issue a reminder to the 3rd expert Prof. Masood Rabbani, UVAS Lahore.

8. Registration of Imported Human Biological from M/s Morgan Technologies Services, Karachi to M/s Al Habib Pharmaceuticals, Karachi deferred in 289thmeeting of Registration Board.

M/s Al-Habib Pharmaceuticals, Karachi applied for the registration following human biological in their name from M/s Morgan Technologies Services, Karachi. The case was initially deferred in 262nd meeting as per following details:

Name of Manufacturer	Name of Drug and Composition& Reg. No.	Date of application / Fee status	Documentary details	Decision of RB in 262nd meeting
M/s GeneScience Pharmaceuticals Co. Ltd., 1718 Yueda Road, High-Tech Development Zone, Changchun, Jilin Province, China	SCIMAX Injection Recombinant Human Granulocyte Colony-Stimulating Factor Injection Each vial (1ml) contains : Recombinant Human Granulocyte Colony Stimulating Factor (rhG-CSF)…300ug/vial. Reg. No. 072504 Shelf life. 02years	Dy.No. 202 R&I DRAP dated 14-3-2016 Fee deposited Rs.15000/- dated 17-11-2011 + Rs. 35000/- dated 12-4-2013 + Rs.50000/- dated 13-11-2014	Legalized COPP No. 2014012 dated 25-6-2014 from china. Valid for two years.	*Registration Board deferred for submission of biosimilarity data and valid legalized CoPP by thefirm.*

The firm then submitted valid legalized CoPP vide no. 2017005 dated 17-01-2017 valid for two years. The firm submitted the biosimilarity data on 17-01-2019 and now the CoPP is not valid. Moreover, the firm submitted that Scimax is a Biotherapeutic product and not a similar

biotherapeutic product. It has 174 amino acids while all other branded Filgrastims including Neupogen have 175 amino acids and Scimax is a patent product. The application is for transfer of registration and the product was already registered in Pakistan.

The case was considered in 289th meeting of Registration Board wherein the Board decided as follows:

"Registration Board deferred the case for following:

a. Evaluation report of analytical parameters of the product in light of Pharmacopoeia.

b. Tabulated summary of non-clinical and clinical data submitted by the firm."

In this context, it is submitted that the Filgrastim Injection available in Pharmacopoeia has 175 amino acids while the applied product has 174 amino acids and the firm has already submitted that their product is patent.

Tabulated summary of Non-clinical and clinical data submitted by the firm is as under:

Non-clinical In-vivo Studies c. Biological/ Pharmacodynamic activity d. Non- clinical toxicity as determined in one repeat dose toxicity study	Non-clinical Studies i. Study of anti-leucopenia effect of Scimax in Canis familiaris and Kunming hybrid mice in comparison with Filigsment of Kirin Japan ii. Non-comparative study of effects of Scimax on voluntary activities of mice iii. Non-comparative study of effects of Scimax on cardiovascular system and central nervous system of anesthetic cat Toxicology i. Non-comparative single dose toxicity study in mice ii. Non-comparative Long-term toxicity study in Beagle dogs iii. Non-comparative Long-term toxicity study in rats
Clinical	Only overview provided of following studies: i. Non-comparative Phase I (Pharmacokinetics & Pharmacodynamics) study of Scimax in healthy subjects. ii. Non-comparative Phase II study of Scimax. iii. Non-comparative Phase III study of Scimax iv. Multi-centre, randomized and controlled study of Scimax in comparison with imported Filgrastim. Details of imported Filgrastim are not provided by the firm.

Decision: Registration Board deferred the case for submission, of evidence of availability of product in reference regulatory authorities, by the firm.

9. Change in manufacturing site of already registered Solvent for Herceptin 440mg (Reg. No. 032131) applied by M/s Roche Pakistan Limited, Karachi.

M/s Roche Pakistan Limited, Karachi applied for the the change in manufacturing site of following registered biologicals as per following details:

Reg. No. & Date of Reg.	Brand Name & Composition	Last Renewal Submission	Already Approved Manufacturing Site	Newly Applied Manufacturing Site
032131 04-08-2004	Solvent for Herceptin 440mg Each vial contains: Bacteriostatic water for injection…..20ml	28-07-2014	M/s Genentech, Inc., South San Francisco, California, USA	M/s F. Hoffmann-La Roche Ltd Wurmisweg, CH-4303 Kaiseraugst, Switzerland

The firm has submitted the following documents:

a. Application on Form-5A

b. Fee Challan of Rs. 50000/-

c. Copy of initial registration letter dated 04-08-2004
d. Copy of last renewal submission dated 28-07-2014
e. Legalized CoPP No. 17004503 dated 23-08-2017 issued by Swissmedic indicating new manufacturing site.
f. An undertaking that the provided information is true and correct.

The above product is imported in combo pack with Herceptin injection. The last renewal submission has been verified by RRR section.

Decision: **Keeping in view the valid legalized CoPP and approval of Swissmedic (Reference Regulatory Authority); Registration Board approved the change in manufacturing site for Solvent for Herceptin 440mg (Reg. No. 032131) from M/s Genentech, Inc., South San Francisco, California, USA to M/s F. Hoffmann-La Roche Ltd., Wurmisweg, CH-4303 Kaiseraugst, Switzerland as per current Import Policy for finished drugs.**

10. Change in container closure system of already registered human biologicals applied by M/s PharmEvo (Private) Limited, Karachi.

M/s PharmEvo (Private) Limited, Karachi applied for the change in container closure system of already registered following human biologicals as per following details:

Sr. No.	Reg. No.	Brand Name & Composition	Existing Container Closure	New Container Closure
1.	045790	Innogen R Injection Each ml contains: Human Recombinant Insulin….100IU	Glass Vial with a **grey rubber stopper**, 13mm in diameter made of **bromobutyl rubber mixture**. The **aluminium cap** is 13mm in diameter and is made of **aluminium tape**, one-sidedly lacquered on the outside surface.	Glass Vials with a **Combi-seal**composed of an **aluminium cap**, size 13mm, equipped with a **double layer rubber disc** and a **plastic button.** The **cap** is made of an **aluminium tape**, lacquered on the external surface. **Rubber disc** is made of **bromobutyl mixture** West 4780/40 (innerlayer in contact with the product) and isopropene mixture West 7778/40 (outer layer). **Plastic button** is made of **polypropylene**. External surface of the button is uniform matte or smooth with "**FLIP OFF"** text.
2.	045791	Innogen M30 (30/70) Injection Each ml contains: Human Recombinant Insulin….100IU		
3.	045792	Innogen N Injection Each ml contains: Human Recombinant Insulin……100IU		

The firm has submitted the following documents:

i. Fee Challan of Rs. 5000/- for each product
ii. Copy of initial registration letter for each product
iii. Copy of last renewal submission for each product
iv. Justification for the new container closure system indicating that the inner layer in direct contact with drug product is bromobutyl rubber for both rubber stopper and double-layer rubber disc without change.
v. Comparative stability study data of previous and new container closure system for 36 months of 05 and 06 batches respectively indicating no significant differences in the stability results.
vi. Long term stability study data of 03 batches for 36 months and accelerated stability data of 03 batches for 06 months of new container closure system indicating that the drug product is stable till 36 months.
vii. Accelerated Leachables/ Extractables studies.

Decision: **Registration Board approved the change in container closure system of Innogen R (Reg. No. 045790), Innogen M30 (30/70) (Reg. No. 045791) and Innogen N (Reg. No. 045792).**

11. Deferred cases of M/s Medinet Pharmaceuticals, Rawalpindi

The following products of M/s Medinet Pharmaceuticals, Rawalpindi were deferred in 260th meeting of Registration Board for expert opinion of following and valid legalized COPP/FSC & GMP:

a. Brig. Tariq Satti, AFBMTC, Islamabad.
b. Brig. Qamar-un-Nisa, AFBMTC, Islamabad.
c. Dr Shamsi, Karachi

The expert opinion was not received from above experts therefore later on as per practice the firm was asked to provide complete Biosmilarity data of the products as per guidelines approved in 278th meeting of Registration Board. The firm has submitted Legalized FSC and GMP which valid at that time but expired in April and June 2019 respectively. After two letter the firm has submitted the data which have been evaluated below;

1.	**Name and address of Importer**	M/s Medinet Pharmaceuticals, Building No.601, Lane No.5, Main Peshawar Road, District Rawalpindi
	Detail of Drug Sale License	Drug Sale License No.01374-0176-022646D valid till 13-12-2019
	Name and address of Manufacturer	Probiomed S.A de C.V. San Esteban No.88, Col. Santo Tomas, C.P. 02020, Deleg, Azcapotzalco, Mexico City, Mexico.
	Brand Name +Dosage Form + Strength	**Bioyetin** Prefilled Syringe 2000 IU/0.300mL
	Composition	Each prefilled syringe contains: Human recombinant erythropoietin……2000 IU
	Diary No. Date of R& I & fee	Dy No. 1166, 30529, 37424 & 15485 Dated 26-2-2015, 11-09-2018, 12-11-2018 & 29-08-2019 Fee deposited: Rs. 50000/- dated 26-2-2015 + Rs. 50000/- dated 15-3-2016.
	Pharmacological Group	Therapeutic Protein
	Type of Form	Form 5-A
	Finished Product Specification	BP specification
	Shelf Life	2 years
	Document Details	Legalized GMP Certificate No. 183300516A0174 dated 20-03-2018 valid until 2-06-2019. Legalized Free sale certificate No. 183300CI170155 dated 23-04-2018 with one year of validity and copy of translation notarized by Notary Public.
	Pack size & Demanded Price	Cardboard box with one or six syringes prefilled with 0.3 ml solution with 2000 IU and sterile needle
	International Availability	**Epogen**
	Products already registered in Pakistan	Epokine by RG
2.	**Name and address of Importer**	M/s Medinet Pharmaceuticals, Building No.601, Lane No.5, Main Peshawar Road, District Rawalpindi **.**
	Detail of Drug Sale License	Drug Sale License No.01374-0176-022646D valid till 13-12-2019
	Name and address of Manufacturer	Probiomed S.A de C.V.

		San Esteban No.88, Col. Santo Tomas, C.P. 02020, Deleg, Azcapotzalco, Mexico City, Mexico.
	Brand Name +Dosage Form + Strength	**Bioyetin** Prefilled Syringe 4000 IU/0.300mL
	Composition	Each prefilled syringe contains: Human recombinant erythropoietin……4000 IU
	Diary No. Date of R& I & fee	Dy. No. 1165,30529, 37424 & 15485 Dated 26-2-2015, 11-09-2018, 12-11-2018 & 29-08-2019 Fee deposited: Rs. 50000/- dated 26-2-2015 + Rs. 50000/- dated 15-3-2016.
	Pharmacological Group	Therapeutic Protein
	Type of Form	Form 5-A
	Finished Product Specification	BP specification
	Shelf Life	2 years
	Document Details	Legalized GMP Certificate No. 183300516A0174 dated 20-03-2018 valid until 2-06-2019. Legalized Free sale certificate No. 183300CI170170 dated 25-04-2018 with one year of validity and copy of translation notarized by Notary Public.
	Pack size & Demanded Price	Cardboard box with one or six syringes prefilled with 0.3 ml solution with 4000 IU and sterile needle
	International Availability	**Epogen**
	Products already registered in Pakistan	Epokine by RG
3.	**Name and address of Importer**	M/s Medinet Pharmaceuticals, Building No.601, Lane No.5, Main Peshawar Road, District Rawalpindi **.**
	Detail of Drug Sale License	Drug Sale License No.01374-0176-022646D valid till 13-12-2019
	Name and address of Manufacturer	Probiomed S.A de C.V. San Esteban No.88, Col. Santo Tomas, C.P. 02020, Deleg, Azcapotzalco, Mexico City, Mexico.
	Brand Name +Dosage Form + Strength	**Bioyetin** Prefilled vial 10,000 IU/2 mL
	Composition	Each prefilled vial contains: Human recombinant erythropoietin……10,000 IU
	Diary No. Date of R& I & fee	Dy No. 1164 30529, 37424 & 15485 Dated 26-2-2015, 11-09-2018, 12-11-2018 & 29-08-2019 Fee deposited: Rs. 50000/- dated 26-2-2015 + Rs.50000/- dated 15-3-2016
	Pharmacological Group	Therapeutic Protein
	Type of Form	Form 5-A
	Finished Product Specification	BP specification
	Shelf Life	2 years
	Document Details	Legalized GMP Certificate No. 183300516A0174 dated 20-03-2018 valid until 2-06-2019. Legalized Free sale certificate No. 183300CI170183 dated 17-05-2018 with one year of validity and copy of translation notarized by Notary Public.
	Pack size & Demanded Price	Cardboard box with one vial with 2 ml solution with 10.000 IU
	International Availability	**Epogen**
	Products already registered in	Epokine by RG

	Pakistan	

The detail of biosimilarity data submitted by the firm as under:

The firm has submitted the following explanation with Biosmilarity data which has been reproduced as under:
The comparability exercise of **Bioyetin®** (erythropoietin alpha) was carried out using mainly the reference drug product indicated in the "List of Reference Biotechnological Medicines" (COFEPRIS):**Recormon® (erythropoietin beta), since in Mexico there is no currently commercialized a reference drug product containing recombinant human erythropoietin alpha.**

The erythropoietin analogues show differences in their glycosylation pattern (Halstenson, 1991), which give them particular binding characteristics and *in vitro* biological activity (Higuchi, 1992; Storring, 1998), which nevertheless result in same *in vivo* biological effect as endogenous human erythropoietin.
Consequently, **the erythropoietin alpha medicine Procrit® was included as an erythropoietin alpha drug in the comparative evaluation of the glycosylation profile and *in vivo* biological activity of Bioyetin®**. Finally, with the intention of obtaining more information, the analysis of the European Standard of Erythropoietin BRP was added in the physical-chemical and functional characterization and comparability exercise, composed of a mixture of the alpha and beta erythropoietin analogues ina relationship 1:1 (mass/mass).
The results of the tests that evaluated the molecular structures showed that **Bioyetin®** and Recormon® show expected differences in the analyzes that evaluate the heterogeneity of the glycoforms contained in each of these medicines, as well as their subsequent impact on the binding and *in vitro* biological activity.
However, these differences were not observed in the evaluation of the heterogeneity of **Bioyetin®** versus Procrit®.
The firm has also submitted the comparative data with Eur. Ph. Reference standard.

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison Physicochemical Characterization	a) Molecular mass by mass spectrometer. b) Primary sequence Analysis by Peptide Mapping of Epoetin Alpha in Reducing and Non-Reducing Conditions c) Amino acid sequence in the N-terminus end by Edman Degradation d) Electrophoretic 'profile' and 'apparent' molecular' mass' by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) in Reducing and Non-Reducing Conditions e) Immuno-detection (Immuno-recognition) by Western-Blot in denaturant reducing conditions. f) Higher order (Upper Order) structure by fluorescence spectrometry. g) Higher order (Upper Order) structure using UV absorption spectrometry h) Secondary structure by circular dichroism i) Disulfide bond and peptide profile identification by peptide mapping j) Free cysteines using colorimetry (Quantification of Free Sulfhydryls) k) Determination of sialic acid in Erythropoietin. l) Determination of the N-Glycosylation profile of Epoetin alpha using normal phase HPLC (HILIC). m) Characterization of N-Glycans of Erythropoietin using the rapid testing kit HILI-UPLC*

	Biological Activity	a) **Binding to the receptor:** The evaluation of the affinity, recognition and activation of the receptor of Erythropoietin is carried out by surface plasmon resonance (SPR) using biosensorsI b) *In vitro* biological **potency** : Evaluation of "in vitro" biological activity Biological potency by means of proliferation tests Carried out by the UDIBI of the IPN c) In vivo biological activity by means of the induction of erythropoiesis in mice B6D2F1 d) In vivo biological activity by means of the polycythemia test on CB6F1&mice
	Impurities	Not Provided
	Stability Studies	Stability studies is provided.
	Non-clinical Comparison	Not provided
	Clinical Comparison	The firm has submitted multiple clinical study report regarding the safety & efficacy of the product. Clinical study data in comparison with reference drugs is provided.

Remarks of Evaluator:

i. Quality comparison has been performed with Erythropoietin Beta Instead of Alpha (Reason by firm given above)
ii. Impurities, Non-clinical comparison and comparative clinical data have not been provided.
iii. FSC & GMP expired but valid at time of submission.

Decision: Registration Board deferred the case for submission of following by the firm:

a. **Valid legalized GMP and Free Sale Certificates**
b. **Quality comparison with Innovator product under biosimilarity studies**
c. **Data of impurities, comparative Non-clinical and clinical studies under biosimilarity studies.**

4.	Name and address of Importer	M/s Medinet Pharmaceuticals, Rawalpindi Building No. 601, Lane No. 05, Main Peshawar Road, Rawalpindi
	Detail of Drug Sale License	Drug Sale License No.01-374-0176-022646Ddated 13-12-2017 valid till 13-12-2019
	Name and address of Manufacturer	Probiomed S.A de C.V. San Esteban No.88, Col. Santo Tomas, C.P. 02020, Deleg, Azcapotzalco, D.F., Mexico.
	Brand Name +Dosage Form + Strength	FILATIL Prefilled Syringe 300MCG/1ML (Filgrastim)
	Diary No. Date of R& I & fee	Dy. No. 1798 (R&I) dated 21-11-2014 Fee deposited: Rs. 50000/- dated 17-11-2014 + Rs.50000/- dated 15-3-2016
	Composition	Each prefilled syringe contains: Filgrastim ……300 mcg
	Pharmacological Group	rDNA therapeutic protein
	Type of Form	Form 5-A
	Finished Product Specification	BP specification
	Shelf Life	2 years
	Document Details	Legalized GMP Certificate No.183300516A0174 dated 20-3-2018 valid until 2-06-2019.

	Legalized Free sale certificate No. 183300CI170155 dated 23-04-2018 with one year of validity and copy of translation notarized by Notary Public.
Pack size & Demanded Price	
International Availability	
Products already registered in Pakistan	

The detail of biosimilarity data submitted by the firm as under:

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison Physicochemical Characterization	a) Molecular mass by mass spectrometer. b) Amino acid sequence in the N-terminus end by EdmanDegradation c) Amino acid sequence and peptide profile by reduced peptide mapping d) Electrophoretic 'profile' and 'apparent' molecular' mass' by sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) e) Hydrodynamic'volume by size-exclusion chromatography (SE-UPLC) technique using a fluorescence detector. f) Isoelectric point by capillary isoelectric focusing (cIEF) g) Chromatographic 'profile' and 'polarity' BY the reverse phase liquid chromatography (RP-HPLC) technique h) Upper order structure by fluorescence lifetime spectroscopy i) Secondary structure by circular dichroism j) Disulfide bond and peptide profile identification BY by non-reducing peptide mapping
Biological Activity	a) Binding to the receptor by flow cytometry b) Receptor binding by spectrophotometry in cells c) By G-CSF induced cell proliferation assay in cells 32D Clone 3 d) Biological Potency by in vitro cell proliferation using a mouse lymphoblastoid cell line (32D clone 3) e) Biological Potency by in vitro cell proliferation line NFS-60 (mice myeloblastic cells), f) In vivo assessment of the proliferative activity of Filgrastim using a neutropenic mouse model
Immunochemical properties	
Impurities	c. Aggregates by Identity and purity by molecular exclusion chromatography dad y SEUPLC-UV-FL d. Related isoforms by Reverse phase chromatography
Stability Studies	Stability studies is provided.
Non-clinical Comparison In-vivo Studies	Not Provided
Clinical Comparison	i. Comparison of two presentations of filgrastim in Mexico used to mobilize hematopoietic totipotential cells from the bone marrow to the peripheral blood: prospective study in one single institution (19 Patients) ii. Only clinical reports are provided. Complete studies are not provided.
Decision:	**Registration Board deferred the case for submission, of comparative Non-clinical studies under biosimilarity studies, by the firm.**

12. Change of address of importer for productsunder registration / approved Biological drugs applied by M/s Martin Dow Marker Specialities (Pvt.) Ltd.

Following products of M/s. Martin Dow Marker Specialities (Pvt.) Ltdhave been approved 288th DRB meetings on new company name/title i.e../s. Martin Dow Marker Specialities (Pvt.) Ltd. The drugs are under Registration and now firm has applied for the change in address of importer forapproved/under registrationBiological drugsfrom Karachi Warehouse to Lahore Warehouse and requested to issue Registration letters on Lahore Warehouse address as per provided DSL and also requested to arrange verification of storage facility as soon as possible. The detail is as under:

Sr. No.	Name of product	Previous Address of Importer	New Address of Importer
1.	Gonal-*f* Pen 300 IU (22µg) / 0.5ml	D-7, Shaheed-e-Millat Road, Karachi	75/1-M, Quid-e-Azam Industrial Estate, Township, Kot Lakhpat, Lahore
2.	Gonal-*f* Pen 450 IU (33µg) / 0.75ml		
3.	Gonal-*f* Pen 900 IU (66µg) / 1.5ml		
4.	Ovidrel 250µg/0.5ml		
5.	Crinone® 8% Vaginal Gel		
6.	Luveris 75IU Powder & Solvent for Solution for Injection		

The firm has submitted the following documents for each product:

a. Fee challan of Rs. 5000 for each product.
b. Copy of Form-11 (Drug Sale License valid upto 17-01-2020).
c. Copy of Form-7 dated 17-01-2018.

Decision: Registration Board deferred the case for submission of following by the firm:

a. Reason for changing the storage facility from Karachi to Lahore.
b. Legal provision as per Drug Act, 1976 and rules framed there under conering instant request of the firm.

13. 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	03-06-2005	27-08-2015

		Each vial contains: Menotropin (hMG)…..75IU		
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

The details of the change is as under;

Previous address	New address	Change in Proprietorship
D-180, Roihan Street Block-5, Clifton, Karachi.	Basement Plot No.28C Lane No. 09 Ittehad Commercial Phase VI DHA Karachi.	Previous name of Proprietor: Khalil ur Rehman S/o Raheem Bakhsh New name of Proprietor: Gul Faraz S/o Muhammad Ashraf

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 application for change in proprietorship for previous name of proprietor. The firm has not provided NOC from previous proprieter.

Decision: Registration Board deferred the case for submission, of NOC from previous proprietor of Drug Sale License, by the firm.

17. Change in address of importer of already registered human biologicals applied by M/s Bio Medics Medical System, Rawalpindi.

M/s Bio Medics Medical System, Rawalpindi has applied for change in address for following registered biological products as per details mentioned below;

Sr. No.	Reg. No.	Name of product	Previous address	New address
1.	045680	Injection Heparinol- 5000	Office No. 63rd floor, Royal Plaza 6th road Rawalpindi.	F-597, F-Block, Satellite Town, Rawalpindi
2.	045681	Injection Heparinol- 1000		

The firm has submitted following documents;

i. Fee of Rs.5030/- per product.
ii. Copy of registrationletter
iii. Copy of renewal submission
iv. Copy of previous DSL,
v. Copy of new DSL (new DSL is with changed qualified person)
vi. Copy of verification of storage facility.

Decision: Keeping in view the valid Drug Sale License; Registration Board approved the change of address of importer from M/s Bio Medics Medical System,Office No. 63rd floor, Royal Plaza 6th road Rawalpindi to M/s Bio Medics Medical System,F-597, F-Block, Satellite Town,Rawalpindifor above products subject to storage facility verification report of new address.

18. Basagine Injection approved in 256th meeting of Registration Board applied by M/s Getz Pharma (Pvt.) Limited, Karachi.

Following product of M/s Getz Pharma (Pvt.) Limited, Karachi were approved in 257th meeting of Registration Board as per following details:

Sr. No.	Name of Manufacturer	Brand Name & Composition as per CoPP	Brand Name & Composition as per minutes of RB	Decision of RB in 256th meeting
1.	M/s Gan & Lee Pharmaceuticals Ltd., No.8, Jingsheng North 3rd Street, Golden Bridge Science Industrial Base, Zhongguancun Science Park, Tongzhou District, Beijing, China.	Basagine (Recombinant Insulin glargine injection) Each ml contains; - Recombinant InsulinGlargine…..…..100U	BASAGINE Solution for Injection 100Units/ml Each ml contains: Recombinant InsulinGlargine.. …100Units / ml Shelf Life: 2years (2-8^{0}C)	*Approved asper valid LegalizedCoPPsubject to inspection ofmanufacturerabroad as perImportPolicy forFinishedDrugs,verificationof storage facilities andfixation of MRP byPricing Committee.*

Accordingly, the panel inspection of manufacturer abroad was conducted on 25th& 28thNovember 2016 wherein the panel "Recommended" the facility and rated "Very Good".
154.

It is submitted that as per available record the product at serial number 1 of table at para-138/n is already registered from same source in name of M/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi with brand name Basalin Insulin 100IU/3ml cartridge **(Reg. No. 053809)**. M/s Getz Pharma (Pvt.) Ltd., Karachi applied as new application and provided the authorization letter for both products in their name from M/s Gan & Lee Pharmaceuticals Ltd., China. In this context, the letter was forwarded to PE&R Division for the provision of registration letter of Basalin (Reg. No. 053809) along with renewal status of the product.

As per reply,initial registration letter was issued dated 19-12-2008, the product is registered in the name of M/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi. However, it has been informed by PER division that renewal application has not been received in 2018, neither available in previous years.

To confirm status of the product fromM/s East West Pharmaceuticals Pakistan (Pvt) Ltd., Karachi letter was forwarded on 19th June 2019. However, the letter forwarded was received backwith a note that no company with this title exist at the given address.

After searching for contacts, the firm was asked for address to which the specified letter could be forwarded. The firm informed that address of the firm is still the same and requested to resend the letter.The firm was advised to submit response and clarify its position on the matter within seven (7) days. However, no response has been received yet.

Submitted for consideration of Board please.

Decision: Registration Board advised DBER to issue a reminder to M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi and to ask DRAP office, Karachi to provide the data of import of Basalin by M/s East & West Pharmaceuticals Pakistan (Pvt.) Ltd., Karachi.

19. Imported Human Biologicals applied by M/s Genetics Pharmaceuticals Pvt. Ltd., Lahore deferred in 254th meeting of Registration Board.

Following products of M/s. Genetics Pharmaceuticals Pvt. Ltd were discussed in 254th meeting of Registration Board held on 11-12th November 2015wherein the board decided as under;

"Registration Board deferred the case for completion of applications, remaining fee, CoPP status, information regarding availability in country of origin and deliberations regarding requirement for bio-similarity of products."

1.	**Name of Importer**	**M/s. Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate, Raiwind Road, Lahore – Pakistan.
	Name of Manufacturer	Manufacturer **M/s ZavodMedsintez**(ZavodMedsintez, LLC),Russia, Sverdlovsk region, Novouralsk, 15/3, Torgovaya St. Registration Certificate Holder: **M/s ZavodMedsintez** (ZavodMedsintez, LLC), Russia, 620144, Yekaterinburg, 90a, 8 Marta St.
	Brand Name +Dosage Form + Strength	**Rosinsulin C Injection** Suspension for Subcutaneous injection 100IU/ml
	Composition	Composition per 1ml: Insulin human recombinant……100IU
	Finished product specifications	Store at 2-8°C
	Approval status of this product in Reference countries	NIL
	Pharmacological Group	Hormone
	Shelf life	2 Years
	International Availability of this product	Russia
	Similar Product already registered in Pakistan	Humulin N by Elli Lilly Insulatard by Novonordisk
	Type of Form Dy. No.& Date of application, Fee submitted	Form-5A R&I Dy.No.10252 dated 7-12-2012. DD Bio Dy. No.910/2014 dated 21-04-2014. Rs. 100000/- dated 07-12-2012 Rs. 100000/- dated 10-10-2018 Rs. 100000/- dated 10-10-2018
	Demanded Price/ Pack size	10mL vial 5mL Vial 3mL Cartridge
	General documentation	1. Legalized CoPP No. 07/2017/0002276 valid till 27-05-2019. 2. Legalized Certificate of Registration issued by Ministry of Healthcare of the Russian Federation dated 27-03-2009
	Remarks of Evaluator **(Khurram Khalid AD)**	1. The firm has submitted application with full fee of for all pack sizes.
	Decision	
2.	**Name of Importer**	**M/s. Genetics Pharmaceuticals Pvt. Ltd** 539-A Sundar Industrial Estate, Raiwind Road, Lahore – Pakistan
	Name of Manufacturer	Manufacturer **M/s ZavodMedsinte**(ZavodMedsintez, LLC),Russia, Sverdlovsk region, Novouralsk, 15/3, Torgovaya St. Registration Certificate Holder: **M/s ZavodMedsintez** (ZavodMedsintez, LLC), Russia, 620144, Yekaterinburg, 90a, 8 Marta St.

	Brand Name +Dosage Form + Strength	**Rosinsulin R Injection** Solution for injection 100IU/ml
	Composition	Composition per 1ml: Insulin human recombinant……100IU
	Finished product specifications	Store at 2-8^{0}C
	Approval status of this product in Reference countries	NIL
	Pharmacological Group	Hormone
	Shelf life	2 Years
	International Availability of this product	Russia
	Similar Product already registered in Pakistan	Humulin R by Elli Lilly Actrapid by Novonordisk
	Type of Form Dy No & Date of application, Fee submitted	Form-5A R&I Dy.No.10255 dated 7-12-2012 DD Bio Dy. No.911/2014 dated 21-4-2014 Rs. 100000/- dated 07-12-2012 Rs. 100000/- dated 10-10-2018 Rs. 100000/- dated 10-10-2018
	Demanded Price/ Pack size	10mL vial 5mL Vial 3mL Cartridge
	General documentation	1. Legalized CoPP No. 07/2017/0002275 valid till 27-05-2019. 2. Legalized Certificate of Registration issued by Ministry of Healthcare of the Russian Federation dated 27-03-2009
	Remarks of Evaluator **(Khurram Khalid AD)**	1. The firm has submitted application with full fee of for all pack sizes.

WHO Biosimilarity Guidelines	**Data Submitted by the firm**
Quality Comparison Physicochemical Characterization	Molecular mass, primary, secondary and tertiary structure is compared with reference to European Pharmacopeia instead of comparator drug. Study of identity, peptide mapping and high order structure is provided but results are not compared with comparator.
Biological Activity	Comparative conclusion provided.
Immunochemical properties	Provided (Compared with reference standard)
Impurities	Provided.
Stability Studies	Submitted
Non-clinical Comparison In-vivo Studies In-Vitro Studies	Following data for Rosinsulin R compared to Humulin by Elli Lilly has been provided. a. Primary Pharmacodynamics b. Secondary Pharmacodynamics c. Pharmacokinetic studies d. Toxicology Studies 1. Single-Dose Toxicity 2. Repeat-Dose Toxicity 3. Local Tolerance Following data for Rosinsulin C compared to Humulin by Elli Lilly has been provided.

	a. Acute toxicity b. Subacute toxicity c. Physiological studies. d. Pathomorphological studies.
Clinical Comparison	Phase III clinical data compared with Humulin, a product of Lilly.

Remarks of Evaluator:

It is submitted that the firm has been asked twice by forwarding letters in Jan, 2018 & Dec, 2018 to fulfill deficiencies but comparative quality datain biosimilarity studies with comparator drug could not be submitted by the firm. Thefirm has replied that both the products are Pharmacopeial products and M/s ZavodMedsinte, Russiahas conducted comparative studies as per pharmacopeia.

Decision: Keeping in view the biosimilarity data and valid legalized CoPPs indicating products availability in country of origin; Registration Board approved the products subject to compliance of current Import Policy for finished drugs. Panel of inspectors of DRAP will verify whether the firm has conducted physicochemical characterization in comparison with Pharmacopoeial reference standard or not. Registration letter will be issued after said verification.

20. Local human Biological applied for registration by M/s Macter International Limited, Karachi.

The following product for the local manufacturing biological drug was considered in 246th Meeting of Registration Board held on 10-11th December, 2014 but later on the Registration Board in its 270th meeting advise the division of Biological drugs to come up with working paper in the next meeting. The final guidelines regulatory requirements of Biological drugs using rDNA technology has been approved in 278th meeting of Registration Board. The Detail is as under;

1.	Name of Manufacturer	M/s Macter International Limited,F-216, Site, Karachi
	Brand Name +Dosage Form + Strength	Macgrastim ***300 mcg/1.2ml*** *(Filgrastim-Recombinant human granulocyte colon-stimulating factor*
	Composition	Each vial contains: Filgrastim…..300mcg/1.2ml
	Finished product specifications	BP Specification
	Pharmacological Group	Therapeutic Protein
	Shelf life	2 years when stored
	Products already registered in Pakistan	Grastim by CCL Pharma, Lahore.
	Type of Form Dy No & Date of application, Fee submitted	Form-5, Dy No.1118/2014(R&I) dated 10-10-2014 Rs. 20000 dated 16-09-2014
	Demanded Price / Pack size	Price: As per PRC Pack of 1's (Vial)
	Remarks of Evaluator	

The firm has submitted data as per the said guidelines. The submitted documents are evaluated as under;

Documents required as per 278th RB decision for Biological Drugs (Concentrated Form/Ready to fill Form)	**Documents submitted by firm**
The firms shall provide legalized GMP certificate of biological drug substancemanufacturer abroad (who will provide concentrate / ready to fill bulk of biologicaldrug to Pakistani manufacturers for further processing) as an evidence that themanufacturer is an authorized manufacturer of biological drug in the country oforigin.	Provided
The firms shall provide legalized free sale certificate/CoPP either from country oforigin or by any reference regulatory authority as adopted by Registration Board offinished product as evidence that the final product has been manufactured by sameconcentrate/ready to fill bulk after submission of data to the concerned regulatoryauthority.	Provided
The firm shall provide the complete Bio-similarity studies of the finished product ofsame source (bulk concentrate or ready to fill) manufactured either from country oforigin or by any reference regulatory authority as adopted by Registration Board todemonstrate the bio-similarity.	Provided & Evaluated below
The firm shall provide the lot release certificate of the finished product manufacturedby same bulk concentrate/ ready to fill from country of export (If applicable).	In China Filgrastim (rhG-CSF) is not included in products which require LOT Release Certificate.
The firm shall provide the 6 months accelerated and real time stability studies for drugsubstance.	Provided
The local manufacturer shall manufacture three trial batches of the finished biologicalproduct to finalize the formulation and then perform analyticalstudies(Physicochemical and biological) including protein content, appearance, pH,Osmolarity, composition of key excipients including stabilizers (if formulation is same),visible/subvisible particles, identity testing to parent molecule, purity testing, in vitrobiological activity, sterility, Pyrogen content, safety, potency and toxicity with supportof iso-electro focusing data, gel electrophoresis, Western-Blot and other analyticaltechniques). The firm shall submit the results for processing of registrationapplication.	Provided
The manufacturer shall perform all tests locally as detailed on Certificate of analysis.	Provided
The firm shall also provide the list of finished products being manufactured from samebulk concentrate or ready to fill form in any country of the world (if available).	Provided
The firm shall provide the agreement with the source (of bulk concentrate/ready to fill)that if there shall be any critical change in manufacturing process, biological systemsused to manufacture, etc. the firm shall inform DRAP immediately along with relevantdocuments.	Not Provided
Regular monitoring through pharmacovigilance reporting system shall be observedthrough proper pharmacovigilance cell of the manufacturer and report will beforwarded to the National Pharmacovigilance Centre, Division of Pharmacy Servicesand Biological Division of DRAP. In case of any severe adverse event, immediatemandatory reporting procedure shall be followed.	Layout plane submitted.
The firm shall inform DRAP if there shall be any adverse event or ADR reporting fromthe country of manufacture of concentrate/ready to fill bulk and finished product asrequired vide Rules 30 of Drug (LR&A) Rule.	Provided
If any of the conditions is not fulfilled or public health risk reported at any stage, thedrug registration shall stand cancelled with immediate effect.	Provided
All the provisions as contained in the Drugs Act, 1976 and rules made there underincluding provisions of Lot Release certification from National Control Laboratory forBiologicals shall be strictly adhered to.	Provided

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	i. Molecular Weight by Reducing SDS-PAGE ii. **Assay for chemical structure by following methods** a. Sequencing for recombinant DNA b. UV Spectrum c. Composition of Amino Acids d. Peptide Mapping e. N-terminal sequencing of rhG-CSF by Edman degradation
Biological Activity	**In-vivo activity** by Activity of rhG-CSF in vivo (Effects of rhG-CSF on CY-induced myelosuppression in rhesus Monkeys): In-vitro activity by a. 3H-TdR assay , b. MTT assay using NFS-60 cell line
Immunochemical properties	a. Identification (by Western Blot) b. ELISA (Enzyme-linked Immunosorbent Assay)
Impurities	**Purity assay by following methods** a. Non-Reducing SDS-PAGE & Reducing SDS-PAGE b. Isoelectric focusing c. Reverse Phase HPLC d. SEC-HPLC (Size Exclusion Chromatography HPLC) e. Capillary Electrophoresis
Stability Studies	Stability studies are provided.
Non-clinical Studies	**In Vitro Pharmacodynamic Study:** Effect of rhG-CSF on the proliferation of normal mouse and human bone marrow cells in vitro Effects of rhG-CSF on Acute Radiation-induced Hematopoietic Injury in Mice **Toxicity study is provided but not comparative.**
Clinical Studies	A Comparative Study between Jilifen (rhG-CSF) Hangzhou Jiuyuan Gene Engineering Co., Ltd China and Gran (rhG-CSF) manufactured by Kirin Brewery Company, Japan in Hematological Malignancy **(Conducted in 15 hospitals in Shanghai from Mar to Jun 1998)**
Remarks of Evaluator : a. Comparative Toxicity study is not provided. b. The firm has also applied for the finished import from the same source with same name, which is under process.	

Decision: Registration Board deferred the case for submission of following by the firm:

a. Comparative toxicity studies data under biosimilarity studies.

b. Clarification regarding the import of finished product from same source with same name.

21. Cancellation of registration of Eritromax Lyophilized Powder for Injection 2000IU (Reg. No. 062286) and Eritromax Lyophilized Powder for Injection 4000IU(Reg. No. 062287) applied by M/s Pharmatec Pakistan (Private) Limited, Karachi.

M/s Pharmatec Pakistan (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.	062286	M/s Blausiegel Industrria e Comercio Ltda. Cotia-SP- Brazil	Eritromax Lyophilized Powder for Injection 2000IU Each vial contains: Erythropoietin of alfa (rHu EPO)…….2000IU	1's Vial
2.	062287		Eritromax Lyophilized Powder for Injection 2000IU Each vial contains: Erythropoietin of alfa (rHu EPO)…….2000IU	1's Vial

The firm has submitted the following documents:

a. Copy of initial registration letter dated 04-06-2010
b. Notarized copy of last renewal submission dated 16-07-2015
c. Justification for cancellation
"Lot of alternative and me-too are available in the market. Management is not interested".
d. List of alternative brands:

Sr. No.	Reg. No.	Name of Firm	Name of Product	
1.	062274	M/s Al-Karim Distributor	Sepo	2000IU
2.	062275	M/s Al-Karim Distributor	Sepo	4000IU
3.	079809	M/s Sami Pharmaceuticals	Ropo	2000IU
4.	079811	M/s Sami Pharmaceuticals	Ropo	4000IU
5.	023635	M/s RG Pharmaceutica	Epokine	2000IU
6.	023633	M/s RG Pharmaceutica	Epokine	4000IU
7.	035548	M/s Ferozson Laboratories	Eritrogen	2000IU
8.	035549	M/s Ferozson Laboratories	Eritrogen	4000IU
9.	039820	M/s Medinet Pharmaceuticals	Bioyetin	2000IU
10.	039821	M/s Medinet Pharmaceuticals	Bioyetin	4000IU

e. An undertaking that no case is pending at any forum/ court of law regarding above products.
f. An undertaking that all provided information/ documents regarding above products are true/ correct to best of their knowledge.

Decision: **Keeping in view the justification provided by the firm and alternative brands available in the market; Registration Board cancelled the registration of Eritromax 2000IU (Reg. No. 062286) and Eritromax 4000IU (Reg. No. 062287) from the name of M/s Pharmatech Pakistan (Private) Limited, Karachi.**

22. De-registration of QuinvaxemInjecton (Reg. No.053812) and Vaxem Hib Injection (Reg. No.018932) applied by M/s GlaxoSmithKline Pakistan Limited.

M/s GlaxoSmithKline Pakistan Limited applied for the cancellation of registration of following human biologicals:

Sr. No.	Reg. No.	Name of Manufacturer	Brand Name & Composition	Packing
1.	053812	M/s Janssen Vaccines Corp., (Songdo-dong) 23 Harmony – r0 303beon-gil Yeonsu-gu Incheon, Republic of Korea.	**Quinvaxem Injection** (diphtheria, Tetanus, Pertussis (whole cell), hepatitis B &Haemophilus influenza type b vaccine) Each vial (0.5ml) contains: Diphtheria toxoid…..…..≥7.5 Lf (≥30IU) Tetanus toxoid…….≥3.25 Lf (≥60IU) Pertusis antigen……≥150U (≥4IU) Hib oligosaccharide…….10µg conjugated to approx.25µg of CRM 197 Hepatitis B Surface Antigen…..10µg	Single vial dose = Rs.3000/- 1x50's vials = Rs.150,000/-
2.	018932	Product License Holder: M/s GSK Vaccines S.r.l, Via Fiorentina, 1, 53100 Siena, Italy Manufactured By: M/s GSK Vaccines S.r.l, Bellaria-Rosia, 53018 Sovicille (SI), Italy.	**Vaxem Hib suspension for injection** (*Haemophilus influenza* type be conjugate vaccine) Each vial (0.5ml) contains: 10µ of capsular oligosaccharide of H. *influenza* type b conjugated to approx. 25µg CRM197 protein	Single dose 0.5ml PFS = Rs.1086.80/-

The firm has submitted the following documents:

a. Copy of initial registration letter of product "Quinvaxem Inj." dated 16-12-2016.
b. Copy of initial registration letter of product "Vaxem Hib suspension for Inj." Dated 16-12-2016.
c. Justification for cancellation
   - "Suitable therapeutic alternatives and advance therapies are available in the market.
   - Better / new molecules to cater the same portfolio are also available in the market
   - Virtually there is no demand of this product in local market".
d. List of alternative brands:

Sr. No.	Product	Name of Product	Name of Firm
1.	**Quinvaxem Injection**	Trivac HB	M/s Macter International
2.	Vaxem Hib Injection	Influvac	M/s Abbot
		Pentaxim	M/s Sanofi-Aventis

e. An undertaking that no case is pending at any forum/ court of law regarding above products and that all provided information/ documents regarding above products are true/ correct to best of their knowledge.

Decision: Registration Board referred the case to Committee on availability of life saving drugs.

Item No. VI Division of Quality Assurance & Laboratory Testing

Sr.#.	Subject	Status
01	CASE REFERRED BY PQCB, PUNJAB REGARDING METHOD OF DICLOTRAM SR METHOD, MANUFACTURED BY M/S MAPLE PHARMA, KARACHI.	
02	CASE REFERRED BY PQCB, PUNJAB REGARDING SYRUP BIORON-F MANUFACTURED BY M/S SHAHEEN PHARMACEUTICALS LTD.	
03	CASE REFERRED BY PQCB, PUNJAB REGARDING NUGATORY METHOD OF ANALYSIS OF HEMOROSE-F TABLETS SUBMITTED BY M/S NEOMEDIX PHARMA.	
04	MANUFACTURE & SALE OF SUBSTANDARD ZENTRO 40MG TABLETS BATCH NO. 18008 MANUFACTURED BY M/S BOSCH PHARMACEUTICALS (PVT.) LTD, KARACHI.	
05	MANUFACTURING AND SALE OF SUBSTANDARD INJECTION HEPAFERON (INTERFERON) B. NO. 85 BY M/S PHARMEDIC LAB, LAHORE.	
06	CASE REFERRED BY PQCB LAHORE REGARDING SUBSTANDARD ALENSTRAN 10 MG TABLET BATCH NO. F-T-940 MANUFACTURED BY M/S FARMACEUTICS INTERNATIONAL KARACHI.	
07	CASE REFERRED BY PQCB LAHORE REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE PRODUCT SPECIFICATIONS/METHOD OF ANALYSIS.	03 personal hearings
08	STANDARD OPERATING PROCEDURE FOR DESTRUCTION OF DRUG REGISTRATION BOARD PORTIONS OF DRUGS SAMPLES FOR WHICH 01 YEAR HAVE PASSED AFTER DATE OF EXPIRY SINCE DECLARATION OF STANDARD QUALITY BY CDL.	
09	MEETING OF COMMITTEE ON AVAILABILITY OF LIFE SAVING DRUGS.	
10	CASES OF VALSARTAN RECALL – PRESENCE OF CARCINOGENIC IMPURITIES IN VALSARTAN API AS REPORTED BY EMA PRESS RELEASE DATED 05-07-2018.	
11	PENDING CASES AS IDENTIFIED DURING THE PROCEEDING OF DRUG COURT, QUETTA.	

Case No. 01: Case Referred By PQCB, Punjab Regarding Method Of Diclotram SR Method, Manufactured By M/S Maple Pharma, Karachi.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/F-Isu-Bwp-01-06-19 dated 20-02-2019 has informed that Director DTL Bahawalpur vide Letter No. 1980 dated:09-11-18 stated that the label claim of Diclotram SR (M/S Maple Pharma) is of BP Specs but dissolution of SR product is not mentioned in BP and monograph allow the manufacturer to adjust time limit of release of drug according to drug design but the limit should be within BP specified limit i.e. 1st spec point of about 20-30%, 2nd specs point of about 50% and last step ensure the complete release of drug which is generally understood as more than 80% release (according to BP) but the manufacturer ignored this criteria and mentioned last specification is NLT 65%.

Beside this, there are mistakes in manufacturer specification as the manufacturer said Tris buffer in reagents but preparing phosphate buffer in preparation section. There are mistakes in calculation formula for dissolution also. Mistake is also observed in disintegration method as the method specify the limit of disintegration is 15 minutes, it is also mentioned in the method that Disintegration Time is in accordance of "enteric coated tablets" while product is sustained release.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **199th meeting held on 31-01-2019.** According to the decision of the Board in its 197th meeting, personal hearing notice was served to the firm but the firm was absent. The Board after due discussion and deliberation at length decided to pend the issue. The Board further decided to call the manufacturer in the upcoming meeting along with the clinical evidence supporting their dissolution criteria provided.

CURRENT PROCEEDINGS & DECISION BY THE COMMITTEE:

Subject issue was considered by the Committee of the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **6th meeting held on 20-02-2019.** According to the decision of the Board in its 199th meeting, persnal hearing notice was served to the firm but no one appeared before the Committee to justify their position. Secretary PQCB apprised the Committee about background of the subject matter which was discussed at length The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specification and method of analysis to the Government analyst/Drug Testing Laboratories. The need for product specifications /method of analysis becomes more critical when the drug is not available in official pharmacopoeias and/or the manufacturer has its own customized specifications/method for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample on such method provided by the firm, which have mistakes in its method. The Board expressed its serious concerns over casual behavior on the part of the firms in this regard.

The Committee after due discussion and deliberation unanimously **decided to recommend DRAP for the cancellation of registration of the above-mentioned product** as the manufacturer ignored the dissolution criteria of the official monograph and also provided a method to the Govt. Analyst which is full of mistakes.

Proceeding and Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and the Board after detailed discussion decided as under:

> **"To issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the Provincial Quality Control Board (PQCB), Lahore for failing to fulfil the condition for registration by ignoring the dissolution criteria of the official monograph and also for providing a method to the Government Analyst which is full of mistakes. In case you failed to justify the deviation from the official monograph, supported with the development and validation data of product in question, product registration will be suspended/cancelled."**

Case No. 2: Case Referred By PQCB, Punjab Regarding Syrup Bioron-F Manufactured By M/S Shaheen Pharmaceuticals Ltd.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/F-Isu-Rwp-05/199/19 dated 31-01-2019 has informed that Director DTL Rawalpindi vide letter no. LR/DS/2018/616 dated 10-12-18 stated that sample of syrup **Bioron-F,** Registration No. 054851 manufactured by M/S **Shaheen Pharmaceuticals Ltd.** was received. The received method of test/analysis provided by M/S Shaheen Pharmaceuticals is not workable to be performed in laboratory. Sample as well as standard both do not respond on the method provided.

Further, this formulation in this combination is not available in any pharmacopoeia. You are requested to guide us regarding reporting of these samples.

PREVIOUS PROCEEDINGS & DECISION BY THE BOARD:

Subject issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **197th meeting held on 20-12-2018.** The Board after due discussion and deliberation decided to call M/S **Shaheen Pharaceuticals Ltd.,** in the upcoming meeting to explain their position before the worthy Board regarding the provision of method to the Provincial Drugs Testing Laboratory on which sample as well as standard is not working.

CURRENT PROCEEDINGS & DECISION BY THE BOARD:

Subject issue was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **199th meeting held on 31-01-2019.** According to the decision of the Board in its 197th meeting, personal hearing noice was served to the firm. Mr Malik Amir, representative of the firm appeared before the Board.

The Board after due deliberation and discussion at length decided to direct the Drugs Testing Laboratory, Rawalpindi to file the above-mentioned case. Secretary PQCB apprised the Board about background of the subject matter whichas discussed at length. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specification and method of analysis to the Government analyst/Drug Testing Laboratories. The need for product specifications /method of analysis becomes more critical when the drug is not available in official pharmacopoeias and/or the manufacturer has its own customized specifications/method for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample on such

method provided by the firm, on which standard is not responding.

The Board expressed its serious concerns over casual behavior on the pat of the firms in this regard. The Board after detailed discussion and deliberation decided to allow the Provincial Drug Testing Laboratory, Rawalpindi to file the above-mentioned case. Furthermore, **the Board decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the above- mentioned drug, in the best public interest.**

Proceeding and Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and the Board after detailed discussion decided as under:

> **"To issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore. You failed to fulfill the condition of registration as prescribed under the rules because the method of test/analysis method provided by you was non responsive for test analysis and defective. (Sample as well standard both do not respond to the method provided by the firm). You are required to explain your position that why the registration of Bioron-F, Registration No. 054851 should not be suspended/ cancelled."**

Case No. 03: Case Referred By PQCB, Punjab Regarding Nugatory Method Of Analysis Of Hemorose-F Tablets Submitted By M/S Neomedix Pharma.

The Secretary, Provincial Quality Control Board, Punjab vide reference No.PQCB/F-Isu-Bwp-05/06/19 dated 20-02-2019 has informed that Director DTL Faisalabad vide letter no. 8054/DTL/FSD dated 26-01-2019 stated that the lab has received sample of Tab. Hemorose-F (iron polymaltose complex + Folic acid) manufactured by M/S Neomedix bearing batch No. 484 from Drug Inspector Aziz Bhatti Shaheed Teaching Hospital Gujrat on 27-12-2018.

That requests for the provision of method was sent to manufacturer vide letter no. 6007/DTL/FSD dated 29-12-2018 and 23-01-2019 respectively. The method of analysis was found to be not workable for folic acid as the mentioned concentration (0.00007 mg/ml) for both sample and standard was below the limit of identification and quantification on UV at 280nm.

PROCEEDINGS AND DECISION:

Subject issue was considered by the Committee of the Provincial Quality Control Board, under section 11 of the Drugs Act 1976 in its **6th meeting held on 20-02-2019.** Secretary PQCB apprised the Committee about background of the subject matter which was discussed at length and directed Drugs Testing Laboratory, Faisalabad to file the above-mentioned case. The Board observed that all the manufacturers/ drug registration certificate holders are legally bound to provide product specification and method of analysis to the Government analyst/Drug Testing Laboratories. The need for product specifications /method of analysis becomes more critical when the drug is not available in official pharmacopoeias and/or the manufacturer has its own customized specifications/method for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample on such method provided by the firm on which sample as well as standard is not responding. The Board expressed its serious concerns over casual behavior on the part of the firms in this regard.

The Committee after due discussion and deliberation unanimously **decided to recommend**

DRAP for the cancellation of registration of the above-mentioned product as the manufacturer ignored the dissolution criteria of the official monograph and also provided a method to the Govt. Analyst which is full of mistakes.

Proceeding and Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and the Board after detailed discussion decided as under:

> **"To issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore. You failed to fulfill the condition of registration as prescribed under the rules because the method of test/analysis method provided by you was non responsive for test analysis of Folic acid and is defective. (The method of analysis was found to be not workable for folic acid as the mentioned concentration (0.00007 mg/ml) for both sample and standard was below the limit of identification and quantification on UV at 280nm.). You are required to explain your position that why the registration of your product i.e. Tab. Hemorose-F (iron polymaltose complex + Folic acid) should not be suspended/ cancelled ."**

Case No.04: **Manufacture & Sale of Substandard Zentro 40mg Tablets Batch No. 18008 Manufactured by M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi.**

The FID-VI, DRAP Karachi visited the premises of M/s Khan Medicos, shop No.16, Block No. 11-A, Karimabad market ST-2, FB Area, Karachi on 11-04-18 and taken the following sample U/S 18(1) (c) of the Drugs Act, 1976 for the purpose of test/analysis on prescribed Form-3:

Name:	Zentro 40mg Tablet.
Composition:	Each Tablet contains 40mg Pantoprazole.
Registration No:	035547
Batch No:	18008
Manufacturing Date:	07-17
Expiry Date:	06-20
Manufactured By:	M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi.

The FID-VI, Karachi has forwarded one sealed portion of sample to Central Drugs Laboratory, Karachi vide memorandum No.ARS-25-26/2018-FID-VI (K) dated 11-04-2018 as required under Section 19(3)(i) of the Drugs Act, 1976.

The FID-VI, DRAP, Karachi has also forwarded one sealed portion of sample as Board's Portion vide letter No. ARS-25-26/2018-FID-VI (K) dated 13-04-2018 as required under Section 19(3)(ii) of the Drugs Act, 1976.

The Federal Government Analyst, CDL, Karachi declared the sample as of **Sub-standard** quality **on the basis of dissolution** vide test/analysis **report No.KQ.SC.249/2018** dated 06th June, 2018 which is violation of Section 23 (1) (a) (v) of the Drugs Act, 1976 and rules framed there under.

The area FID-VI, Karachi vide letter No.ARS-25-26/2018-FID-VI (K) dated 13-06-2018 & 28-06-2018 has asked the M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi to explain their position

in the matter of manufacturing and selling of substandard drug with direction to recall the above said batch from the market.

M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi submitted their reply vide letter No.GMRA/221/090718 dated 10th July, 2018 wherein as per contents of their reply they are not satisfied with the results of test report of CDL, Karachi but has not challenged it properly rather submitted to close the case.

The FID-VI, Karachi submitted that the samples of all available generic Pantoprazole capsules/tablets were taken for test & analysis on the complaints of several healthcare professionals regarding the efficacy of almost all generics amid the shortage of market brand. The CDL in-vitro test also confirmed the same. Therefore it is recommended that thorough investigations may be carried out encompassing manufacturers of brand leaders and generics also re-sampling of all available generics Pantoprazole throughout the country may be carried out for further investigations. It is further recommended provided the names of responsible which are as under:

S.No.	Name	Designation	CNIC
1	Shaikh Mohiuddin Chawla	Managing Director and Warrantor	(42201-2175782-3)
2	Muhammad Ishaq	Production Incharge	(42101-1581154-7)
3	Imtiaz Ahmad	Quality Control Incharge	(42401-4079608-7)
4	SM Chawla	Warrantor	

The Division of Drug Licensing, DRAP Islamabad was requested to verify the names provided by the FID-VI, Karachi and provided the following names being responsible persons and technical persons.

M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi	Shaikh Mohiuddin Chawla, **(Director)** M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi
Mr. Ahmad Nasib, **(Director)** M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi	Mr. Farhan Chawala **(Director)** M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi
Mr. Zakarya Nasib, **(Director)** M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi	Muhammad Ishaq, (**Production Incharge)** M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi
Imtiaz Ahmad, (**Quality Control Incharge)** M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi	

Show cause notice has been issued to the technical staff/management of the firm – responsible persons U/S 7(11) of the Drugs Act, 1976 vide letter no. 03-47/2018-(QC) dated 16-01-2019.

The show cause notice was served to the firm and accused persons but the firm did not submit their reply in response to show cause notice.

Proceeding and Decision of the 288th Meeting of Registration Board.

Mr. Navaid Ahmad Akhtar , Group Manager Regulatory affairs (42201-3315232-1) & Dr. Syed Saad Hussain, Manager Pharmacovigilance (42201-8305042-1) of M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi appeared on behalf of M/s Bosch Pharma (Pvt.) Ltd, 221, Sector 23, Korangi Industrial Area, Karachi to plead instant case of Substandard Zentro 40mg Tablets, Batch No. 18008, Reg.No.035547 before the Board in its 288th meeting on 15th February, 2019.

Representatives of the firm submitted that they are not satisfied with the results of the CDL, test report as the protocols were not followed properly. Only stage one of the dissolution was performed while stage II & III were not performed. Also speed of 75 RPM was applied instead of 100 RPM.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided as under:

> "*The QA&LT Division Shall direct the area FID to take samples as per prescribed procedure from portion of Zentro 40mg Tablets, Batch No. 18008 retained by its manufacturer (10 packs as per claim of the firm) i.e. M/s Bosch Pharmaceuticals (Pvt.) Ltd, Karachi for the purpose of test and analysis from CDL, Karachi and submit report for consideration of Registration Board immediately without waiting for the minutes of the meeting. The sample should be divided into three (03) equal portions as prescribed under the law"*

The above said decision was communicated to the area FID with request to comply with the decision of the Registration Board vide reference No.F.03-47/2018-(QC) dated 04th March, 2019.

Preceeding of 291st Meeting of Registration Board.

FID-VI, DRAP, Karachi vide reference No.F.25-26/2018-FID-VI (K) dated 17th May, 2019 submitted that in compliance to the direction of Registration Board in its 288th meeting, he inspected M/s Bosch Pharma (Pvt.) Ltd., on 08-03-2019 and drew the QC retained samples of tablet Zentro, Batch No. 18008 manufactured by M/s Bosch Pharma (Pvt.) Ltd., Karachi on prescribe form-3. The sealed sample was sent to Federal Government Analyst, CDL, Karachi vide memorandum No.ARS-20/2019-FID-VI (K) dated 11-03-2019. The Federal Government Analyst, CDL, Karachi vide test report No. R.KQ.208/2019 dated 10th May, 2019 declared the sample as of standard quality with regard to the test performed.

Description:	*Orange colored, enteric coated tablets*
Identification:	*Pantoprazole Sodium identified.*
Dissolution test:	Complies.
Assay for Pantoprazole:	
Determined amount/tablet:	*40.6813mg*
Stated amount/tablet:	*40mg*
Percentage:	*101.7%*
Limits:	*90.0% to 110.0% Complies.*

NOTE.*01) The previous sample of the said product , having same batch number (18008) and registration number(035547) manufactured by M/s Bosch Pharma (Pvt.) Ltd., Karachi referred by FID Karachi was declared as of substandard quality vide CDL test report No.KQ.SC.249/2018, dated 06-06-2018 on the basis of dissolution test.*

02) The results of the dissolution test of the present sample, although lie within limits, show significant variation, ranging from 68.9% to 99.2% from tablet to tablet. This shows that there is manufacturing problem with the product and availability of active ingredient to patient may vary from tablet to tablet. The manufacturing formula/process be redesigned and dissolution of the product be improved to ensure better quality, safety and efficacy.

Proceeding and Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and the Board after considering the point of Federal Government Analyst, CDL, Karachi, detailed discussion decided as under:

- **The Board showed concern about the results of the dissolution test of the present sample, although lie within limits, show significant variation, ranging from 68.9% to 99.2% from tablet to tablet which shows that there is manufacturing problem with the product and availability of active ingredient to patient may vary from tablet to tablet. The manufacturing formula/process be redesigned and dissolution of the product be improved to ensure better quality, safety and efficacy.**
- **Firm is directed to redesign the manufacturing process so that the variability in the release pattern is minimized during the shelf life of the product. Report of aforementioned work need to be submitted to QA&LT Division and area FID.**
- **Area FID is directed to verify the corrective measures and take samples of the said product from the manufacturing premises as well as from the market to verify the corrective measures from the test/analysis results. Comprehensive report should be submitted for consideration of the Board.**

Case no.05: Manufacturing and sale of substandard injection Hepaferon (Interferon) B. no. 85 by M/s Pharmedic lab, Lahore.

The brief of the case for consideration of the Registration Board

Background of the case

The background of the case is that the Registration Board in its 248th meeting held on 18th-19th March, 2015 discussed the case of supply of sub-standard Hepaferon Injection (Interferon) to Government of Khyber Pakhtunkhwa Batch No.80-87. The Federal Inspector of Drugs (FID) Peshawar was directed by the Registration Board to submit the certified copies of decisions of Drug Court Peshawar and Peshawar High Court, Peshawar in the instant case. The FID has submitted the copies of the orders the Peshawar High Court, Peshawar and the copies of decision of Drug Court Khyber Pakhtunkhwa, Peshawar The Board after thorough deliberations and in the light of decisions of the Courts and view point of the member from the M/o Law Justice and Human Rights decided the case as under:-

*"Registration Board was briefed about the background of the case. Sheikh Sarfraz Ahmad, representative from Ministry of Law was of the view that after the decision of the Drug Court Peshawar a fresh reference requires to be sent to Law Division for seeking opinion. The Board agreed to the proposal***".**

Decision:

The Drugs Registration Board decided that the opinion of Law Division may be solicited in the light of decision of the Drug Court, Khyber Pakhtunkhwa, and Peshawar which are self explanatory in which the Honorable Drug Court ordered that the complaint of the prosecution is dismissed.

Decision of the 254th Meeting of the Registration Board.

Report was being prepared both by the Federal Inspector of Drugs and Provincial Drug Inspector for submission the Honorable Court. When the investigation was under process by FID and Provincial Drug Inspector completed his investigation is submitted before the Court on the basis of report submitted by Provincial Drug Inspector the court acquitted the accused Later when the report of FID was completed, the time for filing appeal had also lapsed.

In this case Federal Drug Inspector should have intervened through Peshawar High Court for stopping the drug court from announcing its decision till the time the report of Federal Inspector of Drug was completed this was must done.

Presently the accused stand acquainted and Board cannot ensure notice to the accused on the here of report of FID because the accused stand accqumtted by the Court

The Law division has decided to consult additional Attorney General DAG for filling application before the court for already condonation of delay in order to file an appeal.

The Board has decided to consult the DAG through Legal Affairs Division of DRAP for filing application on condo nation of delay The decision was communicated to Deputy Director Legal Affairs on 22nd August 2016.

The Federal Inspector of Drugs (FID) Peshawar was directed by the Registration Board to submit the certified copies of decisions of Drug Court Peshawar and Peshawar High Court, Peshawar in the instant case. The FID has submitted the copies of the orders the Peshawar High Court, Peshawar and the copies of decision of Drug Court Khyber Pakhtunkhwa, Peshawar The Board after thorough deliberations and in the light of decisions of the Courts and view point of the member from the M/o Law Justice and Human Rights decided the case as under:-

*"Registration Board was briefed about the background of the case. Sheikh Sarfraz Ahmad, representative from Ministry of Law was of the view that after the decision of the Drug Court Peshawar a fresh reference requires to be sent to Law Division for seeking opinion. The Board agreed to the proposal"***.**

The Drugs Registration Board decided that the opinion of Law Division may be solicited in the light of decision of the Drug Court, Khyber Pakhtunkhwa, and Peshawar which are self explanatory in which the Honorable Drug Court ordered that the complaint of the prosecution is dismissed.

Keeping in view of the decision of the Drug Court Khyber Pakhtunkhwa, Peshawar the M/o Law Justice and Human Rights is requested to furnish view/ comments as whether the responsibility fixed by Federal Inspector of Drugs, Peshawar under Section 23(1)(a)(v)(vii) and 23(1)(a)(vii), 23(1)(b)(f) of Drugs Act, 1976 for prosecution **(Annex-IV)** may be set aside after the decision of the Drug Court Khyber Pakhtunkhwa, Peshawar or otherwise.

As per reference para 433/N FID Peshawar informed that he sent 02 letters to DAG office Peshawar on 05th August and 25th August 2016 but no reply receive from DAG office Peshawar then on 30th August 2016. The FID mentioned that he personally went to DAG office Peshawar High court Peshawar Mr. Manzoor Khan Khalil Senior DAG Peshawar High Court. The DAG informed the FID Peshawar that they cannot give any opinion/comments on the case relevant case.

The FID Peshawar further informed that the DAG also directed him to submit an application to Law Division Islamabad for legal opinion and when Law Division Islamabad shall refer the subject case to DAG office Peshawar High Court then they will look into the subject matter and give legal opinion/comments.

The Federal Inspector of Drug Peshawar forwarded the FR to Director QA, DRAP Islamabad wherein the FID submitted the details of the instant case which are as under:

The case of Hepaferon (Interferon) manufactured by Pharmadic Lahore has been devided into three phases/parts as under:-

1. **Part/phase 1.**

On 01/04/2013 on the Telephonic direction of DDC (QC) (QA) the FID visited Chief Drugs Inspector Khyber Pakhtunkhwa Mr. Sabir Ali to get initial information about the case which was communicated to DRAP Islamabad on 26.04.2014 vide letter No.F.3-20/2013-FID-DRAP-119 after getting the initial and unsigned substandard report from provincial govt. the FID issued a letter to Chief Executive Pharmedic Lab. Lahore and asked to provide the following information vide this officer letter No.F.3-20/2013-FID-DRAP 868 dated 08-04-2013 and reminder and in reference to telephonic direction from Director Biological directed the FID to get the status and storage condition of the Hepaferon lying in LRH Car parking premises the detailed report submitted to Director Biological DRAP Islamabad vide this office letter No. F.3-20/2013-FID-DRAP-1288 dated 25-04-2013 desiring detailed information about the case the FID and in reference to Director Biological Drugs letter No.F-1/-4/2013 dated 25-04-2013 desiring detailed information about the case the FID submitted a detailed report about the preceding of sampling by provincial drugs inspector and report submitted by Director DTL and by anticorruption from unknown Laboratory submitted to Director Biological vide this office letter No. F.3-20/2013-FID DRAP-1288 dated 08-05-2013. Under direction of Chief Justice High Court Peshawar the Director General Health Services requested DRAP Islamabad to conduct sampling from the stock of Interferon lying in the premises of LRH Peshawar. The Director General Health Services issued a letter on 02-08-2013 vide office letter No. S.O (Drugs)/H/2-43/2013-Re-examination to Director Federal Govt. Analyst National Control Laboratory for Biological Islamabad and in response DG Health Services KPK letter the DRAP Islamabad issued a letter to the FID to take sample of Hepaferon Inj. Mfg and supplied by Pharmadic Lahore from LRH and from the stores the stock lying in the company M/s Pharmadic Lahore premises vide letter No. F.3-15/2013-QC dated 19th August 2013

The FID vide DRAP Islamabad letter No. F.3-15/2013-QC dated 31-005-2013 coordination with Director General Health office and Director Anticorruption office to send their representative as witness during sampling on 15-08-2013 and reminder issued on 24-06-2013 vide this office letter No.F.3-20/2013-FID-DRAP-1674. The FID along with representative of DG Health and Director Anti Corruption office drawn samples from three containers on Form-3 on 15-08-2013 from the stock of Interferon (Hepaferon) Injections of the available batches of Batch No. 80,82,85 and 87 lying at different temperature of 4.7 C 35 and 38 C and sent to govt. Analyst Biological NCLB on Form 4 dated 15-08-2013 summary of storage condition and samples submitted to Director Biological National Laboratory Islamabad vide this office letter No.F.No.3-20/2013-FID-DRAP dated 15-08-2013. Sampling received by Director Biological Islamabad on16-08-2013 copies of Form3 and Form-4 and detail report of storage condition submitted to Director Biological and DG Health Services KPK and DDC (QC) Islamabad for Information

On 27-08-2013 vide this office letter No. F.3-20/2013-FID-DCA (P)2134 a detail report about sampling and storage condition submitted to Director General Health Services for information

On 26-08-2013 manufacture portion sent to Manager (QC) M/s Pharmadic Lab Lahore

On 22-10-2013 the office receive all the test report of Interferon from NCLB from B.No.80-87 stock lying in three containers at the basement car parking of LRH hospital Peshawar which are as under :-

S.No.	Name of Drug	B.No. and Temperature	Test Report No. & date	Results/Remarks
01.	Hepaferon Injection 3 MIU (Interferon Alpha 2a)	80(+38 C)	FS-2013/17 14-10-2013	Substandard
02.	do	81(4.7 C)	FS-2013/13 14-10-2013	Substandard
03.	do	82(+38 C)	FS-2013/13 14-10-2013	Substandard
04.	do	82(4.7 C)	FS-2013/13 14-10-2013	Substandard
05.	do	83(+38 C)	FS-2013/13 14-10-2013	Substandard
06.	do	83(4.7 C)	FS-2013/13 14-10-2013	Substandard
07.	do	84(4.7 C)	FS-2013/13 14-10-2013	Substandard
08.	do	85(35C)	FS-2013/13 14-10-2013	Substandard
09.	do	87(+38 C)	FS-2013/13 14-10-2013	Substandard

On 22-10-2014 copies of attested tests reports were submitted to DG Health KPK Peshawar Chief Executive officer DRAP Islamabad Director Anti Corruption Peshawar and Director Pharmadic Lab Lahore with direction to stop sale and recall all the stock from the market.

On 30-10-2013 after receiving the substandard tests reports of Hepaferon (Interferon) from batch No.81-87 the FID visited the storage area of Hepaferon at LRH Car Parking and took the details of stock by physical checking/counting batch wise quantity manufacturing and expiry date recorded on Form-I and ordered under section 18(1) of the Drugs Act 1976 requiring a person not to dispose of stock in his position and sign taken from the store keeper of cold chain system kept in three container at LRH under safe custody of Rehmatullah Khan Sahibzada Khan Barkat Ali Cold Chain operators and Mr. Mohammad Ibrahim Cold Chain supervisor Signature taken on Form-I from all the responsible persons mentioned above.

In reference to the substandard report show cause issued to Chief Exeutive M/s Pharmadic Lahore vide this office letter No.F.10-77-85/2013-LRH-DRAP-2651 dated 28-10-2013 and directed the firm to recall the stock of the said drug from the market and from your distributer outlets under intimation to this office and also directed to provide the sale record batch History and names of Directors and technical staff in QA and production with NIC No.

Another letter No.F.10-77-85/201-LRH-DRAP 2951 dated 29th November 2013 issued to DG Health Services KPK Peshawar with direction not to use these substandard drugs Hepaferon (Injection) B.No.80-87 kept in three container at LRH car parking and inform the same to all field DHQs offices and Health centers not to use the same batch no. whereas available.

On 12.3.2014 a letter issued to Chief Executive M/s Pharmadic Lahore to provide the name of Director/Chief Executive with NIC copy Name of Production Incharge Name of QC Incharge valid copy of DML issued by DRAP Islamabad The same letter was sent to DDG (E&M) Lahore

vide this office letter of even No. dated 12-03-2014 with request to ensure the compliance of this letter through your area FID

The reply of the firm was received vide their letter No. Ref.No.PH/LHR/18225 dated 28-03-204 in which they have provided all the required information name of director/chief executive name of production Incharge QC Incharge along with copies of CNIC and valid copy of DML

Another reply of the firm was communicated to this office by area FID Lahore on 25-112013 vide firm letter No.RefPh/LRH/18062 dated November 02, 2013 in which the firm blames the Director Health for not maintaining the temperature of the cold storage rooms of the 3 containers lying at LRH car Parking but did not provide the undertaking about the storage condition between the firm and DG Health Services KPK who was responsible to maintain the storage condition 2-8 C

In light of above mentioned storage condition and substandard test report received form govt. analyst NCL Biological Islamabad the firm has violated section 23 of Drugs Act 1976 therefore the Director Itikhar Ahmad Sheikh CNIC No.35202-0328994-9 production Incharge Mazhar Hussainan Quality control Incharge Mr. Asim Mehmood of the firm as mentioned above may please be prosecuted in Drugs Court alongwith Director program Hepatitis KPK Dr. Ghulam Subhani store keeper Mr. Mubarak shah may please be nominated as co accused in the case due to negligence or intentionally the storage condition was not maintained from 2-8 C nor tested after purchase and gave huge loss to public money The FID ordered to stop the use of hepaferon on Form-I under section 18(1) of Drugs Act 1976 due to particle and not maintaining the storage condition of the 3 containers lying/kept in the premises of LRH Hospital by KPK Govt.

Part 2.

On the other hand interferon Injection Batch Nos. 87 and 88 sampling conducted from DHQ Hospital Mardan on 23-12-2013 on Form-3 and samples sent to the Director National Biological Islamabad on 24-12-2013 and test reports received from National Institute Biological Islamabad with standard Quality vide Test report No.FS2013/31 and 32 dated 22-02-2014 with the remarks The sample is of standard quality with regards to tests performed however being a biological product this sample report is not applicable to whole lot or some other portion of the same lot stored elsewhere under different storage conditions which needs clarification by the govt analyst NCL Biological because when any sample is drawn from any stock/premises in random it covers the whole stock but the remarks of govt. analyst is doubtful needs clarifications The same repot communicated to DDC (QC) DRAP Islamabad and copy to DG Health KPK and Director M/s Pharmadic Lahore on 20-03-2014 and letter issued to Director NCL for Biological/Govt. Analyst for clarification Reply is still awaited

During sampling of Hepaferon Injection (Interferon Alpha 2A 3MIU/ml batch No. 87 and 88 storage condition was found maintained between 2-8C

However on further scrutiny of the record of DHQ Mardan following fact were revealed

1. The hospital was supplied 180.000 vial of Hepaferon vials in 2011 as per receipt No. Nil dated 22-04-2011. The receipt did not indicate any batch No..
2. However as per statement of store keeper MS DHQ Mardan the stock was returned to M/s Pharmadic for keeping in their cold storage facilities on behalf of hospital then the hospital make arrangement for its own appropriate storage facilities.

3. An undertaking by M/s Pharmadic Lab Dated 22-04-2014 was also found in the record to that effect that the firm will supply the balanced interferon as and when required by DHQ Mardan
4. A receipt dated 26-05-2012 issued by M/s Pharmadic indicate the 180,000 vials interferon was received by M/s Pharmadic Lab Lahore
5. A delivery Challan D.C No.3 dated 26-02-2011 issued by M/s Pharmadic indicate that DHQ Mardan was supplying 180,000 Hepaferon Injection Batch No.87 & 88
6. Lot release certificate of Batch No. 87 and 88 is enclosed

In view of above documents/ statement obtained from record of DHQ Hospital Mardan there appeared to be a number of Locumas which create doubts on the whole process of receipt and return of stock by DHQ Mardan.

Some documents received from the store Keeper given to Anti Corruption during investigation copies stock of 180,000 vials on dated 26th May 2012 and another letter of undertaking issued by pharmedic on 22-04-2011 regarding 180,000 vials letter received by the office of the Medical superintendent DHQ Hospital Mardan by Aurangzeb store Incharge dated 22-04-2011

Statement of MS Dr. Nigar Ahmed DHQ Hospital Mardan dated 03-06-2013 given to Anti Corruption Circle Peshawar In which he states that store Keeper informed him about the arrival of Hepaferon and with the directive of Director Hepatitis on telephone we received the stock and on the direction of Project Director Hepatitis as per the statement of store keeper Mr. Aurangzeb the stock was received and retuned back to M/s Pharmadic Lahore for keeping at their cold storage until the DHQ Mardan will not arrange their own cold storage facilities as per stamen of store keeper Mr. Aurangzaib DHQ Mardan

Part 3

On the request of Director Hepatitis Program KPK and the DRAP Islamabad issued direction to Fid Lahore to take samples from the stock of KPK Government lying with M/s Pharmedic Lahore custody quantity is 837894 vide letter No.4186/PHCP dated 13-01-2014

In continuation to DRAP letter direction Mr. Ajmal sohail area FID Lahore and Dr. Akbar Ali area ADC Lahore visited the premises of M/s Pharmedic Lahore an checked the stock of Hepaferon of the stock of KPK government and it was observed that all the stock of interferon of B.No. 81, 82, 88, 89, 90, 91, 92, 93, 94 and 95 was found kept at room temperature. Therefore the panel could not take samples for test analysis as the storage condition was not maintained under section 18(I) of the Drug Act 1976 requiring a person not to dispose of the stock in his possession on Form-I and required the concerned authority to grant permission for extension in not to dispose of period under clause (i) of subsection (I) of the section 18 of the Drug Act 1976 for 3 months or till the decision

The FID submitted that they are also sending complete suo Moto judgment copies of Honorable High Court Peshawar for information and necessary action attached with this letter

Keeping in view all the facts and correspondence and substandard tests reports issued by Govt. analyst NCL Biological Islamabad the following persons may please be included in prosecution under section 23(1)(a)(v)(vii) and 23(1)(a)(vii) and 23 (1) (b) (f) violation of cold chain storage condition who are directly or indirectly involved

Accused

i. Mr. Iftikhar Ahmed Shiekh, Director/C.E.O
ii. Mr. MazharHussain, Production Incharge.
iii. Mr. AsimMehmood, Quality Control Inchage

Co Accused

i. Dr. GhulamSubhani Director Hapatitis Program (Co-accused)
ii. Mubarik Shah, Store Keeper LRH Hapatitis Program (Co-accused)
iii. Dr. Nigar Ahmed, Ms DHQ Mardan
iv. Mr. Aurengzaib, Store Incharge, DHQ Mardan (Co-accused)
v. Dr. Chuhan Director (Co-accused),
vi. Dr. Sharif, Director (Co-accused)

Witness

1. Mr. Abdul Samad Khan Director/ Federal Govt.analyst NCL for Biological Islamabad.
2. Mr. Rehmatullah Baig Alvi, FID, Peshawar.
3. Mr. Adnan Shaidullah ADC Peshawar.
4. Mr. Ajmal Sohail Asif area FID Lahore.
5. Dr. Akbar Ali area ADC Lahore.
6. Dr. Haroon Director Hepatitis Programme, KPK.
7. Mr. Khawaja Mohammad Kahn sub inspector then anti corruption Peshawar.
8. Mr. Zahid Ali Khan Pharmacist Government KPK MCC Director office.
9. Mr. Zakir Drugs Inspector Peshawar.
10. Mr. Tayyab Abbas Drugs Inspector Peshawar.

Proceeding and decision of 279th meeting of DRB:

The Board decided to issue the show cause notice and personal hearing to the accused persons of the firm responsible for manufacturing and selling of substandard interferon injection, as the purchaser had purchased the injection under the warranty issued by the manufacturer. Hence, they are protected under section 32 of The Drugs Act, 1976.

Proceeding and decision of 284th meeting of DRB:

The board deferred the case till the next meeting of Registration Board.

Proceeding and Decision of the 286th Meeting of Registration Board.

Mr. Syed Anees Ur Rehman Kirmani (Manager Regulatory Affairs) of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore and Shahid, Advocate (35200-1420583-9) appeared on behalf of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore to plead instant case of Substandard Hepaferon Injection (Interferon) drug before the Board in its 286th meeting on 16th November, 2018. The Board decided to defer the case keeping in view of the request of the firm for detailed show cause notice to the accused persons and to come up in the upcoming meeting of Registration Board."

Show cause notice was served to the firm and accused as per decision of 286th meeting of the Registration Board dated 09th April, 2019 and their reply is still awaited.

Proceeding and Decision:

Mr. Syed Anees, Regulatory Manager(38403-868689026-9) of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore and Shahid Sulehri, Legal Manager (35200-1420583-9) appeared on behalf of M/s Pharmedic Laboratories (Pvt.) Ltd., Lahore to plead instant case of Substandard Hepaferon Injection (Interferon) drug before the Board in its 289th meeting on 16th May, 2019.

The representative of the firm informed the Board that delay in reply to show cause notice was due to unavailability of the Chief Executive Officer of the firm, as he was abroad. They also submitted written reply to the show cause notice issued to them vide reference No.03-48/2013-(QC) dated 09th April, 2019.

The Board after hearing the accused deliberated the matter in depth in the light of available record/ investigation report of FID decided to thoroughly review the reply of the show cause notice and defer the case till next meeting of the registration board.
The reply of the firm is reproduced as under:

Subject: MANUFACTURE AND SUPPLY OF SUB-STANDARD HEPAFERON INJECTION 2 MIU (INTERFERON ALPHA 2A) BACTH NO. 80, 81, 83, 84. 85 & 87and 81, 82, 88, 89, 90, 91, 92, 93, 94 & 95 BY M/S PHARMEDIC LABORATORIES (PVT) LIMITED, LAHORE

Sub-Standard Hepaferon (Interferon Alpha-2a) Injection in KPK, false implication of M/s Pharmedic & absolution

Kindly note: This written reply is supported by two attached volumes of record as evidence.

Honorable Sir / Members,

Reference to your letter No. F.No.03-31/2019-(QC) Dated 13th May, 2019 with above mentioned subject,

AND;

Board meeting held on 16 November 2018 in your kind office with our Legal Affairs Manager (Mr. Shahid Sulehri), Regulatory Manager (Mr. Syed Anees Kirmani) & Mr. Hassan Javed Qureshi (Regulatory Officer), M/s Pharmedic state and submit as under;

Introduction:

Pharmedic Laboratories (Pvt) Limited 16-Km, Multan Road Lahore has been manufacturing life-saving standard quality drugs, according to the GMP standards, including anti-hepatitis and anticancer medicines, under the license from Drug Regulatory of Pakistan (DRAP) for more than 30 years, without any complaint. M/s Pharmedic has been exporting its medicines earning foreign exchange and contributing to the economy of the country.

Anti-Hepatitis Manufacturing:

For the treatment of hepatitis, M/s Pharmedic was the pioneer in manufacturing of anti-hepatitis medicines in Pakistan and Pharmedic had been manufacturing and selling standard quality HEPAFERON (INTERFERON ALPHA-2 A) INJECTION, registered with DRAP. for about 13 years with very successful results and on economical rates with the passion to serve humanity and the nation of Pakistan. The efficacy reports from KPK and all over Pakistan are here for your kind consideration that proves our stance.

History:

Pharmedic won the tender being lowest in rate through tender bidding process, advertised by the Health Department of KPK and started supply of Hepaferon (Interferon Alpha-2a) injection. Pharmedic also had provided the col storage containers to facilitate KPK health department which lacked the facility to accommodate the supplied injections.

Pharmedic imported the raw material of Hepaferon injection from china, after verification of DRAP Lahore office. The said injections were supplied after getting LOT RELEASE CERTIFICATES from NCLB Islamabad, which were issued after reviewing &checking of accuracy and verification of quality of our medicine. All record of import, tender, bidding, supply orders and delivery challan are enclosed.

It is to submit that order was awarded through proper channel for 1,509,984 injections Hepaferon along with Virazide tablets 11,324,880 as well as disposable syringes through order number 305/12, 306/12 DGHS Peshawar. Out of which 672,000 injections had been supplied

through cold chain system and the balance 837,984 were kept to supply on demand due to lack of temperature cold storage facility required to keep these injections.

Although Pharmedic had provided 3 temperature controlled cold storage containers to facilitate the buyer, even though, they were not in position to take the remaining stock which was ready to supply at our end. Pharmedic reminded the buyer several times to receive/ lift up the balance quantity but did not get any reply. Pharmedic reaffirmed the balance quantity time and again.

Inspections & Renewal of DML:

It is pertinent to mention here that during the supply against above mentioned orders, the inspections for renewal of our D.M.L. (Drug Manufacturer License) was conducted by (DRAP) Drug Regulatory Authority of Pakistan on dated 27-09-2012, our DML was renewed and our all areas including biological section were declared up to mark and standard. Inspection records enclosed.

Cold Storage Containers:

As M/s Pharmedic was ready to supply all the stock as per order, according to the agreement and schedule set therein, but health department KPK refused to take, due to lack of storage facility. On account of the domestic and human sympathy, on verbal requests of DG health department KPK, Pharmedic provided & handed over three cold store containers to health department KPK and which were placed at LRH Peshawar on written request of DG health KPK to CO LRH Peshawar. Copy Enclosed.

Operational liabilities of cold storage containers:

To operate and maintain these cold store containers, Health Department KPK has appointed several personnel as operator and supervisor. So, it was clear responsibility of health department KPK to handle with care the supplied injections. The said containers should be kept in running condition by direct supply of electricity. In view of electricity short fall conditions of the county in 2011-13, they should have to install stand-by generators for the same but unfortunately, they were found using these cold store containers as office and sleeping therein.

It is pertinent to mention here that main culprit was Mr. Khalid Khan, Analyst DTL Peshawar, who without any authority and jurisdiction, unlawfully conducted tests on our product from some ill-equipped and unauthorized laboratory belonging to one of our company's competitors. He prepared fake reports and declared our product substandard all because Pharmedic, refused to agree to bribery. He prepared and presented these unsigned reports just to blackmail us.

Legal Proceedings:

As a result of these illegal and unjust actions by Mr. Khalid Khan and other involved, proceedings were initiated against us which resulted in registration of FIR No. 3/13 u/s 420,419,109,409,120B PPC 5/2/47 PC Act P/s ACE Peshawar and several types of inquiries were started against us including cases in different courts including Supreme Court of Pakistan, Peshawar High Court, Drug Court and anticorruption court, at the same time. Furthermore, the case was handed over to (NAB) National Accountability Bureau by Honouarble Chief Justice Peshawar High Court.

These proceeding were predecessor to SUO MOTO case by Chief Justice High Court KPK. This Suo Moto case was taken up by the honorable Supreme Court and Suo Moto authority of High Court was revoked. Copy attached.

FID Peshawar:

On direction from DRAP Islamabad, FID Peshawar on 15-08-2013 from the stock of Interferon

(Hepaferon) Injections of the available batches of Batch No. 80 to 85 and 87, stored at different temperature of 4.7°C, 35°C and 38°C and sent to NCLB, with detail report of storage condition of the cold store containers at LRH Peshawar, which were kept by and under responsibility of the Health department KPK, without presence of any company representative as witness. The NCLB declare all these samples substandard (which were kept carelessly and at unfavorable conditions). It is further stated that samples were taken from that place which was being maintained & monitored by the health department, being operated & supervised by the health department KPK's employees. And, due to carelessness and inaccuracy in temperature maintenance, all the injections had already deteriorated which shows clear negligence of health department KPK. It was against the fact of taking pre-damaged injections as samples and observing reports of those. The FID Peshawar took all the stock at LRH Peshawar in his custody.

Further, it is submitted that, interferon Injection Batch Nos. 87 and 88 sampling conducted by same FID from DHQ Hospital Mardan on 23-12-2013 and storage conditions were found as per mentioned on the label of injections and temperature was maintained between 2°C-8°C, and were kept at controlled conditions, those were declared standard by the NCLB, which clearly shows that the main fault was of not keeping the injection at prescribed and necessary storage conditions. It proves the negligence of the health department of KPK. The health department KPK could not keep the supplied injections in favorable conditions and the failed to monitor and maintain the provided cold store containers as per requirements, which resulted in a huge loss to the public.

Replacement of delivered items is a clear matter of common & mutual understandings. It was the responsibility of M/s Pharmedic to replace the short expiry products as per rules and agreement. Pharmedic replaced the quantity asked by the government there. Relevant record is attached herewith.

FID Lahore:

On instructions from DRAP Islamabad, FID Lahore visited the premises of Pharmedic to inspect the stock "kept to deliver" on demand of health department KPK. This stock of interferon of B. no. 81, 82, 88, 89, 90, 91, 92, 93, 94 and 95 was found kept on room temperature because it was gone to "of short expiry" and Pharmedic have planned to destroy the same as per rules. So, this stock was not supplied due to lack of place and keeping facility by the health department KPK and kept at room temperature for destruction. Destruction report attached.

The report of FID Lahore that confirms the quantity I stock of injection present at our premises, also affirms our version and prove our stance that Pharmedic were ready to supply but all were on hold because of health department KPK was not ready to keep the same.

On the other hand, as per negotiations and instructions by health department KPK, M/s Pharmedic agreed to supply the pending/remaining stock by third party.

Supply of Pending Stock:

On demand and desire of health department KPK, M/s Pharmedic supplied the pending injections from third party. Record attached.

Trails, Acquittal & Closure of Inquiries:

Pharmedic was proven not guilty and acquitted from Drug Court of Peshawar by declaring our medicine up-to standard. The Honorable Supreme Court of Pakistan also gave the verdict in our favor. NAB KPK has also closed inquiry and the reference was surrendered in our favor. Copies of judgment of drug court Peshawar, High Court Peshawar with closure certificate from NAB and Supreme Court's Judgment are being presented for your kind perusal.

Management Change:

Mr. Asim, Ex-QC Manager, has left the organization for 3 years. Clearance certificate is attached.

Mr. Mazhar Hussain, Production Manager of Pharmedic laboratories has also been

resigned from his job. Copy attached.

Mr. Iftikhar A. Sheikh, Ex-CEO of M/s Pharmedic, has also resigned from the directorship of the company.

Prayer:

As briefed above, the case was inquired by the highest profile law enforcement agencies of Pakistan and tried through several law authorities. M/s Pharmedic's version of being standard and transparent has been proven. Pharmedic acquitted from drug court. National Accountability Bureau has also closed the inquiry & reference was surrendered in our favor. Hence, taking up the matter again without keeping the factual and legal background in mind, is against the nature of justice.

It is humbly prayed that the case may kindly be disposed off in our favor.

Pharmedic may kindly be declared as manufacturer of quality medicines. Everything which occurred was due to negligence of Health Department of KPK, on the part of health department KPK due to malice and ulterior motives of the then DTL Analyst Mr. Khalid Khan.

Proceeding and Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and the Board and Board consider the following records, material/personal hearings by the counsel as well as management of the company who appeared in 289th meeting before the Board.

- Case forwarded by the FID, DRAP, Peshawar.
- Inspection report of M/s Pharmedic laboratories by FID, DRAP, Lahore and ADC, DRAP, Lahore dated 20-03-2014.
- Test reports by the Federal Government Analyst, NCLB, Islamabad.
- Show cause notice issued to the M/s Pharmadic and accused persons.
- Reply to the show cause notice as well as correspondence by the firm.
- Personal hearing in different meetings of Registration Boards (286th , 289th)

Proceedings of 291st Meeting of Registartion Board.

Registration Board after thorough evaluation of above mentioned records, personal hearings, inspection reports and reply to the show cause notices unanimously decided as under:

i. **The firm failed to comply with the condition of registration prescribed under the law. At the time of inspection dated 20-03-2014 it was revealed that requisite storage facilities (2-8 ºC) were not sufficient to store the manufacture stocks at the recommended temperatures and humidity. The stocks were kept in the corridors at room temperature. This reveals manufacturing and storage conditions do not corresponds in terms of capacity.**
ii. **That the FID recorded the temperature at the time of sampling, which revealed the samples picked up at the controlled temperature (2-8 ºC) were also, declared of substandard quality.**
iii. **On the basis of above findings, the Board decided to cancel the registration of the product i.e. (Hepaferon Injection 3 MIU) Interferon Alpha 2a Registration No.o29537 due to failure of the registration holder to meet the conditions for registration of drugs prescribed under the rules.**
iv. **The Board also decided to recommend the cancellation of the section to the Central Licensing Board approved for manufacturing of biological products.**

Case No. 06: Case Referred By PQCB Lahore Regarding Substandard Alenstran 10mg Tablet Batch No. F-T-940 Manufactured By M/S Farmaceutics International Karachi.

The Secretary, PQCB, Punjab vide letter no. PQCB/R 151-04/2016 dated 31-7-2018, which are about order of PQCB for Tehsil Darya Khan District Bhakkar stating the proceeding and decision of PQCB regarding Sub-standard Alenstran 10 mg tablet batch no. f-T-940 manufactured by M/s Farmaceutics International, F1-A3, S.I.T.E Karachi, in its 190th meeting held on 31-7-2018.

That case states that Provincial Inspector of Drugs, Tehsil Darya Khan District Bakkhar reported that:

i. He, on 23-12-2015, inspected the business premises of M/s Yousaf Medical Store AddaKohawarKalan District Bakkar and took samples of two different types of drugs on Form 4 for the purpose of test and analysis.

ii. One out of the two drug samples after test/ analysis was declared as sub-standard by Government Analyst Drug Testing Laboratory Faisalabad as detailed below:

Name of drug	**Batch no**	**Name of manufacturer**	**DTL report TRA no. and date**	**DTL test report results**
Tablet Alenstran 10 mg	f-T-940	M/s Farmaceutics International F1-A3, S.I.T.E, Karachi	TRA no. 4222/DTL Dated: 15-4-2016	**Analysis with specifications:** **Manufacturer's specifications** **Description:** Oblonged, biconvex film coated tablets, having line of bisection at one side, contained in plastic blister of 10 tablets, packed in unit carton. The blister contains 8 tablets instead of 10 tablets moreover do not bear batch no. of the product on blister. **Assay: (**Cetirizine) Percentage: 96.50% Limit: 90-110% **Disintegration:** Not More Than 30 minutes. **Determined:** comply with the specifications**.** **Result:** the Sample is sub-standard/ misbranded on the basis of tests performed.

That M/s Farmaceutics International, Karachi challenged the DTL report. But the request was not processed as the sample got expired at that time.

That the case was considered by the Provincial Quality Control Board, under section 11 of the Drugs Act, 1976 in its 175th meeting held on 29-11-2017 and 176th meeting held on 15-12-2017. The board decided to Conduct Product Inspection by the said panel as under:

Prof. Dr. Mehmood Ahmad (Member PQCB) convener

Mr. Munawar Hayat (Chief Drugs Controller, Punjab (member PQCB) member

The conclusion is as under:

"The product tablet Alenstran 10 mg, B. no. f-T-940 was declared sub-standard/ misbranded on physical grounds "blister contains 8 tablets of 10 tablets and batch number not mentioned on blister". As per DTL test report assay was 96.5%. The firm is directed, before starting actual blistering procedure, took specimen samples of blisters and make a part of batch manufacturing record to verify batch number,

manufacturing and expiry date. The firm is advised to improve quality control checks on the packaging of tablets (sorting) of blisters before packaging."

The case was again considered by the Provincial Quality Control Board, under Section 11 of the Drugs Act, 1976 in its 190th meeting held on 31-7-2018. Chief Drugs Controller Punjab (member of inspection panel) presented the above-mentioned product specific inspection report and apprised the board regarding major short comings observed during inspection which includes " In-House specifications/ methods of test/ analysis of drugs were not validated, Daily calibration of the instruments such as UV Spectrophotometer, weighing balance and glassware was not being performed, non-availability of the instruments i.e FTIR and TOC and incorrect schedule for ongoing stability studies etc. The report was reviewed critically and the board expressed serious concerns over these short comings/ nonconformities which were critical in nature. The board agreed with the recommendations/ advice tendered by the inspection panel to the firm.

The board after due deliberation on various aspects of the case and detailed scrutiny of the inspection report and keeping in view the gravity of nonconformities, unanimously decided to refer the Product Specific Inspection (PSI) report to the Central Licensing Board (CLB) DRAP Islamabad through Chief Executive Officer DRAP for information and necessary action as required under law.

Proceeding and Decision of the 286th Meeting of Registration Board.

The case was presented before the Registration Board in its 286th meeting on 16th November, 2018 and the Board after perusing the record/ document of the instant case deliberated the matter in depth and decided as under:

"to issue the show cause notice and personal hearing to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore for manufacturing and selling of substandard Alenstran 10mg tablets, Batch No. f-T-940, manufactured by M/s Farmaceutics International F1-A3, S.I.T.E, Karachi."

Show cause notice was served to the firm as per decision of the Registration Board vide file No.03-86/2018-QC (286-RB) on 16th January 2019.

In response to the Show cause notice, the firm submitted their reply vide their letter No. Nil dated 22nd January, 2019 which is reproduced as under:

"The said report is not yet shared with us, neither from CLB nor from the author.

Panel has never inspected the facility and we are worried, whether it is mistakenly quoted or otherwise as modus operandi.

There is absolutely no issue on quality of product and test report of Govt. Analyst on which SCN builds itself confirm compliance of drug with all quality parameter. There is absolutely no safety, efficacy or quality issue with the product.

It is therefore requested to read our earlier letter since, it is time barred case, (DTL report issued on dated 15-04-16) after nine month delay drug inspector send us report on 19-01-17). It is sincerely hoped that rule of law will be respected in its spirit. We will thankful of protecting interest of justice."

Proceeding and Decision of the 288th Meeting of Registration Board.

Mr. Jameel Hussain Querishi, Advocate High Court (38403-21018809-1) of M/s Farmaceutics International F1-A3, S.I.T.E, Karachi appeared on behalf of M/s Farmaceutics International, F1-A3, S.I.T.E Karachi to plead instant case of substandard Alenstran 10 mg Tablets, Batch No. F-T-**940** before the Board in its 288th meeting on 15th February, 2019.

Representatives of the firm submitted that Panel has never inspected their facility.

The Board after hearing the accused deliberated the matter in depth in the light of available record & decided as under:

- Inspection report shall be obtained from provincial Quality Control Board (PQCB), Lahore for product specific inspection of M/s Farmaceutics International, F1-A3, S.I.T.E Karachi and the matter may be placed before the Registration Board or the Central Licensing Board as the case may be.
- The area Federal Inspector of Drugs shall take the samples of the said product for test analysis from Central Drug Laboratory, Karachi and submit the report to QA&LT, DRAP, Islamabad.

Preceeding of 291st Meeting Of Registration Board.

Above said decision was communicated PQCB, Punjab vide reference No. 03-11/2019-QC (288-RB) dated 30th May, 2019 with request to comply with the decision of Registration Board.

In response to the above said letter, the Secretary, PQCB, Punjab vide reference No.PQCB-151-04/2016 dated 23 July, 2019 forwarded the product inspection report of Alenstran 10mg Tablet, Batch No. F-T-940, Manufactured by M/s Farmaceutics International, F1-A3, S.I.T.E Karachi for record and ready reference.

The inspection report is reproduced as under:

Panel members:
Prof. (Rtd) Dr Mahmood Ahmad
Mr. Muhammad Munawar Hayat CDC Punjab
Date of Inspection: 16-07-2018.
Last GMP Inspection by FID before more than one year: Satisfactory level of compliance

Premises

Unit started in 2004, Total area (Half acar), covered area 18,000 sq feet),
Production on ground floor (General Tablets, Capsule, liquid syrup). Cephalosporin section (dedicated facility), Administration block.
First floor: QC lab, Liquid injection

Staff.

Designation	*Current*	*Tablet Alenstran 10mg B.No.FT-940, Date of Mfg. Jan/2015, Exp. Date. Jan. 2017*
Managing Director	*Muhammad Anis*	*Muhammad Anis*
Production Manager	*Madam Shella*	*Sidra Sajid*
QC Manager	*Shagufta Andaleeb*	*Shazia Perveen*
Warrantor	*Muhammad Anis*	*Muhammad Anis*

***Products** (list provided)*
Currently in manufacturing =10

Observations:-

*1. Product specification of film coated tablets Alenstran 10mg (Tablet Cetrizine HCl 10mg) is Farmaceutics specification, is mentioned in registration letter year 2008, its method of analysis is UV spectrophotometry, which is **not validated** according to international guidelines.*

*2. Dissolution test is **not mentioned in specification** of firm/ SOP/ method of analysis which was prepared in 05-02-2014.*

3. *In SOP of analysis, the assay of API mentioned in BP 2007 is used for tablet assay.*
4. *Daily internal calibration of UV spectrophotometer is* ***not being performed.***
5. ***Validation parameter of method of analysis of in house specification was not performed.***
6. *Schedule for ongoing stability studies was* ***not correct*** *and testing of some products on due date were not performed.*
7. ***FTIR is not available.***
8. *IPQC: physical, DT, weight variation, hardness, friability before coating.*
9. *Raw material bioberden test is performing.*
10. ***TOC is not available.***
11. *Residual testing is not performing.*
12. *Material test, import from China.*
13. *Packing material testing: Physical.*
14. *BP latest addition: 2007 available.*
15. *Test of finished product is as per Farmaceutic Specification.*
16. *Standard dates are available.*
17. *Conductivity meter is available.*
18. ***Many instruments of analytical lab are under maintenance.***

Batch processing Record:-

1. *BMR record available.*
2. *QC retained sample: available.*
3. *QC method In house method available* ***without validation.***
4. *Shift time: 9AM to 5PM.*
5. *Batch manufacturing is starting on 01-01-2015 (one day before weighing, receiving next date, manufacturing cycle, next date compression and coating on 02-01-2015, next listing and release on 03-01-2015*
6. *Line clearance: available.*
7. *Batch size: 200, 000 tablets.*
8. *Fluid bid dryer not available, using try dryer.*
9. *Production yield:98.9%*
10. *In process QC: Available.*
11. *Reconciliation sheet: Not available.*

Short Coming/Remarks

1. *The firm has challenge the report on 23.01.2017.as letter from DI Darya Khan was received on 19-01-2017. (Letter No15, dated 15-01-2017).*
2. *Toll manufacturing for M/s Meezab International.*
3. *Identification by UV spectrophotometer.*
4. *The In house in UV spectrophotometry performed, which is not validated according to international guidelines.*
5. *Impurities test was not performed.*
6. *Weight balance calibration daily is not available.*
7. *No external glass ware calibration.*
8. *Strains are not available*

Conclusion:

"The product tablet Alenstran 10 mg, B. no. f-T-940 was declared sub-standard/ misbranded on physical grounds "blister contains 8 tablets of 10 tablets and batch number not mentioned on blister". As per DTL test report assay was 96.5%. The firm is directed, before starting actual blistering procedure, took specimen samples of blisters and make a part of batch manufacturing record to verify batch number,

manufacturing and expiry date. The firm is advised to improve their in process quality control checks on the packaging of tablets (sorting) of blisters before packaging."

Proceeding and Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019. The Board considered the record of the case forwarded by PQCB, Lahore, copy of inspection report for PSI by the PQCB and proceedings of the 288th meeting wherein personal hearing was given to the firm and unanimously decided as under:

1. Inspection report reveals that product specific inspection of Alenstran 10 mg tablets was conducted by the Chief Drug Controller, Punjab on 16-07-2018. He recorded following observations:

- *Product specification of film coated tablets Alenstran 10mg (Tablet Cetrizine HCl 10mg) is Farmaceutics specification, is mentioned in registration letter year 2008, its method of analysis is UV spectrophotometry, which is* ***not validated*** *according to international guidelines.*
- *Dissolution test is* ***not mentioned in specification*** *of firm/ SOP/ method of analysis which was prepared in 05-02-2014.*
- *In SOP of analysis, the assay of API mentioned in BP 2007 is used for tablet assay.*
- *Daily internal calibration of UV spectrophotometer is* ***not being performed.***
- ***Validation parameter of method of analysis of in house specification was not performed.***
- *Schedule for ongoing stability studies was* ***not correct*** *and testing of some products on due date were not performed.*
- ***FTIR is not available.***
- *IPQC: physical, DT, weight variation, hardness, friability before coating.*
- *Raw material bioberden test is performing.*
- ***TOC is not available.***
- *Residual testing is not performing.*
- *Material test, import from China.*
- *Packing material testing: Physical.*
- *BP latest addition: 2007 available.*
- *Test of finished product is as per Farmaceutic Specification.*
- *Standard dates are available.*
- *Conductivity meter is available.*
- ***Many instruments of analytical lab are under maintenance.***

2. **The firm submitted misleading statement vide their letter dated 22-01-2019 that the panel has never inspected the facility and we are worried whether it is mistakenly quoted or otherwise as modus operandi.**

3. Keeping in view the above discrepancies, observations recorded by the Chief Drug Controller, Punjab and misleading statement in violation to section 23 (1) (f) of the Drugs Act, 1976, the Board decided to cancel the registration of the product Alenstran 10 mg tablets with immediate effect.

Case No.07: CASE REFERRED BY PQCB LAHORE REGARDING DIFFERENT MANUFACTURERS FOR NOT PROVIDING THE PRODUCT SPECIFICATIONS/METHOD OF ANALYSIS.

The Secretary, PQCB, Punjab vide letter no. PQCB/Dtl-D/197/2018 dated 20-12-2018 addressed to the Chief Executive Director Officer, DRAP, Islamabad with request to look into the matter personally and to direct the quarter concerned to expedite the matter.

Brief Facts of the Case:

The Director, Drug Testing Laboratory, Rawalpindi, Lahore and Bahawalpur reported that they have to file the cases pertaining to testing of the various drug samples due to non co-operation of the manufacturers. These firms failed to provide method and standards for test/analysis due to which it was not possible to conduct test/analysis and to report the same in the best public interest. The Directors DTLs have requested the Board to recommend the DRAP for cancellation of registration of the following Drugs whose test/analysis method/specification were not provided to the Government Analyst concerned by the pharmaceutical firm, as according to the clause XIX of the condition of registration of the drugs under the section 7 of the Drugs Act, 1976, manufacturer is bound to provide the complete method of analysis of the product.

S/N	DTL	Drug Inspector Area	Form 6 Date	DTL letter No. and Date	Manufacturer	Product name	Reg.No	Reason
1	Rawalpindi	Deputy Drug controller Hassan Abdal	11-10-2018	LR/DS/2018/561 17-11-2018	M/s Lisko Pakistan pvt Ltd	Tablet Muscadol Forte Batch No.061	067174	No response from firm to provide product specification, method of analysis and reference standard despite of 3 letters from DTl dated 18-10-18, 30-10-18 & 06-11-18
2	Lahore	DI Aziz Bhatti town Lahore	03-09-2018	6032/DTL 7-11-2018	M/s Ferroza international Pharma Lahore	Tab. Melide (Nimsulide 100mg) Batch No. 019	035543	No response from firm to provide product specification, method of analysis and reference standard despite of 3 letters from DTL dated; 12-09-18, 28-09-18 & 11-10-18.
3	Bahawalpur	DI Tehsil Okara	12-10-18	2002 15-11-2018	M/s Danas Pharma (Pvt) Ltd	Cyclofen Batch No.TA945	054592	No response from firm to provide product specification, method of analysis and reference standard despite of 3 letters from DTl dated; 17-10-18, 29-10-18 & 06-11-18

The case was considered by the Provincial Quality Control Board, (PQCB) Punjab in its 196th meeting held on 13-11-2018. The Secretary, PQCB appraised the Board about the background of the case which was discussed at length. The Board observed that all the manufacturers/ drug

Registration certificate holders are legally bound to provide product specifications and method of analysis to Government analyst/Drug testing Laboratories as and when required. The need for product specification/method of analysis becomes more critical when the drug is not available in the official pharmacopoeia and/ or the manufacturer has its own customized speciation/ method for analysis. In such circumstances it becomes quite challenging and almost impossible for a Government Analyst to conduct testing of the drug sample without having manufacturer specification/method of test/analysis.

The Board expressed its serious concerns over casual behavior and non co-operation on the part of the above listed firms in this regard. The Board after detailed discussion and deliberation decided to allow the provincial Drug Testing laboratory, Multan to file only those cases where Manufacturer Specifications are not provided by the respective firm and also not available in official compendia. Furthermore, the Board decided to recommend the Drug Regulatory Authority of Pakistan (DRAP) Islamabad for cancellation of registration of the drugs listed above, in best public interest.

Proceeding and Decision of 289th Meeting of Registration Board:

The case was presented before the Registration Board in its 289th meeting on 16th May, 2019 and the Board after detailed deliberation decided to issue to issue the show cause notice for suspension/cancellation of drugs to the firm/ responsible persons as provided by the provincial quality control board (PQCB), Lahore for not providing the specifications/method of analysis of the above said products manufactured by the said manufacturers to the Drug Testing Laboratories.

Preceeding of 291st Meeting of Registration Board.

Show cause notices were issued to all the three manufacturers vide No.F. 03-31/2019-QC (289th - RB) dated 03rd July, 2019.

Reply of M/s Lisko Pakistan (Pvt.) Ltd.

M/s Lisko Pakistan (Pvt.) Ltd., submitted their reply in response to the above said show cause notice vide reference No. Nil dated 13-07-19 and is reproduced as under:

With respect to the letter No. F. No.03-31/2019-QC (289th RB) dated 03rd July, 2019 which was received on 10th July, 2019, we are grateful to you for giving us an opportunity to clarify our position. As per your letter, we did not respond to letter from DTL, Rawalpindi in this regard we would like to clarify our position. As per DTL, Rawalpindi, the first letter for product specification of Muscadol forte tablet was sent to us dated 30th October, 2018 but unfortunately we didn't receive this letter. We came to know about the matter through letter which came to us as reminder by DTL Rawalpindi, which was written on 6th November, 2018 and was received at our factory on 19th November, 2018 and we sent our reply with product testing methods on 22nd November, 2018 , which was received at DTL Rawalpindi on 26th November 2018 (We are attaching testing methods with diary number of DTL, Rawalpindi which confirms its receipt in lab on 26th November) later we received a letter from Chief Drug Controller, Punjab dated 27th November, 2018 (copy attached) in which we were directed to provide the requisite information to the Director Drug Testing Laboratory, Rawalpindi at our earliest, failing to which legal action will be initiated against our firm but we would like to draw your attention that our testing method was received at drug testing laboratory, Rawalpindi on 26th November, 2018 which is earlier and before the final time given to us by Chief Drug Controller Punjab.

Therefore we request you to kindly withdraw this show cause notice by considering that we have

submitted product testing methods within time given by Chief Drug Controller, Punjab. We shall be highly thankful for this act of kindness.

Reply of M/s Danas (Pvt.) Ltd.

M/s Danas Pharma (Pvt.) Ltd., submitted their reply in response to the above said show cause notice vide reference No. Nil dated 12-07-19 and is reproduced as under:

In response to your show-cause Notice stated above received by us. 05-07-2019 regarding non provision of methods & tests/analysis for our product to reputable DTL Bahawalpur;

3	*Bahaw alpur*	*DI Tehsil Okara*	*12-10-18*	*2002 15-11-2018*	*M/s Danas Pharma (Pvt) Ltd*	*Cyclofen Batch No.TA945*	*054592*	*No response from firm to provide product specification, method of analysis and reference standard despite of 3 letters from DTI dated; 17-10-18, 29-10-18 & 06-11-18*

On the grounds, we would like to inform you that we had already dispatched the desired information to reputable DTL, Bahawalpur on 26/11/2018 (Leopards Courier Slip No.324337941). Even by the time we received the minutes of 289th meeting, we had once again provided the same to said respected Drugs Testing Laboratory through our letter dated 03/07/2019 (Leopards Courier Slip No.343898481).

In this respect, we are pleased to furnish the following in justification of our stance taken above:-

1. Copies of our letter dated 26/11/2018 with test/analysis methods and leopards courier slip #324337941

2. Copies of our letter dated 03/07/2019 with test/analysis methods and leopards courier slip # 343898481

Hence, therefore, in the light of above submission, still if your honorable Sir, think we have done or being overlooked by us. We are extremely apologetic for the same with the humble request/pray to condone the same by the competent authority.

We further believe and hope the above submissions found in order and show cause notice be vacated in this regard.

Assuring you our best cooperation and regards,

Reply of M/s Ferroza International Pharmaceuticals (Pvt.) Ltd.

M/s Ferroza International (Pvt.) Ltd., submitted their reply in response to the above said show cause notice vide reference No. Nil dated 06-08-19 and is reproduced as under:

Dear Sir,

With due respect, It is stated that with the reference to your letter F.No.03-31/2019-QC (289th RB), that DTL Lahore has delivered letters to firm to provide product specifications and method of analysis of Melide Tablet (Nimsulidc l00mg) Batch No. 019. Sir we would like to bring it in your notice that DTL Lahore send reminder on 11 -06-19 and we received on 20-06- 2019 and we send the requirements to DTL Lahore on 15-07-2019 vide our slip no. 40069576157. We would also like to inform you that whenever we get letter from any DTL regarding product specifications we immediately send the required specifications to DTL as we have send to different DTLs. Sir we did not receive any letter from PQCB for clarifications as well.

Sir you are kindly requested that considering these facts that we have already send product specifications to DTL Lahore, so kindly close this case.

It is further stated that if we are required for the personal hearing please do call us we will be available for personal hearing.

Personal hearing letters were issued to all the three manufacturers vide No.F.03-41/2019-QC dated 29 August, 2019.

Proceedings of 291st meeting of the Registration Board.

Dr. Sarfarz, Regulatory Affair Manager (42101-8965452-1) of M/s Lisko Pakistan (Pvt.) Ltd., appeared on behalf of M/s Lisko Pakistan (Pvt.) Ltd., for instant case and stated that we received a reminder letter from DTL, Rawalpindi which was written on 06-11-2018 and was received on 19-11-2018. In response to the said letter, they issued their reply with product testing method on 22-11-2019 which was received on 26-11-2019. He also stated that the first letter was not received to them.

M. Latif, G.M. Production (12101-809983-3) of M/s Danas Pharma (Pvt.) Ltd., Islamabad appeared on behalf of M/s Danas Pharma (Pvt.) Ltd., Islamabad for instant case and stated that they have already dispatched the desired information to DTL, Bahawalpur on 26/11/2018 (Leopards Courier Slip No.324337941).

Mr. Usman Khalid, Director (35202-8048278-9) M/s Ferroza International Pharmaceuticals (Pvt.) Ltd., Lahore appeared on behalf of M/s Ferroza International Pharmaceuticals (Pvt.) Ltd., Lahore for instant case and stated that have already dispatched the desired information on 15-07-2019 vide our slip no. 40069576157.

Decision of 291st meeting of Registration Board.

The case was presented before the Registration Board in its 291st meeting held on 04th September, 2019 and the Board after detailed discussion unanimously decided as under:

"It should be verified from the provincial quality control Board, Lahore whether the requisite information is received from the above mentioned companies to the concerned DTL's or otherwise."

Case No: 08. Standard Operating Procedure For Destruction Of Drug Registration Board Portions Of Drugs Samples For Which 01 Year Have Passed After Date Of Expiry Since Declaration Of Standard Quality By CDL.

The Federal Inspector of Drugs take sample for the purpose of test/Analysis either 3 portions (from the manufacturing site) or 4 portions (from the market). After obtaining results from CDL, Karachi the sample is either failed (Spurious, Unregistered, Substandard, Adulterated, Counterfeit, Misbranded etc.) or passed (Standard quality). In case of failed samples, the matter is processed in the light of DRAP Act, 2012. However, once the sample is declared of standard quality the investigation is stopped but the Board's portion still remains to be disposed off.

There were two proposals:

i. To dispose the samples. OR
ii. Keep the sample till one year after expiry.

To be on safe side, it has been decided that the sample should be kept till one year of expiry.

Accordingly SOP has been prepared and duly approved by QA&LT, Division. It was advised that before implementing the same shall be ratified from Drug Registration Board being statutory forum for disposal of Board's portion.

SOP is attached as Annex-A.

Decision of 291st meeting of Registration Board.

Registration Board after detailed discussion approved SOP prepared by QALT Division with the following amendment:

i. **Destruction of samples declared as of standard quality by the CDL, Karachi within three months after its expiry.**
ii. **Destruction of samples declared as of substandard quality by the CDL, Karachi till the decision of the case.**

Case No. 09: 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 Industry Pvt Ltd	Raw material is in process of import
		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 Pharmaceuticals, Karachi	The firm informed that dur to Pak Rupee 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.

Registration Board decided to defer the case till next meeting of the Registration Board.

Case No. 10 : CASES OF VALSARTAN RECALL – PRESENCE OF CARCINOGENIC IMPURITIES IN VALSARTAN API AS REPORTED BY EMA PRESS RELEASE DATED 05-07-2018.

European Medicines Agency (EMA) issued a press release on 05-07-2018 on the subject regarding "EMA reviewing medicines containing valsartan from M/s Zhejiang Huahai, following detection of an impurity" wherein EMA triggered a review that an impurity, N-Nitrosodimethylamine (NDMA), in the valsartan active ingredient which the company supplies to manufacturers producing some of the valsartan medicines available in the EU. The impurities (NDMA, NDEA etc.) are classified as probable carcinogens (a substance that could cause cancer) bases on results from laboratory tests. The presence of NDMA was unexpected and is sought to be related to changes in the way the active substance was manufactured.

02. In this regard, DRAP issued precautionary recall alert vide F.No.13-38/2018-QC dated 12th& 13th July, 2018 about valsartan containing products. This recall was about the detection of above said carcinogenic impurity in valsartan API imported from M/s Zhejiang Huahai, China.

03. DRAP ordered all the field force to implement the recall of the finished drugs containing valsartan manufactured by M/s Zheijhiang Huahai pharmaceuticals, China under sub section 3.7 of Section 3 of the Schedule B-II of the Drugs (Licensing, Registration &Advertising) Rules, 1976. It was also requested to direct the Federal Inspectors of Drugs for preparing inventory of the API of valsartan manufactured by M/s Zheijhgiang Huahai pharmaceuticals, China and "not to dispose off" the same on prescribed form in the public interest till final decision by the Competent Authority.

04. In light of direction issued by DRAP, Islamabad, the field force carried out various activities for investigation of the products containing Valsartan (API) of M/s Zheijhiang Huahai Pharmaceuticals Co. Ltd, China and order not to dispose of the following stocks of various firms on prescribed **Form-1** under section 18 (1) (i) of the Drugs Act, 1976 details of which are as under: -

Firm: M/s. Sami Pharmaceuticals, Karachi
Date of action: 16-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID III, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Manufactured by
01	Valsartan (Raw Material)	000007662	205.631Kg	26-4-17	30-4-41	M/s Zheijhiang Huahai Pharmaceuticals C. Ltd, China
02	Valsartan (Raw Material)	0000014990	300.00Kg	30-01-18	31-12-21	-do-
03	Sevia-160 Tablets	001C	02 Packs	02-17	01-19	M/s Sami pharmaceuticals (Pvt.) Ltd, SITE, Karachi.
04	Sevia-160 Tablets	002C	01 Packs	08-17	07-19	-do-
05	Sevia-160 Tablets	001D	8500 Packs	04-18	03-20	-d0-
06	Sevia-40 Tablets	003D	393 Packs	04-18	03-20	-do-
07	Sevia-40 Tablets	004D	51 Packs	05-18	04-20	-do-
08	Sevia-40 Tablets	005D	1690 Packs	05-18	04-20	-do-

09	Sevia-40 Tablets	006D	1935 Packs	05-18	04-20	-do-
10	Sevia 80 Tablets	001C	02 Packs	03-17	02-19	-do-
11	Sevia-80 Tablets	003C	7057 Packs	08-17	07-19	-do-
12	Sevia-80 Tablets	002D	1654 Packs	03-18	02-20	-do-
13	Sevia-80 Tablets	003D	30709 Packs	04-18	03-20	-d0-
14	Sevia-H160mg+ 25mg Tablets	001C	02 Packs	03-17	02-19	-do-
15	Sevia-H160mg+ 25mg Tablets	001D	3305 Packs	02-18	01-20	-do-
16	Sevia-H 80mg+ 12.5mg Tablets	001C	02 Packs	03-17	02-19	-do-
17	Sevia-H 80mg+ 12.5mg Tablets	002D	20501 Packs	04-18	03-20	-do-

Firm: M/s. Tabros Pharma, Karachi
Date of action: 13-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID V, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Manufactured by
01	Valsartan USP (API)	C5271-18-095	283.40 Kg	06-03-18	02-2022	M/s Zheijhiang Huahai Pharmaceuticals C. Ltd, China
02	Tab. Valtec AMH 10/160/25mg **(physician sample)**	007	1x2x7894	06-18	05-20	M/s Tabros Pharma, (Pvt.) Ltd, Karachi
03	Tab .Valtec AMH 10/160/25mg **(physician sample)**	008	1x2x24713	06-18	05-20	-do-
04	Tab .Valtec AMH 5/160/25mg **(physician sample)**	005	1x2x24420	06-18	05-20	-do-
05	Tab.Valtec 80mg **(physician sample)**	203	1x2x4826	06-18	05-20	-do-
06	Tab.Valtec 160mg **(physician sample)**	140	1x2x7740	06-18	05-20	-do-
07	Tab .Valtec AMH 10/160/25mg	007	1x28x2945	06-18	05-20	-do-
08	Tab .Valtec AMH 10/160/25mg	008	1x28x1738	06-18	05-20	-do-
09	Tab .Valtec AMH 5/160/25mg	005	1x28x1687	06-18	05-20	-do-
10	Tab.Valtec 80mg	203	1x28x17280	06-18	05-20	-do-
11	Tab.Co-Valtec 80/12.5mg	161	1x28x14112	05-18	04-20	-do-
12	Tab.Valtec 160mg	140	1x28x7740	06-18	05-20	-do-
13	Tab.Valtec AM 10/160mg	148	1x28x6804	06-18	05-20	-do-
14	Tab.Valtec AM 10/160mg	149	1x28x6663	06-18	05-20	-do-
15	Tab.Valsar 80mg	008	110,000 Tabs.	06-18	05-20	-do-
16	Tab.Duoval 80/125mg	006	110,000 Tabs.	06-18	05-20	-do-

17	Tab.Valtec AM 5/160	134	200,000 Tabs.	06-18	05-20	-do-
18	Tab.Valtec AM 5/160	135	200,000 Tabs	06-18	05-20	-do-
19	Tab.Valtec AM 5/160	136	200,000 Tabs	06-18	05-20	-do-
20	Tab.Valtec AM 5/160	137	200,000Tabs	06-18	05-20	-do-
21	Tab.Valtec AM 10/160	150	200,000Tabs	06-18	05-20	-do-
22	Tab.Valtec AM 10/160	151	200,000	06-18	05-20	-do-

Firm: M/s. The Searle Company Lahore.
Date of action: 18-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID VIII, Lahore.

Sr. No	Name of drugs	Batch no.	Mfg date	Exp. date	Manufacturer	quantity
1.	Co-Extor 10/160/12.5mg tablets in process coated tablets bulk	0016	07-18	07-20	The Searle Company, 32 km Multan Road, Lahore.	69.31 kg Gross weight approx. In one drum
2	Extor 5/80 mg tablets	0665	06-18	06-20	-do-	13760×14's packs
3	Extor 5/80 mg tablerts	0666	06-18	06-20	-do-	13710×14's packs
4	Extor 5/80 mg tablets	0667	06-18	6-20	-do-	13680×14's packs
5	Extor 5/80 mg tablets	0668	06-18	6-20	-do-	13824×14's packs
6	Extor 5/80 mg tablets	0669	06-18	06-20	-do-	13786×14's packs
7	Extor 5/80 mg tablets	0670	06-18	06-20	-do-	10900×14's packs
8	Extor 5/80 mg tablets	0671	06-18	06-20	-do-	2736×14's packs

Firm: M/s Efroze Chemical Industries, KIA, Karachi
Date of action: 01-08-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID/Additional Director, DRAP, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Manufactured by
01	Angiotan 160mg Tab	N02	14's x 86 packs	04/18	04/20	Efroze Chemical Industries, Karachi.
02	Angiotan 80mg Tab	N02	14's x 85 packs	12/17	12/19	-do-
03	Valcard 10/160mg tab	N04	28's x 258 packs	01/18	01/20	-do-
04	Valcard 10/160mg tab	N13	28's x 117 packs	02/18	02/20	-do-

05	Valcard 10/160mg tab	N15	28's x 239 packs	04/18	04/20	-d0-
06	Valcard 5/160mg tab	N02	28's x 366 packs	02/18	02/20	-do-
07	Valcard 5/160mg tab	N03	28's x 234 packs	02/18	02/20	-do-
08	Valcard 5/160mg tab	N04	28's x 70 packs	02/18	02/20	-do-
09	Valcard 5/80mg tab	N01	20's x 108 packs	12/17	12/19	-do-
10	Valcard 5/80mg tab	N02	20's x 257 packs	01/18	01/20	-do-
11	Valcard 5/80mg tab	N03	20's x 2119 packs	02/18	02/20	-do-

Firm: M/s Efroze Chemical Industries, KIA, Karachi
Date of action: 13-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID/Additional Director, DRAP, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Manufactured by
01	Valsartan (Raw Material)	C5271-17-241	36.320	01-07-17	30-06-21	M/s Zheijhiang Huahai Pharmaceuticals C. Ltd, China
02	Valsartan (Raw Material)	C5271-17-441	199.97	02-12-17	01-11-21	-do-
03	Angiotan H tab	N01	7142 packs	05-18	05-20	Efroze Chemical Industries, Karachi
04	Angiotan 80mg tab	N02	2770 packs	12-17	12-19	-do-
05	Angiotan 160mg tab	N02	6370 packs	04-18	04-20	-d0-
06	Valcard 5/80	N04	9791 packs	04-18	04-20	-do-
07	Valcard 5/80	N03	777 packs	02-18	02-20	-do-
08	Valcard 5/80	N05	9865 packs	04-18	04-20	-do-
09	Valcard 5/160	N04	1797 packs	02-18	02-20	-do-
10	Valcard 5/160	N07	3478 packs	05-18	05-20	-do-
11	Valcard 10/160	N15	1072 packs	04-18	04-20	-do-

Firm: M/s Safe Pharmaceutical Karachi
Date of action: 16-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-VI, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Manufactured by
01	Tab. Amlovastan 5/160mg	T-684	1x14x974 packs	01/17	01/19	M/s Safe Pharmaceuticals (Pvt.) Ltd, C-1-20 Sector 6B North Karachi Industrial area Karachi

Firm: M/s Amarant Pharmaceuticals 158-DGadap Town super Highway, Karachi
Date of action: 18-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-VI, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Manufactured by
01	Tab. Listan 80mg	040	1x14x203 packs	11-17	11-19	M/s Amarant Pharmaceuticals 158-DGadap Town super Highway, Karachi.
02	Tab. Listan 160mg	013	1x14x1033 packs	02-18	02-20	-do-
03	Tab. Listan HT 80/12.5mg	023	1x14x38 packs	12-17	12-19	-do-
04	Tab. Listan HT 160/12.5mg	013	1x14x17 packs	10-17	10-19	-do-
05	Tab. Listan HT 160/12.5mg	014	1x14x160 packs	02-18	02-20	-do-

Firm: M/s Wnsfeild Pharmaceuticals, Hattar
Date of action: 17-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-III, Peshawar.

Sr. No	Name of item	Reg. no.	Batch no.	Mfg date	Exp. date	Claimed to be Manufactured by:	Quantity
1.	Valsartan USP (API)	N.A	C5271-17-290	7-2017	06-2021	Zheijiang Huahai Pharmaceuticals, Company, Chuannan, Duqiao, Linhai, Zheijiang 317016, China.	8.280 kg
2	Tab. Alvostan 5mg/80mg (blisters)	078498	1524	03/2018	03/2018	M/s Wnsfeild Pharmaceuticals	840 blisters
3	Tab. Alvostan 5mg/80mg (blisters)	078498	1529	3/2018	3/2020	-do-	10 blisters
4	Tab. Alvostan 5mg/80mg (blisters)	78498	1611	5/2018	5/2020	-do-	6020 blisters
5	Tab Alvostan 5mg/ 80mg	078498	1524	3/2018	3/2020	-do-	15500 tabs
6	Tab Alvostan 80mg	078498	1529	3/2018	3/2020	-do-	7050 tabs
7	Tab Alvostan 5mg/ 80mg	078498	1544	03/2018	03/2020	-do-	380 tab

Firm: M/s ferozsons Labs Nowshera
Date of action: 18-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-III, Peshawar.

S.No.	Name of Drug	Reg. No.	Batch No.	Quantity	Mfg. Date	Exp. Date	Manufactured by
01	Valsartan (API)	N.A	C5271-	7.485Kg	20-02-	31-01-	M/s Zheijhiang Huahai

			17-031		2017	2021	Pharmaceuticals C. Ltd, China
02	Tab. Covance 5/80mg	_	1S45	5538 x14 Tabs.	05-2018	05-2020	M/s ferozsons Labs Nowshera.
03	-do- (P/S)	_	1S45	23650 x02 Tabs.	05-2018	05-2020	-do-
04	Tab. Covance 5/160mg	_	1N182	3741 x 14 Tabs.	12-2017	12-2019	-do-
05	Tab. Covance 5/160mg (P/S)	_	1M114	1493 x 02 Tabs.	09-2017	09-2019	-do-
06	Tab. Covance 10/160mg	_	1N183	2265 x14 Tabs.	01-2018	01-2020	-do-

Firm: M/s PharmEvo (Pvt) Ltd, A-29, North Industrial Zone, Port Qasim, Karachi.
Date of action: 31-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-VII, Karachi.

Sr. No	Name of drug	Batch no.	Quantity	Mfg date	Exp. date	purported to be Manufactured by:
1.	Avsar tab. 160/5 coated tab	8F010	50kg	4/05/18	5/2020	M/s Pharm Evo (Pvt) Ltd, A-29, North Industrial Zone, Port Qasim, Karachi.
2	Avsar tab 160/5 coated tab	8F011	50kg	4/05/18	5/2020	-do-
3	Avsar tab 160/5mg coated tab	8F019	50kg	5/05/18	5/2020	-do-
4	Valsartan R/M	C5271-17-055	3.93kg net	7/3/2017	2/2021	M/S Zheijiang Huahai Pharmaceuticals, Chuanman, Linhai Zheng China
5	Avsar Tab 160/5mg CP	8F018	1×3 pack loose	5/2/18	5/1/20	M/s PharmEvo (Pvt.) Ltd, A-29, Port Qasim, Karachi
6	Avsar tab 160/10mg CP. (export combodia)	8F044	28×50+40 loose	5/3/18	5/2/20	(Export) –do-
7	Avsar tab 160/10mg PS (combodia)	8F044	2×50+35 loose	5/3/18	5/2/20	(Export)-do-
8.	Nuval D Tab 80/125mg CP	8F074	98×50+38	5/4/18	5/3/20	-do-
9	Avsar Plus tab 320/10/25mg	8F110	62×32+5	5/7/18	5/6/20	-do-
10.	Nuval D Tab 160/25mg CP	8F165	226×24+17	5/14/18	5/13/20	-do-
11	Nuval D Tab 160mg/25mg PS	7C191	83×100+40	3/21/17	3/21/19	-do-
12	Avsar Tab 160/10mg PS	8D070	147×100+26	4/06/18	4/5/20	-do-
13	Avsar tab 160/10mg PS	8F044	46×100+87	5/3/18	5/2/20	-do-
14	Avsar Plus tab 160/10/12.5 PS	8F210	50×100+52	5/17/18	5/16/20	-do-

Firm: M/s Amarant Pharmaceuticals (pvt.) Ltd, Karachi.
Date of action: 13-08-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-VI, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Purported to be Manufactured by
01	Tab. Listan 80mg	038	57 packs	07/17	07/19	M/s Amarant Pharmaceuticals (pvt) Ltd, Karachi
02	Tab. Listan 80mg	039	147 packs	09/17	09/19	-do-
03	Tab. Listan 80mg	040	356 packs	11/17	11/19	-do-
04	Tab. Listan 160mg	012	108 packs	11/17	11/19	-do-
05	Tab. Listan 160mg	013	2338 packs	02/18	02/20	-do-
06	Tab. Listan HT 80/12.5mg	022	02 packs	10/17	10/19	-do-
07	Tab. Listan HT 80/12.5mg	023	438 packs	12/17	12/19	-do-
08	Tab. Listan HT 80/12.5mg	040	03 packs	11/17	11/19	-do-
09	Tab. Listan HT 160/12.5mg	012	28 packs	11/17	11/19	-do-
10	Tab. Listan HT 160/12.5mg	013	331 packs	10/17	10/19	-do-
11	Tab. Listan HT 80/12.5mg	014	511 packs	01/18	01/20	-do-

Firm: M/s Pharm-Evo (pvt) Ltd, A-29, North Western Industrial Zone, port Qasim, Karachi
Date of action: 13-08-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-VII, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Purported to be Manufactured by
01	Avsar Tab.80/5mg cp	8D003	42x100+47=4267 (14's)	April/18	04/20	M/s Pharm-Evo (pvt) Ltd, A-29, North Western Industrial Zone, port Qasim, Karachi
02	-do-	8D004	80x100+70=8070 (14's)	April/18	April/20	-do-
03	-do-	8D005	102x100+38=10238 (14's)	04/18	04/20	-do-
04	-do-	8F048	108x100+59=10859 (14's)	05/18	05/20	-do-
05	-do-	8F049	135x100+96=13596 (14's)	05/18	05/20	-do-
06	-do-	8F050	139x100+77=13977 (14's)	05/18	05/20	-do-
07	-do-	8F064	143x100+28=14328 (14's)	05/18	05/20	-do-
08	-do-	8F065	118x100+98=11898 (14's)	05/18	05/20	-do-
09	-do-	8F066	96x100+90=9690 (14's)	05/18	05/20	-do-

10	Avsar Tab.160/5mg cp	8D019	18x50+14=914 (14's)	04/18	04/20	-do-
11	-do-	8D020	16x50+24=824 (14's)	04/18	04/20	-do-
12	-do-	8D021	32x50+36=1636 (14's)	04/18	04/20	-do-
13	-do-	8D025	83x50+49=4199 (14's)	04/18	04/20	-do-
14	-do-	8D026	115x50+47=5797 (14's)	04/18	04/20	-do-
15	-do-	8D027	90x50+29=4529 (14's)	04/18	04/20	-do-
16	-do-	8F009	189x32+02=6050 (14's)	05/18	05/20	-do-
17	-do-	8F017	132x50+44=6644 (14's)	05/18	05/20	-do-
18	-do-	8F018	123x50+20=6170 (14's)	05/18	05/20	-do-
19	Avsar Tab.160/10mg cp	8D085	72x50+28=3628 (14's)	04/18	04/20	-do-
20	-do-	8D086	117x50+0=5850 (14's)	04/18	04/20	-do-
21	-do-	8D070	1x576=576 (14's)	04/18	04/20	-do-
22	-do-	8D071	1x231=231 (14's)	04/18	04/20	-do-
23	-do-	8D072	1x1302=1302 (14's)	04/18	04/20	-do-
24	-do-	8D084	42x50+31=2131 (14's)	04/18	04/20	-do-
25	-do-	8F044	87x50+45=4395 (14's)	05/18	05/20	-do-
26	-do-	8F045	88x50+21=4421 (14's)	05/18	05/20	-do-
27	-do-	8F046	123x50+28=6178 (14's)	05/18	05/20	-do-
28	Avsar plus Tab.160/5/25mg	8D103	64x32+23=2071 (14's)	04/18	04/20	-do-
29	Avsar plus Tab.160/10/25mg	8D104	19x32+02=610 (14's)	04/18	04/20	-do-
30	-do-	8D105	47x32+14=1518 (14's)	04/18	04/20	-do-
31	Avsar plus Tab. 320/10/25mg cp	8F110	37x32+08=1192 (14's)	05/18	05/20	-do-
32	Avsar plus Tab. 160/5/12.5mg cp	8F224	25x32+07=807 (14's)	05/18	05/20	-do-
33	-do-	8F225	94x32+06=3014 (14's)	05/18	05/20	-do-
34	-do-	8D092	1x26=26 (14's) loose	04/18	04/20	-do-
35	-do-	8D093	1x55=55 (14's) loose	04/18	04/20	-do-
36	-do-	8F223	1x96x(14's) 1x89 x(14's)=188 loose	05/18	05/20	-do-
37	Avsar plus Tab. 160/10/12.5mg	8F210	66x32+02=2114 (14's)	05/18	05/20	-do-
38	-do-	8F211	130x32+26=4186 (14's)	05/18	05/20	-do-

39	-do-	8D090	1x52=52 (14's)	04/18	04/20	-do-
40	-do-	8D091	1x141=141 (14's)	04/18	04/20	-do-
41	Nuval Tab. 80mg cp	8F081	68x50+07=3407 14's	05/18	05/20	-do-
42	Nuval-D Tab. 80/12.5mg	8F072	1x104=104 14's	05/18	05/20	-do-
43	-do-	8F073	1x400 1x319=719 14's	05/18	05/20	-do-
44	-do-	8F074	1x800 1x461=1261 14's	05/18	05/20	-do-
45	Nuval-D Tab. 160/25mg cp	8F165	39x24+02=938	05/18	05/20	-do-
46	Nuval-D Tab. 80/12.5mg cp	8F071	1x7=07 14's	05/18	05/20	-do-
47	Nuval-D Tab. 80/12.5mg	8C196	1x2=02 14's	03/18	03/20	-do-
48	Avsar Tab. 160/10 mg cp	8C221	1x4=04 14's	03/18	03/20	-do-
49	Avsar Tab. 160/10 mg cp	8C222	1x17=17 14's	03/18	03/20	-do-
50	Avsar Tab. 80/5 mg cp	8C002	1x2=02 14's	04/18	04/20	-do-
51	Nuval Tab. 80mg cp	6D128	1x3x14's=03	04/16	04/18	-do-
52	-do-	6J031	1x5x14's=05	08/16	08/18	-do-
53	Nuval-D Tab. 80/12.5mg cp	6J033	1x2x14's=02	08/16	08/18	-do-
54	Nuval Tab. 160mg cp	6K081	1x21x14's=21	09/16	09/18	-do-
55	Nuval-D Tab. 80/12.5mg cp	6N202	1x2x14's=02	12/16	12/18	-do-
56	Avsar Plus Tab. 160/5/12.5mg cp	7A143	1x5x14's=05	01/17	01/19	-do-
57	Avsar Plus Tab. 320/10/25mg	7A145	1x3x14's=03	01/17	01/19	-do-
58	Avsar Tab. 160/5mg cp	7C135	1x4x14's=04	03/17	03/19	-do-
59	Avsar Tab. 160/5mg cp	7C137	1x1x14's=1	03/17	03/19	-do-
60	Avsar Tab. 160/5mg cp	7C138	1x1x14's=1	03/17	03/19	-do-
61	Avsar Tab. 160/10mg cp	7C139	1x2x14's	03/17	03/19	-do-
62	-do-	7C142	1x1x14's	03/17	03/19	-do-
63	Avsar Plus Tab. 160/5/12.5mg cp	7C163	1x13x14's	03/17	03/19	-do-
64	Avsar Plus Tab. 160/5/25mg cp	7C165	1x11x14's	03/17	03/19	-do-
65	Avsar Plus Tab. 320/10/25mg cp	7C166	1x16x14's	03/17	03/19	-do-
66	Nuval-D Tab. 160/25mg cp	7C191	1x18x14's	03/17	03/19	-do-
67	Nuval-D Tab. 80/12.5mg	7C192	1x5x14's	03/17	03/19	-do-

68	Avsar Tab. 160/5mg cp	7D162	1x4x14's	04/17	04/19	-do-
69	Avsar Tab. 80/5mg cp	7F043	1x1x14's	05/17	05/19	-do-
70	Avsar Tab. 160/5mg cp	7F126	1x2x14's	05/17	05/19	-do-
71	Avsar Plus Tab. 160/10/12.5mg cp	7C041	1x1x14's	06/17	06/19	-do-
72	Nuval Tab. 80mg cp	7K103	1x1x14's	09/17	09/19	-do-
73	Avsar Plus Tab. 120/10/25mg cp	7L143	1x1x14's	10/17	10/19	-do-
74	Avsar Tab. 160/5mg cp	7M103	1x2x14's	11/17	11/19	-do-
75	-do-	7M105	1x2x14's	11/17	11/19	-do-
76	Avsar Plus Tab. 160/10/25mg cp	7N177	1x1x14's	12/17	12/19	-do-
77	Nuval Tab. 80mg cp	8B107	1x30x14's	02/18	02/20	-do-
78	Avsar Tab. 160/5mg cp	8B017	1x4x14's	02/18	02/20	-do-
79	Avsar Plus Tab. 160/5/12.5mg cp	8B251	1x1x14's	02/18	02/20	-do-
80	Nuval Tab. 80mg cp	8C003	1x5x14's	03/18	03/20	-do-
81	Avsar Plus Tab. 160/10/25mg cp	8C012	1x1x14's	03/18	03/20	-do-
82	Avsar Plus Tab. 320/10/25mg cp	8C050	1x7x14's	03/18	03/20	-do-
83	Avsar Tab. 160/5mg cp	8C150	1x1x14's	03/18	03/20	-do-

Firm: M/s Sami Pharmaceuticals, Karachi.
Date of action: 08-08-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-III& IV, Karachi.

S.No.	Product Name	Batch No.	Manufacturing Date	Expiry Date	Packs Recalled
01	Sevia 40mg	001B	03/2016	02/2018	6
02	Sevia 40mg	002B	05/2016	04/2018	24
03	Sevia 40mg	003B	07/2016	06/2018	11
04	Sevia 40mg	004B	08/2016	07/2018	39
05	Sevia 40mg	005B	10/2016	09/2018	109
06	Sevia 40mg	006B	12/2016	11/2018	221
07	Sevia 40mg	001C	02/2017	01/2019	160
08	Sevia 40mg	002C	03/2017	02/2019	73
09	Sevia 40mg	003C	04/2017	03/2019	188
10	Sevia 40mg	004C	05/2017	04/2019	162
11	Sevia 40mg	006C	06/2017	05/2019	217
12	Sevia 40mg	007C	08/2017	07/2019	248
13	Sevia 40mg	008C	11/2017	10/2019	343
14	Sevia 40mg	001D	01/2018	12/2019	460
15	Sevia 40mg	002D	02/2018	01/2020	392

16	Sevia 40mg	003D	04/2018	03/2020	4156
17	Sevia 40mg	004D	05/2018	04/2020	1301
18	Sevia 40mg	005D	05/2018	04/2020	2704
19	Sevia 40mg	006D	05/2018	04/2020	1140
20	Sevia 80mg	001B	05/2016	04/2018	22
21	Sevia 80mg	002B	11/2016	10/2018	221
22	Sevia 80mg	001C	03/2017	02/2019	187
23	Sevia 80mg	002C	01/2017	06/2019	477
24	Sevia 80mg	003C	08/2017	07/2019	468
25	Sevia 80mg	001D	01/2018	12/2019	3684
26	Sevia 80mg	002D	03/2018	02/2020	6674
27	Sevia 80mg	003D	04/2018	03/2020	0
28	Sevia 160mg	001B	10/2016	09/2018	1216
29	Sevia 160mg	001C	02/2018	01/2020	555
30	Sevia 160mg	002C	08/2017	07/2019	2078
31	Sevia 160mg	001D	04/2018	03/2020	2094
32	Sevia-H 80/12.5mg	001B	04/2016	03/2018	29
33	Sevia-H 80/12.5mg	002B	09/2016	08/2018	195
34	Sevia-H 80/12.5mg	001C	03/2017	02/2019	104
35	Sevia-H 80/12.5mg	002C	05/2017	04/2019	169
36	Sevia-H 80/12.5mg	003C	08/2017	07/2019	575
37	Sevia-H 80/12.5mg	004C	12/2017	11/2019	809
38	Sevia-H 80/12.5mg	001D	02/2018	01/2020	4943
39	Sevia-H 80/12.5mg	002D	04/2018	03/2020	5084
40	Sevia-H 160/25mg	001B	04/2016	03/2018	4
41	Sevia-H 160/25mg	002B	08/2016	07/2018	708
42	Sevia-H 160/25mg	001C	03/2017	02/2019	349
43	Sevia-H 160/25mg	002C	06/2017	05/2019	575
44	Sevia-H 160/25mg	003C	12/2017	11/2019	625
45	Sevia-H 160/25mg	001D	02/2018	01/2020	5707

Firm: M/s Pharm-Evo (pvt) Ltd, A-29, North Western Industrial Zone, port Qasim, Karachi
Date of action: 18-10-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-VII, Karachi.

S.No.	Name of Drug	Batch No.	Quantity	Mfg. Date	Exp. Date	Purported to be Manufactured by
01	Avsar plus Tab 160/10/25mg cp	7D026	1x29x	04/17	04/19	M/s Pharm-Evo (pvt.) Ltd, A-29, North Western Industrial Zone, port Qasim, Karachi
02	Avsar plus Tab 160/10/12.5mg cp	7D027	1x29x	04/17	04/19	-do-
03	Avsar plus Tab 160/10/12.5mg cp	8D090	27x32+21	04/2018	04/2020	-do-
04	-do-	8D091	20x32+5=645	-do-	-do-	-do-
05	-do-	8F210	19x32+11=608	05/2018	05/2020	-do-
06	-do-	8F211	17x32+31	-do-	-do-	-do-
07	Avsar plus Tab 160/10/25mg Cp	7C160	1x32+25	05/2017	05/2019	-do-
08	-do-	7C161	1x32+22	-do-	-do-	-do-

09	-do-	7C162	1x32+15	-do-	-do-	-do-
10	-do-	8D104	19x32+3	04/2018	04/2020	-do-
11	Avsar Plus Tab 160/10/25mg Cp	8D105	11x32+24=376	04/2018	04/2020	-do-
12	Avsar Plus Tab 160/5/12.5 mg cp	7C163	1x14=14	03/17	03/19	-do-
13	-do-	7C164	1x11=11	03/17	03/19	-do-
14	-do-	8D092	13x32+4=420	04/2018	04/2020	-do-
15	-do-	8D093	23x32+1=737	04/2018	04/2020	-do-
16	-do-	8F223	29x32=928	03/2018	03/2020	-do-
17	-do-	8F224	34x32+21=1109	05/2018	05/2020	-do-
18	-do-	8F225	15x32+26=506	05/2018	05/2020	-do-
19	Avsar Plus Tab 160/5/25 mg cp	7C165	06x32+25=217	03/17	03/19	-do-
20	-do-	8D103	16x32+22=534	04/2018	04/2020	-do-
21	Avsar Plus Tab 320/10/25 mg cp	7C166	08x32+26=282	05/17	05/19	-do-
22	-do-	8F110	02x32+27=91	05/18	05/20	-do-
23	Avsar Tab 160/10 mg	7C139	1x30=30	03/17	03/19	-do-
24	-do-	7C140	1x12=12	03/17	03/19	-do-
25	-do-	7C141	1x4=4	03/17	03/19	-do-
26	-do-	7C142	1x50+28=78	03/17	03/19	-do-
27	-do-	7C143	1x21=21	03/17	03/19	-do-
28	-do-	7C144	1x14=14	03/17	03/19	-do-
29	-do-	7D165	1x24=24	04/17	04/19	-do-
30	-do-	7D166	1x21=21	-do-	-do-	-do-
31	Avsar Tab 160/10 mg cp	7D167	1x19=19	-do-	-do-	-do-
32	-do-	7D168	1x22=22	-do-	-do-	-do-
33	-do-	7D169	1x23=23	-do-	-do-	-do-
34	-do-	8D070	6x50+21=321	04/18	04/20	-do-
35	-do-	8D071	20x50+21=1121	-do-	-do-	-do-
36	-do-	8D072	5x50+21=271	-do-	-do-	-do-
37	-do-	8D084	28x50+2=1402	-do-	-do-	-do-
38	-do-	8D085	12x50+2=602	-do-	-do-	-do-
39	-do-	8D086	8x50+43=443	-do-	-do-	-do-
40	-do-	8F044	1x12=12	05/18	05/20	-do-
41	Avsar Tab 160/ 10 mg cp	8F045	8x50+56=456	-do-	-do-	-do-
42	-do-	8F046	6x50+27=327	-do-	-do-	-do-
43	Avsar Tab 160/ 5 mg cp	7C133	1x13=13	03/17	03/19	-do-
44	-do-	7C134	1x29=29	-do-	-do-	-do-
45	-do-	7C135	1x23=23	-do-	-do-	-do-

46	-do-	7C136	1x26=26	-do-	-do-	-do-
47	-do-	7C137	1x50+27=77	-do-	-do-	-do-
48	-do-	7C138	1x42=42	-do-	-do-	-do-
49	-do-	7D157	19x50+7=957	04/17	04/19	-do-
50	-do-	7D158	55x50+45=2795	-do-	-do-	-do-
51	-do-	7D159	55x50+41=2791	-do-	-do-	-do-
52	-do-	7D160	1x37=37	-do-	-do-	-do-
53	-do-	7D161	1x42=42	-do-	-do-	-do-
54	-do-	7D162	1x50+38=88	-do-	-do-	-do-
55	-do-	7F126	1x47=47	-do-	-do-	-do-
56	-do-	7F127	1x68=68	-do-	-do-	-do-
57	-do-	8D019	22x50=11+80	04/18	04/20	-do-
58	-do-	8D020	15x50+48=798	-do-	-do-	-do-
59	-do-	8D021	15x50=750	-do-	-do-	-do-
60	-do-	8D025	10x50+39=539	-do-	-do-	-do-
61	-do-	8D026	8x50+22=422	-do-	-do-	-do-
62	-do-	8D027	6x50+44=344	-do-	-do-	-do-
63	-do-	8F009	6x50+48=348	05/18	05/20	-do-
64	-do-	8F017	2x50=100	-do-	-do-	-do-
65	-do-	8F018	11x50+44=594	-do-	-do-	-do-
66	Avsar Tab 80/ 5 mg cp	7B109	1x6=6	02/17	02/19	-do-
67	-do-	7B110	1x5=5	-do-	-do-	-do-
68	-do-	7B111	1x3=3	-do-	-do-	-do-
69	-do-	7B112	1x7=7	-do-	-do-	-do-
70	-do-	7B113	1x12=12	-do-	-do-	-do-
71	-do-	7C121	1x4=4	-do-	-do-	-do-
72	-do-	7C122	1x5=5	03/17	03/19	-do-
73	-do-	7D143	1x5=5	04/17	04/19	-do-
74	-do-	7D144	1x12=12	-do-	-do-	-do-
75	-do-	7D145	1x23=23	-do-	-do-	-do-
76	-do-	7D146	1x8=8	-do-	-do-	-do-
77	-do-	7D147	1x12=12	-do-	-do-	-do-
78	-do-	7D148	1x8=8	-do-	-do-	-do-
79	-do-	7F040	1x13=13	-do-	-do-	-do-
80	-do-	7F041	1x8=8	-do-	-do-	-do-
81	-do-	7F042	1x25=25	04/17	04/19	-do-
82	-do-	7F043	1x11=11	-do-	-do-	-do-
83	-do-	7F044	1x10=10	-do-	-do-	-do-
84	-do-	8D003	20x100+18=2018	04/18	04/20	-do-
85	-do-	8D004	6x100+94=694	-do-	-do-	-do-
86	-do-	8D005	9x100+90=990	-do-	-do-	-do-
87	-do-	8F048	7x100+20=720	5/18	5/20	-do-
88	-do-	8F049	7x100+17=717	-do-	-do-	-do-
89	-do-	8F050	5x100+79=579	-do-	-do-	-do-
90	-do-	8F064	2x100+8=208	-do-	-do-	-do-
91	-do-	8F065	8x100+8=808	05/18	05/20	-do-
92	-do-	8F066	9x100+80=980	05/18	05/20	-do-
93	Nuval Tab 160mg cp	7C190	2x24+2=50	3/17	3/19	-do-
94	Nuval Tab	7D149	1x50+24=74	4/17	4/19	-do-

	80 mg cp					
95	-do-	8F081	52x50+3=2603	05/18	05/20	-do-
96	Nuval D Tab 160/ 25 mg cp	7C191	3x24+5=77	3/17	3/19	-do-
97	-do-	8F165	1x24+1=25	3/18	3/20	-do-
98	Nuval Tab 80/ 12.5 mg cp	7C192	4x50+37=237	3/17	3/19	-do-
99	-do-	8F071	137x50+40=6890	05/18	5/20	-do-
100	-do-	8F072	135x50+20=6770	5/18	5/20	-do-
101	-do-	8F073	117x50+41=5891	-do-	-do-	-do-
102	-do-	8F074	5x50+9=259	-do-	-do-	-do-

Firm: M/s Nabi QasimIndustires Pvt Ltd. Karachi
Date of action: 15-11-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID/Additional Director, DRAP, Karachi.

S.No.	Name of Raw Material	Batch No. & Quantity	Mfg. Date	Exp. Date	Quantity	Manufacturer
1	Valsartan USP	VAL-180701	07/2018	07/2021	06Kg	M/S Anhui Menovo Pharmaceutical, China

Firm: M/s Tabroos Pharma, Karachi
Date of action: 16-11-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID/Additional Director, DRAP, Karachi.

S.No.	Name of Raw Material	Batch No. & Quantity	Mfg. Date	Exp. Date	Quantity	Manufacturer
1	Valsartan USP	VAL-180701	07/2018	07/2021	06Kg	M/S Anhui Menovo Pharmaceutical, China

Firm: M/s KanelPahrma, SS-3, Plot-6, RCCI, Rawat
Date of action: 30-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-II, Islamabad.

S.No.	Name Drug	Batch No.	Quantity	Manufacturer
1	VALKEN-80mg Tablet	KK-16015	02X14 tabs	M/s Kanel Pharma
2	VALKEN-A Tablet	KK-16014	01x14 tabs	-do-
3	VALKEN-H Tablet	KL-16001	04x14 tabs	-do-
4	VALKEN-A Tablet	KL-16010	01x14 tabs	-do-
5	VALKEN-H Tablet	KM-16003	01x14 tabs	-do-
6	VALKEN-H Tablet	KD-17005	01x14 tabs	-do-
7	VALKEN-160mg Tablet	KJ-17002	25x14 tabs	-do-
8	VALKEN-H Tablet	KJ-17005	72x14 tabs	-do-
9	VALKEN-A Tablet	KD-18012	5442x14 tabs	-do-

Firm: M/s KanelPahrma, SS-3, Plot-6, RCCI, Rawat
Date of action: 06-08-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-II, Islamabad.

S.No.	Name Drug	Batch No.	Quantity	Manufacturer
1	VALKEN-A Tablet	KL-16010	03X14 tabs	M/s Kanel Pharma
2	VALKEN-80 Tablet	KA-17009	02x14 tabs	-do-

3	VALKEN-80 Tablet	KD-17004	01x14 tabs	-do-
4	VALKEN-160 Tablet	KE-17004	01x14 tabs	-do-
5	VALKEN-A Tablet	KF-17015	02x14 tabs	-do-
6	VALKEN-160 Tablet	KG-17009	21x14 tabs	-do-
7	VALKEN-80 Tablet	KG-17010	51x14 tabs	-do-
8	VALKEN-160 Tablet	KJ-17002	129x14 tabs	-do-
9	VALKEN-H Tablet	KJ 17005	60X14 tabs	-do-
10	VALKEN-80 Tablet	KK-17012	80x14	M/s Kanel Pharma
11	VALKEN-A Tablet	KK-17016	104x14 tabs	-do-
12	VALKEN-160 Tablet	KL-17001	37x14 tabs	-do-
13	VALKEN-H Tablet	KM-17008	21X4	-do-
14	VALKEN-A Tablet	KA-18019	25x14 tabs	-do-
15	VALKEN-A Tablet	KD-18012	313X14 tabs	-do-

Firm: M/s Moon Pharmaceuticals Plot No. 5, SS-4, NIZ, Rawat, Islamabad
Date of action: 27-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-II, Islamabad.

S.No.	Name Drug	Batch No.	Quantity	Manufacturer
1	Mondip 80mg Tablet	T-13	Tablets 17x200x14	M/s Moon Pharmaceuticals Plot No. 5, SS-4, NIZ, Rawat, Islamabad
2	Mondip 80mg Tablet	T-06	Tablets 02x200x14	-do-
3	Mondip 160mg Tablet	T-07	Tablets 09x200x14	-do-
4	Moncard-A 5/80mg Tablet	T-14	Tablets 30x200x14	-do-
5	Valsartan API	C5271-16-192	2967g	M/s Zheijiang Huahai Pharmaceuticals Co Ltd China.

Firm: M/s Jupiter Pharma, Plot No. 25, S-6, RCCI, Rawat, Islamabad
Date of action: 27-07-2018
Action Taken: Ordered not to dispose of
Status of extension in order not to dispose of: Granted
Action taken by: FID-II, Islamabad.

S.No.	Name Drug	Batch No.	Quantity	Manufacturer
1	Amlodine 5/80 Tab	17T022	584 X14 Tablets	M/s Jupiter Pharma
2	Amlodine 5/80 Tab	17T036	809x14 tablets	M/s Jupiter Pharma
3	Amlodine 5/160 Tab	17T035	2 x 14 tablets	M/s Jupiter Pharma
4	Amlodine 5/160 Tab	17T023	58 x 14 tablets	M/s Jupiter Pharma
5	Amlodine 10/160 Tab	17T024	2042 x 14 tablets	M/s Jupiter Pharma

05. It is submitted that the Additional Director, QA&LT vide letter of even number dated 30.08.2018 addressed to all manufacturers having valid registration of valsartan containing drug products and communicated following directions for compliance in the best public interest:

i. companies which are manufacturing valsartan containing finished products, having valid registration as single entity or in combination with other recommended

drugs, must ensure from 29th August, 2018 and onwards the absence or acceptable limits of N-Nitroso Dimethylamine (NDMA) in their products.

ii. All Active Pharmaceuticals Ingredients (API) of valsartan shall be accompanied by Certificate of Analysis from manufacturer, clearly emphasizing the absence or minimum permissible limits of residual contents of N-Nitroso Dimethylamine (NDMA) as per UDS FDA / World Health Organization (WHO) guidelines.

06. That the division of QA&LT, DRAP, Islamabad vide letter F. No. 13-38/2018-QC dated 07-09-2018 communicated the decisions as per minutes of meeting to review the issue of valsartan products held on 07-08-2018 under the chairmanship of CEO DRAP, Islamabad to all the additional directors /officer in-charge of DRAP and all pharmaceutical manufacturers of Valsartan products. The decisions of said meeting between DRAP officers and stakeholders which are reproduced as under: -

"a. DRAP should provide update on the recalled products and inform the industry to hold the stocks as investigation in under process in coordination with global authorities like EMA, US-FDA and WHO.

b. Further, questionnaire would be issued similar to EMA to confirm NDMA is absent in other API manufacturers, once the EMA/ US-FDA/ WHO complete their reviews.

c) The recalled finished product batches on direction of DRAP containing valsartan manufactured by Zheijiang Huahai Pharmaceuticals, China must be segregated under lock/key until further notice.

d) Initiate testing for the presence of NDMA in the API. Finished product that are manufactured by API source other than above can be sold in the market by all manufacturer should initiate testing to confirm absence of the N-Nitrosodimethylamine (NDMA) impurity in finished product and submit testing report within 3 months.

e) Pharmaceutical manufacturer should comply with the Pharmacopoeal requirements for the testing of impurities for all products in future. A committee was constituted to prepare guidelines for the procurement of APIs as per Pharmacopoeal specifications.

f) All the manufacturers should ensure the recall products containing valsartan raw material sourced from M/s. Zheihiang HuaHai Pharmaceuticals, China as soon as possible.

g) The manufacturers are requested to re-start manufacturing of valsartan products from alternate qualified source of valsartan API to ensure availability.

h) It was also directed by CEO, DRAP that manufacturers should build up their capacity to test the NDMA to identify and quantify the API and finished products. Some of the participants disclosed that they have sent purchased orders to Sigma.

i) It was also decided that the firms can Re-Export the API imported from M/s Zheijiang Huahai Pharmaceuticals, China to its manufactures under intimation to concerned DRAP field office."

07. Keeping in view the above-mentioned facts, the case is being submitted for consideration of the Board to decide the fate of the re-called Valsartan (Finished products and API) present at various pharmaceutical firms.

Decision of the 291st meeting of Registration Board.

Registration Board deliberated about the identification of NDMA & EDMA as impurities which are carcinogenic and limits has been prescribed by US FDA and EMA. Above the limits API as well as products poses threat to the consumers. Keeping in view risk the Board decided as under:

i. **Product registration holders shall ensure that the API as well as products containing valsartan are within the prescribed limits impurities i.e. NDMA & EDMA. Every manufacturer holding registration of valsartan containing products are under obligation of law to provide testing facilities of these impurities for every consignment imported and brought into Pakistan. The consignments should be accompanied with the certificates of analysis by the API manufacturers. Meanwhile the manufacturers/importers may temporarily avail testing facilities of the any public sector institutions till the establishment of their own facility. However sampling will be done by the area AD, DRAP and meanwhile the consignment will be released with the restriction that it could only be used if it has qualified requisite tests from the public institutions/testing laboratories and the certificate has been endorsed by the DRAP.**

ii. **Board constituted standard panels comprising of following for destruction of seized stocks of valsartan API as well as finished products containing NDMA manufactured from the raw material of M/s Zheijhiang Huahai pharmaceuticals, China/any other manufacturer contaminated batches as the API has been withdrawn and banned internationally.**

    a) **Area Additional Director.**
    b) **Area Federal Inspector of Drugs.**
    c) **Assistant Director I&E.**

    Any two of the above with the permission of Additional Director.

iii. **The above mentioned panels will make coordination with the respective manufacturer for the destruction of stocks and will prepare destruction certificates for the consideration of the Registration Board. It shall be ensured that destruction /incineration is conducted in the presence of panels and incineration certificates from the environment protection agency is also accompanied with the panel report**

iii. Annex-A

Drug Regulatory Authority of Pakistan

Standard Operating Procedure for Destruction of Drug Registration Board Portions of Drug Samples for which 01 Year have passed after date of expiry since declaration of Stan ard Quality By CDL	**FW No. QALT/QC/SOP/0_**

Issue Date		**Review Date**		**Version**	**01**

Framework					
DEPARTMENT: QUALITY ASSURANCE & LAB TESTING.					
Standard Operating Procedure for Destruction of Drug Registration Board Portions of Drug Samples for which 01 Year have passed after date of expiry since declaration of Standard Quality By CDL					**Version: 01**
Issue Date		**Review Date**	**Supersedes with Date**	**Reference**	**No of Pages**
				DRAP	**06**
	Original / Owner: Director, QA&LT, DRAP, Islamabad. **Copies To: List Attached.**				
Prepared By	**Checked By**	**Re-Checked By**	**Reviewed By**	**Approved By**	**Authorized By**
Assistant Director/ In-charge Samples	**Deputy Director QA&LT**	**Additional Director QA&LT**	**Director QA&LT**	**Secretary Drug Registration Board**	**Chief Executive Officer**
Date	**Date**	**Date**	**Date**	**Date**	**Date**

Prepared By	Checked By	Reviewed By	Approved By	Authorized By
Date	Date	Date	Date	Date

Drug Regulatory Authority of Pakistan

Standard Operating Procedure for Destruction of Drug Registration Board Portions of Drug Samples for which 01 Year have passed after date of expiry since declaration of Stan ard Quality By CDL	**FW No. QALT/QC/SOP/0_**

Issue Date		**Review Date**		**Version**	**01**

Section					
Date	**Date**		**Date**	**Date**	**Date**

Table of Contents

Prepared By	Checked By	Reviewed By	Approved By	Authorized By
Date	Date	Date	Date	Date

Drug Regulatory Authority of Pakistan

Standard Operating Procedure for Destruction of Drug Registration Board Portions of Drug Samples for which 01 Year have passed after date of expiry since declaration of Stan ard Quality By CDL				**FW No. QALT/QC/SOP/0_**	
Issue Date		**Review Date**		**Version**	**01**

1. **Purpose**

   This SOP will ensure safe and appropriate destruction of the DRB portions of drug samples for which 01 Year have passed after date of expiry since they have been declared of Standard Quality by CDL.

2. **Scope**

   This SOP will be applicable for DRB portions of drug samples of standard quality which are not required for any legal purpose.

3. **Requirements**

   3.1. Staff

   3.1.1. Dedicated Assistant Director / In-charge sample section
   3.1.2. Data Entry Operator
   3.1.3. Naib Qasid

   3.2. Ancillary

   3.2.1. Computer
   3.2.2. Data entry register
   3.2.3. Strong plastic bags to place segregated passed samples
   3.2.4. Permanent markers

4. **Responsible persons**

   4.1. DRB:

   4.1.1. Approve the SOPs as well as accord permission for the destruction of the DRB portions of drug samples for which 01 Year have passed after date of expiry since declaration of Standard Quality by CDL.

   4.2. Director QA&LT:

   4.2.1. Review the SOP and ensure the implementation of all activities as per SOP.

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4.3. Additional Director QA&LT:

4.3.1. Re-check the SOP.

4.3.2. Supervise all the operations / activities as per SOP.

4.3.3. Review and audit the implementation of SOP.

4.4. The Committee:

4.4.1. Responsible to supervise and ensure destruction of the samples through incineration and proper disposal of the waste.

4.5. Assistant Director / In-charge, samples section:

4.5.1. Responsible to write / update the SOP and to maintain and record all the activities as per the SOP.

4.6. Computer operator, samples section:

4.6.1. Responsible for data maintenance & register entries and to segregate the samples correspondingly in respect of status of the samples provided by the CDL.

4.7. Naib Qasid

4.7.1. Responsible for lifting, carrying the boxes in supervision of the in-charge sample room

5. <u>Abbreviations and Definitions:</u>

5.1. SOP: Standard Operating Procedure.

5.2. DRB / Board: Drug Registration Board.

5.3. CDL: Central Drug Testing Laboratory, DRAP, Karachi.

5.4. Committee: A committee constituted by the Board in its _____ meeting dated _____ comprising of following members;

1	Secretary DRB	Convener
2	Additional Director QA&LT	Member

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Drug Regulatory Authority of Pakistan

Standard Operating Procedure for Destruction of Drug Registration Board Portions of Drug Samples for which 01 Year have passed after date of expiry since declaration of Stan ard Quality By CDL				**FW No. QALT/QC/SOP/0_**	
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3	Deputy Director QA&LT	Member
4	Assistant Director/ Incharge Sample section	Member

6. Procedure

6.1. DRB portions of those drug samples which have been received in samples section and 01 Year have passed after date of expiry since they have been declared of Standard Quality by CDL will be segregated.

6.2. The segregated pass samples will be packed in separate cartons / bags bearing serial number and marked as "Pass / Standard Samples".

6.3. Record of such drug samples will be properly prepared stating the details of the samples i.e. Name of Drug, Batch Number, Dosage Form, Manufacturer, Test Report Number and Quantity of each Drug Sample.

6.4. The bags / cartons will be transferred from sample store to a designated area specified for the storage of such samples.

6.5. Request for disposal of such samples will be presented in DRB meeting to seek approval from the Board.

6.6. After seeking approval from the Board, the matter will be referred to Division of Administration for seeking of quotations, evaluation and final vendor selection as per prescribed procedures and rules framed there under, for the subject purpose.

6.7. The stock will be handed over to the authorized person of the selected firm upon provision of authorization letter by the firm.

6.8. In-charge samples section will take pictures of the stock loaded in the transportation vehicle as evidence in the presence of the firm representative.

6.9. In-charge samples section will keep record of the name of the authorized person, driver, type and registration plate number of the vehicle being used for transfer of samples.

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6.10. The loaded vehicle will be allowed to leave the premises of the office subject to provision of a receiving of the stock by the firm's representative; and after issuance of gate pass approved by the secretary DRB.

6.11. In-charge samples section will witness the disposal / incineration of the stock at the facility of the firm.

6.12. After completion of the service, a disposal certificate along with emission and ash analysis report issued by the firm will be obtained and maintained in the record.

6.13. A compliance report will be submitted for consideration by the board.

6.14. The procedure will be repeated when required.

7. DISTRIBUTION OF DOCUMENTS:

7.1. Director QA&LT, DRAP, Islamabad.
7.2. Additional Director, QA&LT, DRAP, Islamabad.
7.3. Secretary Drug Registration Board, DRAP, Islamabad.
7.4. Deputy Director Administration, DRAP, Islamabad.
7.5. Deputy Director, QA&LT, DRAP, Islamabad.
7.6. Assistant Director / In-charge Samples Section, DRAP, Islamabad.

8. DOCUMENT HISTORY

Version No.	**Version Date**	**Description Of Change**	**Author Name**
001		First document	

Prepared By	Checked By	Reviewed By	Approved By	Authorized By
Date	Date	Date	Date	Date

Item No. V Additional Agenda

A. Pharmaceutical Evaluation & Registration

Case No. 01: Implementation of Common Technical Document (CTD)

Rule 26 of Drugs (Licensing, Registering and Advertising) Rules, 1976 was amended for incorporation of Common Technical Document (CTD) as Form 5-F for application of registration of pharmaceuticals and biological drugs which has been notified vide S.R.O. 713(I)/2018 dated 09.06.2018.

Registration Board in its 264th meeting has considered and in order to facilitate and encourage the submissions on CTD, Registration Board also approved various exemptions in the modules and sub-modules. Registration Board was also apprised of the approval of amendments in rule 26 of Drugs (Licensing, Registering and Advertising) Rules, 1976 by Federal Government. In the same meeting Registration Board advised to present implementation plan for consideration by the Board.

The exemptions and explanatory notes of module-1 already approved by Registration Board in its 264th meeting and 286th meeting were again discussed at length.

Decision: Registration Board after thorough discussion decided to approve following explanatory notes of Module 1 of CTD. These notes shall facilitate applicants (manufacturer/ importer) as a guidance document.
Registration Board appreciated pharmaceutical Evaluation Cell for extensive work in preparing explanatory notes. The Board further advised to prepare the guidance document for rest of the modules of CTD as well.

MODULE 1: ADMINISTRATIVE PART

Section	Sub-Section	Heading	Explanatory Notes
1.1		Covering Letter and Fee Deposit Slip	• Covering letter on the Applicant company / manufacturer / importer letter head in context to the application for the registration of the Pharmaceutical Drug Product shall be submitted, which should be dully signed by owner/ authorized person on behalf of company/ manufacturer/ importer. • An original cash deposit slip endorsed by Budget & Accounts Division, DRAP of prescribed fee as per Schedule F for specified category shall be attached therewith.
1.2		Table of Contents (From Module 1 to Module 5)	• A comprehensive Table of Contents shall contain Module and sub module heading with page number on the pharmaceutical dossier. The contents of all the Module from 1 to 5 shall be covered. Comprehensive Table of Contents is different form individual table of contents in the beginning of each Module. • Also, a complete list of all documents provided in the application dossier by Module, Section and sub-section shall be included • For hardcopy submissions, the location of each document

			should be identified by the volume number and tab identifiers (name of document or section heading according to PDF format)
1.3	**Applicant Information**		
	1.3.1	Name, address and contact details of Applicant / Marketing Authorization Holder:	• In this section, administrative information related to the applicant is required. • It is necessary to provide the complete particulars of the applicant, which shall contain: □ Name of Licensed Pharmaceutical Manufacturer / Licensed Importer having Drug Sale License by respective licensing authority □ Manufacturing Site Address of Pharmaceutical Company □ Contact details, including postal address, telephone contact number, Fax number, website and email address.
	1.3.2	Name, address and contact details of Manufacturing site.	There could be following three situations: **a) Self Manufacturing** (The applicant is manufacturer) • Provide the details including name, DML number and complete address of the manufacturing site of the applicant (manufacturer). **b) Contract Manufacturing** (The applicant is not manufacturer for the applied product) • Provide the details including name, DML number and complete address of the manufacturing site of the manufacturer. **c) Import** (The applicant is importer for the applied product) • Provide the details including name and complete address of the manufacturing site of the manufacturer abroad. • In case multiple manufacturer(s) are involved, provide details for each.
	1.3.3	Specify whether the Applicant is: g. □ Manufacturer h. □ Importer i. □ Is involved in none of the above (contract giver)	**This point requires the status of applicant for the instant product.** The applicant must select one of the above mentioned options. A manufacturer will provide all the requisite information as per Registration procedure of Pakistan, subsequently mentioned in 1.3.4-1.3.5. • An importer shall provide Drug Manufacturing License from respective Licensing authorities in the country of origin, Certificate of Pharmaceutical Product (CoPP) confirming Market authorization / Free Sale and GMP status of the Manufacturer firm in this section. • c is for Contract Manufacturing as per Rule 20-A of Drugs (Licensing, Registering and Advertising) Rules, 1976.
	1.3.4	Valid Drug Manufacturing License (DML) of manufacturer / Applicant or Drug Sale License, whichever is applicable.	**Must be submitted in all cases.** Copy of valid Drug Manufacturing License (DML) issued by Licensing Division, DRAP or Drug Sale License License (DSL) issued by relevant licensing authority. The address of applicant mentioned on Drug Sale License (DSL) should match with the information provided in sub-section 1.3.1 and sole agency agreement / letter of authorization between applicant and marketing authorization holder (abroad).

	1.3.5	Evidence of approval of manufacturing facility / Approved Section from Licensing Authority	To be provided if option a or c is selected in sub-section 1.3.3 Approval letter of the section in which manufacturing of the applied product is to be carried out needs to be submitted. In case of contract manufacturing, the same evidence from the contract manufacturer should be submitted.
	1.3.6	List of already approved registered drugs in this section	The submission against this point is **optional**
	1.3.7	Identification of Signature(s) of authorized persons, Incharge Production, Quality Control and Incharge Quality Assurance	The submission against this point is **optional**
	1.3.8	Manufacturer's Site Master File and Credential (**for importer**)	• Site master file contains information regarding Management, Human Resource (Technical Staff), Layout Plan, HVAC, Water Treatment Facilities, List of Analytical Equipment, List of Manufacturing Equipment, Storage Facilities (both for API and Finished Product), Fire Management and Risk Management Plan. • ISO certification and any other accreditations (if applicable). • Relevant SOPs dually approved by the management and Technical Head of the production facility. Each page of the Site Master File/Credential shall be dully signed by respective technical heads.
1.4	**Type of Application**		
	1.4.1	Application is for the registration of: □ New Drug Product (NDP) □ Generic Drug Product (GDP)	• New Drug Product include New Molecule/ New strength / Novel dosage form/ New Formulation. • It is important to specify here whether the Applicant has submitted the CTD for a New Drug Product Registration or a Generic Drug Product. The information in the subsequent dossier and exemptions in provision of relevant information depends upon the type of application.
	1.4.1	Pharmaceutical product is intended for: □ Domestic sale □ Export sale □ Domestic and Export sales	Applicant needs to clarify whether the applied product is intended for sale in domestic market or both for domestic and export market. **For Export only registrations application on CTD is already exempted by the Authority.**
	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	Specify the names of Contract acceptor along with DML, Recent GMP, Evidence of Section / facility approval from CLB and notarized copy of Contract between the parties as per Rule 20A of Drugs (L,R & A) Rules, 1976.
1.5	**Detailed Information of Drug, Dosage From & Labeling Claims**		
	1.5.1	Generic name with chemical name & synonyms of the applied drug.	The following necessary information shall be provided in this sub-section: a) (Recommended) International Non-proprietary name (INN): b) Compendial name, if relevant: c) Chemical name(s): d) Chemical Abstracts Service (CAS) registry number: (where applicable) **The submission of following is optional** e) Company or laboratory code: f) Other non-proprietary name(s) (e.g. national name, USAN, BAN):
	1.5.2	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	• Strength of Active ingredient should be stated clearly. In case API is in the form of salt, specify the equivalent strength of the base e.g., AAA sodium 50 mg (equivalent to AAA) etc. • For example, each tablet contains, each ml contains in case of Injectable. However, description like each ampoule / vial contains should be avoided, or in case of syrup / suspension / dry powder for suspension each 5 ml (after reconstitution) contains etc.
	1.5.3	The proposed proprietary name / brand name under which the drug is intended to be sold with trade mark certification / clearance.	• The proposed brand name should be justified along with an assessment / analysis report considering the LASA (Look alike and Sound alike) with specific emphasis on prefix, mid-name and suffix. • The FDA guidance namely "Best Practices in Developing Proprietary Names for Drugs" may also be consulted. An undertaking in this regard that the applicant shall be responsible to change the name in case the name after approval will resemble with already approved / registered names. **The submission of following is optional** • The company should also submit the approval of Trade Mark before submitting the proposed brand name.
	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.	
	1.5.5	Pharmacotherapeutic Group of Active Pharmaceutical Ingredient (API)	• Indicate Pharmacological class of the API with proper reference. Also, state WHO ATC code for each distinct therapeutic indication.
	1.5.6	Pharmacopoeial reference / Status of applied	Mention the reference specifications of the finished product from the following list

		formulation	□ USP □ BP □ Int. Ph. □ JP □ Manufacturer's specifications □ Specifications as per Innovator's product □ Any other (specify exact reference) □ Any other pharmacopoeia as mentioned in Drug specification rules. (specify the exact reference)
	1.5.7	Route of administration	
	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.	If the applicant has selected Generic Drug Product (GDP) in sub-section 1.4.1, the reference of already registered product including the following details needs to be submitted. • Brand name • Manufacturer/Registration holder • Registration number If the applicant has selected New Drug Product (NDP) in sub-section 1.4.1 "Not applicable since this is a new drug" needs to be mentioned against this point
	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.	Evidence of approval / registration / marketing status of the applied formulation in the same composition, salt form and dosage form in one of the reference regulatory authority specified by Registration Board. The name of the reference authority should be mentioned as adopted by Board currently.
	1.5.10	Dosage form of applied drug	• Dosage form of applied drug shall be mentioned clearly, with complete description of a unit like "Film Coated Tablet" & "Sugar Coated Tablet" etc. • Also description of the tablet shape, dimensions, capsule color schemes, diameters, ampoule color and dimensions, granular powder for Dry Suspension, color of solution for reconstitution in amber glass bottle with Aluminum cap, etc. shall be provided.
	1.5.11	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens	In case, where secondary packaging is done on other site, the name of "Secondary Packager" should be added on the label after the name of manufacturer. For products intended to be marketed outside Pakistan (for Export purpose) labels should be in accordance with the requirements of importing country (for which an undertaking should be submitted by the company.
	1.5.12	Description of Batch numbering system	The submission against this point is **optional**
	1.5.13	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed	The submission against this point is **optional**

		pharmaceutical product / Novel Dosage Form).	
	1.5.14	Summary of Product Characteristics (SmPC) including Prescribing Information (PI) along with Patient information Leaflet (PIL) of the Finished Pharmaceuticals Product (FPP).	The submission against this point is **optional**
	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.	
Section	**Sub-Section**	**Heading**	**Explanatory Notes**
	1.5.21	Protocols along with the commitment to follow Good Laboratory Practices (GLP) by the Manufacturer.	Good Laboratory Practice (GLP) is not for Quality Control (QC) laboratories in the manufacturing units but for clinical labs for bioequivalence studies etc. The submission against this point is **optional**
	1.5.22	Protocols to implement Good Pharmacovigilance Practice by the Pharmacovigilance department/section of the Manufacturer / Company.	Firm shall submit commitment to follow guidelines / rules of Pharmacy services division of DRAP for Pharmacovigilance.
1.6	**Miscellaneous Information**		
	1.6.1	Information on Prior-related Applications	The submission against this point is **optional**
	1.6.2	Appendix	

	1.6.3	Electronic Review Package	
	1.6.4	QIS (Quality Information Summary)	The submission against this point is **optional**
	1.6.5	Drug Substance related Document including following: i. Name and address of API manufacturer. j. Approval of manufacturing facility of API by regulatory body of country and validity. k. Vendor qualification / audit is □ Document based □ Site inspection based Reason for point c.	For cases of local manufacturing these documents shall be submitted. In case the API is imported, documents confirming import of API including ADC attested commercial invoice shall be submitted. In case of multiple sources of API, relevant information of all the manufacturers' shall be submitted.

Case No. 02: Request from PPMA for Toll manufacturing:

PPMA vide their letter date 2nd September 2019 has submitted that sequence of Toll manufacturing applications is not structured enough because of which the said applications have not been addressed for so many years. Toll Manufacturing is the most convenient way by virtue of which manufacturer can utilizes their manufacturing capacity by dual cooperation/coordination with each others, hence can improve standards.

In the light of above, PPMA requested that a separate queue may please be arranged to address the pending toll manufacturing applications and a separate time should be allocated in each Registration Board meeting for toll manufacturing applications. This will facilitate a lot to the pharmaceutical industry to enhance the quality as well as utilizing their spare production capacity.

Decision: **Registration Board was apprised that registration applications for contract manufacturing are regularly presented / considered as per their turn alongwith other routine applications. Moreover, separate queue has been maintained for registrations applications of either new DML and sections or various categories (drugs of public health urgency including drugs for treatment of cancer, viral diseases, thalaesemia, immunosuppresants, vaccine and sera, Blood Factors, or non-available drugs Registration applications on CTD Format, Registration Applications with Stability studies, Export Facilitation Applications). The Board advised to communicate aforementioned status to PPMA.**

(Deputy Director PE&R)

Case No. 3: Disclosure of Excipients on Labeling and leaflets for information of patients and prescribers.

With reference to various complaints received through Prime Minister's Pakistan Citizen's Portal by different patients and also direct requests for the availability gluten-free medicines for the patients suffering from Celiac Disease. The patients suffering from Celiac Disease experience severe hypersensitivity to gluten (an ingredient in starch). Moreover, many patients also experience Lactose intolerance. In this context, it is to bring into the notice of this

Board that the following procedure has so far been adopted by the Reference Regulatory Authorities.

USFDA has forwarded a recommendations "Gluten in Drug Products and Associated Labeling Recommendations---A Guidance Document for Industry **(**https://www.fda.gov/media/116958/download**)**". In response thereto, United States of America has also forwarded a legislative proposal to the congress in the name and style of **"Gluten in Medicine Disclosure Act, 2019" (**https://celiac.org/about-the-foundation/featured-news/2019/04/the-gluten-in-medicine-disclosure-act-of-2019-introduced-in-the-house/**).**

The European Union has also directed vide their Directive 2001/83/EC (https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF) vide article 54 of that directive that **"All excipients in parenteral, ocular and topical medicine, as well as the excipients listed in the annex to the guideline, must appear on the labeling. In addition, all excipients listed in the annex must be included in the package leaflet together with the relevant information set out in the annex."** The Union has also specified punishment in case of non-compliance of the said directive under Article 64 of the same as **"Where the provisions of this Title are not complied with, and a notice served on the person concerned has remained without effect, the competent authorities of the Member States may suspend the marketing authorization, until the labeling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Title".**

The drugs act 1976 also has provided a like provision generally under section 3 subsection (s) clause (iii) whereby it is mandatory for the pharmaceutical manufacturers/importers/marketing agents to expressly declare those conditions where the use of drug may be unsafe for patients but the same is generally understood as relating to active pharmaceutical ingredient (API).

It is, therefore, proposed that a direction may be passed of such nature to the Pharmaceutical Manufacturers/importers so that the patients suffering from hypersensitivity to any of the ingredients of the drug may help themselves by avoiding allergic medication(s) and may opt safe option(s) for themselves.

Decision: **Registration Board considered and deliberated the matter at length and decided, keeping in view the miserable condition of patients suffering from Celiac Disease and increasing number of lactose-intolerant patients, as following:-**

i. **Directive 2001/83/EC of the European Council dated 06 November 2001 shall be adopted as such whereby the recommendations and guidelines along with Annexure to those guidelines shall be mandatory for the Pharmaceutical Manufacturers with respect to disclosure of excipients (both quantitative and qualitative) employed in the preparation of drug products;**

ii. **It shall also be mandatory for the manufacturer to perform tests for the presence of Gluten their drug and to categorically identify on the Label with the statement that "Contains Gluten and Contraindicated for Patients with Gluten allergy" or "Free from Gluten and safe for patients of celiac disease";**

iii. **It shall also be mandatory for the manufacturer to perform tests for the presence of Lactose in their drug and to categorically identify on the Label with the statement that "Contains Lactose and Contraindicated for Patients with Lactose-intolerance" or "Free from Lactose and Safe for Patients suffering from Lactose-intolerance";**

Case No. 04: Regulation of insecticides, mosquito coils & repellants, etc.

This case is also founded upon complaints from Prime Minister's Pakistan Citizen's Portal whereby harmful effects have been reported to the use of such substances. Additionally, many times incidences have been reported wherein severe human casualties have been reported on account of uncontrolled use of such substances. Examples in this behalf are:-

i. Poisonous Gas, Not Food, caused death of six of a family (http://www.dawn.com/news/1466191) dated 25th April 2019);
ii. Poisoned Sweets kill 23 people in Pakistan, leaving 52 in Hospital (https://www.abc.net.au/news/2016-04-25/poisoned-sweets-kill-23-people-in-Pakistan/7356394 dated 25th April 2016).

Factually speaking, such substances have exclusively been declared as drugs vide the Drugs Act, 1976 and thereafter, by the DRAP act also. The issue needs critical consideration in this behalf so that such substances may also be regulated and controlled as drugs and measures be taken to ensure strict compliance in this behalf as prescribed by legislature.

Decision: **Registration Board considered and deliberated the matter at length. It was concluded that these substances were exempted from regulation as drugs vide S.R.O. 268(I)/79 dated 21st March 1979 and thereafter by S.R.O. 1113(1)/86 dated 15th December 1986. After promulgation of DRAP Act, 2012, these substances have again been included in the definition of Drugs. Now complaints have also been received from various quarters vide Prime Minister's Citizens Portal with respect to injuries caused by them with their use as insect repellents and the fatalities reported into national press because of their use as such; the Registration Board decided to seek guidance from DRAP's Authority for regulation of these substances as drugs in the best interests of Public Health and Safety.**

Case No. 05: Regulation and Control of Gases (Oxygen) as Drug.

This issue is has also originated out of request submitted by the Deputy Director Purchase, Pakistan Institute of Medical Sciences (PIMS) wherein it has been contended that despite the fact that Medical Oxygen (Liquid Oxygen and Compressed Oxygen) has been included in the list of Essential Drug List of Pakistan and its registration status with DRAP was sought. Moreover, a complaint has also been received through complaint on Prime Minister's Pakistan Citizens' Portal with respect to uncontrolled use of oxygen and its impact about uncontrolled prices, monopoly and related health hazards.

In this regard it is to bring into notice of Board that Oxygen has been declared as drug by:-

i. British National Formulary (BNF 70 pp.214-215);
ii. Martindale, The Complete Drug Reference (36th Edition p.690);
iii. World Health Organization (WHO Model List of Essential Medicines, March 2017 pp.1-2);
iv. National Essential Medicines List 2018, Published by DRAP (S.No. 297 p.13 of National Essential Medicines List 2018);
v. European Pharmacopoeia (European Pharmacopoeia 7.1 pp.3445-3447);
vi. USFDA has also under consideration application of approval of Oxygen as Drug (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=205712) as accessed on 30th January 2019;

vii. MHRA also has approved the Liquid Medical Oxygen as a Drug/Medicinal Product. Hence, it is proposed that Board may please consider it as drug so that it may also be regulated as other drugs in terms of its quality, safety, efficacy and price, etc.

Decision: Registration Board deliberated the matter at length and decided to seek guidance from DRAP's Authority for its regulation as drugs in the best interests of Public Health and Safety

Case No. 06: Illegal and Unlawful use of Letrozole for Pregnancy Induction.

A Complaint has been received vide Prime Minister's Pakistan Citizen's Portal bearing complaint No. PU010719-3415357 dated 01st July 2019 wherein it has been complained that M/s Mass Pharma (Pvt) Limited, Lahore is illegally and unlawfully promoting its registered drug "Fempro Tablets" for inducing pregnancy despite being contraindicated in the situation. In fact the said drug (i.e. Fempro Tablet possessing the active pharmaceutical ingredient Letrozole) is an anticancer medication and has been approved by Reference Regulatory Authorities for treatment of Breast Cancer. The said drug has been reported to cause congenital birth defects and is Embryo-Fetal Toxicity (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020726s035lbl.pdf). Because of its herein-mentioned effects on Embryo and Fetus this drug is expressly warned against use in such or relevant conditions.

Therefore, a need exists that this matter may be deliberated and a warning may be issued to firms against use in such condition as it may lead to some grave health hazard is left unaddressed.

Decision: Registration Board deliberated the matter in detail and observed that all registrations are granted with a set of conditions including following:

"the manufacturer shall follow information in label / patient information leaflet and medical literature regarding clinical use, route of administration, dosage, storage condition of finished propducts and type of container closure system / packaging material in line with innovator brand or reference regulatory authorities or as approved by Registration Board."

Keeping in view position narrated above, the Board decided as follows:

- **To serve show cause notice to M/s Mass Pharma for promoting of letrozle for pregnancy induction in violation to above mentioned condition of registration letter.**
- **All pharmaceutical manufacturer / importers shall be advised to strictly comply with all conditions of registration to ensure availability of safe, effective and quality drugs.**

Export facilitation

Assistant Director Via Letter No. F.1-6/2019-PR-I(EFD) dated 27th August 2019 has communicated to Incharge PEC that M/s Indus Pharma (Pvt.) Ltd., Karachi, has achieved a benchmark of USD 285,043/-, during the fiscal year 2018-2019. In this regard following application have been submitted for consideration on priority against the export facilitation.		
1.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Misartan 80mg Tablets
	Composition	"Each Tablet Contains: Telmisartan…….80mg"
	Diary No. Date of R& I & fee	Dy. No 29602 dated 04-09-2018 Rs.20,000/- Dated 04-09-2018
	Pharmacological Group	Antihypertensive
	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 80 Tablets of M/s Novamed Pharmaceuticals (Reg.# 077140)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-08-2017 concluded acceptable level of CGMP Compliance with Good manufacturing practices
	Remarks of the Evaluator[II]	
	Decision: Approved.	
2.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Onseron 8mg/4ml Injection
	Composition	"Each 4ml contains: Ondansetron (as ondansetron hydrochloride dihydrate)…….8mg"
	Diary No. Date of R& I & fee	Dy. No 29602 dated 04-09-2018 Rs.20,000/- Dated 04-09-2018
	Pharmacological Group	Antiemetics and antinauseants, Serotonin (5HT3) antagonists
	Type of Form	Form-5
	Finished product Specifications	USP
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by MHRA of UK
	Me-too status (with strength and dosage form)	Welsetron 8mg Injection of M/s Welwrd Pharmaceutical (Reg.# 064457)
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-08-2017 concluded acceptable level of CGMP Compliance with Good manufacturing practices
	Remarks of the Evaluator[II]	
	Decision: Approved.	
3.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sacutan 49/51 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril……49mg

		Valsartan……51mg"
	Diary No. Date of R& I & fee	Dy. No 6972 dated 19-02-2019 Rs20,000/- Dated 19-02-2019
	Pharmacological Group	Angiotensin receptor-Neprilysin inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-08-2017 concluded acceptable level of CGMP Compliance with Good manufacturing practices
	Remarks of the Evaluator[II]	Stability studies data as per directions of 278th meeting is required.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board	
4.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Sacutan 24/26 mg Tablet
	Composition	"Each Film Coated Tablet Contains: Sacubitril……24mg Valsartan……26mg"
	Diary No. Date of R& I & fee	Dy. No 6971 dated 19-02-2019 Rs20,000/- 19-02-2019
	Pharmacological Group	Angiotensin receptor-Neprilysin inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-08-2017 concluded acceptable level of CGMP Compliance with Good manufacturing practices
	Remarks of the Evaluator[II]	Stability studies data as per directions of 278th meeting is required.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board.	
5.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Exilant 30mg Capsule
	Composition	"Each Capsule Contains: Dexlansoprazole…30mg"
	Diary No. Date of R& I & fee	Dy.No 6970 dated 19-02-2019 Rs100,000/- 19-02-2019
	Pharmacological Group	Angiotensin receptor-Neprilysin inhibitor
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA

	Me-too status (with strength and dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-08-2017 concluded acceptable level of CGMP Compliance with Good manufacturing practices
	Remarks of the Evaluator[II]	• Source of pellets is M/s Murli Krishna Pharma Pvt. Ltd., Maharashtra, India. • Stability studies data as per directions of 278th meeting is required.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board.	
6.	Name and address of manufacturer / Applicant	M/s Indus Pharma (Pvt.) Ltd. Plot No. 26,27 & 63-67, Sector 27, Korangi Industrial Area, Karachi
	Brand Name +Dosage Form + Strength	Indazin 5mg Tablet
	Composition	"Each Film Coated Tablet Contains: Dapagliflozin…5mg"
	Diary No. Date of R& I & fee	Dy. No 11495 dated 05-03-2019 Rs.20,000/- 05-03-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specifications	Manufacturer specifications
	Pack size & Demanded Price	As per DPC
	Approval status of product in Reference Regulatory Authorities	Approved by USFDA
	Me-too status (with strength and dosage form)	
	GMP status	Firm has submitted copy of GMP inspection report conducted on 16-08-2017 concluded acceptable level of CGMP Compliance with Good manufacturing practices
	Remarks of the Evaluator[II]	• Stability studies data as per directions of 278th meeting is required.
	Decision: Deferred for submission of stability data as per directions of 278th meeting of Registration Board	

Evaluator PEC-II

Import (Veterinary)

7.	Name and address of Applicant	M/s Orient Animal Health (Pvt) Ltd., Commercial 6, Block A, Kazimabad, Model Colony Karachi
	Detail of Drug Sale License	**Address:** Comm-6 Block-A 1st floor Kazimabad Model Colony Karachi **Validity:** 22-10-2020 **Status:** Drug sale by way of Wholesale
	Name and address of manufacturer	Laboratorios Calier, S.A. Barcelones, 26 (Les franqueses del Valles (Barcelona)) – 08520-Spain
	Name and address of marketing authorization holder	Laboratorios Calier, S.A. Barcelones, 26 (Les franqueses del Valles (Barcelona)) – 08520-Spain
	Name of exporting country	Spain
	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 11491: 09-08-2017
	Fee including differential fee	PKR 100,000/-: 09-08-2017
	Brand Name +Dosage Form + Strength	Zuritol 25mg/ml

	Composition	Each ml of solution (for use in drinking water for chickens) contains: Toltrazuril……25mg
	Finished Product Specification	Firm has claimed in house specification
	Pharmacological Group	Antiprotozoals
	Shelf life	2 years
	Demanded Price	Decontrolled
	Pack size	1ltr, 5ltr.
	International availability	Approved by Spain
	Me-too status	Nocox 2.5% oral solution of M/s Hirra Pharmaceutical Industries (Pvt.) Ltd., Lahore. (Reg.#032203)
	Detail of certificates attached	**Free Sale certificate:** Original, legalized certificate issued by DEPARTMENTO DE MEDICAMENTOS VETERINARIOS on 26-01-2017, confirms registration (Registration no. 2586-ESP) & free sale of applied product. **GMP certificate:** Copy of GMP certificate (Certificate No: ES/100HV/17) issued by Agencia Espanola de Medicamentos y Productos Sanitorios Spain, for M/s Laboratorios Calier, S.A. Barcelones, 26 (Les franqueses del Valles (Barcelona)) – 08520-Spain valid upto 09-06-2020. The above GMP certificate is verifiable from following web link as accessed on 02-09-2019: http://eudragmdp.ema.europa.eu/inspections/gmpc/searchGMPCompliance.do?ctrl=searchGMPCResultControlList&action=Drilldown&param=43040 **Sole Agency Agreement:** Copy of sole agency agreement dated 08-05-2014 between the MA holder in Spain and applicant in Pakistan is provided.
	Remarks of the Evaluator: Firm has submitted both accelerated and long term stability data of applied formulation as per Zone-IV-A conditions.	
	Decision: Approved as per policy of inspections of manufacturer abroad.	
8.	Name and address of Applicant	M/s Orient Animal Health (Pvt) Ltd., Commercial 6, Block A, Kazimabad, Model Colony Karachi
	Detail of Drug Sale License	**Address:** Comm-6 Block-A 1st floor Kazimabad Model Colony Karachi **Validity:** 22-10-2020 **Status:** Drug sale by way of Wholesale
	Name and address of manufacturer	**Manufacturing, Filling & Sealing of the vials:** LABORATORIOS MAYMO,S.A. POLIGONO INDUSTRIAL CAN PELEGRI C/Ferro 9 (CASTELLBISBAL (Barcelona)) – 08755 - Spain **Secondary packaging & batch release:** Laboratorios Calier, S.A. Barcelones, 26 (Les franqueses del Valles (Barcelona)) – 08520-Spain. Sterilization by Gamma radiation: ARAGOGAMMA, S.A. Crta Granollers a Cardadeu, KM3,5 (Les Franqueses del Valles (Barcelona)) -08520-Spain
	Name and address of marketing authorization holder	Laboratorios Calier, S.A. Barcelones, 26 (Les franqueses del Valles (Barcelona)) – 08520-Spain
	Name of exporting country	Spain

	Type of Form	Form 5-A
	Diary No. & Date of R& I	Dy. No. 11493: 09-08-2017
	Fee including differential fee	PKR 100,000/-: 09-08-2017
	Brand Name +Dosage Form + Strength	Ceftiomax 50mg/ml suspension for injection for cattle
	Composition	Each ml of suspension for injection for cattle contains: Ceftiofur (as hydrochloride) …… 50mg
	Finished Product Specification	Firm has claimed in house specification
	Pharmacological Group	Antibacterial
	Shelf life	36 months
	Demanded Price	Decontrolled
	Pack size	100 ml
	International availability	Approved by Spain
	Me-too status	Nocox 2.5% oral solution of M/s Hirra Pharmaceutical Industries (Pvt.) Ltd., Lahore. (Reg.#032203)
	Detail of certificates attached	**Free Sale certificate:** Original, legalized certificate issued by DEPARTMENTO DE MEDICAMENTOS VETERINARIOS on 03-11-2016, confirms registration (Registration no. 2183-ESP) & free sale of applied product. **GMP certificate:** • Copy of GMP certificate (Certificate No: ES/143HV/18) issued by Agencia Espanola de Medicamentos y Productos Sanitorios Spain for M/s LABORATORIOS MAYMO,S.A. POLIGONO INDUSTRIAL CAN PELEGRI C/Ferro 9 (CASTELLBISBAL (Barcelona)) – 08755 – Spain, valid upto 25-10-2021. • Copy of GMP certificate (Certificate No: ES/100HV/17) issued by Agencia Espanola de Medicamentos y Productos Sanitorios Spain, for M/s Laboratorios Calier, S.A. Barcelones, 26 (Les franqueses del Valles (Barcelona)) – 08520-Spain valid upto 09-06-2020. • Original GMP certificate (Certificate No: NCF71702/001/CAT), issued by Competent Regional Authority. Direccion de regulacion Planificacion y Recursos Santiarios. Departamento de salud. Generalitat de Catalunya for **M/s ARAGOGAMMA, S.A. Crta Granollers a Cardadeu, KM3,5 (Les Franqueses del Valles (Barcelona)) -08520-Spain,** valid upto 07-02-2020. All above GMP certificates are verifiable from the EUDRA GMP certificate databse. **Sole Agency Agreement:** Copy of sole agency agreement dated 08-05-2014 between the MA holder in Spain and applicant in Pakistan is provided.
	Remarks of the Evaluator: Firm has submitted both accelerated and long term stability data of applied formulation as per Zone-IV-A conditions.	
	Decision: Approved as per policy of inspections of manufacturer abroad.	

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

a. New DML

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

Following registration dossiers have been received vide letter No. dated 07/03/ 2019 stating that the firm has been granted approval of new DML by way of formulation by Central Licensing Board in its 269th meeting for following thirteen (13)sections

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

The following applications have been evaluated and presented before the Board

Sr.#	Section	No. of products	No. of molecules
1.	Dry powder oral suspension section (General)	8	6

Dry powder oral suspension section (General) 8 products/ 6 molecules		
9.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	ROXIL 125mg/5ml granules for oral suspension
	Diary No. Date of R& I & fee	Dy.No 15552 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Composition	Each 5ml of suspension contains: Ciprofloxacin (as HCl) … 125mg/5ml Source of granules: M/s vision Pakistan
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60ml,90ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro Suspension By M/S Byer Health Care **(USFDA Approved)**
	Me-too status	NOVIDAT DRY SUSPENSION 125mg/ 5ml by M/S SAMI
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	Firm has applied ciprofloxacin (as HCl) while the reference product is available as ciprofloxacin base.
	Decision: Deferred for revision of formulation as per reference product along with submission of applicable fee.	
10.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	ROXIL 250mg/5ml granules for oral suspension
	Diary No. Date of R& I & fee	Dy.No 15553 dated 07-03-2019 Rs.20,000/- 06-03-2019

	Composition	Each 5ml of suspension contains: Ciprofloxacin (as HCl) … 250mg/5ml Source of granules: M/s vision Pakistan
	Pharmacological Group	Quinolone Antibiotic
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60ml,90ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cipro Suspension By M/S Byer Health Care **(USFDA Approved)**
	Me-too status	NOVIDAT DRY SUSPENSION 250mg/ 5ml by M/S SAMI
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	Firm has applied ciprofloxacin (as HCl) while the reference product is available as ciprofloxacin base
	Decision: Deferred for revision of formulation as per reference product along with submission of applicable fee.	
11.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	FENTIQ 50mg/5ml Powder for oral suspension
	Diary No. Date of R& I & fee	Dy.No 15554 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Composition	Each 5ml of suspension contains: Fluconazole …… 50mg
	Pharmacological Group	Antifungal
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	35ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Diflucan 50mg/5ml suspensionby M/S Farma Sierra, Carretera De Irun Spain. **(USFDA Approved)**
	Me-too status	FUNGONA 50mg/5ml suspension by M/S SAMI
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decision: Approved.	
12.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	CLOCIN 125mg/5ml granules for oral suspension
	Diary No. Date of R& I & fee	Dy.No 15555 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Composition	Each 5ml of suspension contains: Clarithromycin ……. 125mg/5ml Source of granules: vision
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	60ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 125mg/5ml Suspension By M/S Sandoz Ltd **(USFDA Approved)** Biaxin 125mg/5ml (USFDA approved)
	Me-too status	Clariscot 125mg/ 5ml Suspension By M/S Scotmann
	GMP status	New License (Inspection Date: 19th Feb, 2019)

	Remarks of the Evaluator.	
	Decision: Approved.	
13.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	CLOCIN 250mg/5ml granules for oral suspension
	Diary No. Date of R& I & fee	Dy.No 15556 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Composition	Each 5ml of suspension contains: Clarithromycin ……. 250mg/5ml Source of granules: vision
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	60ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Clarithromycin 250mg/5ml Suspension By M/S Sandoz Ltd **(USFDA Approved)**
	Me-too status	Clariscot 250mg/ 5ml Suspension By M/S Scotmann
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decision: Approved.	
14.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	ZITO 200mg/5ml powder for oral suspension
	Diary No. Date of R& I & fee	Dy.No 15557 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Composition	Each 5 ml (after reconstitution) contains: Azithromycin (as dihydrate) .....200 mg
	Pharmacological Group	Macrolide Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP specifications
	Pack size & Demanded Price	15ml,30ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	Zithromax Suspension By Pfizer **(USFDA Approved)**
	Me-too status	Azomax Dry Suspension 200 mg/ 5ml By M/S Novartis Pharma
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decision: Approved.	
15.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	ARTO-M DRY SUSPENSION 15/90 mg/5ml
	Diary No. Date of R& I & fee	Dy.No 15558 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Composition	Each 5ml (after reconstitution) contains: Artemether…….15 mg Lumefantrine ……..90 mg
	Pharmacological Group	Antimalarial
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	30ml,60ml/ As per SRO
	Approval status of product in Reference Regulatory Authorities.	WHO Recommended Lonart Susp Nafdac (NRN) # 04-8969

		Greenlife Pharmaceuticals pvt Ltd Nigeria
	Me-too status	Qmetem dry suspension by M/S Bosch Pharmaceuticals Arthefant by M/s Novae Pharmaceuticals (Pvt) Ltd (Reg.#077474)
	GMP status	New License (Inspection Date: **19th Feb, 2019**)
	Remarks of the Evaluator.	
	Decision: Approved.	
16.	Name and address of manufacturer / Applicant	M/s IQRA Pharmaceuticals Plot No. 02,Street No.S-9,Rawat,Rawalpindi
	Brand Name +Dosage Form + Strength	LIN-Z DRY SUSPENSION 100 mg/5ml
	Diary No. Date of R& I & fee	Dy.No 15559 dated 07-03-2019 Rs.20,000/- 06-03-2019
	Composition	Each 5 ml (after reconstitution) contains: Linezolid …….100mg
	Pharmacological Group	Antibiotic (Oxazolidinone, Anti-infective)
	Type of Form	Form 5
	Finished Product Specification	Manufacturer's specifications
	Pack size & Demanded Price	60ml,90ml' 120ml / As per SRO
	Approval status of product in Reference Regulatory Authorities.	Linezolid 100 mg/5 ml granules for oral suspension by Pfizer.Approved in MHRA.
	Me-too status	ECASIL 100mg/5ml suspension by M/S Sami Pharmaceuticals
	GMP status	New License (Inspection Date: 19th Feb, 2019)
	Remarks of the Evaluator.	
	Decision: Approved.	

b. New/Additional section(s)

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.

New Approved Sections

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

Sterile Liquid Ampoule
02 Molecules 03 Products

17.	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	Trometek 10mg/ml Injection
	Composition	Each 1ml Ampoule contains: Ketorolac Tromethamine……10mg

	Diary No. Date of R&I &fee	Dy.No 17135 dated 07-03-2019 Rs. 20,000/- 06-03-2019
	Pharmacological Group	Antiinflammatory agents, non-steroids
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Toradol Ketorolac Trometamol 10mg/1ml injection ampoule of M/s Atnahs Pharma Australia Pty Ltd (TGA Approved)
	Me-too status	Ketopan injection 10mg/ ml of M/s Welwrd (Reg. # 068349)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
18.	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	Trometek 30mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Ketorolac Tromethamine …30mg
	Diary No. Date of R&I &fee	Dy.No 17134 dated 07-03-2019 Rs. 20,000/- 06-03-2019
	Pharmacological Group	Antiinflammatory agents, non-steroids
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Ketorolac Tromethamine Injection 30mg/ml by M/s Hospira Pharmaceuticals, USFDA approved
	Me-too status	Toralac Injection 30mg/ml by M/s Vision Pharma (Reg#050290).
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision: Approved.	
19.	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	Mark-Dine 25mg/ml Injection
	Composition	Each 1ml Ampoule Contains: Ranitidine …25mg
	Diary No. Date of R&I &fee	Dy.No 17182 dated 07-03-2019 Rs. 20,000/- 06-03-2019
	Pharmacological Group	H2 receptor antagonist
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Not confirmed
	Me-too status	Friendine Injection of M/s Friends Pharma (Reg.# 076960)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Approval status of product in Reference regulatory authority not confirmed. • As per dossier firm has applied as Ranitidine 25mg/ml Injection but there is cutting on fee challan as well as cover page to Ranitidine 50mg/ml injection. Master formulation also sugeests of 1ml ampoule containing 25mg ranitidine. • Injectable is Approved in MHRA and TGA as Ranitidine (as hydrochloride) firm has applied as ranitidine base

	Decision: Deferred for the following: **□ Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee.** **□ Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
Sterile Liquid Vials Section **06 Molecules 08 Products**		
20.	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 200mg Solution for Infusion
	Composition	Each 100ml Vial contains: Ciprofloxacin (as lactate) …200mg
	Diary No. Date of R&I &fee	Dy.No 8461 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Fluoroquinolone 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	Ciprofloxacin 2 mg/ml solution for infusion (100ml vial) by M/s Hikma Farmacêutica (Portugal), S.A, (MHRA approved.)
	Me-too status	CYCIN INJECTION 200MG I.V / I.M (100ml vial) by M/s High-Q (Reg#019468)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP.
	Decision: Approved The earlier registration (Reg. 061013) of firm's product shall stand cancelled due to none extension of contract manufacturing	
21.	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	Liv-Mark 500mg/100ml Solution for infusion
	Composition	Each 100 ml Vial contains: Levofloxacin (as hemihydrate) …500mg
	Diary No. Date of R&I &fee	Dy.No 8462 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Fluoroquinolone Antibiotics
	Type of Form	Form – 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Levofloxacin 5 mg/ml (100ml)Solution for Infusion by Hospira (MHRA Approved)
	Me-too status	Levort DS Infusion 500mg/100ml of M/s Orta Laboratories
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP.
	Decision: Approved .The earlier registration (Reg. 061015) of firm's product shall stand cancelled due to none extension of contract manufacturing	
22.	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	Markgyl 500mg/100ml solution for Infusion
	Composition	Each 100ml Vial Contains: Metronidazole……500mg
	Diary No. Date of R&I &fee	Dy.No 12233 dated 06-03-2019 Rs. 20,000/- 05-03-2019

	Pharmacological Group	Imidazole derivatives
	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 authority	METRONIDAZOLE BIOSEDRA 500 mg / 100 ml solution for injection for infusion in vials by FRESENIUS KABI FRANCE (ANSM Approved)
	Me-too status	METRONIDAZOLE INFUSION 500mg/100ml by GHAZALI BROTHERS Reg. # 017859
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP.
	Decision: Approved. The earlier registration (Reg. 061021) of firm's product shall stand cancelled due to none extension of contract manufacturing	
23.	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	Medizolid 200mg/100ml Solution for Infusion
	Composition	Each 100 ml Vial Contains: Linezolid …200mg
	Diary No. Date of R&I &fee	Dy.No 12237 dated 06-03-2019 Rs. 20,000/- 05-03-2019
	Pharmacological Group	Oxazolidone Antibiotic
	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 authority	ZYVOX I.V. Injection 200mg/100ml (Infusion bag) by PHARMACIA AND UPJOHN (USFDA Approved)
	Me-too status	Zolrest 200mg/100ml by Bosch Reg. # 055914
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP.
	Decision: Approved. The earlier registration (Reg. 061017) of firm's product shall stand cancelled due to none extension of contract manufacturing	
24.	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	Medizolid 400mg/200ml Solution for Infusion
	Composition	Each 200 ml Vial Contains: Linezolid …400mg
	Diary No. Date of R&I &fee	Dy.No 12236 dated 06-03-2019 Rs. 20,000/- 05-03-2019
	Pharmacological Group	Oxazolidone Antibiotic
	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 authority	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	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP.

		• Submitted Master formulation is not of applied formulation.
	Decision: Deferred for the revision of master formulation along with the applicable fee. The earlier registration (Reg. 061018) of firm's product shall stand cancelled due to none extension of contract manufacturing	
25.	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	Medizolid 600mg/300ml Solution for Infusion
	Composition	Each 300 ml Vial Contains: Linezolid …600mg
	Diary No. Date of R&I &fee	Dy.No 12252 dated 06-03-2019 Rs. 20,000/- 05-03-2019
	Pharmacological Group	Oxazolidone Antibiotic
	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 authority	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	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP. • Submitted Master formulation is not of applied formulation.
	Decision: Deferred for the revision of master formulation along with the applicable fee. The earlier registration (Reg. 061019) of firm's product shall stand cancelled due to none extension of contract manufacturing	
26.	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 400mg/250ml infusion
	Composition	Each 250ml Vial Contains: Moxifloxacin (as hydrochloride) …400mg
	Diary No. Date of R&I &fee	Dy.No 8463 dated 26-02-2019 Rs.20,000/- Dated 21-02-2019
	Pharmacological Group	Fluoroquinolone Antibiotics
	Type of Form	Form – 5
	Finished product Specification	Manufacturer's specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Avelox 400 mg/250 ml solution for infusion (Vial) by M/s Bayer plc (MHRA Approved)
	Me-too status	Moxiget 400mg/250ml Inj. (Vial) by M/s Getz (R#050650)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP.
	Decision: Approved .The earlier registration (Reg. 061020) of firm's product shall stand cancelled due to none extension of contract manufacturing	
27.	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	Potradol 1000mg/100ml Infusion
	Composition	Each 100ml Vial Contains: Paracetamol……1000mg
	Diary No. Date of R&I &fee	Dy.No 12254 dated 06-03-2019 Rs. 20,000/- 05-03-2019

	Pharmacological Group	Antipyretic & Analgesic
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Perfalgan 10mg/ml (100ml), solution for infusion (MHRA approved)
	Me-too status	Provas 10mg/ml Infusion M/s Sami Pharmaceuticals Karachi,
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Panel inspection report was checked and it could not be verified that section under consideration has facility to fill vials as both SVP and LVP.
	Decision: Approved.	
Sachet Section 07 Molecules 10 Products		
28.	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	Weltika 4mg Sachet
	Composition	Each Sachet Contains: Montelukast (as sodium) …4mg
	Diary No. Date of R&I &fee	Dy.No 17136 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Leukotrine Receptor Antagonist
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	SingulairPaediatric 4 mg Granules by Merck Sharp &Dohme Limited (MHRA Approved)
	Me-too status	Aerotel Sachet of M/s Highnoon Laboratories. (Reg.#044768)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision: Approved	
29.	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	Ome-Mark 20/1680 mg Sachet
	Composition	Each Sachet Contains: Omeprazole …20mg Sodium Bicarbonate …1680mg
	Diary No. Date of R&I &fee	Dy.No 17155 dated 07-03-2019 Rs. 20,000/- Dated 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 authority	Zegerid Powder for oral suspension by Santaurus (USFDA Approved)
	Me-too status	Risek Insta Sachet by Getz
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision: Approved	
30.	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	Ome-Mark 40/1680 mg Sachet
	Composition	Each Sachet Contains:

		Omeprazole …40mg Sodium Bicarbonate …1680mg
	Diary No. Date of R&I &fee	Dy.No 17150 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form – 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Zegerid Powder for oral suspension by Santaurus (USFDA Approved)
	Me-too status	Risek Insta Sachet by Getz
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision: Approved	
31.	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	Eso-Mark 40/1100mg Sachet
	Composition	Each Sachet Contains: Esomeprazole…40mg Sodium Bicarbonate…1100mg
	Diary No. Date of R&I &fee	Dy.No 17145 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form – 5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Not confirmed
	Me-too status	Not confirmed
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Approval status of product in Reference regulatory authority not confirmed. • Me-too status not confirm from available database.
	Decision Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
32.	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	Eso-Mark 20/1100mg Sachet
	Composition	Each Sachet Contains: Esomeprazole…20mg Sodium Bicarbonate…1100mg
	Diary No. Date of R&I &fee	Dy.No 17144 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form – 5
	Finished product Specification	
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference regulatory authority	Not confirmed
	Me-too status	Not confirmed
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML

	Remarks of the Evaluator	• Approval status of product in Reference regulatory authority not confirmed. • Me-too status not confirm from available database.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
33.	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	Stornate Sachet 2gm
	Composition	Each Sachet Contains: Strontium Renlate……2gm
	Diary No. Date of R&I &fee	Dy.No 17177 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Other drugs affecting bone structure and mineralization
	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 authority	PROTOS strontium ranelate 2g granules for oral suspension sachet by Servier Laboratories (TGA Australia Approved)
	Me-too status	Onita Sachet by PharmEvo((Reg# 057746)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision: Approved	
34.	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	Medi-Husk 135mg/3.5g Sachet
	Composition	Each Sachet Contains: Mebeverine Hydrochloride…135mg Ispaghula Husk…3.5g
	Diary No. Date of R&I &fee	Dy.No 17172 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Synthetic anticholinergic, esters with tertiary amino group in combination with Bulk-forming laxative
	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 authority	Fybogel Mebeverine effervescent granules by M/s Reckitt Benckiser Healthcare (UK) Ltd. (MHRA approved)
	Me-too status	Colospas Fibro Sachet by M/s Nabiqasim (Reg#058672)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision Approved with innovator's specifications,	
35.	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	**Citromed 4mg Sachet**
	Composition	Each Sachet Contains: Sodium Bicarbonate …1760mg Sodium Citrate …630mg Citric Acid…720mg Tartaric Acid…890mg
	Diary No. Date of R&I &fee	Dy.No 17169 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Systemic and Urinary Alkalizer

	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 authority	Not confirmed
	Me-too status	Not confirmed
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Approval status of product in Reference regulatory authority not confirmed. • Me-too status not confirmed from availabale database.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm.** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
36.	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	Citromed 5gm Sachet
	Composition	Each Sachet Contains: Sodium Bicarbonate …2200mg Sodium Citrate …786mg Citric Acid…900mg Tartaric Acid…1110mg
	Diary No. Date of R&I &fee	Dy.No 17158 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Systemic and Urinary Alkalizer
	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 authority	Not confirmed
	Me-too status	Not confirmed
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	• Approval status of product in Reference regulatory authority not confirmed. • Me-too status not confirmed from availabale database.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) alongwith registration number, brand name and name of firm** • **Evidence of approval of applied formulation in reference regulatory authorities/agencies which were declared/approved by the Registration Board**	
37.	Name and address of Manufacturer / Applicant	Medimarker’s Laboratories (Pvt.) Ltd. Plot # A-104 S.I.T.E Area Hyderabad, Sindh Pakistan
	Brand Name +Dosage Form + Strength	Medsmec 3gm Sachet
	Composition	Each Sachet Contains: Dioctahederal Smectite …3gm
	Diary No. Date of R&I &fee	Dy.No 17151 dated 07-03-2019 Rs. 20,000/- Dated 06-03-2019
	Pharmacological Group	Antidiarroheal
	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 authority	Smecta 3 g powder for oral suspension in sachet by M/s Ipsen Pharma (ANSM approved)

	Me-too status	Diosecta 3g sachet by M/s Woodwards Pharma. (Reg# 061111)
	GMP status	16/10/2018 Regularization of manufacturing facility and renewal of DML
	Remarks of the Evaluator	
	Decision: Approved with innovator's specification,	

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

a. New DML /section

New License:

M/s Shine Laboratories, Masa Kaswal, 9-KM Sohawa, Main GT Riad, Gujjar Khan was granted with Drug Manufacturing License by the way of formulation vide letter No.F.1-25/2017-Lic dated 24th June, 2019 with the following 02 sections,

- Liquid Section (Veterinary) (General)
- Powder Section (Veterinary) (General)

Dry powder section:

The firm has applied for:
Number of products: 13
Number of molecules/formulations: 10

38.	Name and address of Manufacturer / Applicant	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Amentic-10 Oral Powder
	Composition	Each 100 gm powder contains: Amantadine HCl……..… 10 g
	Diary No. Date of R&I & fee	Dy No. 10141; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-viral (for treatment and treatment of Influenza A)
	Type of Form	Form 5
	Finished Product Specification	MGF specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Amantabak 10% Powder By M/s. Attabak Pharma, Islamabad, Reg # 75697
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
39.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Amentic-98 Oral Powder
	Composition	Each 100 GM Powder Contains: Amantadine Hcl……..… 98 G
	Diary No. Date of R&I & fee	Dy No. 10142 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-viral (for treatment and treatment of Influenza A)
	Type of Form	Form 5
	Finished Product Specification	MGF specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Amadine 98 Powder By M/s. Aptly Pharma,. Reg # 93841
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the

		product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
40.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	DOXTIC-50 Oral powder
	Composition	Each gm contain Doxycycline HCL…..500mg
	Diary No. Date of R&I & fee	Dy No.10126 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-biotic
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	DOXY MIX 50 by M/s Breez pharma Islamabad, Reg # 59166
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
41.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Fosfoshine Oral powder
	Composition	Each 100 gm contains Calcium Fosfomycin……..20gm Tylosin Tartrate…….10gm Fructose…….18gm Sodium Phosphate….15gm Magnesium Sulphate…10mg
	Diary No. Date of R&I & fee	Dy No.10135 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-biotic
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	FOSOMAX by M/s BIOGEN Islamabad, Reg # 63808
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
42.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Respitic -60 Oral Powder
	Composition	Each 100 gm contains Tylosin tartrate ……20g Doxycycline HCL….40g colistin Sulphate……10gm Bromhexine HCL…….2g
	Diary No. Date of R&I & fee	Dy No.10140 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial/bronchodilator
	Type of Form	Form 5

	Finished Product Specification	MFG Specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	BROCOTYD by M/s univet pharma Islamabad, Reg # 58962
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
43.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Floxey Oral Powder
	Composition	Each Gram Contains Neomycin Sulphate……150mg Florfenical……..100mg Oxytetracycline HCL…..300mg
	Diary No. Date of R&I & fee	Dy No.10128 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Anibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	30g, 50g, 100g, 125g, 250g, 500g, 1kg, 5kg Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	E-COL By M/s. Evergreen Pharma, Lahore, REg #81733
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
44.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Respitic -30 Oral Powder
	Composition	Each 100 gm contains Tylosin tartrate ..……10gm Doxycycline HCL ….20gm Colistin Sulphate……3gm Bromhexine HCL….1gm
	Diary No. Date of R&I & fee	Dy No.10139 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial/bronchodilator
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	PULMOCIN plus by M/s Biogen Pharma Islamabad, Reg #71020
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	

45.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Ovamycin Oral powder
	Composition	Each 150gm Contain Lincomycin……33.3gm Spectinomycin…..66.7gm
	Diary No. Date of R&I & fee	Dy No.10124 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	MYCOSPECTIN by M/s Biogen Pharma Islamabad, Reg # 41238
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
46.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	ESB Shine Oral powder
	Composition	Each 100gm contain Sulphaclozine Sodium Monohydrate….30gm
	Diary No. Date of R&I & fee	Dy No.10133 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-coccidial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	E-COX by M/s Biogen Pharma Islamabad Reg # 57033
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
47.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	FOXY Oral powder
	Composition	Each 1000gm Contain Florfenicol……150gm Oxytetracycline….150gm
	Diary No. Date of R&I & fee	Dy No.10132 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	30g, 50g, 100g, 125g, 250g, 500g, 1kg, 2.5kg, 5kg,10kg, , Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	S.T FLOXY by M/S Leads Pharma Islamabad, Reg # 78243
	GMP status	NEW License

	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
48.		M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Ls Bron Oral powder
	Composition	Each kg contains Licomycin HCL….100mg Colistin Sulphate…800,000,000 IU
	Diary No. Date of R&I & fee	Dy No.10123 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG spec
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	COLIN by M/S Biogen Pharma Islamabad, Reg # 49726
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
49.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Nurespi-60 Oral powder
	Composition	Each 100 gm contains Tylosin tartrate ……20g Doxycycline HCL….40g Bromhexine HCL….1g
	Diary No. Date of R&I & fee	Dy No.10129 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial/bronchodilator
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	TYLOBID by M/s Attabak pharma Islamabad, Reg # 75715
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
50.	**Name and address of Manufacturer / Applicant**	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Nurespi-30
	Composition	Each 100 gm contains Tylosin tartrate ……10gm Doxycycline HCL….20gm Bromhexine HCL….0.25gm
	Diary No. Date of R&I & fee	Dy No.10131 ; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterail/bronchodilator
	Type of Form	Form 5
	Finished Product Specification	MFG specs

	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Senidec super Oral powder by M/S Biogen Pharma Islamabad,Reg # 48229
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed for manufacturer specifications and the product is **not present** in available pharmacopoeia (USP,BP,JP).
	Decision: Approved with innovator's specification.	
Oral Liquid Section: The firm has applied for; • Number of product: 22 • Number of molecules/formulations: 10		
51.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Floro Shine 20 Oral Liquid
	Composition	Each 100ml Contain Florfenicol……20gm
	Diary No. Date of R&I & fee	Dy No.10152; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 1litre, 2.5litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Ty Flor by M/S FarmAid GroupHattar, Reg # 88027
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
52.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Floro Shine-23 Oral Liquid
	Composition	Each 100ml Contain Florfenicol……23gm
	Diary No. Date of R&I & fee	Dy No.10153; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml,150ml,250ml,450ml, 1litre, 2.5litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	floro fort oral liquid by M/S Demorson pharma Reg # 74073
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
53.	**Name and address of Manufacturer / Applicant**	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Floro Shine-10 Oral Liquid

	Composition	Each 100ml Contain Florfenicol……10gm
	Diary No. Date of R&I & fee	Dy No.10151; dated 28/06/2019 ;Rs.20,000 28/06/2019
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	MGF specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 1litre, 2.5litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	FLOROBAK by M/s Attabak Pharma Islamabad, Reg# 63839
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
54.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Floro Shine-25 Oral Liquid
	Composition	Each 100ml Contain Florfenicol……25gm
	Diary No. Date of R&I & fee	Dy No.10154; dated 28/06/2016; Rs.20,000 28/06/2019
	Pharmacological Group	Anti-bacterial
	Type of Form	Form 5
	Finished Product Specification	MFG spec
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 1litre, 2.5litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	FLORFENICOL oral liquid by M/s Attabak Pharma Islamabad, Reg # 75707
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
55.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	E.C.Shine-10 Liquid
	Composition	Each 100ml Contain Enrofloxacin ….10gm Colistin Sulphate…..48MIU
	Diary No. Date of R&I & fee	Dy No.10155; dated 28/06/2016; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG Specs
	Pack Size & Demanded Price	100ml, 150ml,250ml, 500ml, 1litre, 2.5litre, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Colifox oral liquid by M/s Biogen Pharma Islamabad, Reg # 49719
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP,

		JP). As per master formulation, the firm is using 2640mg of Colistin sulphate and 1mg of colistin Sulphate contains International Units equal or greater than 15,000IU, therefore the total IUs are 39.6MIUs. The firm has not provided the actual potency with respect to International units to be used in manufacturing to justify their master formulation.
	Decision: Deferred for revision of formulation along with applicable fee.	
56.	**Name and address of Manufacturer / Applicant**	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	E.C.Shine-20 Oral Liquid
	Composition	Each 100ml Contain Enrofloxacin ….20gm Colistin Sulphate…..48MIU
	Diary No. Date of R&I & fee	Dy No. 10156; dated 28/06/2016; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml,250ml, 500ml, 1litre, 2.5litre, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Cannot be confirmed
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP, JP). As per master formulation, the firm is using 2640mg of Colistin sulphate and 1mg of colistin Sulphate contains International Units equal or greater than 15,000IU, therefore the total IUs are 39.6MIUs. The firm has not provided the actual potency with respect to International units to be used in manufacturing to justify their master formulation. Me-too status could not be confirmed.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Revision of formulation along with applicable fee.**	
57.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	E.C.Shine-25 Oral Liquid
	Composition	Each 100ml Contain Enrofloxacin ……25gm Colistin Sulphate…..48MIU
	Diary No. Date of R&I & fee	Dy No.10157; dated 28/06/2016; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml,250ml, 500ml, 1litre, 2.5litre, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Me-too cannot be confirmed
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP,

		JP). As per master formulation, the firm is using 2640mg of Colistin sulphate and 1mg of colistin Sulphate contains International Units equal or greater than 15,000IU, therefore the total IUs are 39.6MIUs. The firm has not provided the actual potency with respect to International units to be used in manufacturing to justify their master formulation. Me-too status could not be confirmed.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Revision of formulation along with applicable fee.**	
58.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	OVAFLOR-C-23 Oral Liquid
	Composition	Each 100ml Contain Florfenicol……23gm Colistin Sulphate…50MIU
	Diary No. Date of R&I & fee	Dy No.10144; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG Specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 500ml, 1litre, 2.5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	MAXIFLOR PLUS By M/s Biogen Pharma Islamabad, Reg # 75617
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP). As per master formulation, the firm is using 2630mg of Colistin sulphate and 1mg of colistin Sulphate contains International Units equal or greater than 15,000IU. Therefore the total IUs are 39.45MIUs. The firm has not provided the actual potency with respect to International units to be used in manufacturing to justify their master formulation.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Revision of formulation along with applicable fee.**	
59.	Name and address of Manufacturer / Applicant	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	OVAFLOR-C 10 Oral Liquid
	Composition	Each 100ml Contain Florfenicol……10gm Colistin Sulphate…50MIU
	Diary No. Date of R&I & fee	Dy No.10143; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG spcs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1litre, 2.5litre Decontrolled

	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Floro-C liquid BY M/s Demorson Pharma, Reg # 74079
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP). As per master formulation, the firm is using 2630mg of Colistin sulphate and 1mg of colistin Sulphate contains International Units equal or greater than 15,000IU. Therefore the total IUs are 39.45MIUs. The firm has not provided the actual potency with respect to International units to be used in manufacturing to justify their master formulation.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Revision of formulation along with applicable fee.**	
60.	**Name and address of Manufacturer / Applicant**	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	OVAFLOR-C 25 Oral Liquid
	Composition	Each 100ml Contain Florfenicol……25gm Colistin Sulphate…50MIU
	Diary No. Date of R&I & fee	Dy No10145; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1litre, 2.5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Flocol By M/s Demaarson Pharma, Reg # 74082
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP). As per master formulation, the firm is using 2630mg of Colistin sulphate and 1mg of colistin Sulphate contains International Units equal or greater than 15,000IU. Therefore the total IUs are 39.45MIUs. The firm has not provided the actual potency with respect to International units to be used in manufacturing to justify their master formulation. Moreover master formulation is not correct, The firm is using 23kg of florfenicol for 100litre of liquid while it should be 25kg.
	Decision: Deferred for following: • **Evidence of applied formulation/drug already approved by DRAP (generic / me-too status) along with registration number, brand name and name of firm** • **Revision of formulation along with applicable fee.**	
61.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Bromo Shine 1% liquid
	Composition	Each ml Contain Bromhexixne HCL….10mg

	Diary No. Date of R&I & fee	Dy No.10148; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Bromo Bak by M/S ealigance Pharma, Reg # 58904
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP). Overage has been added by the firm without providing any reason.
	Decision: Deferred for submission of justification of overage in the formulation.	
62.	Name and address of Manufacturer / Applicant	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Bromo Shine 2% Liquid
	Composition	Each ml Contain Bromhexixne HCL….20mg
	Diary No. Date of R&I & fee	Dy No.10149; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Bromo plus by M/S elegance Pharma Reg # 73917
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP). Overage has been added by the firm without providing any reason.
	Decision: Deferred for submission of justification of overage in the formulation.	
63.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Bromo Shine 5% Oral Liquid
	Composition	Each ml Contain Bromhexixne HCL….50mg
	Diary No. Date of R&I & fee	Dy No.10136; dated 28/06/2019 ; Rs.20,000 28/06/2019
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	MGF specs
	Pack Size & Demanded Price	100g, 250g, 500g, 1kg, 5kg, 10kg, 25kg, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Bromhexixne 5 % oral liquid by M/s cherish pharma Lahore, Reg # 69631
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP,

		JP). Overage has been added by the firm without providing any reason.
	Decision: Deferred for submission of justification of overage in the formulation.	
64.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Bromo Shine 10% oral liquid
	Composition	Each ml Contain Bromhexine HCL….100mg
	Diary No. Date of R&I & fee	Dy No. 10150 dated 28/06/2019 ; ; Rs.20,000 28/06/2019
	Pharmacological Group	Mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml,1000ml, 5 litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Bromocin By M/s Biogen Pharma Islamabad Reg # 63803
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP). Overage has been added by the firm without providing any reason.
	Decision: Deferred for submission of justification of overage in the formulation.	
65.	Name and address of Manufacturer / Applicant	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	A.G Enrotic Oral Liquid
	Composition	Each ml contain Enrofloxacin ….100mg Aminophyllin….100mg Guaifenesin…..40mg
	Diary No. Date of R&I & fee	Dy No.10130; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	Antibiotic/bronchodilatory/expectorant
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 500ml, 1litre, 2.5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	ENSOL AG Oral Liquid By M/s Biogen Pharma Islamabad, Reg # 49720
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
66.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Nutil Oral Liquid
	Composition	Each ml Contain Tilmicosin…..….250mg
	Diary No. Date of R&I & fee	Dy No.10127; dated 28/06/2019; Rs.20,000 28/06/2019
	Pharmacological Group	antibiotic

	Type of Form	Form 5
	Finished Product Specification	MFG
	Pack Size & Demanded Price	100ml, 150ml, 250ml, 450ml, 1litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	T mycin oral solution by M/S Alina combine pharma, Reg # 48268
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
67.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Respi Shine Oral liquid
	Composition	Each 100 ml contains Tylosin tartrate ……10gm Doxycycline HCL ….20gm Colistin Sulphate……3gm Bromhexine HCL….1gm
	Diary No. Date of R&I & fee	Dy No.10134 dated 28/06/2019 ; ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial/bronchodilator
	Type of Form	Form 5
	Finished Product Specification	MFg specs
	Pack Size & Demanded Price	100ml, 250ml, 500ml, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Pulmocine plus oral liquid By M/s Biogen Pharma R # 71020
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
68.	Name and address of Manufacturer / Applicant	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Aqua Nu oral liquid
	Composition	Each 100 ml Liquid Doxycycline HCL…….20g Tylosin Tartrate…….10g Guaifensein ……20g Aminophylline ……8g
	Diary No. Date of R&I & fee	Dy No.10125 dated 28/06/2019 ; ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial, bronchodilator, expectorant
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 200ml, 500ml, 1000ml, 2.5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	TYCO-G Oral By M/s Attabak Pharma Islamabad, R# 75704
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP/BP/JP)
	Decision: Approved with innovator's specification.	

69.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	SULPHA SHINE Oral Liquid
	Composition	Each100 ml contains Enrofloxacin…..75 mg Sulphamethoxy Paradiazine….50mg Sulphamethazine…….50g Trimethoprim….25mg
	Diary No. Date of R&I & fee	Dy No10146. dated 28/06/2019 ; ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial/mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 250ml, 250ml, 450ml, 500ml,1000ml, 2.5litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	SULPHACINA by M/s BIO-OXIME Pharma, reg # 74786
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
70.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	SULPHA SHINE Nu Oral Liquid
	Composition	Each ml contains Enrofloxacin…..75 mg Sulphamethoxy Paradiazine….75mg Sulphamethazine…….50g Trimethoprim….25mg
	Diary No. Date of R&I & fee	Dy No.10147 dated 28/06/2019 ; ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial/mucolytic agent
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 250ml, 250ml, 450ml, 500ml,1000ml, 2.5litre, 5litre Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	ENSUFIC By M/S Biorific pharma Islamabad, Reg # 88140
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	
71.	Name and address of Manufacturer / Applicant	M/s. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Shine T.Dox 60
	Composition	Each 100 ml contains Tylosin tartrate BP……20gm Doxycycline HCL BP….40gm
	Diary No. Date of R&I & fee	Dy No. 10138 dated 28/06/2019 ; ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs

	Pack Size & Demanded Price	100ml, 200ml, 500ml, 1000ml, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Cannot be confirmed
	GMP status	NEW License
	Remarks of Evaluator	Me-too status **could not be** confirmed. The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	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**	
72.	Name and address of Manufacturer / Applicant	M/S. Shine Laboratories, Masa Kiswal, 9-Km Sohawa, Main G.T Road, Gujar Khan
	Brand Name+DosageForm+Strength	Shine T.Dox 30 Liquid
	Composition	Each 100 ml contains Tylosin tartrate ……10gm Doxycycline HCL….20gm
	Diary No. Date of R&I & fee	Dy No. 10137 dated 28/06/2019 ; ; Rs.20,000 28/06/2019
	Pharmacological Group	Antibacterial
	Type of Form	Form 5
	Finished Product Specification	MFG specs
	Pack Size & Demanded Price	100ml, 200ml, 500ml, 1000ml, Decontrolled
	Approval status of product in Reference Regulatory Authorities	
	Me-too status	Sensidel-L ORAL LIQUID By M/S Biogen Pharma Islamabad, reg # 49718
	GMP status	NEW License
	Remarks of Evaluator	The firm has claimed manufacturer's specifications and the product is not present in available pharmacopoeia (USP, BP, JP).
	Decision: Approved with innovator's specification.	

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

m. Export facilitation

Evaluation of registration dossiers on priority bases in lieu of export facilitation:

The following dossiers have been received vide letter no. F.1-6/2019-PR-I (EFD) dated 27th August, 2019 as the firms have achieved the benchmark of USD 100,000/- for export during the fiscal year 2018-19.

1. M/s Pacific Pharmaceuticals, 30km,, Multan Road, Lahore:

The firm has an export figure of USD 526,006.46/- for the fiscal year 2018-19.

5Molecules/7 Products

73.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	RINABIN Tablet 250mg
	Composition	Each tablet contains: Terbinafine (as HCl)…… 250mg
	Diary No. Date of R&I & fee	Dy. No. 40330 dated 05/12/2018 Rs,20,000/- 05/12/2018
	Pharmacological Group	Anti-fungal
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×10, price as per SRO

	Approval status of product in Reference Regulatory Authorities	Lamisil tablet by M/s Novartis, USFDA approved
	Me-too status	Lamisil Sandoz 250mg tablet by M/s Sandoz, Reg # 13209
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator	
	Decision: Approved.	
74.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	ALZIPIL Tablet 10mg
	Composition	Each film coated tablet contains: Donepezil Hydrochlroide……10mg
	Diary No. Date of R&I & fee	Dy. No.40353 dated 05/12/2018 Rs 20,000/- 05/12/2018
	Pharmacological Group	Aromatase Enzyme inhibitor
	Type of Form	From 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's Price as per SRO
	Approval status of product in Reference Regulatory Authorities	Aricept 5mg/10mg film coated tablet by M/s Eissai Manufacturing ltd, MHRA approved
	Me-too status	Donep tablet 10mg by M/s Genome pharma, reg # 68379
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator	
	Decision: Approved.	
75.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	ALZIPIL Tablet 5mg
	Composition	Each film coated tablet contains: Donepezil Hydrochlroide……5mg
	Diary No. Date of R&I & fee	Dy. No.40352 dated 05/12/2018 Rs 20,000/- 05/12/2018
	Pharmacological Group	Aromatase Enzyme inhibitor
	Type of Form	From 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	10's price as per SRO
	Approval status of product in Reference Regulatory Authorities	Aricept 5mg/10mg film coated tablet by M/s Eissai Manufacturing ltd, MHRA approved
	Me-too status	Donep tablet 5mg by M/s Genome pharma, reg # 68378
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator	
	Decision: Approved.	

76.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	MODANIL tablet 200mg
	Composition	Each tablet contains: Modafinil……200mg
	Diary No. Date of R&I & fee	Dy. No.40135 dated 05/12/2018 Rs 20,000/- 05/12/2018
	Pharmacological Group	Dopamine reuptake inhibitor
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×10's Price as per SRO
	Approval status of product in Reference Regulatory Authorities	Provigil 100mg/200mg tablet by M/s Cephalon, USFDA approved
	Me-too status	Monalert 200mg tablet by M/s Hilton pharma Reg # 47171
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator	
	Decision: Approved.	
77.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	FINA-GROW Tablet 5mg
	Composition	Each film coated tablet contains: Finasteride…… 5mg
	Diary No. Date of R&I & fee	Dy. No.30422 dated 10/09/2018 Rs 20,000/- 10/09/2018
	Pharmacological Group	Testosterone-5-alpha reductase inhibitor
	Type of Form	From 5
	Finished Product Specification	USP
	Pack Size & Demanded Price	1×10's , 2×7's price as per SRO
	Approval status of product in Reference Regulatory Authorities	Proscar tablet 5mg by M/s Merck, USFDA approved
	Me-too status	Fenstar tabket 5mg by M/s Hansel Pharma, reg # 64798
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator	The firm was granted the Tablet (hormone) section vide letter No.F.1-9/89-Lic (Vol-IV) dated 22nd Feb, 2018.
	Decision: Deferred for followings: • **Clarification required whether the applied product is steroidal hormone or otherwise.** • **Evidence of manufacturing facility of applied product.**	
78.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	GALV-MET Tablet 50mg/500mg
	Composition	Each film Coated tablet contains: Vildagliptin…… 50mg Metfromin…….. 500mg
	Diary No. Date of R&I & fee	Dy. No.8811 dated 27/02/2019 Rs 20,000/- 27/02/2019
	Pharmacological Group	Anti-diabetic
	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	Galvumet (50/500, 50/850, 50/1000 mg) film coated tablet by M/s Novartis, TAG Australia Approved
	Me-too status	Galmet 50mg/500mg Tablet by M/S Vision (Reg. No.81905)
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator	Shelf Life: 18 months The firm has applied for Manufacturer specifications and the product is Not PRESENT in available pharmacopoeia (USP, BP, JP).
	Decision: Deferred for the following: **□ Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee.**	
79.	Name and address of Manufacturer / Applicant	M/s Pacific Pharmaceuticals, 30km, Multan Road, Lahore.
	Brand Name+DosageForm+Strength	GALV-MET Tablet 50mg/1000mg
	Composition	Each film Coated tablet contains: Vildagliptin…… 50mg Metfromin…….. 1000mg
	Diary No. Date of R&I & fee	Dy. No.8812 dated 27/02/2019 Rs 20,000/- 27/02/2019
	Pharmacological Group	Anti-diabetic
	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	Galvumet (50/500, 50/850, 50/1000 mg) film coated tablet by M/s Novartis, TAG Australia Approved
	Me-too status	Galmet 50mg/1000mg Tablet by M/S Vision (Reg. No.81907)
	GMP status	Inspection report dated 10th May, 2010 shows that the firm was operating at good level of GMP compliance. Following sections were inspected during the inspection, 1. Tablet (General and Anti TB) Section 2. Capsule (General) section 3. Oral Liquid section
	Remarks of Evaluator	Shelf Life: 18 months The firm has applied for Manufacturer specifications and the product is Not PRESENT in available pharmacopoeia (USP, BP, JP).
	Decision: Deferred for the following: **□ Adjustment of weight of API as per salt factor is required in Master Formula and Form-5 along with applicable fee.**	
M/s Fynk Pharmaceuticals, 19-km GT Road, Kalashah Kaku, Lahore: The firm has an export figure of USD 197,943/- for the year 2017-18. **1-Molecule/ 1 Product**		
80.	Name and address of Manufacturer / Applicant	M/s Fynk Pharceuticals, 19-km GT Road, Kalashah Kaku, Lahore
	Brand Name+DosageForm+Strength	EPRISPA 50mg tablet
	Composition	Each Film Coated Tablet contains: Eperisone Hydrochloride……. 50mg
	Diary No. Date of R&I & fee	Dy. No.7543 dated 21/02/2019 Rs 20,000/- 21/02/2019

	Pharmacological Group	Centrally acting antispasmodic
	Type of Form	Form 5
	Finished Product Specification	Innovator's specifications
	Pack Size & Demanded Price	20's and 30's price as per SRO
	Approval status of product in Reference Regulatory Authorities	Expose 50mg film coated tablet by M/s Alfasigma S.P.A, AIFA Italy approved
	Me-too status	Perispa 50mg tablets by M/s Platinum pharma. Reg # 39302
	GMP status	Not available
	Remarks of Evaluator	14&16-07-2019 The panel recommended the grant of DML.
	Decision: Approved with innovator's specification.	

Evaluator PEC-VIII

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

a. New cases

81.	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	Laxetil Solution
	Composition	"Each 5ml Contains: Lactulose…3.335g or Each 15ml Contains: Lactulose…10g"
	Diary No. Date of R&I & fee	Duplicate Dossier
	Pharmacological Group	Laxative
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	120ml, 240ml, 300ml, 400ml: As per PRC
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Lactusure Syrup of Medisure Laboratories Pakistan
	GMP status	**Conclusion:** "In the light of inspected areas, facilities status of equipment and hygiene and sanitation of area and equipment, control procedures and documentations, internal and external inspection and audit reports safety of the workers, stability protocols and data, product development, recalls and complaints handling & other CGMP issues, M/s Genix Pharma Pvt. Ltd Karachi was considered at an **satisfactory level of compliance with cGMP guidelines as of today**. The management was also suggested to further strengthen stability and analytical sections."
	Remarks of Evaluator	Submit source & stability studies of applied of three batches conducted by manufacturer of API.
	Decision: Deferred for submission of COA, GMP of API manufacturer and stability studies of three batches of API conducted in accordance with zone IV-A conditions.	
82.	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" Contract manufactured by Astellas Pharmaceuticals (Pvt) Ltd. 15-C Industrial Estate, Hayatabad.
	Brand Name +Dosage Form +Strength	Bontin-D3 5mg Injection
	Composition	Each ml Contains: Cholecalciferol (Vitamin D3)…5mg (200,000 IU)

	Diary No. Date of R&I & fee	Dy. No. 24520 dated 14-12-2017 Rs. 50,000/- 14-12-2017
	Pharmacological Group	Vitamin D Analogue
	Type of Form	Form-5
	Finished Product Specification	USP Specification
	Pack Size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities	Approved in ANSM (as provided by firm)
	Me-too status	D-Tres 5mg/ml injection (as provided by firm)
	GMP status	**M/s. Astellas Hayatabad,** 02/10/2017 **Recommendations:** "1- Repair the second stability chamber or install new chamber for a new section (additional sections). 2- Increase the number of technical staff including QA staff for new sections before commencement of production. Over all the firm was operating under satisfactory level of GMP." **"M/s Harrison Pharmaceuticals:**
	Remarks of Evaluator	• Submit latest GMP inspection report of Applicant. • Evidence of section approval of manufacturer. • Detail about number of sections & number of already approved contracts of applicant. Mention type of type glass container for applied formulation.
	Decision: Deferred for the following: • **Submission of latest GMP inspection report of Applicant.** • **Evidence of section approval of manufacturer.** • **Detail about number of sections & number of already approved contracts of applicant.** • **Mention type of type glass container for applied formulation.** • **For assessment of manufacturing capacity of M/s. Astellas Pharmaceuticals for contract manufacturing.**	

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

n. Export facilitation

83.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form + Strength	Rifamin 200mg Tablet
	Diary No. Date of R& I & fee	Dy.No 15199 dated 07-03-2019 Rs. 20,000
	Composition	Each Film Coated Tablet Contains: Rifaximin…200mg
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Rixago 200mg Tablet OBS Pharma Karachi
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's Specifications	

84.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form + Strength	Rifamin 200mg Tablet
	Diary No. Date of R& I & fee	Dy.No 15200 dated; *date is not mentioned:* Rs. 20,000
	Composition	Each Film Coated Tablet Contains: Rifaximin…550mg
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Rixago 550mg Tablet OBS Pharma Karachi
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's Specifications	
85.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form + Strength	Terbirex 125mg Tablet
	Diary No. Date of R& I & fee	Dy.No 15209 dated; 07-03-19*:* Rs. 20,000
	Composition	Each Tablet Contains: Terbinafine (as hydrochloride)…125mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	10's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA & TGA
	Me-too status	Logirid Tablet 125mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's Specifications	
86.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form + Strength	Terbirex Cream
	Diary No. Date of R& I & fee	Dy.No 15207 dated; 07-03-19*:* Rs. 20,000
	Composition	Each Gram Cream Contains: Terbinafine (as hydrochloride)…10mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	1's: As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (salt form of API is not verifiable)

	Me-too status	Exinofin Cream of Brookes Pharmaceuticals, Karachi
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of the Evaluator.	Mention type of primary packaging material.
	Decision: Deferred for the following: • **For clarification regarding type of primary packaging material for applied formulation.** • **For evidence of approval of applied formulation "Terbinafine (as hydrochloride) 10mg/g Cream" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.**	
87.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form + Strength	Terbirex Tablets 250mg
	Diary No. Date of R& I & fee	Dy.No 15210 dated; 07-03-19*:* Rs. 20,000
	Composition	Each tablet contains: Terbinafine (as hydrochloride)…250mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	10's: Rs.474.00
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA
	Me-too status	Logirid Tablet 250mg of Lowitt Pharmaceutical (Pvt) Ltd,
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of the Evaluator.	
	Decision: Approved as per innovator's Specifications	
88.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form + Strength	Terbirex Gel
	Diary No. Date of R& I & fee	Dy. No. 15208 dated; 07-03-19*:* Rs. 20,000
	Composition	Each gram contains: Terbinafine (as hydrochloride)…10mg
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	10gm: Rs.185.00
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA FDA (salt form of API is not verifiable)
	Me-too status	Cutis Gel of Tabros Pharma (Pvt) Ltd Karachi
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of the Evaluator.	Salt form is verifiable from reference agencies. Mention type of primary packaging material.
	Decision: Deferred for the following: • **For clarification regarding type of primary packaging material for applied formulation.** • **For evidence of approval of applied formulation "Terbinafine (as hydrochloride) 10mg/g**	

	Gel" in reference regulatory authorities/agencies which were declared/approved by the Registration Board in its 275th meeting.	
89.	Name and address of manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form + Strength	Zolid Tablets
	Diary No. Date of R& I & fee	Dy. No. 15211 dated; 07-03-19*:* Rs. 20,000
	Composition	"Each film coated tablet contains: Linezolid…600mg"
	Pharmacological Group	Antifungal
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack size & Demanded Price	12's: Rs.1069.00
	Approval status of product in Reference Regulatory Authorities.	Approved in MHRA
	Me-too status	Linzol Tablet 600 mg of M/s Regal Pharmaceuticals,
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of the Evaluator.	
	Decision: Registration Board decided to approve applied drug product as per Innovator's specifications & with a condition that manufacturer shall use Linezolid polymorphic form II to keep applied formulation in-line with innovator Product.	
90.	Name and address of Manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form +Strength	Xostat Tablet 40mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…40mg
	Diary No. Date of R&I & fee	DyNo.32088;26-09-2018; Rs. 20,000/-
	Pharmacological Group	Anti-gout
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	20's: Rs. 396.00
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA
	Me-too status	Febuxin 40mg Tablet of AGP Pvt. Ltd. Karachi
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of Evaluator	
	Decision: Approved as per innovator's Specifications	
91.	Name and address of Manufacturer / Applicant	M/s Shaigan Pharmaceuticals Limited, Post Office Dhagal, 14Km Adyala Road Rawalpindi.
	Brand Name +Dosage Form +Strength	Xostat Tablet 80mg
	Composition	Each Film Coated Tablet Contains: Febuxostat…80mg
	Diary No. Date of R&I & fee	DyNo.29166;31-08-2018; Rs. 20,000/-
	Pharmacological Group	Anti-gout
	Type of Form	Form-5
	Finished Product Specification	Innovator's specification
	Pack Size & Demanded Price	20's: Rs. 725.00
	Approval status of product in Reference Regulatory Authorities	Approved in US-FDA

	Me-too status	Febuxin 80mg Tablet of AGP Pvt. Ltd. Karachi
	GMP status	GMP inspection conducted on 06-08-2018 with conclusive remarks that firm is GMP compliant as of today.
	Remarks of Evaluator	
	Decision: Approved as per innovator's Specifications	

Evaluator PEC-IX

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

a. New cases

101.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bkay 500mg/2ml Injection
	Composition	Each 2ml Contains: Amikacin as sulphate…500mg
	Diary No. Date of R& I & fee	Dy No. 27975: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 5's ampule ; as per PRC
	Approval status of product in Reference Regulatory Authorities.	DBL AMIKACIN 500mg/2mL (as sulfate) injection vial. TGA approved
	Me-too status	Aminex Injection 500mg/2ml. Reg. No. 83170
	GMP status	The firm was inspected on 07.06.2018, wherein acceptable level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has submitted Form 5 with 31 points. • The firm has claimed 36 months of shelf life.
	Decision: Approved.	
102.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bkay 250mg/2ml Injection
	Composition	Each 2ml Contains: Amikacin as sulphate…250mg
	Diary No. Date of R& I & fee	Dy No. 27974: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1's, 5's ampule; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Aimwel 250mg Injection. Reg. No. 68218
	GMP status	The firm was inspected on 07.06.2018, wherein acceptable level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has submitted Form 5 with 31 points. • The firm has claimed 36 months of shelf life.
	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.	
103.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bkay 100mg/2ml Injection
	Composition	Each 2ml Contains: Amikacin as sulphate…100mg
	Diary No. Date of R& I & fee	Dy No. 27974: 16.08.2018 PKR 20,000/-: 16.08.2018

	Pharmacological Group	Aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's ampule; as per PRC
	Approval status of product in Reference Regulatory Authorities.	AMIKACIN 100mg/2mL (as sulfate) injection vial. MHRA approved
	Me-too status	Dunkin 100mg Injection. Reg. No. 70764
	GMP status	The firm was inspected on 07.06.2018, wherein acceptable level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has submitted Form 5 with 31 points. • The firm has claimed 36 months of shelf life.
	Decision: Approved	
104.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bkay 50mg/ml Injection
	Composition	Each ml Contains: Amikacin as sulphate…50mg
	Diary No. Date of R& I & fee	Dy No. 27972: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's (1ml) ampule; as per PRC
	Approval status of product in Reference Regulatory Authorities.	AMIKACINE MYLAN 50 mg/1 ml, solution injectable. ANSM approved
	Me-too status	Amicin 50mg Injection. Reg. No. 58220
	GMP status	The firm was inspected on 07.06.2018, wherein acceptable level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has submitted Form 5 with 31 points. • The firm has claimed 36 months of shelf life.
	Decision: Approved	
105.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Bkay 25mg/ml Injection
	Composition	Each ml Contains: Amikacin as sulphate…25mg
	Diary No. Date of R& I & fee	Dy No. 27971: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Aminoglycosides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5's (1ml) ampule; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Aika 25mg/ml Injections. Reg. No. 48456
	GMP status	The firm was inspected on 07.06.2018, wherein acceptable level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has submitted Form 5 with 31 points. • The firm has claimed 36 months of shelf life.
	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.	
106.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Prelox 100mg/5ml Oral dry Suspension

	Composition	Each 5ml Contains: Cefpodoxime as Proxetil…100mg
	Diary No. Date of R& I & fee	Dy No. 27969: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	50ml; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Vantin (cefpodoxime proxetil for oral suspension, USP) 50mg, 100mg base in USFDA (flavored granules for oral Suspension), which was not discontinued or withdrawn for safety or efficacy reasons.
	Me-too status	Qink Dry Suspension. Reg. No. 53636
	GMP status	The firm was inspected on 07.06.2018, wherein acceptable level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has submitted Form 5 with 31 points. • The reference product is in the form of flavored granules for oral Suspension. The firm applied for powder for suspension.
	Decision: Deferred for revision of formulation in line with the reference product	
107.	Name and address of manufacturer / Applicant	M/s Bosch Pharmaceuticals (Pvt.) Ltd. Bosch House 221, Sector 23, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Prelox 200mg tablet
	Composition	Each film-coated tablet Contains: Cefpodoxime as Proxetil…200mg
	Diary No. Date of R& I & fee	Dy No. 27970: 16.08.2018 PKR 20,000/-: 16.08.2018
	Pharmacological Group	Third-generation cephalosporins
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10's; as per PRC
	Approval status of product in Reference Regulatory Authorities.	Vantin (cefpodoxime proxetil film-coated tablet) 100mg, 200mg base in USFDA, which was not discontinued or withdrawn for safety or efficacy reasons.
	Me-too status	Abacus 200mg Tablets, film-coated. Reg. No. 47019
	GMP status	The firm was inspected on 07.06.2018, wherein acceptable level of GMP compliance was reported.
	Remarks of the Evaluator.	• The firm has submitted Form 5 with 31 points.
	Decision: Approved	
108.	Name and address of manufacturer / Applicant	M/s Genetics Pharmaceuticals Pvt. Ltd. 539-A, Sundar Industrial Estate, Raiwind, Lahore
	Brand Name +Dosage Form + Strength	Gomela 25mg Tablet
	Composition	Each Film Coated Tablet Contains: Agomelatine…25mg
	Diary No. Date of R& I & fee	Dy No. 27834: 15.08.2018 PKR 50,000/-: 15.08.2018
	Pharmacological Group	Other antidepressants
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	1's, 28's as per SRO
	Approval status of product in Reference Regulatory Authorities.	AGOMELATINE ARDIX agomelatine 25 mg film-coated tablet blister pack. TGA approved
	Me-too status	VALDOXAN 25MG TABLET. Reg. No. 78160 (does not depict film-coating)
	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 with innovator's specifications	
109.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Rovatin Tablet 20mg
	Composition	Each film-coated tablet contains: Rosuvastatin as calcium…20mg
	Diary No. Date of R& I & fee	Dy No. 7210: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	HMG CoA reductase inhibitors
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications
	Pack size & Demanded Price	1x10's; Rs. 400/-
	Approval status of product in Reference Regulatory Authorities.	Crestor 20mg film-coated tablets. MHRA approved
	Me-too status	Rostat 20mg Tablet. Reg. No. 55731
	GMP status	• The 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.	• The firm revised the formulation to film-coated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved with innovator's specifications	
110.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Glistat Tablet 1mg
	Composition	Each tablet contains: Glimepiride…1mg
	Diary No. Date of R& I & fee	Dy No. 7211: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x10's; Rs. 000/-
	Approval status of product in Reference Regulatory Authorities.	AMARYL glimepiride 1mg uncoated tablet. **TGA** approved
	Me-too status	Zeprid 1mg Tablet. Reg. No. 83026
	GMP status	As above
	Remarks of the Evaluator.	• The firm was asked for clarification of demanded price. The firm did not replied • The firm revised the formulation to uncoated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved	
111.	Name and address of manufacturer / Applicant	AJM Pharma Plot No. A-44, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Glistat Tablet 2mg
	Composition	Each tablet contains: Glimepiride…2mg
	Diary No. Date of R& I & fee	Dy No. 7212: 26.02.2018 PKR 20,000/-: 22.02.2018
	Pharmacological Group	Sulfonylureas
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	2x10's; Rs. 000/-

	Approval status of product in Reference Regulatory Authorities.	AMARYL glimepiride 2mg uncoated tablet. **TGA** approved
	Me-too status	Zeprid 2mg Tablet. Reg. No. 83027
	GMP status	As above
	Remarks of the Evaluator.	• The firm was asked for clarification of demanded price. The firm did not replied • The firm revised the formulation to uncoated tablet along with submission of Rs. 5000/- fee.
	Decision: Approved	
112.	Name and address of manufacturer / Applicant	Jupiter Pharma Plot No. 25, Street # S-6, National Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Gemjup Tablet 320mg
	Composition	Each film-coated tablet contains: Gemifloxacin as mesylate…..320mg
	Diary No. Date of R& I & fee	Dy No. 14985: 23.04.2018 PKR 20,000/-: 23.04.2018
	Pharmacological Group	Fluoroquinolones
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specification.
	Pack size & Demanded Price	1x7's; As per SRO
	Approval status of product in Reference Regulatory Authorities.	FACTIVE® (gemifloxacin mesylate) tablets, for oral use. USFDA approved
	Me-too status	Gexa 320mg film-coated Tablets. Reg. No. 77857
	GMP status	The firm was inspected on 31.01.2018 with the following conclusion: Keeping in view the above stated observations during inspection, areas visited, documents reviewed it is concluded that M/s Jupiter Pharma Rawat is operating at fair level of cGMP compliance as of today.
	Remarks of the Evaluator.	
	Decision: Approved with innovator's specifications	

b. Deferred cases

113.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Iborine Capsule 200mg
	Composition	Each capsule contains: Mebeverine HCl…….200mg
	Diary No. Date of R& I & fee	Dy No. 1735: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Synthetic anticholinergics, esters with tertiary amino group
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed manufacturer's specifications.
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	COLOFAC® MR 200mg Capsules. **MHRA** approved
	Me-too status	Mebrest-200 Capsule. Reg. No. 80547
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.

		• The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under discussion.
	Prvious decision	The Board in its 289th meeting deferred the case for further delibration
	Evaluation by PEC	• The firm submitted that they use the testing method as specified by the manufacturer of the pellets.
	• **Decision: Deferred for further delibration**	
114.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Tecso Capsule 20mg
	Composition	Each capsule contains: Esomeprazole magnesium trihydrate (enteric coated pellets) eq. to esomeprazole…… 20mg
	Diary No. Date of R& I & fee	Dy No. 1726: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM® (esomeprazole magnesium) 20mg delayed-release capsules (in the form of enteric-coated granules). USFDA approved
	Me-too status	Obpra Capsule 20mg by Obson Pharma. Reg. No. 54165
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018. Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under discussion. • The pellets have been assayed on the basis of esopemrazole Mg (%) as trihydrate.
	Prvious decision	The Board in its 289th meeting deferred the case for further delibration
	Evaluation by PEC	• The firm submitted that they use the testing method as specified in USP.
	• **Decision: Approved**	
115.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Tecso Capsule 40mg
	Composition	Each capsule contains: Esomeprazole magnesium trihydrate (enteric coated pellets) eq. to esomeprazole…… 40mg
	Diary No. Date of R& I & fee	Dy No. 1727: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Proton pump inhibitors
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	NEXIUM® (esomeprazole magnesium) 40mg delayed-release capsules (in the form of enteric-coated granules). USFDA approved
	Me-too status	Obpra Capsule 40mg by Obson Pharma. Reg. No. 54166
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.

		Sourcce of pellets: The firm M/s Vision Pharmaceuticals was inspected on 11.02.2019, wherein the panel recommended the grant of GMP certificate.
	Remarks of the Evaluator.	• The source of pellets is Vision Pharmaceuticals, Islamabad, wherein all the testing methods are under discussion. • The pellets have been assayed on the basis of esopemrazole Mg (%) as trihydrate.
	Prvious decision	The Board in its 289th meeting deferred the case for further delibration
	Evaluation by PEC	• The firm submitted that they use the testing method as specified in USP.
	• **Decision: Approved**	
116.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 150mg
	Composition	Each capsule contains: Pregabalin…….150mg
	Diary No. Date of R& I & fee	Dy No. 1724: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 150 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 150mg Capsule. Reg. No. 82184
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Prvious decision	The Board in its 289th meeting deferred the case for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)
	Evaluation by PEC	• The firm submitted in-house specifications
	• **Decision: Approved with innovator's specifications**	
117.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 100mg
	Composition	Each capsule contains: Pregabalin…….100mg
	Diary No. Date of R& I & fee	Dy No. 1723: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 100 mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 100mg Capsule. Reg. No. 82185
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product

		specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Prvious decision	The Board in its 289th meeting deferred the case for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)
	Evaluation by PEC	• The firm submitted in-house specifications
	• **Decision: Approved with innovator's specifications**	
118.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 75mg
	Composition	Each capsule contains: Pregabalin…….75mg
	Diary No. Date of R& I & fee	Dy No. 1722: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 75mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 75mg Capsule. Reg. No. 82186
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Prvious decision	The Board in its 289th meeting deferred the case for provision of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)
	Evaluation by PEC	• The firm submitted in-house specifications
	• **Decision: Approved with innovator's specifications**	
119.	Name and address of manufacturer / Applicant	Invictus Pharmaceuticals, Plot No. 21, 26, Street No. NS-2, national Industrial Zone (RCCI) Rawat Rawalpindi
	Brand Name +Dosage Form + Strength	Provic Capsule 50mg
	Composition	Each capsule contains: Pregabalin…….50mg
	Diary No. Date of R& I & fee	Dy No. 1721: 14.01.2019 PKR 20,000/-: 14.01.2019
	Pharmacological Group	Other antiepileptics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed in-house specifications
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Alzain 50mg Capsules, Hard. **MHRA** approved
	Me-too status	Scirica 50mg Capsule. Reg. No. 82187
	GMP status	The firm has been granted DML on the basis of inspection 13.11.2018 & 17.12.2018.
	Remarks of the Evaluator.	• The firm was asked to provide complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria). However, the firm did not submit the same.
	Prvious decision	The Board in its 289th meeting deferred the case for provision

		of complete finished product specifications (list of tests, reference to analytical procedures, and proposed acceptance criteria)
	Evaluation by PEC	• The firm submitted in-house specifications
	• **Decision: Approved with innovator's specifications**	
120.	Name and address of manufacturer / Applicant	M/s Cunningham Pharmaceuticals Pvt Ltd. Plot # 81, Sunder Industrial Estate, Raiwind Road Lahore, Pakistan
	Brand Name +Dosage Form + Strength	Mecol 500mcg Tablet
	Composition	Each Sugar Coated Tablet Contains: Mecobalamin…….500mcg
	Diary No. Date of R& I & fee	Dy No. 18689: 22.05.2018 PKR 20,000/-: 22.05.2018
	Pharmacological Group	Vitamin B12 (cyanocobalamin and analogues)
	Type of Form	Form 5
	Finished Product Specification	JP
	Pack size & Demanded Price	2x15's; As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Methicobide tablet 500 mcg sugar-coated. Approved by **PMDA** Japan
	Me-too status	Balin 500mcg Tablet (sugar-coated). Reg. No. 74877
	GMP status	GMP Certificate issued on 12-03-2018
	Remarks of the Evaluator.	• The firm has submitted 33 points form 5.
	Previous decision	The Board in its 290th meeting deferred the case for submission of valid Form 5.
	Evaluation by PEC	• The firm submitted Form 5.
	Decision: Approved	
121.	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.
	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.	
122.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solvent 5 ml (Type I glass ampule) for Medisonate Injection

	Composition	Each 5ml ampule contains: Sodium chloride…..0.9%
	Diary No. Date of R& I & fee	Dy No. 15539: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Electrolyte solutions
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	5ml, As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Sodium Chloride 0.9% w/v Injection BP 5 ml in hermitically sealed translucent plastic ampule. **MHRA** approved.
	Me-too status	Water for Injection (sterile) **3ml** (ampule). Reg. No. 76465
	GMP status	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 mentioned sodium hydroxide and HCl for pH adjustment in manufacturing outlines. However, these are not present in Master formula. The firm was asked for justification in line with the reference product. The firm did not reply.
	Previous decision	The Board in its 289th meeting deferred the case for further clarification/revision of formulation.
	Evaluation by PEC	• The firm submitted that sodium hydroxide and HCl are used for pH adjustment.
	• **Decision: Approved**	
123.	Name and address of manufacturer / Applicant	M/s Mediate Pharmaceutical Pvt Ltd. Plot No. 150-151, Sector 24, Korangi Industrial Area, Karachi, Pakistan
	Brand Name +Dosage Form + Strength	Solvent 1 ml (Type I glass ampule) for Medisonate Injection
	Composition	Each 1ml ampule contains: Sodium bicarbonate…..5%
	Diary No. Date of R& I & fee	Dy No. 15534: 26.04.2018 PKR 20,000/-: 26.04.2018
	Pharmacological Group	Electrolyte solutions
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	1ml, As per DRAP Policy
	Approval status of product in Reference Regulatory Authorities.	Could not be confirmed
	Me-too status	Sodium Bicarbonate Injection. Reg. No. 76428 (**does not specify the pack volume**)
	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 sodium hydroxide and HCl for pH adjustment in manufacturing outlines. However, these are not present in Master formula. Justification in line with the reference product is required. • Complete finished product specifications in line with general chapters of pharmacopeia (list of tests, reference to analytical procedures, and proposed acceptance criteria) are required.
	Previous decision	The Board in its 289th meeting deferred the case for the following. • Proof of International availability of same dosage form with same strength in reference regulatory authority as defined in 275th meeting of the Registration Board. • Complete finished product specifications in line with general chapters of pharmacopeia (list of tests, reference

		to analytical procedures, and proposed acceptance criteria) are required.
	Evaluation by PEC	• The product is present in 1ml pack size (50mg/ml) in combo pack of Artesunate injection. W.H.O. prequalified. • The firm submitted finished product specifications.
	• **Decision: Approved with innovator's specifications.**	

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

a. New Cases

124.	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	NC-Farm Powder
	Composition	Each 100gm Contains: Chlortetracycline HCl…40gm Neomycin Sulphate…12gm Furaltadone HCl…30gm
	Diary No. Date of R& I & fee	Dy No. 27964: 16.08.2018 PKR 20,000/-: 09.08.2018
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	10g, 20g, 30g, 50g, 100g, 250g, 500g, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg; decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	N.C.BAK WATER SOLUBLE POWDER. Reg No. 53509
	GMP status	The firm was inspected on 07.09.2017, wherein the following Observations/Recommendations were made: "1- Improve quality assurance system as per GMP GUIDELINES. 2- Develop annual product review system for marketed products. Overall the firm was working under satisfactory level of GMP."
	Remarks of the Evaluator.	• Revise "Neomycin Sulphate" to "Neomycin as Sulphate" in label claim only. • Provide complete finished product specifications (reference, testing method and acceptance criteria).
	Decision: Deferred for revision "Neomycin Sulphate" to "Neomycin as Sulphate" in label claim only	
125.	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	Zental Liquid
	Composition	Each 1000ml Contains: Closantel…110gm
	Diary No. Date of R& I & fee	Dy No. 27967: 16.08.2018 PKR 20,000/-: 09.08.2018
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	Manufacturer specs
	Pack size & Demanded Price	10ml, 30ml, 50ml, 100ml, 250ml, 500ml, 1L, 2.5L, 5L, 10L, 15L, 20L, 25L; decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	CENNATAL LIQUID. Reg No. 63659
	GMP status	The firm was inspected on 07.09.2017, wherein the following Observations/ Recommendations were made:

		"1- Improve quality assurance system as per GMP GUIDELINES. 2- Develop annual product review system for marketed products. Overall the firm was working under satisfactory level of GMP."
	Remarks of the Evaluator.	• The firm has claimed liquid. However, no solvent is present in the compositions and no solution formation has been mentioned in the manufacturing outlines. • Provide complete finished product specifications (reference, testing method and acceptance criteria).
	Decision: Deferred for clarification regarding the compostion.	
126.	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	Linco-44 Powder
	Composition	Each 100gm Contains: Lincomycin HCL…4.4gm
	Diary No. Date of R& I & fee	Dy No. 27966: 16.08.2018 PKR 20,000/-: 09.08.2018
	Pharmacological Group	Lincosamides
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	10g, 20g, 30g, 50g, 100g, 250g, 500g, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg; decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	LINCOS-P POWDER.. Reg No. 49667
	GMP status	The firm was inspected on 07.09.2017, wherein the following Observations/Recommendations were made: "1- Improve quality assurance system as per GMP Guidelines. 2- Develop annual product review system for marketed products. Overall the firm was working under satisfactory level of GMP."
	Remarks of the Evaluator.	•
	Decision: Approved	
127.	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	Quindox Powder
	Composition	Each 1000gm Contains: Olaquindox…100g
	Diary No. Date of R& I & fee	Dy No. 27965: 16.08.2018 PKR 20,000/-: 09.08.2018
	Pharmacological Group	Antibiotics
	Type of Form	Form 5
	Finished Product Specification	The firm has claimed innovator's specifications.
	Pack size & Demanded Price	10g, 20g, 30g, 50g, 100g, 250g, 500g, 1kg, 5kg, 10kg, 15kg, 20kg, 25kg; decontrolled
	Approval status of product in Reference Regulatory Authorities.	NA
	Me-too status	QUINDOX POWDER. Reg No. 87139
	GMP status	The firm was inspected on 07.09.2017, wherein the following Observations/ Recommendations were made: "1- Improve quality assurance system as per GMP GUIDELINES. 2- Develop annual product review system for marketed products. Overall the firm was working under satisfactory level of GMP."
	Remarks of the Evaluator.	•
	Decision: Approved	

128.	Name and address of manufacturer / Applicant	M/s Macter International Limited E-40/A, S.I.T.E., Karachi Pakistan
	Brand Name +Dosage Form + Strength	Maxil 250mg tablet for oral suspension
	Composition	Each tablet for oral suspension contains: Amoxicillin Trihydrate eq. to Amoxicillin……..250mg
	Diary No. Date of R& I & fee	Dy. No 26242 Dated 31-07-2018, Rs. 20,000/- dated 30-07-2018
	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.	Flemoxin SOLUTAB 250 mg Dilution (Netherland)
	Me-too status	Dispermox 250mg Tablet of M/s Zafa Pharmaceutical Lab.
	GMP status	GMP inspection by area FID dated 24-15-2018 shows firm good level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved	
129.	Name and address of manufacturer / Applicant	M/s Macter International Limited E-40/A, S.I.T.E., Karachi Pakistan
	Brand Name +Dosage Form + Strength	Maxil 500mg tablet for oral suspension
	Composition	Each tablet for oral suspension contains: Amoxicillin Trihydrate eq. to Amoxicillin……..500mg
	Diary No. Date of R& I & fee	Dy. No 26243 Dated 31-07-2018, Rs. 20,000/- dated 30-07-2018
	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.	Flemoxin SOLUTAB 500 mg Dilution (Netherland)
	Me-too status	Dispermox 500mg Tablet of M/s Zafa Pharmaceutical Lab (Pvt) Ltd.
	GMP status	GMP inspection by area FID dated 24-15-2018 shows firm good level of GMP compliance.
	Remarks of the Evaluator.	
	Decision: Approved	
Priority basis (Export facilitation)		
130.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Diamet XR Tablet 500mg
	Composition	Each film coated tablet contains: Metformin HCl (extended release)……..500mg
	Diary No. Date of R& I & fee	Dy. No 32327 Dated 27-09-2018, Rs. 20,000/- dated 27-9-2018
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	USP
	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.	Diagemet XL 500 mg prolonged release tablets (UK)

	Me-too status	Diabescot-Xr Tablet 500Mg of M/s Scotmann
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance"
	Remarks of the Evaluator	
	Decision: Approved	
131.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Diamet ER Tablet 750mg
	Composition	Each tablet contains: Metformin HCl (extended release)……..750mg
	Diary No. Date of R& I & fee	Dy. No 203 Dated 02-01-2019, Rs. 20,000/- dated 02-01-2019
	Pharmacological Group	Antidiabetic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Glucophage SR 750 mg prolonged release tablets (UK)
	Me-too status	Glucophage XR Tablet of M/s Merck
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance"
	Remarks of the Evaluator	
	Decision: Approved	
132.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.2
	Composition	Each film coated tablet contains: Ezetimibe……..10mg Atorvastatin……20mg
	Diary No. Date of R& I & fee	Dy. No 7989 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors
	Type of Form	Form-5
	Finished product Specification	Innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**EZETIMIBE AND ATORVASTATIN CALCIUM (USFDA)**
	Me-too status	
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance"
	Remarks of the Evaluator	The applied product was already registered in the name of applicant with reg. no. 062853 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision: Deferred for confirmation of status of previous registration from RRR section.	

133.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Ezestatin Tablet 1.4
	Composition	Each film coated tablet contains: Ezetimibe……..10mg Atorvastatin……40mg
	Diary No. Date of R& I & fee	Dy. No 7990 Dated 22-02-2019, Rs. 20,000/- dated 22-02-2019
	Pharmacological Group	Cholesterol absorption inhibitors
	Type of Form	Form-5
	Finished product Specification	Innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**EZETIMIBE AND ATORVASTATIN CALCIUM (USFDA)**
	Me-too status	
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance"
	Remarks of the Evaluator	The applied product was already registered in the name of applicant with reg. no. 062854 dated 28th May 2010, but they did not apply for renewal. Now firm apply for registration with full fee.
	Decision: Deferred for confirmation of status of previous registration from RRR section.	
134.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Silflow capsule 4mg
	Composition	Each capsule contains: Silodosin…….4mg
	Diary No. Date of R& I & fee	Dy. No 8886 Dated 27-02-2019, Rs. 50,000/- dated 27-02-2019
	Pharmacological Group	α_1 -adrenoceptor antagonist
	Type of Form	Form-5 D
	Finished product Specification	Innovator's specification
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**SILODOSIN (USFDA)**
	Me-too status	
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance"
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability data	
135.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Silflow capsule 8mg
	Composition	Each capsule contains: Silodosin…….8mg
	Diary No. Date of R& I & fee	Dy. No 8887 Dated 27-02-2019, Rs. 20,000/- dated 27-02-2019
	Pharmacological Group	α_1 -adrenoceptor antagonist
	Type of Form	Form-5
	Finished product Specification	Innovator's specification

	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**SILODOSIN (USFDA)**
	Me-too status	**SILOGET 8MG (Silodosin) Capsules of M/s Getz**
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance"
	Remarks of the Evaluator	
	Decision: Deferred for submission of stability data	
136.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore Manufacturer: M/s Global Pharmaceuticals Pvt. Ltd. Plot # 204-205, Industrial Triangle Kahuta road Islamabad
	Brand Name +Dosage Form + Strength	MERO IV INJECTION 500mg
	Composition	Each vial contains: Meropenem USP……500mg
	Diary No. Date of R& I & fee	Dy. No 9813 Dated 04-03-2019, Rs. 50,000/- dated 01-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Meropenem 500 mg powder for solution for injection or infusion of (UK)
	Me-too status	**Mopen 500mg Injection of M/s Hilton Pharma**
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of the Evaluator	infusion contains 570.78 mg meropenem trihydrate equivalent to 500 mg anhydrous meropenem. Composition not same as reference.
	Decision: Deferred for correctness in composition as per reference product.	
137.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore Manufacturer: M/s Global Pharmaceuticals Pvt. Ltd. Plot # 204-205, Industrial Triangle Kahuta road Islamabad
	Brand Name +Dosage Form + Strength	MERO IV INJECTION 1gm
	Composition	Each vial contains: Meropenem USP……1gm
	Diary No. Date of R& I & fee	Dy. No 9814 Dated 04-03-2019, Rs. 50,000/- dated 01-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	**MEROPENEM (USFDA)**

	Me-too status	Mopen 1gm Injection of M/s Hilton Pharma
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of the Evaluator	infusion contains 570.78 mg meropenem trihydrate equivalent to 500 mg anhydrous meropenem. Composition not same as reference.
	Decision: Deferred for correctness in composition as per reference product.	
138.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore Manufacturer: M/s Global Pharmaceuticals Pvt. Ltd. Plot # 204-205, Industrial Triangle Kahuta road Islamabad
	Brand Name +Dosage Form + Strength	Pipzo 4.5gm Injection
	Composition	Each vial contains: Sterile piperacillin sodium eq. to piperacillin……4gm Sterile Tazobactam sodium eq. to tazobactam…..0.5gm
	Diary No. Date of R& I & fee	Dy. No 9815 Dated 04-03-2019, Rs. 50,000/- dated 01-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	Piperacillin/Tazobactam 4 g / 0.5 g powder for solution for infusion (UK)
	Me-too status	Tanzo Injection of M/s Bosch ,
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of the Evaluator	
	Decision: Approved	
139.	Name and address of manufacturer / Applicant	M/s CCL Pharmaceuticals Pvt. Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore
	Brand Name +Dosage Form + Strength	Zotonix tablet 20mg
	Composition	Each film coated tablet contains: Pantoprazole sodium sesquihydrate eq. to pantoprazole (Delayed release)…….20mg
	Diary No. Date of R& I & fee	Dy. No 31238 Dated 17-09-2018, Rs. 20,000/- dated 17-09-2018
	Pharmacological Group	PPI's
	Type of Form	Form-5
	Finished product Specification	USP
	Pack size & Demanded Price	As per SRO
	Approval status of product in Reference Regulatory Authorities.	PANTOLOC Control 20 mg gastro-resistant tablets (Germany)

	Me-too status	Gastasid Tablets of M/s Ali Gohar Pharmaceuticals (Pvt) Ltd,
	GMP status	DML of M/s CCL Pharma No. 000052 by way of formulation dated 21-07-2015 GMP inspection dated 20th & 24th April 2018 and the panel recommendations "The firm was found to be satisfactory level of GMP compliance" M/s Global Pharma issued a letter dated 18th December 2017 of additional section of dry powder (carbapenem)
	Remarks of the Evaluator	
	Decision: Approved	

M/s Avensis Pharmaceuticals Karachi

CLB in its 267th meeting held 31-12-2018 has considered and approved the new DML with following sections: The details of molecules and products applied are as below:

Dry powder injection (cephalosporin) Section	Molecule	Product	Approved (Meeting)
	1	4	288
	4	7	289
	2	6	291

Dry powder injection (cephalosporin) Section: 2 molecules / 6 products

140.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	CEFTAX 250mg Injection
	Composition	Each vial contains: Cefotaxime (As cefotaxime sodium B.P.)……250mg
	Diary No. Date of R& I & fee	Dy. No 10774 Dated 05-03-2019, Rs. 20,000/- dated 05-3-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	B.P.
	Pack size & Demanded Price	1x1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	
	Me-too status	Cefon Injection 250mg (Vial) of M/s Tabros Pharma
	GMP status	CLB in its 267th meeting approved the new Section for Dry powder injection (cephalosporin) Section on dated 31st December 2018.
	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.	
141.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	CEFTAX 500mg Injection
	Composition	Each vial contains: Cefotaxime (As cefotaxime sodium B.P.)……500mg
	Diary No. Date of R& I & fee	Dy. No 10762 Dated 05-03-2019, Rs. 20,000/- dated 05-3-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	B.P.
	Pack size & Demanded Price	1x1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefotaxime Sodium for Injection 500mg(Powder for solution for injection or infusion.) of M/s Villerton Invest SA Rue Edward

		Steichen 14 2540 Luxembourg
	Me-too status	Cefon Injection 500mg (Vial) of M/s Tabros Pharma
	GMP status	CLB in its 267th meeting approved the new Section for Dry powder injection (cephalosporin) Section on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision: Approved	
142.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	CEFTAX 1gm Injection
	Composition	Each vial contains: Cefotaxime (As cefotaxime sodium B.P.)……1gm
	Diary No. Date of R& I & fee	Dy. No 10775 Dated 05-03-2019, Rs. 20,000/- dated 05-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	B.P.
	Pack size & Demanded Price	1x1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Cefotaxime Sodium for Injection 1gm (Powder for solution for injection or infusion.) of M/s Villerton Invest SA Rue Edward Steichen 14 2540 Luxembourg
	Me-too status	Cefon Injection 1gm of M/s Tabros Pharma
	GMP status	CLB in its 267th meeting approved the new Section for Dry powder injection (cephalosporin) Section on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision: Approved	
143.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Axis IM 250mg injection
	Composition	Each vial contains: Ceftriaxone (As ceftriaxone sodium USP)……250mg
	Diary No. Date of R& I & fee	Dy. No 10780 Dated 05-03-2019, Rs. 20,000/- dated 05-03-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE (USFDA)**
	Me-too status	TRAXON I.M/I.V INJECTION 250 of M/s HANMI PHARMA,
	GMP status	CLB in its 267th meeting approved the new Section for Dry powder injection (cephalosporin) Section on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision: Approved	
144.	Name and address of manufacturer / Applicant	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Axis IM 500mg injection

	Composition	Each vial contains: Ceftriaxone (As ceftriaxone sodium USP)……500mg
	Diary No. Date of R& I & fee	Dy. No 10781 Dated 05-03-2019, Rs. 20,000/- dated 05-3-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE (USFDA)**
	Me-too status	TRAXON I.M/I.V INJECTION 500 of M/s HANMI PHARMA,
	GMP status	CLB in its 267th meeting approved the new Section for Dry powder injection (cephalosporin) Section on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision: Approved	
145.	**Name and address of manufacturer / Applicant**	M/s Avensis Pharmaceuticals F-24/1, Eastern Industrial Zone, Bin Qasim Karachi Pakistan
	Brand Name +Dosage Form + Strength	Axis IM 1gm injection
	Composition	Each vial contains: Ceftriaxone (As ceftriaxone sodium USP)……1gm
	Diary No. Date of R& I & fee	Dy. No 10782 Dated 05-03-2019, Rs. 20,000/- dated 05-3-2019
	Pharmacological Group	Antibiotic
	Type of Form	Form 5
	Finished Product Specification	USP
	Pack size & Demanded Price	1x1's & As per SRO
	Approval status of product in Reference Regulatory Authorities.	**CEFTRIAXONE (USFDA)**
	Me-too status	TRAXON I.M/I.V INJECTION 1gms of M/s HANMI PHARMA,
	GMP status	CLB in its 267th meeting approved the new Section for Dry powder injection (cephalosporin) Section on dated 31st December 2018.
	Remarks of the Evaluator.	
	Decision: Approved	

Evaluator PEC-XIII

146.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Bydoxil 500 mg capsule
	Composition	Each capsule contains: Cefadroxil (as Monohydrate) …….. 500mg
	Diary No. Date of R& I & fee	Dy.No.15724;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	1st Generation Cephalosporin Antibiotics
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	As per policy of MOH & as per SRO
	Approval status of product in Reference Regulatory Authorities.	MHRA Approved

	Me-too status	Galen 500mg Capsule of M/s Ankaz Pharma Karachi (Reg.No.070647)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has General capsule section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No 31 & 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd, 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
147.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Pimerive 1 gm Injection
	Composition	Each vial contains: Cefepime as HCl (with L-arginine)……1g
	Diary No. Date of R& I & fee	Dy.No.15726;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Cephalosporin
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 1's glass vial with solvent for injection & as per policy of MOH
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Nuxipim 1gm Injection of M/s Bosch (Reg. # 044357)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
148.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Pimerive 500mg Injection

	Composition	Each vial contains: Cefipime as HCl (with L-Arginine)……..500mg
	Diary No. Date of R& I & fee	Dy.No.15725;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Cephalosporin
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 1's glass vial with solvent for injection & as per policy of MOH
	Approval status of product in Reference Regulatory Authorities.	Approved by USFDA
	Me-too status	Feldopim Injection of M/s WnsFeild Pharma (Reg. # 046970)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
149.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Bestcef 400 mg Capsule
	Composition	Each capsule contains: Cefixime as Trihydrate……..400mg
	Diary No. Date of R& I & fee	Dy.No.15729;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Third Generation Cephalosporin Antibiotic
	Type of Form	Form - 5
	Finished product Specification	JP
	Pack size & Demanded Price	As per policy of MOH & As per SRO
	Approval status of product in Reference Regulatory Authorities.	Suprax 400mg capsule of M/s Sanofi Aventis (USFDA Approved)
	Me-too status	Xalfocin 400mg Capsule of M/s Martin Dow (Reg. # 080646)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin Capsule section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January,

		2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
150.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Bestcef 100 mg Dry Suspension
	Composition	Each 5ml contains: Cefixime as Trihydrate……..…..100mg
	Diary No. Date of R& I & fee	Dy.No.15727;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Third Generation Cephalosporin Antibiotic
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 1's (90ml) & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Fixicef Powder for oral Suspension of M/s Atco Lab (Reg. # 080273)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder suspension section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
151.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Bestcef 200 mg Dry Suspension
	Composition	Each 5ml contains: Cefixime as trihydrate……..200mg
	Diary No. Date of R& I & fee	Dy.No.15728;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Third generation cephalosporin antibiotic
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x 1's (90ml) & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Fixicef Powder for oral Suspension of M/s Atco Lab (Reg. # 080272)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the

		grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder suspension section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
152.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Cefatak Injection 1g (500mg+ 500mg)
	Composition	Each vial contains: Cefoperazone (as Sodium)….500mg Sulbactam (as Sodium)……..500mg
	Diary No. Date of R& I & fee	Dy.No.15733;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form - 5
	Finished product Specification	JP
	Pack size & Demanded Price	1x 1's glass vial with solvent for injection & as per policy of MOH
	Approval status of product in Reference Regulatory Authorities.	PMDA Japan Approved
	Me-too status	Cebac Injection 1gm of M/s Bosch (Reg.#037630)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
153.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Bac 250 mg (I/V) Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……. 250mg
	Diary No. Date of R& I & fee	Dy.No.15730;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Cephalosporin
	Type of Form	Form - 5

	Finished product Specification	USP
	Pack size & Demanded Price	1x 1's with 2ml Lidocaine for injection & as per policy of MOH
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Stracef 250mg I.V. of M/s Swiss Pharma (Reg. # 042469)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
154.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Cefatak Injection 2g
	Composition	Each vial contains: Cefoperazone (as Sodium)…….….1000mg Sulbactam (as Sodium)……....1000mg
	Diary No. Date of R& I & fee	Dy.No.15734;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form - 5
	Finished product Specification	JP
	Pack size & Demanded Price	1x 1's glass vial with solvent for injection & as per policy of MOH
	Approval status of product in Reference Regulatory Authorities.	Approved by 3 European countries Czech, Slovakia, Poland
	Me-too status	Bezone Injection of M/s Medisave (Reg. #069025)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-

		A, Punjab Small industrial State, Taxila.
	Decision: Approved	
155.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Ceftabak 1gm (I/M) Injection
	Composition	Each vial of dry substance contains: Ceftriaxone as Ceftriaxone Sodium……....1g
	Diary No. Date of R& I & fee	Dy.No.15737;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Antibiotic (Cephalosporin)
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's glass vial with 2ml Lidocaine & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rocephin Injection 1g of M/s Roche Pakistan (Reg. # 008436)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
156.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Ceftabak 500 mg (I/M) Injection
	Composition	Each vial contains: Ceftriaxone Sodium eq. to Ceftriaxone……500mg
	Diary No. Date of R& I & fee	Dy.No.15736;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Cephalosporin Antibiotic
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's glass vial with 2ml Lidocaine & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Prezone Injection 500mg of M/s Drugs Inn Islamabad (Reg. # 023168)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.

	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
157.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Ceftabak 250 mg (I/M) Injection (Dry powder)
	Composition	Each vial contains: Ceftriaxone sodium eq. to Ceftriaxone…….250mg
	Diary No. Date of R& I & fee	Dy.No.15735;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Third generation Cephalosporins
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's glass vial with 2ml Lidocaine & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Unixone Injection 250mg I/M of M/s Caliph Pharmaceuticals (Pvt.) Ltd. (Reg.No.082556)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg-II section, Reg Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from Name of m/s Wenovo Pharmaceuticals, plot No 31 & 32, Punjab Small industrial State, taxila and granted registration of the same in favour of M/s horizon Healthcare pvt Ltd , 35-A, Punjab Small industrial State, taxila.
	Decision: Approved	
158.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Bac 1 g (I/V) Injection (Dry powder)
	Composition	Each vial contains: Ceftriaxone as Sodium ……..….. 1000mg
	Diary No. Date of R& I & fee	Dy.No.15732;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Third generation Cephalosporins
	Type of Form	Form - 5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's glass vial with 2ml Lidocaine & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Trivolive 1gm Injection I.V. of M/s Olive Pharmaceuticals (Reg. # 045231)

	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd , 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	
159.	Name and address of manufacturer / Applicant	M/s Wenovo Pharmaceuticals, Taxilla Plot # 31& 32 Punjab Small Industrial Estate Taxilla.
	Brand Name +Dosage Form + Strength	Bac 500 mg (I/V) Injection
	Composition	Each vial contains: Ceftriaxone as Sodium ……..……. 500mg
	Diary No. Date of R& I & fee	Dy.No.15731;27-04-2018; Rs.20,000 (26-04-2018)
	Pharmacological Group	Cephalosporin
	Type of Form	Form -5
	Finished product Specification	USP
	Pack size & Demanded Price	1x1's glass vial with 2ml Lidocaine & As per SRO
	Approval status of product in Reference Regulatory Authorities.	USFDA Approved
	Me-too status	Rogzone Injection 500mg I/V of M/s Rogen Pharmaceuticals, (Reg. # 072364)
	GMP status	Last GMP inspection was conducted on 29-10-2018 and the report concluded that there is some need of improvements which have been discussed and agreed. Panel recommends the grant of GMP certificate.
	Previous remarks of the Evaluator	Firm has Cephalosporin dry powder injection section as mentioned in the submitted section approval letter.
	Previous decision	Deferred in 290th DRB meeting for confirmation of same products already registered in the name of applicant.
	Evaluation by PEC	As per cancellation letter No. F. 15-1/2019-REG-V (M-286) dated 30th August, 2019 Issued by Reg -II section, Registration Board in its 287th meeting held on 3-4 January, 2019 decided to cancel the registration of this product from name of M/s Wenovo Pharmaceuticals, Plot No. 31& 32, Punjab Small Industrial State, Taxila and granted registration of the same in favour of M/s horizon Healthcare Pvt Ltd, 35-A, Punjab Small industrial State, Taxila.
	Decision: Approved	

Deferred cases (Human):

160.	Name and address of manufacturer / Applicant	M/s ICI Pharmaceuticals 5, West wharf, Karachi Contract manufacture by Nabiqasim industry 17/24, Korangi industrial area Karachi
	Brand Name +Dosage Form + Strength	Etipro IV infusion
	Composition	Dy.No. Duplication 30-Aug-2016, 50,000/- (duplicate)
	Diary No. Date of R& I & fee	Each Vial Contains:- Omeprazole (as Sodium) ...……..… 40 mg
	Pharmacological Group	Proton Pump Inhibitor
	Type of Form	Form-5
	Finished product Specification	As per innovator
	Pack size & Demanded Price	1's/ As Per SRO
	Approval status of product in Reference Regulatory Authorities.	Omeprazole IV of sandoz (TGA)
	Me-too status	Loprot of Nabiqasim
	GMP status	Last GMP Inspection (M/s Nabiqasim Industries) dated 03-08-2017 with conclusive remarks of acceptable cGMP compliance. Last GMP inspection (M/s ICI Pakistan) was conducted on 25-01-2018 and the report concludes the firm to be GMP compliant.
	Previous remarks of the Evaluator.	• No USP or BP monograph is available for applied formulation. • ICI has 2 sections • They are already manufacturing 6 products on contract manufacturing bases.
	Previous decision(s)	Deferred whether application was submitted by M/s ICI or Wyeth **(M-289)**.
	Evaluation by PEC	The firm has clarified that the subject application was submitted by ICI Pakistan (Pvt) Ltd., 17/24, Korangi Industrial Area, Karachi.
	Decision: Approved.	
161.	Name and address of manufacturer / Applicant	M/s Macquin's International, Karachi
	Brand Name +Dosage Form + Strength	Euro Suspension 125mg/5ml
	Composition	Each 5ml suspension contains: Ciprofloxacin……..…..125mg
	Diary No. Date of R& I & fee	Dy. No.405; 30-11-2011; Rs.12,000/- (18-6-2014)
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, Rs.160/-
	Approval status of product in Reference Regulatory Authorities.	Ciproxin® 250 mg/5 ml granules and solvent for oral Suspension byM/sBayerHealthcare,MHRAapproved.
	Me-too status	Ciprin 125mg/5ml suspension of M/s Werrick pharmaceuticals
	GMP status	Last inspection report 8-11-2016 firm is operating at satisfactory level of compliance with GMP guidelines.
	Previous remarks of the Evaluator.	•
	Previous decision(s)	Deferred for further deliberation regarding manufacturing facility of diluent for reconstitution of ciprofloxacin suspension. **(M-275)** Deferred for clarification of applied composition since reference product contains Ciprofloxacin as base only whereas

		firm has applied for Ciprofloxacin as hydrochloride **(M-283)**.
	Evaluation by PEC	Registration Board in 269 meeting decided to approve the formulation of ciprofloxacin 125mg/5ml granules and solvent for oral suspension as per reference product approved by USFDA and MHRA. The firm has revised master formulation with ciprofloxacin base alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1957818) dated 29-08-2019.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
162.	Name and address of manufacturer / Applicant	M/s Macquin's International, Karachi
	Brand Name +Dosage Form + Strength	Euro DS Dry suspension
	Composition	Each 5ml contains: Ciprofloxacin…….250mg
	Diary No. Date of R& I & fee	Dy. No.411; 30-11-2011; Rs.12,000/- (18-6-2014)
	Pharmacological Group	Anti-bacterial
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specification
	Pack size & Demanded Price	60ml, Rs.260/-
	Approval status of product in Reference Regulatory Authorities.	Ciproxin 250 mg/5 ml granules and solvent for oral suspension by M/s Bayer Healthcare, MHRA approved.
	Me-too status	Hiflox Dry suspension 250mg/5ml by M/s Hilton (Reg#067499)
	GMP status	Last inspection report 8-11-2016 firm is operating at satisfactory level of compliance with GMP guidelines.
	Previous remarks of the Evaluator.	Rs.8000/- fee challan is not attached.
	Previous decision(s)	Deferred for following: • For deliberation in light of decision taken in 269th Registration Board meeting regarding manufacturing facility of diluent for reconstitution of ciprofloxacin suspension. • Verification of Fee challan of Rs. 8,000/-
	Evaluation by PEC	Photocopy of Fee challan of Rs. 8000/- has been submitted. The firm has revised master formulation with ciprofloxacin base alongwith submission of fee challan of Rs. 5000/- (Deposit slip # 1957817) dated 29-08-2019.
	Decision: Registration Board referred the case to QA & LT Division for updated GMP status of the firm.	
163.	Name and address of manufacturer / Applicant	M/s Noa Hemis Pharmaceuticals, Plot No. 154, Sector-23, Korangi Industrial Area, Karachi-74900
	Brand Name +Dosage Form + Strength	Etecav 0.5 mg Tablet
	Composition	Each film coated tablet contains: Entecavir (as monohydrate)……0.5 mg
	Diary No. Date of R& I & fee	Dy.No.1506, 30-7-2010, Rs.8000/-+Rs.12000/- (10-05-13)
	Pharmacological Group	Anti-viral
	Type of Form	Form-5
	Finished product Specification	Manufacturer's Specs
	Pack size & Demanded Price	As per PRC
	Approval status of product in Reference Regulatory Authorities.	MHRA approved.
	Me-too status	Enteca 0.5mg Tablet by GETZ pharma, Karachi R.No. 50711
	GMP status	The firm was granted GMP certificate based on inspection dated 28th February, 2019.
	Previous remarks of the Evaluator.	

	Previous decision(s)	Deferred for product specific inspection by panel comprising of Director DTL Karachi, DDG (E & M) & area FID **(M-246)**.
	Evaluation by PEC	
	Decision: Approved with innovator's specifications.	
164.	**Name and address of manufacturer / Applicant**	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore **contract manufacturing by** M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Taq-D Injection 200,000 IU
	Composition	Each ml contains: Vitamin D3 (Cholecalciferol)…200,000 IU
	Diary No. Date of R& I & fee	2130, 05-05-2016, Rs. 50,000/-, (04-05-2016)
	Pharmacological Group	Vitamin D
	Type of Form	Form 5
	Finished product Specification	USP
	Pack size & Demanded Price	(1x1's),1 cc ampoule blistered in Alu-PVC, As per SRO
	Approval status of product in Reference Regulatory Authorities.	Vitamin D3 GOOD 200,000 IU/ml drinkable solution in ampoule by Bouchara Pharm (ANSM France Approved)
	Me-too status	Bio D-3 by Biolabs
	GMP status	Not provided
	Remarks of the Evaluator.	• Last GMP inspection report of both the firms. • The Form-5/application for registration of drug has not been signed by the applicant/any authorized personnel. • Justification of 5% overage on the basis of scientific data.
	Decision of previous meeting of Registration Board	Decision: Deferred for submission of the following: • Last GMP inspection report of both the firms (which should have been conducted within the period of last one year). • Signed Form-5/application for registration of drug by the applicant/any authorized personnel. • Justification of 5% overage on the basis of scientific data. (**M-274)**
	Evaluation by PEC	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last 1 year. • Form 5 signed by authorized and technical persons. • Firm has submitted an undertaking from English Pharmaceuticals that 5% overage in the batch is kept to minimize the weight variation.
	Decision of previous meeting of Registration Board	Deferred for scientific justification for addition of 5% overage (**M-285)**
	Evaluation by PEC	Firm has submitted revised formulation without addition of any overage. The capacity inspection of the manufacturer (M/s English Pharmaceuticals) has been conducted and discussed in the instant meeting of Registration Board.
	Decision: Approved.	

165.	Name and address of manufacturer / Applicant	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore contract manufacturing by M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Papta Injection 2.25g
	Composition	Each vial contains: Piperacillin as sodium…..2g Tazobactam as sodium….0.25g
	Diary No. Date of R& I & fee	2135, 04-05-2016, Rs. 50,000/- (04-05-2016)
	Pharmacological Group	Penicillin 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.	USFDA Approved
	Me-too status	Tazopip by Cirin
	GMP status	Not provided
	Remarks of the Evaluator.	• M/s Festel Laboratories 8 products are contract manufactured by Kings Pharmaceuticals Lahore. • Last GMP inspection report of both the firms. • The Form-5/application for registration of drug has not been signed by the applicant/any authorized personnel. • Justification of 5% overage on the basis of scientific data. • The product is available in USFDA as follows: • ZOSYN® (piperacillin and tazobactam) Injection in GALAXY Containers are supplied as a frozen, iso-osmotic, sterile, non-pyrogenic solution in single dose plastic containers as follows: I. 2.25 g (piperacillin sodium equivalent to 2 g piperacillin/tazobactam sodium equivalent to 0.25 g tazobactam) in 50 mL. Each container has 5.58 mEq (128 mg) of sodium. II. 4.5 g (piperacillin sodium equivalent to 4 g piperacillin/tazobactam sodium equivalent to 0.5 g tazobactam) in 100 mL. Each container has 11.17 mEq (256 mg) of sodium. III. ZOSYN® Injection in GALAXY Containers should be stored at or below -20°C (-4°F).
	Decision of previous meeting of Registration Board	Decision: Deferred for submission of the following: • Last GMP inspection report of both the firms (which should have been conducted within the period of last one year). • Signed Form-5/application for registration of drug by the applicant/any authorized personnel. • Justification of 5% overage on the basis of scientific data. • Clarification for packaging material and storage condition as product approved in reference regulatory authority is in Galaxy Containers supplied as a frozen, ososmotic, sterile, non-pyrogenic solution in single dose plastic containers stored at or below -20°C (-4°F) (**M-274).**

	Evaluation by PEC	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last 1 year. • Form 5 signed by authorized and technical persons. • Firm has submitted an undertaking from English Pharmaceuticals that 5% overage in the batch is kept to minimize the weight variation. • Firm has **NOT** submitted clarification for packaging material and storage condition as product approved in reference regulatory authority is in Galaxy Containers supplied as a frozen, 1469sosmotic, sterile, non-pyrogenic solution in single dose plastic containers stored at or below -20°C (-4°F)
	Decision of previous meeting of Registration Board	Deferred for scientific justification for addition of 5% overage and clarification for packaging material and storage condition as product approved in reference regulatory authority is in Galaxy Containers supplied as a frozen, ososmotic, sterile, non-pyrogenic solution in single dose plastic containers stored at or below -20°C (-4°F). (**M-285)**
	Evaluation by PEC	Firm has submitted the product label of FDA Approved product "Zosyn" which specifies that the injection is available in two different packaging • ZOSYN® for Injection vials should be stored at controlled room temperature (20°C to 25°C[68°F to 77°F]) prior to reconstitution. • ZOSYN® Injection in GALAXY Containers should be stored at or below -20°C (-4°F). The firm is using simple glass vials like reference product and already approved me-too products therefore their product will be intended to be stored at room temperature. The capacity inspection of the manufacturer (M/s English Pharmaceuticals) has been conducted and discussed in the instant meeting of Registration Board.
	Decision: Approved.	
166.	Name and address of manufacturer / Applicant	M/s Festel Laboratories, Jinnah Industrial Estate, Link Kattarband Road, Thokar Niaz Baig, Multan Road, Lahore contract manufacturing by M/s. English Pharmaceutical Industries, Link Kattar Bund Road, Thokar Niaz Baig, Multan Road , Lahore
	Brand Name +Dosage Form + Strength	Papta Injection 4.5g
	Composition	Each vial contains: Piperacillin as sodium…..4g Tazobactam as sodium….0.5g
	Diary No. Date of R& I & fee	2134, 05-05-2016, Rs. 50,000/- (04-05-2016)
	Pharmacological Group	Penicillin 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.	USFDA Approved

	Me-too status	Tazopip by Cirin
	GMP status	Not provided
	Remarks of the Evaluator.	• Last GMP inspection report of both the firms. • The Form-5/application for registration of drug has not been signed by the applicant/any authorized personnel. • Justification of 5% overage on the basis of scientific data. • The product is available in USFDA as follows: • ZOSYN® (piperacillin and tazobactam) Injection in GALAXY Containers are supplied as a frozen, iso-osmotic, sterile, non-pyrogenic solution in single dose plastic containers as follows: I. 2.25 g (piperacillin sodium equivalent to 2 g piperacillin/tazobactam sodium equivalent to 0.25 g tazobactam) in 50 mL. Each container has 5.58 mEq (128 mg) of sodium. II. 4.5 g (piperacillin sodium equivalent to 4 g piperacillin/tazobactam sodium equivalent to 0.5 g tazobactam) in 100 mL. Each container has 11.17 mEq (256 mg) of sodium. III. ZOSYN® Injection in GALAXY Containers should be stored at or below -20°C (-4°F)
	Decision of previous meeting of Registration Board	Decision: Deferred for submission of the following: • Last GMP inspection report of both the firms (which should have been conducted within the period of last one year). • Signed Form-5/application for registration of drug by the applicant/any authorized personnel. • Justification of 5% overage on the basis of scientific data. • Clarification for packaging material and storage condition as product approved in reference regulatory authority is in Galaxy Containers supplied as a frozen, isoosmotic, sterile, non-pyrogenic solution in single dose plastic containers stored at or below -20°C (-4°F) (**M-274)**
	Evaluation by PEC	Firm has submitted following documents: • GMP certificate of M/s English Pharmaceuticals issued on the basis of inspection conducted on 26-01-2018 • GMP inspection report of M/s Festel Laboratories recommending renewal of DML conducted on 24-1-2016. This inspection report is not conducted within a period of last 1 year. • Form 5 signed by authorized and technical persons. • Firm has submitted an undertaking from English Pharmaceuticals that 5% overage in the batch is kept to minimize the weight variation. • Firm has **NOT** submitted clarification for packaging material and storage condition as product approved in reference regulatory authority is in Galaxy Containers supplied as a frozen, isoosmotic, sterile, non-pyrogenic solution in single dose plastic containers stored at or below -20°C (-4°F)
	Decision of previous meeting of Registration Board	Deferred for scientific justification for addition of 5% overage and clarification for packaging material and storage

		condition as product approved in reference regulatory authority is in Galaxy Containers supplied as a frozen, ososmotic, sterile, non-pyrogenic solution in single dose plastic containers stored at or below -20°C (-4°F). (**M-285)**
	Evaluation by PEC	Firm has submitted the product label of FDA Approved product "Zosyn" which specifies that the injection is available in two different packaging • ZOSYN® for Injection vials should be stored at controlled room temperature (20°C to 25°C[68°F to 77°F]) prior to reconstitution. • ZOSYN® Injection in GALAXY Containers should be stored at or below -20°C (-4°F). The firm is using simple glass vials like reference product and already approved me-too products therefore their product will be intended to be stored at room temperature. The capacity inspection of the manufacturer (M/s English Pharmaceuticals) has been conducted and discussed in the instant meeting of Registration Board.
	Decision: Approved.	

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
167.	M/s GETZ Pharma (Pvt.) Limited, 29-30/27, Korangi industrial Area, Karachi	FORTIDE DPI Powder for inhalation 400mcg + 12 mcg Each capsule contains: Budesonide……400mcg Formoterol Fumarate Dihydrate…….12mcg Adrenergics in combination with corticosteroids or other drugs, excl. Anticholinergics (ATC code: R03AK07) In-house specifications	Form 5-D Dy. No.27050 dated 07-08-2018 Rs. 50,000/- dated 23-07-2018 30's: Rs. 1000/-	Symbicort® Turbohaler® 400 micrograms/12 micrograms/inhalation, inhalation powder (MHRA approved) GMP inspection dated 26-06-2018 wherein firm was considered to be operating at an acceptable level of compliance with GMP guidelines as of today

STABILITY STUDY DATA	
Drug	FORTIDE DPI Powder for inhalation 400mcg + 12 mcg
Name of Manufacturer	M/s GETZ Pharma (Pvt.) Limited, 29-30/27, Korangi industrial Area, Karachi
Manufacturer of API	**Budesonide**: M/s Avik Pharmaceutical Ltd. Valsad District, India **Formoterol Fumarate Dihydrate**: M/s Vamsi Labs Ltd, Maharashtra,India
API Lot No.	**Budesonide**: BDS/M/011/18 **Formoterol Fumarate Dihydrate**: FF-0170818 (Micronised)

Description of Pack (Container closure system)	Alu Alu Blister		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C/75%±5% RH Real Time: 30˚C ± 2˚C/75%±5% RH		
Time Period	Accelerated: 6 months Real Time: 6 months		
Frequency	Real Time: 0,3 & 6 (months) Accelerated: 0, 3 & 6 (months)		
Batch No.	463DS01	463DS02	463DS03
Batch Size	3571 Capsules	3571 Capsules	3571 Capsules
Manufacturing Date	11/2018	11/2018	11/2018
Date of Initiation	06/11/2018	06/11/2018	06/11/2018
No. of Batches	03		
Date of Submission	9558 (25-06-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	**Budesonide:** Copy of COA (Batch # BDS/M/011/18) from M/s Avik Pharmaceutical Ltd. Valsad District, India is submitted. **Formoterol Fumarate Dihydrate:** Copy of COA (FF-0170818 (Micronised)) from M/s Vamsi Labs Ltd, Maharashtra,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.	**Budesonide**: Copy of GMP certificate (certificate No. S-GMP/1806914) issued by Food & Drugs Control Administration, India. It is valid until 01/07/2020. **Formoterol Fumarate Dihydrate**: Copy of GMP certificate (certificate No. NEW-WHO-GMP/CERT/PD/75003/2018/11/25587) issued by Food & Drugs Administration, Maharashtra India. It is valid until 02/11/2021.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Budesonide**: The firm has submitted copy of commercial invoice for the purchase of Budesonide (Micronised) attested by DRAP, Karachi dated 24-09-2018. **Formoterol Fumarate Dihydrate**: The firm has submitted copy of commercial invoice for the purchase of Formoterol fumarate dihydrate (Micronised) attested by DRAP, Karachi dated 25-09-2018.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes

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

REMARKS OF EVALUATOR

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

Details of Investigation:

FORTIDE DPI (Budesonide + Formoterol Fumarate Dihydrate) Powder for Inhalation 400mcg + 12mcg
Pack Size: 30 Dry Powder Inhaler Capsules (Alu-Alu Blister)

Panel members:

Dr. Najam.us.Saquib - Additional Director, DRAP, Karachi.
Dr. Saif-Ur-Rehman Khattak - Director CDL, Karachi.
Mr. Asfandyar - Assistant Director CDL, DRAP, Karachi.

Q. No.	Question	Observation by panel
1.	Do you have documents confirming the import of Budesonide API & Formoterol fumarate dihydrate API including approval from DRAP?	The firm has imported "Budesonide API" from M/s Avik Pharmaceuticals Ltd, India and has approval from DRAP for import vide License No. 3024/16-DRAP (K) dated 15.11.2016. The firm has imported "Formoterol fumarate dihydrate API" from M/s Vamsi Labs Ltd., India and has approval from DRAP for import vide License No. 2932/16-DRAP (K) dated 03.11.2016.
2.	What was the rationale behind selecting the particular manufacturer of API?	There is proper vendor evaluation process being implemented by the firm and the rationale behind vendor selection is controlled through Postal Audit checklist / Physical Site Inspection and availability of valid GMP approval by competent authority. Further, M/s Avik Pharmaceuticals Ltd, India has Certificate of Suitability (CEP) for Budesonide API and M/s Vamsi Labs Ltd., India has Certificate of Suitability (CEP) for Formoterol fumarate dihydrate API issued by European Directorate for the Quality of Medicines & HealthCare (EDQM).
3.	Do you have documents confirming the import of Budesonide & Formoterol fumarate dihydrate reference standard and impurity standards?	Firm has imported Budesonide reference standard from British Pharmacopoeia vide DC No. 000562 dated 15.02.2018 and impurity standard was imported from European Directorate for the Quality of Medicines & HealthCare (EDQM) vide DC No. GP/734 dated 26.09.2017. Firm has imported Formoterol fumarate dihydrate reference standard from USP vide DC No. 3015 dated 28.02.2018 and impurity standard was imported from European Directorate for the Quality of Medicines & HealthCare (EDQM) vide DC No. GP/734 dated 26.09.2017.
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm has certificate of analysis for APIs, Reference standards and Impurity standards.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm has provided copy of valid GMP certificate of M/s Avik Pharmaceuticals Ltd, India valid till 01-07-2020 and copy of valid GMP certificate of M/s Vamsi Labs Ltd, India valid till 02-11-2021.

6.	Do you use API manufacturer method of testing for testing API?	The firm has used method of testing adopted from British Pharmacopeia (BP) monograph for Budesonide API & European Pharmacopeia (Ph. Eur.) monograph for Formoterol fumarate dihydrate API and the same has been verified as per USP chapter 1226 (verification of compendial procedure).
7.	Do you have stability studies reports on API?	The firm has stability study report on Budesonide API & Formoterol fumarate dihydrate API.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing has been performed as per SIM method and degradation products have been quantified.
9.	Do you have method for quantifying the impurities in the API?	Yes, the firm has method for quantifying the impurities in the API adopted from British Pharmacopeia (BP) monograph for Budesonide API & European Pharmacopeia (Ph. Eur.) monograph for Formoterol fumarate dihydrate API.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm has remaining quantities of the APIs and Reference standards & Impurity standards.
11.	Have you used pharmaceutical grade excipients?	The firm have used pharmaceutical grade excipient i.e., Lactose monohydrate.
12.	Do you have documents confirming the import of the used excipients?	The firm has necessary documents confirming the import of the used excipient.
13.	Do you have test reports and other records on the excipients used?	The firm has test report and other record on the excipient used.
14.	Do you have written and authorized protocols for the development of Fortide DPI Powder for Inhalation 400mcg + 12mcg?	The firm has written and authorized protocol for the development of Fortide DPI Powder for Inhalation 400mcg + 12mcg.
15.	Have you performed Drug-excipient compatibility studies?	Since firm has used same excipient as used by the innovator. Therefore, compatibility study was not performed.
16.	Have you performed comparative dissolution studies?	Firm has performed Pharmaceutical Equivalence studies with reference product "Symbicort Turbuhaler" Batch no. SKCC, Manufactured by M/s AstraZeneca, Canada. The firm's products (Fortide DPI Powder for Inhalation 400mcg + 12mcg) is pharmaceutically equivalent to innovator product. Firm has performed comparative testing on following parameters, in addition to Assay, both for reference product (Symbicort Turbuhaler) and for test product (Fortide DPI Powder for Inhalation 400mcg + 12mcg): *Uniformity of Delivered Dose (UODD):* UODD test has been performed to ensure uniformity, consistency & accuracy of each emitted dose delivered to patient at the site of action. *Aerodynamic Particle Size Distribution (APSD):* *a) By Glass Twin Impinger - Apparatus A as per Ph. Eur pharmacopoeia* This test has been performed to ensure that the delivered dose effectively and in the required

		particle dimensions reached to its site of action i.e. bronchial tubes and alveoli in alignment with the pharmacopeial recommendation. *b) By Next Generation Impactor (NGI) - Apparatus E as per Ph. Eur pharmacopoeia* This test has been performed to ensure stage wise distribution of an aerosol cloud, taking into consideration their aerodynamic diameter that defines where the particles in that cloud are deposited after inhalation. While performing APSD, drug distribution with respect to their particle size is ensured by assessing the following: i. <u>Mass of the active substance deposited per discharge from stage 2 to 4:</u> Taking into account the cut-off diameters of stage 2-4 (between 1-5µm), mass of each API has been quantified as a percentage of the total delivered dose. ii. <u>Fine Particle Fraction (FPF):</u> Fine Particle Fraction (FPF) is expressed as a percentage of the delivered dose (the dose that leaves the inhaler device and is available to the patient). iii. <u>Mass Median Aerodynamic Diameter (MMAD):</u> Mass Median Aerodynamic Diameter (MMAD) is defined as the diameter at which 50% of the particles (by mass) are larger and 50% are smaller. iv. <u>Geometric Standard Deviation (GSD):</u> Geometric Standard Deviation (GSD) is a measure of the spread of an aerodynamic particle size distribution.
17.	Do you have product development (R&D) section	The firm has dedicated product development (R&D) section with requisite manufacturing and analysis facilities.
18.	Do you have necessary equipment available in product development section for development of Fortide DPI Powder for Inhalation 400mcg + 12mcg?	The firm has necessary equipments available in product development section for development of Fortide DPI Powder for Inhalation 400mcg + 12mcg. Further, the firm has similar equipments available in Production section with different capacities.
19.	Are the equipment in product development section qualified?	The available equipments in product development section are qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm has proper maintenance / calibration with 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 qualified staff in product development section with proper knowledge and training in product development. There are 50 Scientists (Pharmacist & Chemist) working only in R&D Section.

<table>
<tr><td>22.</td><td>Have you manufactured three stability batches for the stability studies of Fortide DPI Powder for Inhalation 400mcg + 12mcg as required?</td><td>The firm has manufactured three stability batches of Fortide DPI Powder for Inhalation 400mcg + 12mcg. Packed in Alu-Alu blisters:
<table>
<tr><td colspan="3">Fortide DPI Powder for Inhalation
400mcg + 12mcg</td></tr>
<tr><td>Batch No.</td><td>Date of Mfg.</td><td>Batch Size</td></tr>
<tr><td>463DS01</td><td>November 2018</td><td>3571 Capsules</td></tr>
<tr><td>463DS02</td><td>November 2018</td><td>3571 Capsules</td></tr>
<tr><td>463DS03</td><td>November 2018</td><td>3571 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 is the capacity of their R&D equipment where probable simulation of manufacturing procedure of production batches are expected as well as quantity of capsules required per testing frequencies.</td></tr>
<tr><td>24.</td><td>Do you have complete record of production of stability batches?</td><td>The firm has complete record of production of stability batches. All the Log Books are properly maintained.</td></tr>
<tr><td>25.</td><td>Do you have protocols for stability testing of stability batches?</td><td>The firm has detailed protocols for stability testing of stability batches having protocol number:
<table>
<tr><td colspan="2">Fortide DPI Powder for Inhalation
400mcg + 12mcg</td></tr>
<tr><td>Batch No.</td><td>Protocol No.</td></tr>
<tr><td>463DS01</td><td>FS-130-18</td></tr>
<tr><td>463DS02</td><td>FS-131-18</td></tr>
<tr><td>463DS03</td><td>FS-132-18</td></tr>
</table></td></tr>
<tr><td>26.</td><td>Do you have developed and validated the method for testing of stability batches?</td><td>The firm has developed and validated the method for testing of stability batches.</td></tr>
<tr><td>27.</td><td>Do you have method transfer studies in case when the method of testing being used by your firm is given by any other lab?</td><td>The firm has developed and validated method of testing for finished product and complete Method Validation Report is available. Therefore, method transfer is not applicable.</td></tr>
<tr><td>28.</td><td>Do you have documents confirming the qualification of equipments / instruments being used in the test and analysis of Budesonide API & Formoterol fumarate dihydrate API and the finished drug?</td><td>The firm has proper documents confirming the qualification of equipment / instrument being used in the test and analysis of Budesonide API & Formoterol fumarate dihydrate API and the finished drug.</td></tr>
<tr><td>29.</td><td>Do your method of analysis stability indicating?</td><td>The firm has performed forced degradation (FD) study on their product Fortide DPI Powder for Inhalation 400mcg + 12mcg for the conformance of its stability indicating nature.</td></tr>
<tr><td>30.</td><td>Do your HPLC software 21CFR Compliant?</td><td>The HPLC software is 21CFR Compliant as per record available with the firm. The firm have number of WATER’s HPLC with Empower 3 software having following features:
Have Audit trail
Have Backup system
Have Data traceability
Have Data achieving system
Have Data integrity
Have Data security
System Security Policy</td></tr>
</table>

31.	Can you show Audit trail reports on Fortide DPI Powder for Inhalation 400mcg + 12mcg testing?	Audit trail on the testing reports are available.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm has remaining quantities of stability batches.
33.	Do you have stability batches kept on stability testing?	The firm has three stability batches kept on real time stability testing. 09 months real time stability data is available.
34.	Do you have valid calibration status for the equipments used in Fortide DPI Powder for Inhalation 400mcg + 12mcg production and analysis?	The firm has valid calibration status for the equipment used in production and analysis of Fortide DPI Powder for Inhalation 400mcg + 12mcg.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Adequate monitoring and control are available for stability chamber. Chambers are controlled and monitored through software having alarm system for alerts as well.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	The firm has dedicated section for manufacturing of DPI. Related manufacturing area, equipment, personnel and utilities are in compliance.
37.	Any remarks by PEC: 1. To confirm and verify all requirements for manufacturing of trial batches of said product in R&D section of the firm. 2. To verify the availability of necessary apparatus for carrying out the test for Uniformity of Delivered Dose and Aerodynamic Particle Size Distribution.	1. The firm has necessary equipments for manufacturing of trial batches of Fortide DPI Powder for Inhalation 400mcg + 12mcg including Ball Mill, Encapsulation Machine etc. 2. For Uniformity of Delivered Dose and Aerodynamic Particle Size Distribution, please refer to point # 16 of this report.

Conclusion and recommendation:

1. On the basis of risk based assessment, the authenticity of stability data submitted by the firm in respect of Fortide DPI Powder for Inhalation 400mcg + 12mcg is verifiable to satisfactory level.
2. Firm has dedicated section with necessary utilities and trained personnel to manufacture and control the product.
3. Necessary registration of Fortide DPI Powder for Inhalation 400mcg + 12mcg may kindly be granted to the firm.

Decision: Registration Board decided to approve registration of Fortide DPI Powder for Inhalation 400mcg + 12mcg by M/s GETZ Pharma (Pvt.) Limited, 29-30/27, Korangi industrial Area, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

d. Exemption from onsite verification of stability data

168.	Name and address of manufacturer / Applicant	M/s Wilson's pharmaceuticals, 387-388, Industrial Area, Islamabad.
	Brand Name +Dosage Form + Strength	Excel Tablets 80 mg
	Composition	Each tablet contains: Azilsartan Medoxomil (as Potassium) ……..80mg
	Diary No. Date of R&I & fee	Dy No.2954; Date:18-03-2011: Rs.15,000 **Duplicate** (18-March 2011) + Rs. 35,000 (challan # 0781379,29-10-2018)
	Pharmacological Group	Antihypertensive agent
	Type of Form	Form-5D (18-03-2011)
	Finished product Specification	Manufacturer's Specifications
	Pack size & Demanded Price	10's, 20's, 30's, 60's ; As per SRO
	Approval status of product in Reference Regulatory Authorities.	Approved in US-FDA (Edarbi Tablets of Takeda Pharma, USA)
	Me-too status	N/A
	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	Excel Tablets 80mg		
Name of Manufacturer	M/s Wilson's pharmaceuticals, 387-388, Industrial Area, Islamabad.		
Manufacturer of API	M/s Ami Life sciences Pvt. Ltd, Gujarat , India		
API Lot No.	AZP/50310517		
Description of Pack (Container closure system)	Alu /Alu Blister Pack		
Stability Storage Condition	Accelerated:40˚C ± 2˚C/75%±5% RH 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.	Trial #01	Trial #02	Trial #03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	12-2017	12-2017	12-2017
Date of Initiation	December, 2017	December, 2017	December, 2017
No. of Batches	03		
Date of Submission	2165 (29-03-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API.	Copy of COA (Batch# AZP/50310517) from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India is submitted.

2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India has been submitted. It is valid until 23-04-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the import of 960.30g of Azilsartan Medoxomil potassium salt (Invoice#EXP/A/138/2017-18) attested by ADC DRAP, Islamabad dated 16-08-2017
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 6months Accelerated and Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 29-03-2018 vide diary no. 23459

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	Firm has referred to onsite inspection 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 throughout proposed shelf life and on accelerated studies for six months.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the import of 960.3 g of Azilsartan Medoxomil Potassium salt (Invoice# EXP/A/138/2017-18) attested by ADC DRAP, Islamabad dated 16-08-2017. Copy of Form 3, Form 7 and form 6 is also provided.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of commercial invoice for the procurement of working standards and impurity standards.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India has been Submitted. It is valid until 26-04-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Mechanism for Vendor prequalification.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Copy of COA (Batch# AZP/50310517) from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India is submitted.
Copy of COA of working standards (Batch# AZP/50400817) have been Submitted.
COAs of impurity standards have been submitted.
Impurity A, Impurity B, Impurity C. Impurity D</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of 13 qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP For the Development of “Excel Tablets 80mg”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 01</td><td>1500 tablets</td><td>12-2017</td></tr>
<tr><td>Trial # 02</td><td>1500 tablets</td><td>12-2017</td></tr>
<tr><td>Trial # 03</td><td>1500 tablets</td><td>12-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>The firm has submitted reconciliation sheet mentioning following details:
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>Trial # 01</td><td>570 Tabs (3×10’s, 19 Packs)</td><td>256</td><td>314</td></tr>
<tr><td>Trial # 02</td><td>570 Tabs (3×10’s, 19 Packs)</td><td>256</td><td>314</td></tr>
<tr><td>Trial # 03</td><td>570 Tabs (3×10’s, 19 Packs)</td><td>256</td><td>314</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated).</td><td>Firm has submitted photocopies of digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 11-11-2017 to 01-06-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Azilsartan Medoxomil Potassium Salt.</td></tr>
</table>

14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Excel Tablets 80mg" along with Stability Study Reports.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated (5oC±3oC) and 24 Months Real Time 25oC±2oC/60%±5%RH Stability Study Data of 03 Batches for Azilsartan Medoxomil potassium salt from M/s Ami Life sciences Pvt. Ltd, Gujarat, India.
16.	Analysis reports for excipients used.	The firm has submitted copy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has submitted that ingredients of Excel Tablets 80mg and Edarbi Tablets (innovator brand) are same.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 and pH 7.8 buffers with Edarbi Tablets 80mg manufactured by M/s. Takeda, Osaka, Japan with Batch # EB-TL40-04. The firm's product (Excel Tablets 80mg) results are comparable with Edarbi Tablets 80mg.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Excel Tablets 80mg from 22-12-2017 to 23-12-2018.

Remarks:

S #	Short comings	Response of Firm
1.	Valid GMP certificate is required as Photocopy of GMP Certificate issued by Food and Drugs Control Administration, Gujarat State, India is valid until 23-04-2019.	The firm has submitted copy of GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India which is valid till 24-04-2022.
2.	The protection of the drug product from moisture was identified as a critical factor since the product is sensitive to moisture, the container closure system has been chosen to minimize exposure to humidity and the aluminum blisters are integrated with desiccant by the innovators. What precautions are taken by the applicant in this regard?	Innovator's drug product Edarbi is supplied in Bottle of 30 and 90 tablets. Bottle will be opened 30 or 90 times while administering drug to patient whereas container closure system for Wilson's drug product is alu-alu blister (as primary packaging) in inner carton (as secondary packaging) and it ensures product integrity & protection from heat, light & moisture. Seal integrity test / Vacuum leakage test is performed on tablet blisters and no traces of moisture were found. Sealing test reports are attached. Uptil now (12th month real time stability), no significant physical and chemical change is observed in drug product.
3.	Stability studies reports on conditions of Zone IV-A for API conducted by API manufacturer is required.	The firm has submitted that As per ICH Guidelines for refrigerated API storage, temperature and relative humidity conditions are same for all climatic zones i.e., for long term 5ºC ±3 ºC and for accelerated 25 ºC± 5 ºC/60% ±5%RH.
4.	Stability studies report's print provided for API conducted by API manufacturer is not readable.	Readable copies are Attached

5.	The firm has submitted audit trail reports of Excel Tablets 80mg from 22-12-2017 to 23-6-2018. Remaining audit trail is missing	Audit trail reports for testing of applied formulation are available.
6.	Record of Digital data logger for temperature and humidity monitoring of stability chambers after 6- 2018 is missing	The firm has submitted remaining record of digital data logger for temperature and humidity.

Decision: Registration Board decided to approve registration of Excel (Azilsartan Medoxomil Potassium) Tablets 80 mg by M/s Wilson's pharmaceuticals, 387-388, Industrial Area, Islamabad. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks
169.	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.	Tigrelor 90mg tablet Each film-coated tablet contains: Ticagrelor...90mg (Platelet Aggregation Inhibitor) Innovators' specifications	Form- 5 Dy.No.931 Dated: 22-12-2014 Rs.50,000/- (17-12-2014) 2 x 10's ; as per SRO	Brilinta 90 mg film-coated tablets of M/s AstraZeneca UK Limited (MHRA Approved) / Not applicable Last GMP inspection was conducted on 12-12-2017 and GMP certificate was issued on 15-12-2017.

STABILITY STUDY DATA			
Drug	Tigrelor 90mg tablet		
Name of Manufacturer	M/s Pharmatec Pakistan (Pvt.) Limited, D-86/A, S.I.T.E., Karachi.		
Manufacturer of API	M/s Nantong Chanyoo Pharmatech Co., Ltd. China		
API Lot No.	RD-TG-201709061		
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, 3, 6 (month) Real Time: 0, 3, 6, 9, 12 (months)		
Batch No.	17PD064TICT05	17PD081TICT06	17PD089TICT07
Batch Size	2500 tablets	2500 tablets	2500 tablets
Manufacturing Date	Nov-2017	Dec-2017	Dec-2017
Date of Initiation	29-01-2018	29-01-2018	30-01-2018
No. of Batches	04		
Date of Submission	16-08-2018 (27937)		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

Sr. No.	Documents To Be Provided	Status
1.	CoA of API	Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.
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

Firm has submitted 6 months accelerated and 12 months real time stability study data of four 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: 02-07-2019 vide diary no. 10339

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 "Apixa 2.5mg and 5mg (Apixaban) Tablets", which was presented in 289th meeting of Registration board. Registration Board decided to approve registration of above stated drug product of M/s. Pharmatec Pakistan (Private) Ltd, Karachi. **Date of inspection**: 30-04-2019 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 commercial invoice for the import of Ticagrelor (5kg) from M/s. Nantong Chanyoo Pharmatech Co., Ltd, China attested by ADC DRAP, Karach dated 27-10-2017.

<table>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted COAs of following working standards & impurity Standards :
Ticagrelor working standard (B # WS201603001)
Ticagrelor working standard (B # WTG01-170401)
Impurity standards
TG16 WRS (B# WTG05-170401)
De-Ethoxyl of TG WRS (B# WTG06-170401)</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate (certificate No.2017006) issued by Nantong Food & Drug Administration, China. It is valid until 07/09/2020.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted SOP for evaluation of vendors.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>Firm has submitted copy of COA of Ticagrelor (Batch # RD-TG-201709061) from M/s Nantong Chanyoo Pharmatech Co., Ltd., China.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Ticagrelor 90mg Tablet”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>17PD064TICT05</td><td>2500 Tablets</td><td>29-01-2018</td></tr>
<tr><td>17PD064TICT06</td><td>2500 Tablets</td><td>29-01-2018</td></tr>
<tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>30-01-2018</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>17PD064TICT05</td><td>2500 Tablets</td><td>1800 Tablets</td><td>700 tablets</td></tr>
<tr><td>17PD064TICT06</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 tablets</td></tr>
<tr><td>17PD064TICT07</td><td>2500 Tablets</td><td>2330 Tablets</td><td>170 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 29-11-2017 to</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Ticagrelor.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Ticagrelor 90mg Tablet” along with Stability Study Reports.</td></tr>
</table>

	etc.)	
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s Nantong Chanyoo Pharmatech Co., Ltd. China. The storage conditions for real time stability data are 25±2ºC/60±5%RH.
16.	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The compatibility of Ticagrelor 900mg (API) and 40mg Sodium lauryl sulphate (Excipient) was studied by HPLC analytic techniques after storage of mixture under accelerated conditions. HPLC analysis of these mixtures has not shown any significant physical and chemical instability. Hence the study concludes that Ticagrelor and sodium lauryl sulphate are compatible.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution profile at pH 1.2, pH 4.5, pH 6.8 between Ticagrelor 90mg tablet and Brilinta 90mg tablet. The results suggest similarity factor (f2) > 50 and difference factor (f1) < 15 in all three media.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of "Ticagrelor 90mg Tablet" from.

Observations communicated	**Response by the applicant**
Digital data logger record does not cover the duration of stability study data. Clarification is required.	Digital logger sheets which cover the duration stability study data.
Justification is required for preparation of four batches for the purpose of carrying out stability studies.	The first batch exhibiting the batch number 17PD048TICT04, is the pre-formulation batch, the very initial batch developed at every step of formulation development, this supports in making decision. These steps include process feasibility studies, formulation optimization and manufacturing process.
Audit trail reports of only one date are submitted. It is important to submit the audit trail reports at all time points of stability studies as well as comparative dissolution study.	Audit trail on the testing time point is submitted.
Polymorphic formof Ticagrelor API is required to be submitted.	The firm has submitted that polymorphic form-II was used and further stated that same form of molecule is discussed in the patent of Astra Zeneca. The form-II of Ticagrelor is confirmed by the melting points & X-ray Diffraction.

Storage conditions under which stability studies were conducted are at 25ºC±2ºC/60%±5% RH.

Decision: Deferred for submission of scientific justification for conducting API stability studies at storage conditions of 25ºC±2ºC/60%±5% RH.

e. Exemption cases (Deferred)

Sovel 400/100mg Tablet (Sofosbuvir/Velpatasvir) of M/s Indus Pharmaceuticals, Karachi

The following case was forwarded by Deputy Director (Appellate Board) through letter No. F.1-3/2018-AB(M-151) dated 4th February 2019 containing decision of the Appellate Board which was taken in its 151st meeting held on 16-01-2019 as per Appeal No. 07/2018 of M/s Indus Pharmaceuticals, Karachi for their product "Sovel 400/100mg Tablet" which was rejected by Registration Board in 277th meeting. The letter further provided the decision which is as:

*"**The Board agreed with the submission made by the firm and allowed the appeal. The Secretary, Registration Board is directed to place the product "Sovel 400/100mg Tablet (Sofosbuvir/Velpatasvir) on the agenda of the forthcoming meeting of Registartion Board for issuance of the registration of product accordingly"***

Accordingly the agenda of the same product (as already rejected in 277th meeting) is placed before the Board for its consideration.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date & Remarks	Previous DRB Decision / Remarks (if any)
170.	M/s Indus Pharma (Pvt.) Ltd. 26-27 & 63-67, Sector 27, Korangi Industrial Area 74900. Karachi.	SOVEL Tablet 400mg / 100mg Each film coated tablet contains:- Sofosbuvir…400mg Velpatasvir…100mg (Anti-Viral)	Form 5-D Dairy No. 1426 dated 5-10-2016 Rs.50,000/- Rs. 5,855/- per pack of 28 tablets. Rs.209.12/- per tablet.	EPCLUSA by M/s Gilead Sciences Inc. USA. Not applicable. GMP compliant dated 16-8-2017.	The Firm has claimed Manufacturer's Specifications.

STABILITY STUDY DATA

Drug	SOVEL Tablet 400mg / 100mg (Sofosbuvir + Velpatasvir)		
Name of Manufacturer	M/s Indus Pharma (Pvt.) Ltd. Karachi.		
Manufacturer of API	Sofosbuvir: M/s Beijing Huikang Boyuan Chemical Tech Co., Ltd. China.		
	Velpatasvir: M/s Xian Reyphon Pharmaceutical Co., Ltd. China.		
API Lot No.	Sofosbuvir: 151218		
	Velpatasvir: 161202		
Description of Pack (Container closure system)	HDPE Plastic Bottle.		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time: 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0,1,3,6 (Month) Real Time: 0,3,6 (Month)		
Batch No.	P-1/SVL-400/100mg	P-2/SVL-400/100mg	P-3/SVL-400/100mg
Batch Size	2,500 Tablets	2,500 Tablets	2,500 Tablets
Manufacturing Date	01-2017	01-2017	01-2017

Date of Initiation	25-01-2017	31-01-2017	31-01-2017
No. of Batches	03		
Date of Submission	18-08-2017 (Dy. No. 12428)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API	**Sofosbuvir:** COA of Sofosbuvir (Batch # 130313) from Beijing Huikang Boyuan Chemical Tech Co., Ltd is submitted. **Velpatasvir Copovidone:** COA of Velpatasvir Copovidone (Batch # 160502) from Reyphon Pharmaceutical, Shaanxi province, China
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sofosbuvir :** M/s Beijing Huikang Boyuan Chemical Tech Co., Ltd. China: Copy of GMP Certificate for Pharmaceutical Products issued by Liaoning Food and Drug Administration, China is submitted. **Velpatasvir:** M/s Xi'an Reyphon Pharmaceutical Co., Ltd. China: Copy of GMP Certificate for Pharmaceutical Products issued by Xi'an Food and Drug Administration, China is submitted.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	**Sofosbuvir:** Copy of ADC (Karachi) attested invoice is submitted dated 10-01-2016. **Velpatasvir:** Copy of ADC (Karachi) attested invoice is submitted dated 28-12-2016.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

PREVIOUS REMARKS OF EVALUATOR[1]

- The firm has clarified that at the time of application a tentative test method was submitted specifying the dissolution 75% in 45min, but during formulation development, lab scale and pilot scale batches were manufactured and the dissolution specifications now meet the USP criteria i.e. 75% in 30min and complies FDA's proposed specifications for this formulation and has submitted revised test methods and specifications.
- The firm also clarified that at the time of initial submission of dossier, a tentative formulation with powdered form of Velpatasvir was submitted in Master Formulation as well as in Method of Manufacturing, but during formulation development, lab scale and pilot scale batches were manufactured with Velpatasvir Co-Povidone

(1:1 dried dispersion form) and the same material will be used in commercial manufacturing. A copy of COA of Velpatasvir Co-Povidone (1:1 dried dispersion form) from M/s Reyphon China, along with revised Master Formulation and Method of Manufacturing has been submitted.

- The firm has provided 06 Months Accelerated and 06 Months Real Time Stability Data for 03 Pilot Scale Batches.

During the proceedings of the Registration Board a case of personal hearing of M/s AGP Limited, Karachi was discussed. The firms' representative apprised Registration Board that M/s Beijing Huikang Boyuan Chemical Tech Co. Ltd. (Supplier) is not a licensed pharmaceutical unit rather it is an R&D plant therefore they are unable to provide GMP certificate from concerned province / state drug administration.

Decision: Registration Board deferred the case for the following:

- Clarification of above since the API (Sofosbuvir) is of the same source (M/s Beijing Huikang Boyuan Chemical Tech Co. Ltd); while the firm has submitted GMP Certificate for Pharmaceutical Products issued by Liaoning Food and Drug Administration, China.
- Moreover the firm was directed to submit Legalized GMP Certificate for Pharmaceutical Products issued by Liaoning Food and Drug Administration, China.

Now the firm vide letters dated 20-11-2017 (Dy. No. 21537) and 19-12-2017 (Dy. No. 25206) has submitted the following clarification:

1. Company Profile of M/s Beijing Huikang stating that the headquarters and R&D Centre are located at Fengtai District of Beijing whereas the plant is based in Fluoride Industrial Park, Fuxin City, Liaoning Province.
2. Acknowledgement receipt from FDA of the following Drug Master File Submission:
   DMF Number Assigned:28919
   Date of Submission: December 24, 2014
   DMF Type: II
   Subject (Title): SOFOSBUVIR as manufactured in Beijing, China.
   Holder: Beijing Huikang Bouyuan Chemical Co., Ltd.
   Submitted By: Beijing Huikang Bouyuan Chemical Co., Ltd.
   Agent: None
   The status of DMF is marked "A".
   "A" = Active. This means that the DMF was found acceptable for filing, administratively, and has not been closed.
3. Drug Master File (Module 3, Applicant's Part) for Sofosbuvir depicting following information:
   Head Office: Beijing Huikang Bouyuan Chemical Co., Ltd. No.5 Haiying Road, Fengtai District, Beijing-100070, China.
   Manufacturing Site: Fuxin Long Rui Pharmaceutical Co., Ltd. Fluoride Industrial Park, Fuxin City, Liaoning Province, China.
   Note: Fuxin Long Rui Pharmaceutical Co., Ltd. and Beijing Huikang Bouyuan Chemical Co., Ltd. belongs to same owner.
   Batch Analyses: COAs of 03 consecutive batches illustrating the actual results that have been obtained from routine quality control by Beijing Huikang Bouyuan Chemical Co., Ltd. Add: No.7 Haiying Road, Science City, Fengtai District, Beijing, China.
4. Legalized photocopy of GMP Certificate for Pharmaceutical Products of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. issued by Fuxin Food and Drug Administration, China.

Proceedings: Mr. Mirza Danish Hussain Barlas (Manager Regulatory Affaiirs) appeared before the Board to present the case. Mr. Danish agreed to the statement of M/s AGP Limited, Karachi (as discussed in previous meeting) that M/s Bejing Huikang Boyuan Chemical Co., Ltd is an R&D unit and apprised the Board that since in 2014, China forbid any sort of manufacturing in Capital City (Beijing) therefore their principal manufacturer i.e. M/s Bejing Huikang Boyuan Chemical Co., Ltd, shifted their commercial manufacturing facility to Liaoning Province under the name of M/s Fuxin Long Rui Pharmaceutical Co., Ltd.

Mr. Danish hence requested the Board to consider the GMP certificate of M/s Fuxin Long Rui Pharmaceutical Co., Ltd. since their imported API i.e Sofosbuvir was manufactured by M/s Fuxin Long Rui Pharmaceutical Co., Ltd.

Upon inquiring Mr. Danish could not submit any legal document, issued by relevant authority confirming the

relationship between M/s Bejing Huikang Boyuan Chemical Co., Ltd & M/s Fuxin Long Rui Pharmaceutical Co., Ltd.

Decision of 277th meeting of Registration Board: Registration Board upon consideration of submission made by representative of firm decided to reject the case since the firm could not satisfy the Board regarding GMP status of their supplier of Sofosbuvir i.e. M/s Bejing Huikang Boyuan Chemical Co., Ltd.

Previous Decision: As per directions of Appellate Board, Registration Board decided to approve the product with as Innovator's specifications. Manufacturer will place first three production batches of the product on long term stability studies throughout proposed shelf life and on accelerated studies for six months **(M-288)**.

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: 25-06-2019 vide diary no. 9559

	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).	**Sofosbuvir:** Copy of ADC (Karachi) attested invoice is submitted dated 10-01-2016. **Velpatasvir Copovidone:** Copy of ADC (Karachi) attested commercial invoice is submitted dated 28-12-2016.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted CoAs of following working standards & impurity Standards : Sofosbuvir intermediate (CAS # 1334513-02-8) Sofosbuvir intermediate (CAS # 863329-66-2) Sofosbuvir working standard Impurity standards Velpatasvir impurity A
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Sofosbuvir :** M/s Beijing Huikang Boyuan Chemical Tech Co., Ltd. China: Copy of GMP Certificate for Pharmaceutical Products issued by Liaoning Food and Drug Administration, China is submitted. **Velpatasvir Copovidone:** M/s Xi'an Reyphon Pharmaceutical Co., Ltd. China: Copy of GMP Certificate for Pharmaceutical Products issued by Xi'an Food and Drug Administration, China is submitted.
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	**Sofosbuvir:** COA of Sofosbuvir (Batch # 130313) from Beijing Huikang Boyuan Chemical Tech Co., Ltd is submitted.

<table>
<tr><td></td><td></td><td>Velpatasvir Copovidone: COA of Velpatasvir Copovidone (Batch # 160502) from Reyphon Pharmaceutical, Shaanxi province, China</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of Sofosbuvir/Velpatasvir 400mg/100mg Tablet”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>P-1/SVL-400/100mg</td><td>2500 Tablets</td><td>20-01-2017</td></tr>
<tr><td>P-2/SVL-400/100mg</td><td>2500 Tablets</td><td>31-01-2017</td></tr>
<tr><td>P-3/SVL-400/100mg</td><td>2500 Tablets</td><td>31-01-2017</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>P-1/SVL-400/100mg</td><td>15 bottles</td><td>6 bottles</td><td>48 bottles + 1 loose</td></tr>
<tr><td>P-2/SVL-400/100mg</td><td>15 bottles</td><td>1 bottle</td><td>59 bottles + 1 loose</td></tr>
<tr><td>P-3/SVL-400/100mg</td><td>15 bottles</td><td>1 bottle</td><td>63 bottles + 1 loose</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 01-01-2017 to 30-07-2017.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Sofosbuvir and Velpatasvir-Co-povidone.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Sovel Tablet 400mg /100mg” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>Sofosbuvir: The firm has submitted photocopy of 06 months Accelerated and 24 months Long term Stability Study Data of 03 Batches from M/s Beijing Huikang Boyuan Chemical Tech Co., Ltd. China. The storage conditions under which long term stability studies were conducted are 25ºC±2ºC/60±5%RH.</td></tr>
</table>

		Velpatasvir copovidone: The firm has submitted photocopy of 06 months Accelerated and 6 months Long term Stability Study Data of 03 Batches from M/s Xi'an Reyphon Pharmaceutical Co., Ltd. China. The storage conditions under which long term stability studies were conducted are 25ºC±2ºC/60%±5%RH. Moreover, long term stability studies beyond 6 months are being collected.
16.	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has submitted we used all the ingredients same as used in innovator product Epclusa tablet 400mg/100mg.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution for "Sovel tablet & MyHep All Tablet" and concludes that both, reference product and test product shows more than 85% dissolution release within 15 minutes in three recommended mediums at 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 complete audit trail reports of Sovel 400mg/100mg Tablet.

The storage conditions under which stability studies of both APIs were conducted are 25ºC±2ºC/60%±5%RH.

Decision: Registration Board after thorough deliberation and considering the fact that the stability studies for the applied product were initiated in January 2017 while the inspection which confirms robust systems as defined in 278th meeting of Registration Board was carried out in March 2019. Since the firm does not possess robust systems during the period of stability studies, the Board decided to consider the case after onsite inspection by the panel for verification of authenticity of submitted stability data and associated documents, import of API, quality, specification, test analysis, facilities.

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
171.	M/s Helix Pharma (Pvt.) Ltd. A-56, S.I.T.E, Manghopir road, Karachi.	OMO / ASPER TABLETS 81mg/40mg Each Film coated delayed released tablet contains: Aspirin (Delayed-release) …….81 mg Omeprazole (Immediate release)……. 40 mg (PPI and analgesic) Firm has claimed Mfg. Specs. (Helix Pharma)	Form-5D Dy. No. 1576 4-05-2017 Rs. 50,000/- (Challan # 0587028) Pack Size: 10's , 20's & 30's (As per PRC)	YOSPRALA Tablets 81mg/40mg by Arelez Pharmaceuticals US Inc. Not applicable GMP compliant dated 24/09/2018

STABILITY STUDY DATA			
Drug	OMO / ASPER TABLETS 81mg/40mg (Aspirin + Omeprazole)		
Name of Manufacturer	Helix Pharma (Pvt.) Ltd., Karachi.		
Manufacturer of API	**Aspirin:** M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA.		
	Omeprazole: M/s Metrochem API Pvt. Ltd, INDIA.		
API Lot No.	**Aspirin:** CA1709001 **Omeprazole:** OMP/1709477		
Description of Pack (Container closure system)	Alu / Alu Blister Pack		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C & 75±5%RH Real Time : 30˚C ± 2˚C & 65±5%RH		
Time Period	Accelerated: 06 Months Real Time: 06 Months		
Frequency	Accelerated: 0, 3 ,6 (Months) Real Time : 0, 3 ,6 (Months)		
Batch No.	TF 001	TF 002	TF 003
Batch Size	500 Tablets	500 Tablets	500 Tablets
Manufacturing Date	01 - 2018	01 – 2018	01 – 2018
Date of Initiation	02-02-2018	02-02-2018	02-02-2018
No. of Batches	03		
Date of Submission	4212 (30/1/2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT		
Sr. No.	**Documents To Be Provided**	**Status**
1.	COA of API	Yes
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Aspirin:** Firm has submitted copy of GMP Certificate (#SN20150132) of manufacturer "JQC (Huayin) Pharmaceutical Co., Ltd. CHINA." issued by SFDA, China which is valid till 29/04/2020. **Omeprazole:** Firm has submitted copy GMP Certificate of manufacturer "Metrochem API Pvt Ltd, Plot No: 62/C/6, Pipeline road, Phase-I, IDA, Jeedimetla INDIA" issued by Drugs Control Administration, Government of Telangara , India.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	Copy of ADC (Karachi) attested invoice provided.

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

REMARKS OF EVALUATOR

- Dissolution is according to USFDA.

Now the firm has requested for Exemption from On-site Investigation of their submitted stability data vide Letter No. 1857 (R&I) dated 15-01-2018 and provided the following documents in conjunction with the checklist approved by the Registration Board in its 276th Meeting.

Data for exemption from On-site investigation of submitted stability data

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	• Registration Board approved RAMELTON Tablets 8mg (Ramelteon) in its 273rd Meeting. ○ Date of Inspection: 18-08-2017. ○ The HPLC is 21CFR Compliant. ○ Audit trail on the testing reports of ―Ramelton (Ramelteon) Tablets 8mg were available.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	**Aspirin:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 30-11-2017, Commercial Invoice attestation on dated 30/11/2017 for 0.8 Kg of Aspirin **Omeprazole:** The firm has submitted photocopies of ADC (Karachi) attested Form 6 dated 24-10-2017, Commercial Invoice attestation on dated 24/10/2017 for 2.0 Kg of Omeprazole.
3.	Documents for the procurement of reference standard and impurity standards.	• The firm has submitted analytical reports/COA of reference standard & impurity standards. Reference/Working standard: omeprazole and aspirin provided Impurity standard: omeprazole and aspirin provided • The firm has clarified that the reference standard and impurity standards are procured along with the APIs' consignment and not separately.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	**Aspirin:** Firm has submitted copy of GMP Certificate of manufacturer "JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA." issued by SFDA, China which is valid till 29/04/2020**.** **Omeprazole:** Firm has submitted copy GMP Certificate of manufacturer "M/s Metrochem API Pvt. Ltd, INDIA" issued by Drugs Control Administration, Government of Telangara, India valid till 2018.
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	• **ASPIRIN API:** Photocopy of COA of Batch No. CA1709001 issued by "M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA" is submitted. • **Reference standards and impurity standards:** The firm has submitted copy of Working Standards (Aspirin),

<table>
<tr><td></td><td></td><td>USP Reference Standard and impurity standards provided by the API Manufacturer - M/s JQC (Huayin) Pharmaceutical Co.,Ltd. CHINA.
• OMEPRAZOLE API:
Photocopy of COA of Batch No. OMP/1709477 issued by M/s Metrochem API Pvt. Ltd, INDIA is submitted.
• Reference standards and impurity standards:
The firm has submitted copy of Working Standards (Omeprazole),USP Reference Standard and impurity standards provided by the API Manufacturer - M/s Metrochem API Pvt. Ltd, INDIA along with procuring invoice of Reference standard & impurity standards.</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>Firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>Firm has submitted copy of R&D staff list</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted copy of generalized SOP with the title ‘Protocol For Development of New Product’.
Effective date 12-08-2017.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted copy of Trial batch manufacturing record. Details are as under:
<table>
<tr><th colspan="4">OMP TABLETS 81/40mg</th></tr>
<tr><th>Batch No.</th><th>Bach size</th><th>Mfg. Started</th><th>Mfg. Completed</th></tr>
<tr><td>TF001</td><td>500 Tabs</td><td>16-01-2018</td><td>16-01-2018</td></tr>
<tr><td>TF002</td><td>500 Tabs</td><td>17-01-2018</td><td>17-01-2018</td></tr>
<tr><td>TF003</td><td>500 Tabs</td><td>18-01-2018</td><td>18-01-2018</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>OMO Tablets 81/40mg ;
Stability Pack Size : 3 x 10’s

• TF001: Batch Size : 500 Tablets
Yield 492 Tablets (16 Packs) , 01 Pack used for testing method validation. 01 Pack used for Initial testing, 01 Pack used for Comparative Dissolution Profile. 13 (3x10’s) Packs placed on stability (Accelerated : 03 Packs , Real Time : 10 Packs) out of which 09 packs are remaining (Accelerated : 01 Pack , Real Time : 08 Packs).
• TF002: Batch Size : 500 Tablets
Yield 493 Tablets (16 Packs) , 01 Pack used for Initial testing. 15 (3x10’s) Packs placed on stability (Accelerated : 03 Packs , Real Time : 12 Packs) out of which 11 packs are remaining (Accelerated : 01 Pack , Real Time : 10 Packs).
• TF003: Batch Size : 500 Tablets
Yield 490 Tablets (16 Packs) , 01 Pack used for Initial testing. 15 (3x10’s) Packs placed on stability (Accelerated : 03 Packs , Real Time : 12 Packs) out of which 11 packs are remaining (Accelerated: 01 Pack , Real Time : 10 Packs).</td></tr>
<tr><td colspan="3">QA/QC DATA</td></tr>
</table>

<table>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>• Previously Reported in panel inspection:
The firm has installed software for recording the temperature/Humidity of the chamber (for real time stability software V5.7T Thermo, India & for Accelerated Stability studies, software is Logit Chrt; Technoman; Pakistan) & the data can been verified for 01 year.

Now the firm has submitted copy of record of digital data logger (Logit Chart, Technoman) for temperature and humidity monitoring of stability chambers.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>• The firm has submitted photocopy of method used for analysis of APIs (Aspirin) & Omeprazole) 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 OMO Tablets 81/40mg & OMO Tablets 325/40mg.
• Complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.) are submitted with 06 months stability data (Accelerated & Real Time).</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>ASPIRIN: The firm has submitted copy of accelerated, 06 Months (40°C ± 2°C & 75±5%RH) &long term, 48 Months (30°C ± 2°C & 65±5%RH) stability study reports of 03 batches of ASPIRIN from M/s JQC (Huayin) Pharmaceutical Co. Ltd. CHINA.

OMEPRAZOLE: The firm has submitted copy of accelerated, 06 Months (25°C ± 2°C & 60±5%RH) &long term, 60 Months (5°C ± 3°C) stability study reports of 03 batches of Omeprazole from M/s Metrochem API Pvt. Ltd, INDIA.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted copy of COAs for the excipients used in the applied formulation.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>• The firm has not submitted Drug-excipients compatibility studies and has referred to the Innovator Product (YOSPRALA).</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>• Firm has submitted Comparative dissolution study of their product (OMO Tablets all SKUs (81/40mg & 325/40mg) with Innovator’s Brand “YOSPRALS” conducted on following dates ;
• 81/40 mg : 29/11/2018 to 04/12/2018
• 325/40mg: 06/12/2018 to 12/12/2018
• The details are as follows:
<table>
<tr><th>Feature</th><th>Reference Product</th><th>Product of HELIX Pharma</th></tr>
<tr><td>Brand name</td><td>YOSPRALA Tablets 81mg/40mg</td><td>OMO Tablets 81/40mg</td></tr>
<tr><td>Batch No.</td><td>3146921</td><td>TF001</td></tr>
<tr><td>Mfg. date</td><td>Not mentioned Exp. 07-2019</td><td>01-2018</td></tr>
</table></td></tr>
</table>

		<table><tr><th>Feature</th><th>Reference Product</th><th>Product of HELIX Pharma</th></tr><tr><td>Brand name</td><td>YOSPRALA Tablets 325mg/40mg</td><td>OMO Tablets 325/40mg</td></tr><tr><td>Batch No.</td><td>3149884</td><td>TF001</td></tr><tr><td>Mfg. date</td><td>Not mentioned Exp. 06-2019</td><td>01-2018</td></tr></table> • Comparative dissolution studies have been performed in following media: **ASPIRIN :** i. 0.1N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. **OMEPRAZOLE :** i. 1.2N Hydrochloric Acid Solution ii. pH 4.5 Acetate buffer solution. iii. pH 6.8 phosphate buffer solution. • Copy of Calculation Sheets and HPLC chromatograms has been submitted for Comparative dissolution studies.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted copy of Audit Trail for Initial, 3rd and 6th Month Testing Intervals of OMO TABLETS 81/40mg & OMO TABLETS 325/40mg.

Evaluation by PEC:

Sr.#	Deficiency/Observation	Response by Pharma.
i.	Clarification regarding GMP certificate, as on GMP name of firm is JQC (Huayian) Pharmaceuticals but on china FDA site firm certified under the provided certificate number is Huayin Jinjincheng Pharmaceutical Co., Ltd. Is mentioned	Firm replied that the submitted GMP for manufacturer of Aspirin JQC (Huayian) Pharmaceuticals is the abbreviation of Huayin Jinjincheng Pharmaceutical Co., Ltd. Is mentioned on SFDA.
ii.	The GMP certificate of Metrochem API Pvt Ltd, India is not valid after 2-2018. Provide the valid GMP certificate	The GMP certificate of Metrochem API Pvt Ltd, India valid up to 11-1-2019. Is provided
iii.	Mechanism for Vendor pre-qualification and list of R&D staff not attached only annexure heading is attached	Provided
iv.	API stability of omeprazole at conditions of zone IV-A as provided stability is at Accelerated: 25°C ± 2°C & 60±5%RH and Real Time: 5°C ± 3°C.	The storage conditions of omeprazole is at cold conditions that's whyAPI stability of omeprazole was provided at Accelerated: 25°C ± 2°C & 60±5%RH and Real Time: 5°C ± 3°C.
v.	The innovators finished product release specifications tests for this dosage form including tests for content uniformity Justify the exemption of these tests as it is very important because omeprazole is being incorporated via coating solution.	As per USP monographs of uniformity of contents if the weight of the API is more than 25 mg then the content uniformity test is optional however as per your requirement they provides the content uniformity test of omeprazole on the base of weight variation.

vi.	Since API of omeprazole is being incorporated via coating solution so how it is possible to ensure that proper amount of active has been incorporated in dosage form while using 100% quantity in master formulation	Since API of omeprazole is being incorporated via coating solution to ensure proper amount of active has been incorporated in dosage using 50% overage that has already been submitted along with stability.

Previous Decision: Registration board decided to defer the case for submission of stability studies of three batches of API both accelerated & real time according to zone IV-A conditions **(M-289)**.

Evaluation by PEC: The firm has submitted 06 Month Stability data (Accelerated & Real Time) of both APIs according to climatic zone IV-A i.e ; for Omeprazole ; Accelerated: 25°C ± 2°C & 60±5%RH and Real Time: 5°C ± 3°C & for Aspirin ; Accelerated: 40°C ± 2°C / 75±5%RH and Real Time: 30°C ± 2°C /65%±5%RH.

Decision: Registration Board decided to approve registration of OMO / ASPER (Omeprazole/Aspirin) 81mg/40mg TABLETS by M/s. Helix Pharma (Pvt.) Ltd. A-56, S.I.T.E, Manghopir road, Karachi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

Sr. No.	Name & Address of Manufacturer / Applicant	Brand Name (Proprietary Name + Dosage Form + Strength), Composition, Pharmacological Group, Finished Product Specification	Type of Form, Initial Diary & Date, Fee (including differential fee), Demanded Price / Pack size	International Availability / Local Availability GMP Inspection Report Date Remarks
172.	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi	Tikanox-60 Tablets Each Film coated tablet contains: Ticagrelor…….60mg Platelet activation inhibitor Manufacturer's specifications	Form 5-D Dairy No.1984 dated 25-05-2016, Rs.50,000/-, 24-05-2016, Not mentioned	Brilinta Tablet of Astrazeneca Pharms **(USFDA approved)** **N/A** Last GMP inspection was conducted on 14-12-2017 The company is found complying CGMP as of today and panel unanimously agreed to issue CGMP certificate for export along with COPP, The management was advised to continue the process of up gradation.

STABILITY STUDY DATA

Drug	Tikanox-60 Tablets		
Name of Manufacturer	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi		
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd. Gujarat, India		
API Lot No.	82160137		
Description of Pack (Container closure system)	PVC Blister of 1×10's pack		
Stability Storage Condition	Accelerated: 40°C ± 2°C/75%±5% RH Real Time: 30°C ± 2°C/65%±5% RH		
Time Period	Accelerated: 0,1,2,3,4,6,8,12,16,20,24,26 weeks Real Time: 0,1,2,3,4,6,8,12,16,20,24,26 weeks		
Frequency	Accelerated: 26 (weeks) Real Time: 26 (weeks)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tablets	1000 tablets	1000 tablets

Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	28-07-2017	30-07-2017	30-07-2017
No. of Batches	03		
Date of Submission	1213 (10-01-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr.#	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# 82160137) from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the import of 600g of Ticagrelor (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 26 weeks Accelerated and 26 weeks Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 1213 vide diary no. 10-01-2019

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	The firm has submitted reference of already approved product in 285th meeting the decision as: Registration Board decided to approve registration of Vebuvir Tablets 400 mg (Sofosbuvir) of M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 km, Adyala road, post office Dahgal, Rawalpindi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months. **Date of inspection**: 8th August, 2018 The HPLC software of the firm is 21 CRF compliant.

<table>
<tr><td></td><td></td><td>The firm has provided USB data loggers, which are set for recording temperature and humidity after each hour.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of commercial invoice for the import of 600g of Ticagrelor (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of commercial invoice for the procurement of working standards.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Mechanism for Vendor pre-qualification.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA (Batch# 82160137) from M/s. Glenmark Pharmaceuticals Ltd. Gujarat, India is submitted.
• Copy of COA of working standards have been submitted
• COAs of impurity standards have been submitted.
Impurity A
Impurity B
Impurity C</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of “Excel Tablets 40mg”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>T-001</td><td>1000 Tablets</td><td>07-2017</td></tr>
<tr><td>T-002</td><td>1000 Tablets</td><td>07-2017</td></tr>
<tr><td>T-003</td><td>1000 Tablets</td><td>07-2017</td></tr>
</table></td></tr>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>T-001</td><td>866</td><td rowspan="3">634</td><td>232</td></tr>
<tr><td>T-002</td><td>881</td><td>247</td></tr>
<tr><td>T-003</td><td>871</td><td>237</td></tr>
</table></td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 18-07-2017 to 06-02-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along</td></tr>
</table>

		with COA for Ticagrelor.
14.	Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)	The firm has submitted photocopy of Finished Product Testing Procedure for "Tikanox-60 Tablets" along with Stability Study Reports.
15.	Reports of stability studies of API from manufacturer.	The firm has submitted photocopy of 06 Months Accelerated (40°C±2°C/75%±5%RH) and 36 Months Real Time (25°C±2°C/60%±5%RH) Stability Study Data of 03 Batches for Ticagrelor from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India
16.	Analysis reports for excipients used.	The firm has submitted photocopy of Analytical reports of excipients used.
17.	Drug-excipients compatibility studies.	The firm has submitted that ingredients of Tikanox-60 Tablets and Brilinta 60mg Tablet (innovator brand) are same.
18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies with Brilinta 60mg Tablets manufactured by M/s. Astrazeneca Pharms, USA (Batch#JP0010, EXP 02/20). The firm's product (Tikanox-60 Tablets) results are comparable with BRILINTA 60mg Tablets.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Tikanox-60 Tablets from 11-08-2017 to 26-01-2018.

The storage conditions under which real time stability studies of API were conducted are not as per Zone IVA. The firm has not performed comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8.

Previous Decision: Registration Board deferred the case for submission of stability data of API from supplier conducted at Zone IV-A conditions and submission of comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8 **(M-288)**.

Evaluation by PEC:

The firm has submitted long term stability data of three batches of API conducted at Zone IV-A.

The firm has performed comparative dissolution studies conducted at pH 1.2, pH 4.5, pH 6.8 with Brilinta 60mg Tablets manufactured by M/s. Astrazeneca Pharms, USA ((Batch#JP0010, EXP 02/20). The firm's product (Tikanox-60 Tablets) results are comparable with BRILINTA 90mg Tablets.

Previous Decision: Registration Board deferred the case for confirmation of polymorphic form of API Ticagrelor **(M-289).**

Evaluation by PEC:

The firm has submitted that for conducting trials of TIKANOX 30mg & TIKANOX 60mg Tablets, polymorphic form II of Ticagrelor was used, detail of which is supplied by API manufacturer **"Glenmark Life Sciences"**.

Moreover, the API manufacturer has made declaration that Glenmark consistently manufactures Ticagrelor Form II which is characterized by the 2θ values at 5.5, 6.8, 10.6, 13.5, 14.9, 18.3 and 24.3 ±0.2°.

Decision: Registration Board decided to approve registration of TIKANOX (Ticagrelor) 30mg TABLETS by M/s. Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

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
173.	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi	Tikanox-90 Tablets Each Film coated tablet contains: Ticagrelor…...90mg Platelet activation inhibitor Manufacturer's specifications	Form 5-D Dairy No.1985 dated 25-05-2016, Rs.50,000/-, 24-05-2016, Not mentioned	Brilinta Tablet of Astrazeneca Pharms **(USFDA approved)** **N/A** Last GMP inspection was conducted on 14-12-2017 The company is found complying CGMP as of today and panel unanimously agreed to issue CGMP certificate for export along with COPP, The management was advised to continue the process of up gradation.

STABILITY STUDY DATA

Drug	Tikanox-90 Tablets		
Name of Manufacturer	M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi		
Manufacturer of API	M/s Glenmark Pharmaceuticals Ltd. Gujarat, India		
API Lot No.	82160137		
Description of Pack (Container closure system)	PVC Blister of 1×10's pack		
Stability Storage Condition	**Accelerated:** 40˚C ± 2˚C/75%±5% RH **Real Time:** 30˚C ± 2˚C/65%±5% RH		
Time Period	Accelerated: 0,1,2,3,4,6,8,12,16,20,24,26 weeks Real Time: 0,1,2,3,4,6,8,12,16,20,24,26 weeks		
Frequency	Accelerated: 26 (weeks) Real Time: 26 (weeks)		
Batch No.	T-001	T-002	T-003
Batch Size	1000 tablets	1000 tablets	1000 tablets
Manufacturing Date	07-2017	07-2017	07-2017
Date of Initiation	23-07-2017	24-07-2017	25-07-2017
No. of Batches	03		
Date of Submission	121 (10-01-2019)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# 82160137) from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019.

3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the import of 600g of Ticagrelor (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

- The firm has submitted 26 weeks Accelerated and 26 weeks Real Time Stability Data for 03 Batches.

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

The firm has requested for Exemption from On-site Investigation of their submitted stability data and provided the following documents in conjunction with the checklist approved by the Registration Board in its 278th Meeting:
Date of submission: 1213 vide diary no. 10-01-2019

Administrative Portion

1.	Reference of last onsite panel inspection for instant dosage form conducted during last two years.	The firm has submitted reference of already approved product in 285th meeting the decision as: Registration Board decided to approve registration of Vebuvir Tablets 400 mg (Sofosbuvir) of M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14 km, Adyala road, post office Dahgal, Rawalpindi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months. **Date of inspection**: 8th August, 2018 The HPLC software of the firm is 21 CRF compliant. The firm has provided USB data loggers, which are set for recording temperature and humidity after each hour.
2.	Documents for the procurement of API with approval from DRAP (in case of import).	The firm has submitted copy of commercial invoice for the import of 600g of Ticagrelor (Invoice#2007000394) attested by ADC DRAP, Islamabad dated 08-09-2016.
3.	Documents for the procurement of reference standard and impurity standards.	The firm has submitted copy of commercial invoice for the procurement of working standards.
4.	Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Food and Drugs Administration, Maharashtra State, India (Certificate No 6081505) has been submitted. It is valid until 03-05-2019.
5.	Mechanism for Vendor pre-qualification	The firm has submitted Mechanism for Vendor pre-qualification.
6.	Certificate of analysis of the API, reference standards and impurity standards	• Copy of COA (Batch# 82160137) from M/s. Glenmark Pharmaceuticals Ltd. Gujarat, India is submitted.

<table>
<tr><td></td><td></td><td>• Copy of COA of working standards have been submitted
• COAs of impurity standards have been submitted.
Impurity A
Impurity B
Impurity C</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
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<tr><td colspan="3">Production Data</td></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of “Tikanox-90 Tablets”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
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<tr><td>T-002</td><td>878</td><td>244</td></tr>
<tr><td>T-003</td><td>870</td><td>236</td></tr>
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<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 18-07-2017 to 06-02-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COA for Ticagrelor.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for “Tikanox-90 Tablets” along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated (40ºC±2ºC/75%±5%RH) and 36 Months Real Time (25ºC±2ºC/60%±5%RH) Stability Study Data of 03 Batches for Ticagrelor from M/s Glenmark Pharmaceuticals Ltd. Gujarat, India</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that ingredients of Tikanox-90 Tablets and Brilinta 90mg Tablet (innovator brand) are same.</td></tr>
</table>

18.	Record of comparative dissolution data.	The firm has performed comparative dissolution studies with Brilinta 90mg Tablets manufactured by M/s. Astrazeneca Pharms, USA (Batch#JP0010, EXP 02/20). The firm's product (Tikanox-90 Tablets) results are comparable with BRILINTA 90mg Tablets.
19.	Compliance Record of HPLC software 21CFR & audit trail reports on product testing.	The firm has submitted audit trail reports of Tikanox-60 Tablets from 11-08-2017 to 26-01-2018.

The storage conditions under which real time stability studies of API were conducted are not as per Zone IVA. The firm has not performed comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8.

Previous Decision: Registration Board deferred the case for submission of stability data of API from supplier conducted at Zone IV-A conditions and submission of comparative dissolution profiling at pH 1.2, pH 4.5 and pH 6.8 **(M-288)**.

Evaluation by PEC:

The firm has submitted long term stability data of three batches of API conducted at Zone IV-A.

The firm has performed comparative dissolution studies conducted at pH 1.2, pH 4.5, pH 6.8 with Brilinta 90mg Tablets manufactured by M/s. Astrazeneca Pharms, USA ((Batch#JP0010, EXP 02/20). The firm's product (Tikanox-90 Tablets) results are comparable with BRILINTA 90mg Tablets.

Previous Decision: Registration Board deferred the case for confirmation of polymorphic form of API Ticagrelor **(M-289).**

Evaluation by PEC:

The firm has submitted that for conducting trials of TIKANOX 30mg & TIKANOX 60mg Tablets, polymorphic form II of Ticagrelor was used, detail of which is supplied by API manufacturer **"Glenmark Life Sciences"**.

Moreover, the API manufacturer has made declaration that Glenmark consistently manufactures Ticagrelor Form II which is characterized by the 2θ values at 5.5, 6.8, 10.6, 13.5, 14.9, 18.3 and 24.3 ±0.2°.

Decision: Registration Board decided to approve registration of TIKANOX (Ticagrelor) 60mg TABLETS by M/s Shaigan Pharmaceuticals, 14-Km, Adyala Road, Post Office Dahgal, Rawalpindi. Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.

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
174.	M/s Wilson's Pharmaceuticals , I-9, Industrial Area, Islamabad	Excel Tablets 40mg Each uncoated tablet contains: Azilsartan Medoxomil (as Potassium)…...40mg Anti-hypertensive Manufacturer's specifications	Form 5-D Dairy No. Nil dated 18-03-2011, Rs.15,000/-, 18-03-2011, 35,000/- 29-10-2018, 10's, 20's, 30's & 60's: 28.0 / Tablet	Edarbi Tablet of Takeda Pharma **(USFDA approved)** **N/A** Last GMP inspection conducted on 24-01-2018 concluding good level of cGMP compliance at the time of inspection.

STABILITY STUDY DATA

Drug	Excel Tablets 40mg
Name of Manufacturer	M/s Wilson's Pharmaceuticals, I-9, Industrial Area, Islamabad
Manufacturer of API	M/s Ami Lifesciences Pvt. Ltd, Gujarat , India
API Lot No.	AZP/50310517

Description of Pack (Container closure system)	Alu Alu Blister pack		
Stability Storage Condition	Accelerated: 40˚C ± 2˚C/75%±5% RH Real Time: 30˚C ± 2˚C/65%±5% RH		
Time Period	Accelerated: 0,1,2,3,4,6 months Real Time: 0, 3, 6 months		
Frequency	Accelerated: 06 (months) Real Time: 06 (months)		
Batch No.	Trial # 01	Trial # 02	Trial # 03
Batch Size	1500 tablets	1500 tablets	1500 tablets
Manufacturing Date	12-2017	12-2017	12-2017
Date of Initiation	December, 2017	December, 2017	December, 2017
No. of Batches	03		
Date of Submission	35870 (29-10-2018)		

DOCUMENTS / DATA PROVIDED BY THE APPLICANT

Sr. No.	Documents To Be Provided	Status
1.	COA of API.	Copy of COA (Batch# AZP/50310517) from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India is submitted.
2.	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	Copy of GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India has been submitted. It is valid until 26-04-2019.
3.	Protocols followed for conduction of stability study and details of tests.	Yes
4.	Data of 03 batches will be supported by attested respective documents like chromatograms, laboratory reports, data sheets etc.	Yes
5.	Documents confirming import of API etc.	The firm has submitted copy of commercial invoice for the import of 960.30g of Azilsartan Medoxomil potassium salt (Invoice#EXP/A/138/2017-18) attested by ADC DRAP, Islamabad dated 16-08-2017.
6.	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
7.	Commitment to continue real time stability study till assigned shelf life of the product.	Yes
8.	Commitment to follow Drug Specification Rules, 1978.	Yes

REMARKS OF EVALUATOR

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

REQUEST OF EXEMPTION FROM ON SITE INSPECTION

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

Date of submission: 39582 vide diary no. 03-12-2018

<table>
<tr><th colspan="3">Administrative Portion</th></tr>
<tr><td>1.</td><td>Reference of last onsite panel inspection for instant dosage form conducted during last two years.</td><td>Firm has referred to onsite inspection 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 throughout proposed shelf life and on accelerated studies for six months.</td></tr>
<tr><td>2.</td><td>Documents for the procurement of API with approval from DRAP (in case of import).</td><td>The firm has submitted copy of commercial invoice for the import of 960.30g of Azilsartan Medoxomil potassium salt (Invoice#EXP/A/138/2017-18) attested by ADC DRAP, Islamabad dated 16-08-2017.</td></tr>
<tr><td>3.</td><td>Documents for the procurement of reference standard and impurity standards.</td><td>The firm has submitted copy of commercial invoice for the procurement of working standards and impurity standards.</td></tr>
<tr><td>4.</td><td>Approval of API/ DML/GMP certificate of API manufacturer issued by regulatory authority of country of origin.</td><td>Copy of GMP certificate issued by Food and Drugs Control Administration, Gujarat State, India has been submitted. It is valid until 26-04-2019.</td></tr>
<tr><td>5.</td><td>Mechanism for Vendor pre-qualification</td><td>The firm has submitted Mechanism for Vendor pre-qualification.</td></tr>
<tr><td>6.</td><td>Certificate of analysis of the API, reference standards and impurity standards</td><td>• Copy of COA (Batch# AZP/50310517) from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India is submitted.
• Copy of COA of working standards have been submitted
• COAs of impurity standards have been submitted.
Impurity A
Impurity B
Impurity C</td></tr>
<tr><td>7.</td><td>Documents for the procurement of excipients used in product development?</td><td>The firm has submitted photocopy of Commercial invoices/COAs of the excipients used in the formulation of applied product</td></tr>
<tr><td>8.</td><td>List of qualified staff involved in product development with relevant experience.</td><td>The firm has submitted List of qualified staff involved in product development department.</td></tr>
<tr><th colspan="3">Production Data</th></tr>
<tr><td>9.</td><td>Authorized Protocols/SOP for the development & stability testing of trial batches.</td><td>The firm has submitted photocopy of “Protocols/SOP for the Development of “Excel Tablets 40mg”.</td></tr>
<tr><td>10.</td><td>Complete batch manufacturing record of three stability batches.</td><td>The firm has submitted photocopy of Batch Manufacturing Records of following 03 Batches:
<table>
<tr><th>Batch No.</th><th>Batch Size</th><th>Mfg. Date</th></tr>
<tr><td>Trial # 01</td><td>1500 Tablets</td><td>12-2017</td></tr>
<tr><td>Trial # 02</td><td>1500 Tablets</td><td>12-2017</td></tr>
<tr><td>Trial # 03</td><td>1500 Tablets</td><td>12-2017</td></tr>
</table></td></tr>
</table>

<table>
<tr><td>11.</td><td>Record of remaining quantities of stability batches.</td><td>
<table>
<tr><th>Trial No</th><th>Total no. of Tablets For stability testing</th><th>Tablets used for testing</th><th>Remaining Quantities of tablets</th></tr>
<tr><td>Trial # 01</td><td>570 Tabs (3×10's, 19 Packs)</td><td>256</td><td>314</td></tr>
<tr><td>Trial # 02</td><td>570 Tabs (3×10's, 19 Packs)</td><td>256</td><td>314</td></tr>
<tr><td>Trial # 03</td><td>570 Tabs (3×10's, 19 Packs)</td><td>256</td><td>314</td></tr>
</table>
</td></tr>
<tr><td colspan="3">QA / QC DATA</td></tr>
<tr><td>12.</td><td>Record of Digital data logger for temperature and humidity monitoring of stability chambers (real time and accelerated)</td><td>Firm has submitted photocopies of digital data logger record for Accelerated stability chamber and Real Time stability chamber starting from 11-11-2017 to 01-06-2018.</td></tr>
<tr><td>13.</td><td>Method used for analysis of API along with COA.</td><td>The firm has submitted photocopy of Raw Material Specifications, Raw Material Testing Procedures along with COAs for Azilsartan Medoxomil Potassium Salt.</td></tr>
<tr><td>14.</td><td>Method used for analysis of FPP & complete record of testing of stability batches (i.e. chromatograms, lab reports, raw data sheets etc.)</td><td>The firm has submitted photocopy of Finished Product Testing Procedure for "Excel Tablets 40mg" along with Stability Study Reports.</td></tr>
<tr><td>15.</td><td>Reports of stability studies of API from manufacturer.</td><td>The firm has submitted photocopy of 06 Months Accelerated (5ºC±3ºC) and 24 Months Real Time 25ºC±2ºC/60%±5%RH Stability Study Data of 03 Batches for Azilsartan Medoxomil potassium salt from M/s Ami Lifesciences Pvt. Ltd, Gujarat, India.</td></tr>
<tr><td>16.</td><td>Analysis reports for excipients used.</td><td>The firm has submitted photocopy of Analytical reports of excipients used.</td></tr>
<tr><td>17.</td><td>Drug-excipients compatibility studies.</td><td>The firm has submitted that ingredients of Excel Tablets 40mg and Edarbi Tablets (innovator brand) are same.</td></tr>
<tr><td>18.</td><td>Record of comparative dissolution data.</td><td>The firm has performed comparative dissolution studies in three media including pH 1.2, pH 4.5 and pH 6.8 and pH 7.8 buffers with Edarbi Tablets 40mg manufactured by M/s. Takeda, Osaka, Japan with Batch # EB-TL40-04. The firm's product (Excel Tablets 40mg) results are comparable with Edarbi Tablets 40mg.</td></tr>
<tr><td>19.</td><td>Compliance Record of HPLC software 21CFR & audit trail reports on product testing.</td><td>The firm has submitted audit trail reports of Excel tablet 40mg from 14-12-2017 to 21-06-2018.</td></tr>
<tr><td colspan="3">Previous Decision: Registration Board deferred the case for submission of stability data of API conducted at Zone IV-A (M-288).
The firm has submitted that As per ICH Guidelines for refrigerated API storage, temperature and relative humidity conditions are same for all climatic zones i.e., for long term 5ºC ±3 ºC and for accelerated 25 ºC± 5 ºC/60% ±5%RH.
Decision: Registration Board decided to approve registration of Excel (Azilsartan Medoxomil Potassium) Tablets 40 mg by M/s Wilson's pharmaceuticals, 387-388, Industrial Area, Islamabad. . Manufacturer will place first three production batches of both products on long term stability studies throughout proposed shelf life and on accelerated studies for six months.</td></tr>
</table>

175.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.	
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.	
	Status of the applicant	□ **Manufacturer** □ Importer □ Is involved in none of the above (contract giver)	
	Dy No. and date of submission	Dy No. 13406, : 5-12-2018	
	Details of fee submitted	PKR 20,000/-: 3-12-2018	
	The proposed proprietary name / brand name	**Dexlan DR Capsule 60mg**	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as Delayed release pellets)…….60mg	
	Dosage form of applied drug	Capsule	
	Route of administration	Oral	
	Pharmacotherapeutic Group of (API)	Antacids/ Antiflatulents/Antipeptic ulcerant	
	Pharmacopoeial reference	Firm has submitted:- "Innovators Specifications"	
	Proposed Pack size	10's, 14's, 20's, 28's and 30's	
	Proposed unit price	As per Innovator's Price	
	The status in reference regulatory authorities	USFDA Approved	
	For generic drugs (me-too status)		
	Valid drug manufacturing license/Drug Sale License	Copy of Drug manufacturing License by way of formulation issued on 21-7-2015 is submitted.	
	Evidence of approval of manufacturing facility / approved section from licensing authority	Copy of grant of Additional section (Capsule General section Revised) from CLB is submitted	
	Type of Application	□ New Drug Product (NDP) □ **Generic Drug Product (GDP)**	
	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	**Domestic Manufacturing**	
	List of registered products	NA	
	Manufacturer's site master file and credentials (for importers)	Yes	
	Identification of signature of authorized persons , Incharge Production, Quality Control & Quality Assurance of manufacturer.		Yes
	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens		Yes
	Description of Batch numbering system		Yes
	Training evidence of technical staff with respect of manufacturing of applied drug		Not Applicable

	(mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).	
	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	N/A
	Electronic Review Package	N/A
	QIS (Quality Information Summary)	Yes

	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd. Plot No. 22, Industrial Triangle Kahuta road, Islamabad
	b. Approval of manufacturing facility of API by regulatory body of country and validity.	Copy of Drug manufacturing License by way of Semi-basic issued on 2-12-2014 is submitted.
	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, specification, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, manufacturing process development, container closure system, microbiological attributes and compatibility, controls of drug product, reference standards or materials and stability studies.

	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	Exempted
	Manufacture	Exempted
	Characterization	Exempted
	Control of drug substance	Exempted
	Reference standards or materials	Exempted
	Container closure system	Exempted
	Stability	Exempted
	3.2.P: Drug Product	
	Description and composition	Firm has submitted description and composition of drug product

of drug product		
Pharmaceutical development	Firm has provided details of drug substance, excipients, formulation development, overages, physicochemical and biological properties, manufacturing process development, container closure system, microbiological attributes and compatibility.	
Manufacture	Firm has submitted detail of manufacturer, batch formula, description of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.	
Control of excipients	N/A	
Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.	
Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards	
Container closure system	HDPE bottle with dessicant	
Stability	Firm has provided complete stability study data of 3 batches as per Zone IV-B	
Comparative dissolution profile		
MODULE 4: NON-CLINICAL / SAFETY		
Pharmacology	Firm has submitted that being a generic product non-clinical data is not Applicable	
Pharmacokinetics	Firm has submitted that being a generic product non-clinical data is not Applicable	
Toxicology	Firm has submitted that being a generic product non-clinical data is not Applicable	
MODULE 5: CLINICAL / EFFICACY		
Firm has submitted that being a generic product clinical data is not Applicable while in-vitro dissolution tests complementary to bioequivalence studies.		
STABILITY STUDY DATA		
Manufacturer of API	M/s Vision Pharmaceuticals Pvt Ltd. Plot No. 22, Industrial Triangle Kahuta road, Islamabad Firm is obtaining API pellets from the above Manufacturer.	
API Lot No.	Batch NO. DLP287	
Description of Pack (Container closure system)	Alu-Alu blister pack	
Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH	
Time Period	Real time: 6 months Accelerated: 6 months	
Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6(Months)	
Batch No.	DXB T1/18	DXB T2/18	DXB T3/18
Batch Size	1500 capsules	1500 capsules	1500 capsules
Manufacturing Date	July-2018	July-2018	July-2018
Date of Initiation	July-2018	July-2018	July-2018
No. of Batches	03		
DOCUMENTS / DATA PROVIDED BY THE APPLICANT			

	Documents To Be Provided	Status
	COA of API	Yes
	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	cGMP certificate is valid until 25-1-2019.
	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.	Yes
	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
	REMARKS OF EVALUATOR	

Dexlan DR Capsule 60mg

S.No	Shortcoming/Letter communicated to firm	Firm Reply / Evaluation of the firm's reply
1.	1. Ref to your response (Annexure-IV). Process validation data is not provided. Summary of validation studies including the proposed protocol that will be used for the validation of three commercial batches is not provided.	Firm has submitted, "Process validation will be performed of 3 stability batches and it shall be submitted to drap. However, Process validation protocol is submitted."
	2. Ref to your response (Annexure-X). The submitted justification for specification is not considered satisfactory. All specifications are developed as per In-house standards and the same is mentioned in justification. Kindly justify the specification with the scientific rationale.	Firm has only provided the use of the test parameter and not the justification.
	3. Ref to your response (Annexure-XV). Your response is considered not satisfactory. You have to perform comparative dissolution profile of your drug product against the innovators product in three dissolution mediums i.e. pH1.2, 4.5 and 6.8 as per dissolution parameters defined in FDA dissolution database. Results of dissolution should be presented after calculation of similarity factor f2.	Firm has performed CDP only on pH 7.0

176.	Name, address of Applicant / Marketing Authorization Holder	M/s CCL Pharmaceuticals Pvt Ltd. 65-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Name, address of Manufacturing site.	M/s CCL Pharmaceuticals Pvt Ltd. 62-Industrial Estate, Kot Lakhpat, Lahore-54770, Pakistan.
	Status of the applicant	□ **Manufacturer** □ Importer □ Is involved in none of the above (contract giver)
	Dy No. and date of submission	Dy No. 13405, : 5-12-2018
	Details of fee submitted	PKR 20,000/-: 3-12-2018

	The proposed proprietary name / brand name	Dexlan DR Capsule 30mg	
	Strength / concentration of drug of Active Pharmaceutical ingredient (API) per unit	Each capsule contains: Dexlansoprazole (as Delayed release pellets)…….30mg	
	Dosage form of applied drug	Capsule	
	Route of administration	Oral	
	Pharmacotherapeutic Group of (API)	Antacids/ Antiflatulents/Antipeptic ulcerant	
	Pharmacopoeial reference	Firm has submitted:- "Innovators Specifications"	
	Proposed Pack size	10's, 14's, 20's, 28's and 30's	
	Proposed unit price	As per Innovator's Price	
	The status in reference regulatory authorities	USFDA Approved	
	For generic drugs (me-too status)		
	Valid drug manufacturing license/Drug Sale License	Copy of Drug manufacturing License by way of formulation issued on 21-7-2015 is submitted.	
	Evidence of approval of manufacturing facility / approved section from licensing authority	Copy of grant of Additional section (Capsule General section Revised) from CLB is submitted	
	Type of Application	□ New Drug Product (NDP) □ Generic Drug Product (GDP)	
	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	Domestic Manufacturing	
	List of registered products	NA	
	Manufacturer's site master file and credentials (for importers)	Yes	
	Identification of signature of authorized persons , Incharge Production, Quality Control & Quality Assurance of manufacturer.		Yes
	Proposed label (outer (secondary) & inner (primary)) & colour scheme in accordance with Drug (Labelling & Packing) Rules, 1986 along with specimens		Yes
	Description of Batch numbering system		Yes
	Training evidence of technical staff with respect of manufacturing of applied drug (mandatory in case of specially designed pharmaceutical product / Novel Dosage Form).		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	N/A
	Electronic Review Package	N/A
	QIS (Quality Information Summary)	Yes
	Drug Substance related Document including following:	
	a. Name and address of API manufacturer.	M/s Vision Pharmaceuticals Pvt Ltd. Plot No. 22, Industrial Triangle Kahuta road, Islamabad
	b. Approval of manufacturing facility of API by regulatory body of country and validity.	Copy of Drug manufacturing License by way of Semi-basic issued on 2-12-2014 is submitted.
	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, specification, and characterization, control of the API, reference standard, container closure system and stability.
	Drug Product	Firm has submitted summary of drug product including description and composition of drug product, pharmaceutical development, manufacture, control of excipients, manufacturing process development, container closure system, microbiological attributes and compatibility, controls of drug product, reference standards or materials and stability studies.
	MODULE 3: QULITY / CMC	
	3.2.S: Drug substance	
	General Information	Exempted
	Manufacture	Exempted
	Characterization	Exempted
	Control of drug substance	Exempted
	Reference standards or materials	Exempted
	Container closure system	Exempted
	Stability	Exempted
	3.2.P: Drug Product	
	Description and composition of drug product	Firm has submitted description and composition of drug product
	Pharmaceutical development	Firm has provided details of drug substance, excipients, formulation development, overages, physicochemical and biological properties, manufacturing process development, container closure system, microbiological attributes and compatibility.
	Manufacture	Firm has submitted detail of manufacturer, batch formula, description

		of manufacturing process and process controls, controls of critical steps and intermediates, process validation and or evaluation.		
	Control of excipients	N/A		
	Control of drug product	Firm has submitted details of specification, analytical procedures, validation of analytical procedures, batch analysis, and characterization of impurities and justification of specification.		
	Reference standard or materials	Firm has submitted certificate of analysis of reference standards and impurity standards		
	Container closure system	HDPE bottle with dessicant		
	Stability	Firm has provided completed stability study data of 3 batches as per Zone IV-B		
	Comparative dissolution profile			
	MODULE 4: NON-CLINICAL / SAFETY			
	Pharmacology	Firm has submitted that being a generic product non-clinical data is not Applicable		
	Pharmacokinetics	Firm has submitted that being a generic product non-clinical data is not Applicable		
	Toxicology	Firm has submitted that being a generic product non-clinical data is not Applicable		
	MODULE 5: CLINICAL / EFFICACY			
	Firm has submitted that being a generic product clinical data is not Applicable while in-vitro dissolution tests complementary to bioequivalence studies.			
	STABILITY STUDY DATA			
	Manufacturer of API	M/s Vision Pharmaceuticals Pvt Ltd. Plot No. 22, Industrial Triangle Kahuta road, Islamabad Firm is obtaining API pellets from the above Manufacturer.		
	API Lot No.	Batch NO. DLP287		
	Description of Pack (Container closure system)	Alu-Alu blister pack		
	Stability Storage Condition	Real time : 30˚C ± 2˚C / 75% ± 5%RH Accelerated: 40˚C ± 2˚C / 75% ± 5%RH		
	Time Period	Real time: 6 months Accelerated: 6 months		
	Frequency	Accelerated: 0, 3,6 (Months) Real Time: 0, 3,6(Months)		
	Batch No.	DXB T1/18	DXB T2/18	DXB T3/18
	Batch Size	1500 capsules	1500 capsules	1500 capsules
	Manufacturing Date	July-2018	July-2018	July-2018
	Date of Initiation	July-2018	July-2018	July-2018
	No. of Batches	03		
	DOCUMENTS / DATA PROVIDED BY THE APPLICANT			
	Documents To Be Provided		**Status**	
	COA of API		Yes	

	Approval of API by regulatory authority of country of origin or GMP certificate of API manufacturer issued by regulatory authority of country of origin.	cGMP certificate is valid until 25-1-2019.
	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.	Yes
	All provided documents will be attested (name, sign and stamp) for ensuring authenticity of data / documents.	Yes
	REMARKS OF EVALUATOR	

Dexlan DR Capsule 30mg

S.No	Shortcoming/Letter communicated to firm	Firm Reply / Evaluation of the firm's reply
2.	4. Ref to your response (Annexure-IV). Process validation data is not provided. Summary of validation studies including the proposed protocol that will be used for the validation of three commercial batches is not provided.	Firm has submitted, "Process validation will be performed of 3 stability batches and it shall be submitted to drap. However, Process validation protocol is submitted."
	5. Ref to your response (Annexure-X). The submitted justification for specification is not considered satisfactory. All specifications are developed as per In-house standards and the same is mentioned in justification. Kindly justify the specification with the scientific rationale.	Firm has only provided the use of the test parameter and not the justification.
	6. Ref to your response (Annexure-XV). Your response is considered not satisfactory. You have to perform comparative dissolution profile of your drug product against the innovators product in three dissolution mediums i.e. pH1.2, 4.5 and 6.8 as per dissolution parameters defined in FDA dissolution database. Results of dissolution should be presented after calculation of similarity factor f2.	Firm has performed CDP only on pH 7.0

Inspection Report

PART-I:

1.3 General Information.

Name of Manufacturer	M/s CCL Pharmaceuticals (Pvt.) Ltd.
Physical Address	62 Industrial Estate, Kot Lakhpat, Lahore.
Drug Manufacturing License No. and validity	000052 by way of formulation Valid till 20-07-2020.
Contact Address	Mr. Irfan Sohail Senior Manager Regulatory Affairs 0308-8884984
Date of Inspection.	26-08-2019
Purpose of Inspection	Verification of authenticity of stability data for purpose of

	registration of drugs with reference to DRAP's letter No. F.13-11/2017-PEC (Pt) dated 30-07-2019.
Name of Inspector	01. Mr. Shaheen Iqbal Director, DTL, Lahore. 02. Ms. Aisha Irfan Area FID, DRAP, Lahore. 03. Mr. Hafiz Ahsan Assistant Director, PEC (DRAP) Islamabad.
Name of firm Representatives	• Dr. Rizwan Mahmood Director Quality Operations • Mr. Kamran Atif Director Regulatory Affairs • Mr. Irfan Sohail Senior Manager Regulatory Affairs • Mr. Shahid Anwar General Manager R&D • Mr. Muhammad Fiaz Quality Control Manager • Mr. Farhan Qureshi Quality Assurance Manager

General Information about unit:

The firm is located in the industrial area at 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan. The firm was established in 1965 initially and shifted to the existing site in 1984. The firm has production facility, supply chain, engineering, quality control, quality assurance, research & development, regulatory and administrative departments. The production operations at firm involve manufacturing, packaging and distribution of finished pharmaceutical products. The firm is manufacturing generic products.

1.4 Focus of Inspection:

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

Sr. No.	Name / Composition of Drugs
01	Dexlan DR Capsule 30mg Each capsule contains: Dexlansoprazole (as Delayed release pellets)…….30mg
02	Dexlan DR Capsule 60mg Each capsule contains: Dexlansoprazole (as Delayed release pellets)…….60mg

Panel also visited the R&D Laboratory and Quality Control Laboratory of the firm. The data was evaluated according to the checklist provided as given below:

Details of investigation:

i) Dexlan DR Capsule 30mg and Dexlan DR Capsule 60mg

Q. No.	Questions	Observation by panel
1.	Do you have documents confirming the import of Dexlansoprazole delayed release pellets APIs including approval from DRAP?	The firm has procured 2kg Dexlansoprazole DDR 22.5% pellets from M/s. Vision Pharmaceuticals, Islamabad (Batch No. DLP287 and Invoice No. is 501646). API Dexlansoprazole was procured from M/s Integrin Life Sciences, Telangana, India by Vision Pharma.
2.	What was the rationale behind selecting the particular manufacturer of API?	Firm informed that they selected M/s Vision Pharmaceuticals, Islamabad based on their Vendor Qualification SOP.
3.	Do you have documents confirming the import of reference standard and impurity	Firm purchased Dexlansoprazole working standard from M/s Vision Pharmaceuticals, Islamabad, invoice

	standards?	no. 501646 dated 03.05.2018, and Dexlansoprazole sulphone and sulphide impurities from M/s Vision Pharmaceuticals, Islamabad, through Ref no. PO#IMP-0419 dated 01.04.2019 manufactured by M/s Integrin Life Sciences, Telangana, India
4.	Do you have certificate of Analysis of the API, reference standards and impurity standards?	The firm had certificate of analysis for Dexlansoprazole DDR Pellets, working standards and impurities standards manufactured by M/s Integrin Life Sciences, Telangana, India.
5.	Do you have GMP certificate of API manufacturer issued by regulatory authority of country of origin?	Firm had provided valid GMP Certificate of M/s Vision Pharmaceuticals, Islamabad issued by Additional Director (QA & LT-I), DRAP, Islamabad dated 25th Feb, 2019.
6.	Do you use API manufacturer method of testing for testing API?	The firm used pellets manufacturer's method of testing which was validated.
7.	Do you have stability studies reports on API?	The firm had stability studies reports on DDR pellets from Vision Pharma conducted at Zone IV-A conditions.
8.	If yes, whether the stability testing has been performed as per SIM method and degradation products have been quantified?	The stability testing had been performed as per SIM method.
9.	Do you have method for quantifying the impurities in the API?	Firm had testing method to quantify the impurities as per raw material manufacturers.
10.	Do you have some remaining quantities of the API, its reference standard and impurities standards?	The firm had some remaining quantities of the DDR pellets (Quantity = 187.25g) whereas working standard and impurities are NIL.
11.	Have you used pharmaceutical grade excipients?	Since the product is filling of already prepared pellets in Hard gelatin capsule and capsule shells used (size # 2 for 60mg & size # 4 for 30mg) were of pharmaceutical grade as per the COA and related documents.
12.	Do you have documents confirming the import of the used excipients?	The firm has purchased Hard gelatin capsule shell from local source i.e., M/s Gelcap, Karachi.
13.	Do you have test reports and other records on the excipients used?	The firm has test reports and other records on the excipient used.
14.	Do you have written and authorized protocols for the development of Dexlansoprazole Capsule?	The firm had written and authorized protocols for the development of Dexlansoprazole Capsules. However, firm was advised to improve the product development protocol.
15.	Have you performed Drug-excipient compatibility studies?	Not applicable.
16.	Have you performed comparative dissolution studies?	The firm has performed comparative dissolution studies with reference product DEXILANT 30mg and 60mg capsules manufactured by M/s. Takeda, USA. The dissolution profiles of the firm capsules are comparable to that of the reference product.
17.	Do you have product development (R&D) section	The firm had product development (R&D) section.

18.	Do you have necessary equipment available in product development section for development of Dexlansoprazole Capsule?	The firm had used commercial production area for filling of pellets in capsules using automatic capsule filling machine.
19.	Are the equipment in product development section qualified?	The equipments used in product development were qualified.
20.	Do you have proper maintenance / calibration / re-qualification program for the equipment used in PD section?	The firm had proper maintenance / calibration / re-qualification program for the equipment used in product development section.
21.	Do you have qualified staff in product development section with proper knowledge and training in product development?	The firm had 06 Pharmacists and 02 Chemists in product development section with suitable knowledge and training in product development.
22.	Have you manufactured three stability batches for the stability studies of Dexlansoprazole Capsule as required?	The firm had manufactured three stability batches for the stability studies of Dexlansoprazole Capsules (30mg and 60mg) with batch numbers i.e. DXA-T1-18, DXA-T2-18 and DXA-T3-18 for 30mg strength and DXB-T1-18, DXB-T2-18 and DXB-T3-18 for 60mg strength. The batch size for these batches are 1,500 capsules each.
23.	Do you have any criteria for fixing the batch size of stability batches?	The firm had criteria for fixing the batch size of stability batches as per their internal document CQP-004-H in the light of DRAP letter No. F.3-2/2014-I&E dated 08-12-2015.
24.	Do you have complete record of production of stability batches?	The firm had record of production of stability batches for which firm has provided Trial Forms.
25.	Do you have protocols for stability testing of stability batches?	The firm had detailed protocols for stability testing of stability batches.
26.	Do you have developed and validated the method for testing of stability batches?	The firm had developed and validated method of testing for finished product based on method of testing of API manufacturer. Validation of assay method was completed in September, 2018 while first analysis of trial batches was performed in July, 2018. Dissolution method validation was not performed.
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?	NA
28.	Do you have documents confirming the qualification of equipment / instruments being used in the test and analysis of Dexlansoprazole Capsule API and the finished drug?	The firm had 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 had used spike method to demonstrate that their method is stability indicating.
30.	Do your HPLC software 21CFR Compliant?	HPLC used in the stability studies of current products was gradient and not 21CFR 11 compliant. However, now the firm has procured HPLC software 21CFR Compliant.
31.	Can you show Audit trail reports on Dexlansoprazole Capsule testing?	The audit trail was not active on the testing reports and log of data was available in the HPLCs. The data

		was also confirmed through record, chromatograms and logbooks.
32.	Do you have some remaining quantities of degradation products and stability batches?	The firm had remaining quantities (108 capsules of each batch) of stability batches.
33.	Do you have stability batches kept on stability testing?	The firm had stability batches kept on stability testing.
34.	Do you have valid calibration status for the equipment used in Dexlansoprazole Capsule production and analysis?	The firm had valid calibration status for the equipment used in Dexlansoprazole Capsule production and analysis.
35.	Do proper and continuous monitoring and control are available for stability chamber?	Adequate monitoring and control was available for stability chamber. The firm has provided uninterrupted power supply by UPS and generator.
36.	Do related manufacturing area, equipment, personnel and utilities be rated as GMP compliant?	Requisite facilities were satisfactory and GMP compliant.

CLARIFICATION:

(iii) The firm has developed Process Validation Protocols and has committed to perform Process Validation on commercial batch.

(iv) The firm has performed comparative dissolution profile at three mediums i.e. 0.1N HCl pH 1.2, Acetate buffer pH 4.5 & Phosphate buffer pH 6.8.

RECOMMENDATIONS:

Based on the area inspected, the technical personnel met and the documents reviewed, and considering the findings of inspection, the panel is of the opinion that the data provided by the firm M/s. CCL Pharmaceuticals (Pvt.) Ltd., 62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan regarding stability studies of following products was satisfactory and the stability studies were conducted by the firm.

Decision: Deferred for following:

- **Clarification / justification for not submitting details of drug substance as mentioned in 3.2.S of Module 3 of CTD.**
- **Justification is required for not performing process validation as mentioned in 3.2.P.3.5 of Module 3 of CTD.**

Case No. 1: Registration of Drug(s) of M/s Reign Pharmaceuticals PCSIR KLC (Pvt) Ltd. TBIC Building-I, PCSIR Laboratories Complex, Off University Road, Karachi for Export Purpose Only.

Firm has applied for registration of drug(s) only for export purpose as per following details:

Sr.#	Name of Drug(s)	Generic/RRA Status	Diary No. date & Remarks.
I	II	III	IV
1.	Tramadol-X Tablet Each film coated tablet contains: Tramadol Hydrochloride……200mg	Me too not available MHRA approved formulation is extended release	Dy.No.633/19-EFD (PE&R) dated 17-06-2019 Rs.20000/- dated 08.01.19 Rs 30,000/- dated 19.06.2019

Decision of 29th PRVC:

Product deferred for justification of "X" in brand name and clarification of applied formulation (extended release or immediate release)

Firm clarified that "X" in brand name is just to differentiate from other brand names in market. Newly proposed brand names: **Reign's tramadol 200 tablet.**

Furthermore, firm clarified that above mentioned product is film coated tablet.

Decision of 30th PRVC:

Chairman Registration Board deferred product for approval status of applied formulation (film coated) in SRA.

Updated Status:

Now the firm has stated that despite of unavailability of applied formulation (Tramadol 200mg film coated tablet) in RRA, they want to manufacture same as per requirement of importing country.

Decision: Registration Board approved above mentioned product of M/s Reign Pharmaceuticals PCSIR KLC (Pvt) Ltd. 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 any safety, efficacy and quality of drug product.

Case.No.02: Registration of drugs

Registration Board in its 289th meeting approved following veterinary drugs in the name of M/s. Chakwal Pharma International, Lahore for import from M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands. Details are as follow;

S. No.	Approved Products of M/s. Chakwal Pharma, Lahore/ Manufacturer	Details of Already Registered Products.	Regn. No.
	II	III	IV
1.	Alfamec1% Solution for injection Each ml contains:- Ivermectin…….10mg Manufactured By M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 Ja Woerden Netherlands.	Alfamec 1% Injectable Solution. Each ml contains:- Ivermectin…10mg M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured By M/s. Alfasan International B.V., The Netherlands.	048180
2.	Lincomycin-Spectinomycin 5/10 Solution for injection Each ml solution contains:- Lincomycin (as Hydrochloride)……..50mg Spectinomycin (as Hydrochloride)……..…….100mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 Ja Woerden Netherlands.	Lincomycin-Spectinomycin 5/10 Injectable Solution. Each ml contains:- Lincomycin (as HCl)……...50mg Spectinomycin (As HCl)...100mg M/s. Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048182
3.	Xylazine 2% Solution for injection Each ml solution contains:- Xylazine (as Hydrochloride)…….20mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 Ja Woerden Netherlands.	Xylazine 2% Injectable Solution. Each ml contains:- Xylazine (as HCl)……20mg M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048181
4.	Multivitamin Solution for injection Each ml solution contains:- Vitamin A…15,000 IU Cholecalciferol…1000 IU Alfa-Tocoferol Acetate…20mg Thiamine Hydrochloride…10mg Riboflavine Sodium Phosphate…6.85mg Pyridoxine Hydrochloride…3mg Cyanocobalamine….50mcg Nicotinamide….35mg D-Panthenol…..…25mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 Ja Woerden Netherlands.	Multivitamins Injectable Solution. Each ml contains:- Vitamin A (as Synthetic concentrate oily form) ....15000 IU. Cholecalciferol (as concentrate Oily form) ……1000 IU. Alpha Tocopheryl Acetate …..20mg. Thiamine Hydrochloride ……..10mg. Riboflavine Sodium Phosphate....6.85mg. Pyridoxin Hydrochloride…….3mg. Cyanocobalamin…50mcg. Nicotinamide…35mg. Dexpanthenol …25mg. M/s.Alina Combine Pharmaceuticals (Pvt) Ltd., Karachi./ Manufactured by M/s. Alfasan International B.V., The Netherlands.	048185

5.	Amoxycilline 20% LA Suspension for Injection Each ml Suspension contains:- Amoxycillin Trihydrate……..…200mg Manufactured by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 Ja Woerden Netherlands.	Amoxcin Trihydrate 20% Injectable Each ml contains: - Amoxycillin Trihydrate equivalent to 200mg amoxycillin base M/s. Shayan Traders Rawalpindi./ Manufactured by M/s. Alfasan Int Holland.	022144

While processing of registration letters it has been observed that the same products are already found registered in the name of other importers (M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi and M/s. Shayan Traders Rawalpindi). M/s. Chakwal Pharma International, Lahore informed that their principle had already cancelled the agency agreement dated 06-03-2009 due to not reaching the agreed annual targets for several years and provided a copy of it.

Decision:- **Keeping in view the termination of distribution agreement by M/s. Alfasan Nederland B.V. Kuipersweg 9, 3449 JA Woerden Netherlands , Registration Board decided to issue show cause to M/s. Alina Combine Pharmaceuticals (Pvt) Ltd, Karachi and M/s. Shayan Trader, Rawalpindi as to why the registration of the abovementioned products may not be cancelled because of termination of their distribution agreement.**

HUMAN IMPORT

Case.No.03: REQUEST OF M/S. MEDINET PHARMACEUTICALS, RAWALPINDI FOR CHANGE OF NAME OF MANUFACTURER FOR REGISTERED PRODUCT ANFOTERICINA FADA INJECTION (REG.NO. 033128).

M/s. Medinet Pharmaceuticals, Rawalpindi requested for change of name of manufacturer for registered products the details are as under. The case was presented in 286th meeting of Registration Board.

S.#	Regn. No.	Existing Name/ Composition	Existing Name of manufacturer	Proposed Name of manufacturer & Market authorization holder (as per CoPP)	Initial registration with renewal	Remarks/ Diary No. R&I
I	II	III	IV	V	VI	VII
1.	031391	Varedet Injection Each vial contains:- Vancomycin HCI.....500mg	M/s. FADA Pharma S.A., Argentina.	Manufacturer & Product License Holder:- M/s. Laboratorio Inernacional Argentino S.A., 1641, Tabare St. C.A.B.A. Argentine Republic.	27-7-2004 Last renewal submitted on 17-7-2014	Dy. No. 7355 R&I dated 27-02-2018.
2.	031392	Varedet Injection Each vial contains:- Vancomycin HCI.....1000mg	-do-	-do-	27-7-2004 Last renewal submitted on 17-7-2014	-do-
3.	031393	Duvig Injection Each vial contains:- Dobutamine HCI…….250mg	-do-	-do-	27-7-2004 Last renewal submitted on 17-7-2014	-do-
4.	033128	Anfotericina Fada Injection Each vial contains:- Amphotericin B …….50mg	-do-	M/s. Laboratorio Internacional Argentino S.A. Av. 12 de Octubre 4444, Quilmes, Buenos Aires, Republica Argentina.	03-12-2004 Last renewal submitted on 21-11-2014	-do-

Firm has deposited fee of Rs.5,000x4=20,000/- & submitted following supporting documents:-

i) Copies of registration letters.
ii) Copies of renewal status.
iii) Original & legalized CoPP issued by Argentian Authority.
iv) Original & Legalized GMP issued by Argentian Authority.
v) Copy of Drug Sale License.
vi) Copy of change of corporate name amendment of the articles in corporation.

It is pertinent to mentioned that the firm has requested for change of name of manufacturer for all the products from M/s. FADA Pharma S.A., Argentina to M/s. Laboratorio Inernacional Argentino S.A., 1641, Tabare St. C.A.B.A. Argentine Republic. However, as per CoPP of product at Sr. No.4, the name and address of manufacturer is mentioned as M/s. Laboratorio Internacional Argentino S.A. Av. 12 de Octubre 4444, Quilmes, Buenos Aires, Republica Argentina. which is different from the one requested by the firm. Similarly the address of the

manufacturer abroad was not mentioned on initial registration letter.
Case was presented before Registration Board in its 283rd meeting & Board decided as follow;

> *"Registration Board deferred the case for confirmation of address of manufacturer from previous import clearance documents in order to ascertain that the manufacturing site(s) is/are the same."*

The firm has now provided previous import documents wherein it can be confirmed that, for products at Sr.No.1-3, the manufacturing site remains the same.

Decision: Registration Board decided as follow;

a. For products at Sr.No.1-3, approved the change in name of manufacturer from M/s. FADA Pharma S.A., Argentina to M/s. Laboratorio Inernacional Argentino S.A., 1641, Tabare St. C.A.B.A. Argentine Republic on same terms and conditions.
b. For product at Sr.No.4, deferred the case for seeking clarification from the firm regarding the address/status of manufacturer

With reference to above decision for the product Anfotericina Fada Injection (Reg.No.033128)(at Sr.no.04). The firm has submitted as under:-

1. The drug under question Anfotericina Fada Injection 500mg (Amphotericin B) is manufactured at plant 4444, 12 de Octubre Av., Quilmes Buenos Aires, Argentina and there is no change in the manufacturing site of the drug.
2. The company legal address is at 1641, Tabare St. C.A.B.A. Argentina republic which is mentioned in the invoices as being the legal and business address of the company. This address is written in the export documents of all the products in the place of manufacturing site which made confusion in the change of the address.
3. Since GMP and COPP are issued by the Regulatory body of the country (Argentina), therefore, address of the representative manufacturing site is mentioned on the GMP and COPP.

The firm has not provided previous import documents so it cannot be confirmed that, for this product, the manufacturing site remains the same or different.

Decision of 289th meeting:

Registration Board deferred the case for further deliberation.

The firm has provided import documents attested by Assitant Director DRAP Karachi, having address mentioned in the following table:-

Sr. NO.	Product	Address as per GMP	Address as per COPP	Address as per Import Clearance Invoice
1.	Anfotericina Fada Injection 50mg (Reg.No. 033128)	M/s Laboratoria Internacional Argentino S.A 4444, 12 de Octubre Av., Quilmes Buenos Aires, Argentina.	M/s Laboratoria Internacional Argentino S.A. Av. 12 de Octubre 4444, Quilmes, Buenos Aires, Republica Argentina	M/s Laboratoria Internacional Argentino S.A 12 de Octubre 4444, Quilmes, Oeste, Republica Argentina

Decision: Registration Board approved the change in name of manufacturer from M/s. FADA Pharma S.A., Argentina to M/s Laboratoria Internacional Argentino S.A. Av. 12 de Octubre 4444, Quilmes, Buenos Aires, Republica Argentina of the Product at Sr no.4 on same terms and conditions.

Case.No.04: 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 registration of these 2 products.

Decision: Registration Board deferred the case for further deliberation.

Case.No.05: 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 apkistan. 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: Registration Board deferred the case for further deliberation.

B. Division of Biological Evaluation & Research

Sr. No.	Details of application	No. of Cases
A	Imported Human Biologicals from Non-Reference Countries	2
B	Imported Veterinary Biologicals from Reference Countries	5
C	Miscellaneous/ Deferred cases	24
Total		31

A: Imported Human Biologicals from Non-Reference countries.

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	
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
Remarks of Evaluator	i. The has submitted copy of letter from Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) the contents of which is reproduced as under; *"PEG L-asparaginase (Pegaspargase) Injection manufactured by Jiangsu Hengrui Medicine co., Ltd China is being used at Shaukat Khanum Memorial Cancer Hospital and Research Centre (SKMCH&RC) since November,2018.* *We continuously using this product and more than 200 vials have already been consumed in the hospital.* *We have found this product satisfactory and request the authorities to make this product freely available in Pakistan for the patient care."* ii. The firm does not provide original & Legalized CoPP instead submit Copy of CoPP notarized by Notary public Pakistanis submitted and submit

	undertaking that the firm will submit the original Legalized CoPP up to 25-09-2019. iii. The Characterization of impurities for the substance, the firm has submitted that they will provide in coming week.

Discussion:

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.

Decision: 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.

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.

Name of Applicant	M/s Amson Vaccine & Pharma (Pvt) Ltd., Plot No. 115, Industrial Triangle, Kahuta Road, Islamabad.
DSL details	DSL License No.920-ICT/2013 dated 02-08-2018 valid upto 01-08-2020.
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., China.
Brand Name +Dosage Form + Strength	Group ACYW 135 Meningococcal Polysaccharide Vaccine (freeze-dried), for Injection
Composition	Each single human dose (0.5ml) contains: Meningococcal Group Apolysaccharide.....50µg Meningococcal Group C polysaccharide.....50µg Meningococcal Group Y polysaccharide.....50µg Meningococcal Group W135 polysaccharide.....50µg **Diluent:** Water for injection.....0.5ml
Finished product specifications	Pharmacopoeial Reference is not Provided
Pharmacological Group	Meningococcal Polysaccharide Vaccine
Shelf life	24 Months (2^{o}C to 8^{o}C)
International availability	Menomune ACYW135 of M/s Sanofi Pasteur, USA
Alternate Products already registered in Pakistan	Menvac ACYW of M/s Sind Medical Store, Karachi.
Type of Form Dy. No. Date of Application, Fee submitted	Initially Form-5 F then Form-5A Dy.No.8969, 15567 & 16548(R&I) Dated: 27-02-2019, 26-08-2019 & 02-09-2019 Rs. 100,000/- Dated: 27-02-2019.
Pack Size/ Demanded Price	1's Vial (lyophilized powder) + 1's Vial (Diluent)/ As per DPC
General documentation	Legalized CoPP No. 2018-043 dated 06-08-2018 valid for 24 months.
Remarks of Evaluator	i. The product is in combopack but the firm has not provided any details of diluents in Form-5A. ii. Accelerated stability data provided is of 100 days instead of 06 months. iii. In stability studies, tests for identity, appearance, weight variation, abnormal

	toxicity, pyrogens, bacterial endotoxin and sterility are not performed. iv. In finished product specifications, pharmacopoeial reference is not provided. v. In finshed product specifications, the limit of each polysaccharide is 50-65µg while in stability studies limit is mentioned as 35-65µg.
Decision:	**Registration board deferred the case for submission of following by the firm:** **a. Form-5A indicating details of diluents as the product is in combopack** **b. Accelerated stability data of 06 months.** **c. Stability data covering all the parameters as per finished product specifications.** **d. Finished product specifications as per decision of 267th meeting of Registration Board.** **e. Clarification regarding the difference in limit of each polysaccharide in finished product specifications and stability studies.**

B: Imported Veterinary Biologicals from Reference countries.

1.	Name of Importer	M/s. Hipra Pakistan (Private) Limited, Office no. 3&4, 5th floor, 105-B-II,Ali Tower, M.M Alam Road, Gulberg, Lahore
	DSL details	License to sell drug as Distributor No. 0011000 0001301 valid upto 30-01-2020
	Name of Manufacturer	M/S LABORATORIOS HIPRA, S.A. Avda. La Selva,135, 17170 Amer (Girona) Spain
	Brand Name +Dosage Form + Strength	Hiprapox Lyophilisate and solvent for injectable suspension
	Composition	Each dose of 0.01 ml vaccine contains: Live attenuated Fowl pox virus, strain FPV92……10^4-$10^{4.4}$ DIE_{50} (*) (*) Infective dose in embryo 50% **Composition of Solvent:** Disodium Phosphate dodecahydrate.....0.02900 mg Potassium dihydrogen phosphate.....0.00200 mg Sodium Chloride.....0.08000 mg Potassium Chloride.....0.00200 mg Water for Injection.....P.Qs.ad 0.01 ml
	Finished product specifications	BP Specification
	Pharmacological Group	Veterinary vaccine
	Shelf life	24 months at 2-8ºC
	International availability	Spain
	Products already registered in Pakistan	
	Type of Form Dy No & Date of application, Fee submitted	Form 5-A Dy.No. (R&I) Date:26-03-2019 Rs.100,000/- Date: 26-03-2019
	Demanded Price / Pack size	Decontrolled/ 1000 Doses
	General documentation	Legalized COPP dated 13-11-2018 Issued by: Departamento de medicamentos veterinarios de la Agencia Espanola de Medicamentos y Productos Sanitarios (Translation: Department of Veterinary medicines of the Spanish Agency of Medicines & health Products.) GMP No.ES/101HV/16 dated 19-11-2016.

	Remarks of Evaluator	
	Decision: Keeping in view the 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. Hipra Pakistan (Private) Limited, Office no. 3&4, 5th floor, 105-B-II,Ali Tower, M.M Alam Road, Gulberg, Lahore
	DSL details	License to sell drug as Distributor No. 0011000 0001301 valid upto 30-01-2020
	Name of Manufacturer	M/S LABORATORIOS HIPRA, S.A. Avda. La Selva,135, 17170 Amer (Girona) Spain
	Brand Name +Dosage Form + Strength	Avisan Multi/Co Emulsion for Injection
	Composition	Each dose of vaccine contains: Inactivated Infectious Bronchitis Virus, strain H52……>/=10^6 EID_{50} Inactivated Newcastle Disease Virus,strain Lasota……..>/=10^8 EID_{50} Inactivated EDS-76 Virus, strain 127…..>/=307.2 HAU Avibacterium paragallinarum serotype A…….>/=1.25x10^9 microorganisms Avibacterium paragallinarium serotype B…….>/=1.25x10^9 microorganisms Avibacterium paragallinarium serotype C…….>/=1.25x10^9 microorganisms
	Finished product specifications	Innovator's Specification
	Pharmacological Group	Veterinary vaccine
	Shelf life	24 months at 2-8ºC
	International availability	Spain
	Products already registered in Pakistan	
	Type of Form Dy No & Date of application, Fee submitted	Form 5-A Dy.No. 1823 (R&I) Date:26-03-2019 Rs.100,000/- Date: 26-03-2019
	Demanded Price / Pack size	Decontrolled/ 1000 Doses
	General documentation	Legalized COPP No. 27514/2018 dated 17-12-2018 Issued by: Departamento de medicamentos veterinarios de la Agencia Espanola de Medicamentos y Productos Sanitarios (**Translation:** Department of Veterinary medicines of the Spanish Agency of Medicines & health Products.)
	Remarks of Evaluator	iii. The product is not licensed to be placed in the country of origin as per CoPP. Reason mentioned on CoPP is Commercial reasons for lacking market authorization.
	Decision: Registration Board deferred the case for submission of evidence of availability of the product in reference regulatory authorities.	
3.	Name of Importer	**M/s. Hipra Pakistan (Private) Limited, Office no. 3&4, 5th floor, 105-B-II,Ali Tower, M.M Alam Road, Gulberg, Lahore**
	DSL details	License to sell drug as Distributor No. 0011000 0001301 valid upto 30-01-2020
	Name of Manufacturer	M/S LABORATORIOS HIPRA, S.A. Avda. La Selva,135, Amer,17170 (Gerona) Spain

	Brand Name +Dosage Form + Strength	**Evant** Oral Suspension
	Composition	Each dose of vaccine contains: Eimeria acervulina, strain 003……332-450 Eimeria maxima, strain 013…….196-265 Eimeria mitis, strain 006…….293-397 Eimeria praecox, strain 007…….293-397 Eimeria tenella, strain 004……..276-374 **Composition of Solvent (Hipramune T):** Montanide IMS (**Adjuvant)** Blue coloring Agent Red coloring Agent Vanillin
	Finished product specifications	BP's Specification
	Pharmacological Group	Veterinary vaccine
	Shelf life	10 months at 2-8^{o}C
	International availability	Spain
	Products already registered in Pakistan	
	Type of Form Dy No & Date of application, Fee submitted	Form 5-A Dy.No. 1819 (R&I) Date:26-03-2019, Rs.100,000/- Date: 26-03-2019,
	Demanded Price / Pack size	Decontrolled/ 1000 Doses vaccie& 50ml diluent
	General documentation	Legalized COPP No. 25690/2018 dated 22-03-2018 Issued by: Departamento de medicamentos veterinarios de la Agencia Espanola de Medicamentos y Productos Sanitarios (Translation: Department of Veterinary medicines of the Spanish Agency of Medicines & health Products.)
	Remarks of Evaluator	i. The product is not licensed to be placed in the country of origin as per CoPP. Reason mentioned on CoPP is "under registration procedure in Spain". ii. Diluent is not mentioned/indicated in the CoPP but mentioned in Form-5A & label
	Decision:	**Registration Board deferred the case for submission of following by the firm:** **a. Valid legalized approval of product in country of origin.** **b. Evidence of availability of product in combopack in country of origin.**
4.	Name of Importer	**M/s. Hipra Pakistan (Private) Limited, Office no. 3&4, 5th floor, 105-B-II,Ali Tower, M.M Alam Road, Gulberg, Lahore**
	DSL details	License to sell drug as Distributor No. 0011000 0001301 valid upto 30-01-2020
	Name of Manufacturer	M/S LABORATORIOS HIPRA, S.A. Carretera C-63, Km 48,300, poligono Industrial El Rieral, Amer, 17170 Gerona Espana (Spain) **Translation as per Google translator:** Laboratorios Hipra, S.A. road C-63,300, Poligono Industrial El Rieral, Amer, 17170 Gerona Espana. **Address as per Authorization Letter/Form-5A:** M/S LABORATORIOS HIPRA, S.A.de La Selva, 135, 17170 Gerona Espana (Spain)

	Brand Name +Dosage Form + Strength	**NASYM** Lyophilisate suspension
	Composition	Each dose of vaccine contains: BRS virus, strain Lym56 (live attenuated)……..$10^{4.7}$-$10^{6.5}$ $CCID_{50}$
	Finished product specifications	European Pharmacopeia's Specification
	Pharmacological Group	Veterinary vaccine
	Shelf life	24 months at 2-8°C
	International availability	Spain
	Products already registered in Pakistan	
	Type of Form Dy No & Date of application, Fee submitted	Form 5-A Dy.No. 1820 (R&I) Date:26-03-2019 Rs.100,000/- Date: 26-03-2019
	Demanded Price / Pack size	Decontrolled/ 10*1 Doses
	General documentation	Legalized COPP No. 25689/2018 dated 22-03-2018 Issued by: Departamento de medicamentos veterinarios de la Agencia Espanola de Medicamentos y Productos Sanitarios (Translation: Department of Veterinary medicines of the Spanish Agency of Medicines & health Products.) GMP No.ES/101HV/16 dated 19-11-2016.
	Remarks of Evaluator	i. The product is not licensed to be placed in the country of origin as per CoPP. Reason mentioned on CoPP is "under registration procedure in Spain". ii. Address of Manufacturer on CoPP and Form-5A/Authorization letter are different (as mentioned above) iii. Stability data is complete upto 12 months while demanded shelf life is 24 months.
	Decision:	**Registration Board deferred the case for submission of following by the firm:** **a. Valid legalized approval of product in country of origin.** **b. Clarification regarding the difference in address of manufacturer on CoPP from Form-5A & Letter of Authorization.** **c. Stability studies data of 24 months.**
5.	Name of Importer	M/s. Hipra Pakistan (Private) Limited, Office no. 3&4, 5th floor, 105-B-II,Ali Tower, M.M Alam Road, Gulberg, Lahore
	DSL details	License to sell drug as Distributor No. 0011000 0001301 valid upto 30-01-2020
	Name of Manufacturer	M/S LABORATORIOS HIPRA, S.A. Avda. La Selva,135 17170 Amer (Girona) Spain
	Brand Name +Dosage Form + Strength	Hipradog-7 Powder and solvent for injectable suspension
	Composition	Each dose of 1 ml vaccine contains: **Freez-dried fraction:** Attenuated Canine Parvovirus, C-780916 strain……$>10^6$ $TCID_{50}$ Attenuated Canine Distemper virus, Lederle strain…….$>10^4$ $TCID_{50}$ Attenuated Canine Adenovirus, type 2, Manhattan strain…..$>10^4$ $TCID_{50}$ Attenuated Canine Parainfluenza virus, Penn 103/70 strain……$>10^5$ $TCID_{50}$ **Liquid fraction:** Leptospira interrogans serovar icterohaemorrhagiae inactivated ……$>10^9$

		microrg Leptospira interrogans serovar canicola inactivated ……>10^9 microrg
	Finished product specifications	European Pharmacopeia Specification
	Pharmacological Group	Veterinary vaccine
	Shelf life	18 months at 2-8°C
	International availability	Spain
	Products already registered in Pakistan	
	Type of Form Dy No & Date of application, Fee submitted	Form 5-A Dy.No. 1822(R&I) Date:26-03-2019 Rs.100,000/- Date: 26-03-2019
	Demanded Price / Pack size	Decontrolled/ 1 Doses
	General documentation	Legalized COPP dated 14-02-2019 Issued by: Departamento de medicamentos veterinarios de la Agencia Espanola de Medicamentos y Productos Sanitarios (Translation: Department of Veterinary medicines of the Spanish Agency of Medicines & health Products.) GMP No.ES/101HV/16 dated 19-11-2016.
	Remarks of Evaluator	Stability studies are performed on only 30 vials.
	Decision: Registration Board deferred the case for submission, of stability study protocol along with relevant data, by the firm.	

C: Miscellaneous/ Deferred Cases

1. Registration of Human Biologicals in name of M/s Vikor Enterprises (Pvt.) Ltd., Karachi.

Following human biological was initially approved in name of M/s Sind Medical Store, Karachi in 284th meeting of Registration Board. Now, M/s Vikor Enterprises (Pvt.) Ltd., Karachi applied for the registration of said product in their name as per following details:

Sr. No.	**Name and address of Importer**	M/s Vikor Enterprises (Pvt.) Ltd., Plot No. Z2-A, S.I.T.E., Manghopir Road, Karachi.
1.	Detail of DSL	License No. 4672 dated 10-05-2019 valid till 01-05-2021
	Name and address of Manufacturer	**Product License Holder &Manufacturer:** M/s Bharat Biotech International Ltd., Genome Valley, Shameerpet Mandal, Medchal District-500 078, Telangana, India
	Brand Name +Dosage Form + Strength	Typbar TCV Typhoid Vi Conjugate Vaccine
	Diary No. Date of R& I & fee	Dy. No. 9882 & 13994 Dated: 27-06-2019 & 02-08-2019 Rs. 100000/- Dated: 26-06-2019
	Composition	Each dose OF 0.5mL contains: Purified Vi Capsular Polysaccharide of *Salmonella typhi Ty2* conjugated to Tetanus Toxoid…….25µg
	Pharmacological Group	Human Typhoid Vaccine
	Type of Form	Form-5F
	Finished Product Specification	WHO Specifications

	Shelf Life	36 months (2^0C-8^0C)
	Document Details	Legalized CoPP No. 8735/STORES/2019 dated 11-01-2019 valid upto 15-04-2020.
	Pack size/ Demanded Price	1's Vial (0.5mL)
	International Availability	
	Products already registered in Pakistan	GHC 5000 Injection of M/s Foray Pharmaceuticals, Rawalpindi.
	WHO Prequalification Status	https://extranet.who.int/gavi/PQ_Web/PreviewVaccine.aspx?nav=0&ID=318accessed on 03-09-2019

The firm has provided the following documents for each product:

i. Application of Form-5F
j. Fee Challan of Rs. 100000/-
k. Copy of termination letter in name of M/s Sind Medical Store, Karachi received directly from M/s Bharat Biotech International Limited, India.
l. Copy of Authorization letter in name of M/s Vikor Enterprises Private Limited, Karachi.

Remarks of Evaluator:

The above product was initially approved in 284th meeting in name of M/s Sind Medical Store, Karachi wherein the Board decided as follows:

"Keeping in view the WHO Prequalification and valid legalized CoPP indicating the availability of product in country of origin; Registration Board approved the product subject to price fixation by the Federal government and compliance of current Import Policy for finished drugs. The firm will submit new brand name along with NOC from manufacturer abroad and Chairman Registration Board is authorized for issuance of Registration letter."

Later the authorization was cancelled by the manufacturer. Registration Board in its 286th meeting decided as follows:

"Registration Board advised M/s Sind Medical Stores, Karachi to submit updated Sole agency agreement within 30 days."

M/s Sind Medical Store, Karachi has not yet submitted the updated sole agency agreement.

Now, M/s Vikor Enterprises, Karachi applied for the registration of said product in their name and submitted that the name change is not possible since M/s Bharat Biotech International Ltd., are the originator of this product and Typbar TCV is their brand name which is internationally recognized, even it is in WHO preferred vaccines (with the same name) and till to date this product is not available with any other name globally, so that would not be possible for their principal to give new name for them.

The firm has not provided the original letter of authorization.

The termination letter received from M/s Bharat Biotech International Limited, India on 24-09-2018 was photocopy while original is not submitted by the firm.

Decision: Registration Board deferred the case for submission of following by the firm:

a. Original letter of authorization in name of M/s Vikor Enterprises Private Limited, Karachi.
b. Original termination letter from M/s Bharat Biotech International Limited, India in name of M/s Sind Medical Store, Karachi.

Registration Board further directed M/s Sind Medical Store, Karachi for personal hearing before Registration Board to explain their position regarding the cancellation of their

authorization for registration of Typbar TCV by M/s Bharat Biotech International Limited, Genome Valley, Shameerpet Mandal, Medchal District-500078, Telangana, India and authorization in name of M/s Vikor Enterprises (Pvt.) Ltd., Plot No. Z2-A, S.I.T.E., Manghopir Road, Karachi. If M/s Sind Medical Store, Karachi will not attend the meeting, Registration Board will decide as per rules.

2. Request for price revision applied by M/s Allmed Karachi.

M/s Allmed Karachi has placed request for price revision in appellate board. The same is reproduced as under;

1. "Through instant appeal, the appellant (**M/s Allmed**) challenged the decision of the Drug Pricing Committee (the "Committee or DPC") issued vide SRO No.1610(I)/2018 dated 31st December, 2018, wherein, the final MRP of the Product has been fixed in the following manner:

Brand Name/Composition/Company	Pack Size	Approved Maximum Retail Price
ATG-Fresenius (concentrate for Solution for infusion) Each ml contains: Anti-Thymocyte Immunoglobulin….2% (Allmed Labs) Imported from: Neovii biotech	5ml/vial	Rs.39,415.51

2. The appellant has alleged that its product Grafalon is a New Chemical Entity ("NCE") derived from rabbits after immunization and is used as an immunosuppressive agent to prevent organ rejection. It is the claim of the appellant that at the time of introduction of the product in the country there was no other registered Rabbit Anti-Human Thymocyte available across the country.
3. The appellant also filed Suit No.408 of 2013 in the Hon'ble Sindh High Court, Karachi against fixation of MRP of the product @ Rs.5000/vial at the time of registration.
4. It was further argued that despite the apparent differences in production methods, the DPC has set a higher MRP for Thymoglobulin of M/s Sanofi. The appellant claimed that its product is different from Thymoblogulin having a different molecular structure, production methods and other characteristics and also a better safety profile.
5. The appellant contended that being an NCE, the price fixation of its product falls under Para 4 of 2018 Policy, wherein "MRP fixation of originator Brand of NCE shall be based on average price of the same brand in India and Bangladesh. If the Originator Brand is available in only one of these countries, MRP shall be fixed at its par after considering available in only one of these countries, MRP shall be fixed at its part after considering the exchange rate parity." The trade price of Grafalon in India is Rs.25,740/- (INR). The equivalent MRP of Grafalon 20mg/ml 5ml vial based on the regional price calculated according to the Drug Pricing Policy 2018 para 5(I)(i) would be Rs.59,656.22/- as per following calculation:
   i. Trade Price of Grafalon in India = 25, 740/-INR
   ii. MRP of Grafalon in India = 30, 282.35/-INR
   iii. MRP of Grafalon in Pakistan considering the Exchange rate Parity = Rs. 59,656.22/- under Para 4 of the aforesaid policy.

6. Recently, the MRP of the product has been allowed 9% increase through SRO 34(I)/2019 under Para 12(8) of the 2018 Policy. However, appellant raised concerns that even after a 9% increase in MRP the product will not be at par with other NCEs in terms of Para 4 of the 2018 Policy.
7. As per appellant, the DPC has failed to appreciate the fact the product is an NCE and not a therapeutic equivalent of Thymogloblulin as evident from scientific studies conducted by research institutions around the world. Therefore, its price has to be fixed under paragraph 4 of the 2018 Policy which stipulate that the MRP of an originator brand of NCE is to be fixed on average price of the same brand in India and Bangladesh and if the originator brand is available in only one of these countries, MRP shall be fixed at par after considering the exchange rate parity. Accordingly, since the notified prices of the product have not been commuted in view of Para 4 of the 2018 Policy, the MRP of the Product is liable to be re-fixed in the following manner:

Sr. No.	Product Name	Reg. No.	Packing	Demanded MRP
1.	Grafalon 20mg/ml	033134	10's	Rs.55,383/- per 5ml vial

8. The Board considered the submissions made by the appellant and observed that the DPC has decided the hardship application of "ATG Fresenius Concentrate for solution for infusion (Graflon Concentrate for solution)" in its 29th Meeting held on 12th& 13th April, 2018, as follows:-

   "Mr.Feroze Ahmed, Assistant Manager Regulatory Affairs, Ismail Mastoi and Imran Danish appeared on behalf of pharmaceutical concern and submitted C&F providing and landed cost to justify increase in MRP's. Company representative, after providing history of increase in MRP of the drugs after registration in 2005, submitted calculation of price fixation of its drug @ Rs.55383on the basis of pro-rata of another drug, Thymoglobulin of M/s Sanofi Aventis.

   DPC noted that comparison of the biological drug of the applicant with that of biological drug of M/s Sanofi Aventis is not correct as both are different biological drugs. Moreover, Drug Pricing Policy, 2015 does not have any provision that allow increase in MRP on the basis of pro-rata of MRP o another biological drug.

   DPC noted that according to copies of bill of entries submitted, the company is paying income tax @ 6%, Government of Sindh CESS @ 1.11% in addition to insurance @ 1% and L/C & clearing charges estimated @ 1.5%."

9. MRP of the said drug was determined according to 2015 Policy and documents/evidence submitted by the company, as under:

Sr. No.	Name of Drug	C& F	Landed cost	Import Levy	MRP under DPP-2015	1st Year Increase	2nd Year Increase	3rd Year Increase	MRP as per SRO.1610(I)/2018 dt 31-12-2018
1	ATG – Fresenius	Rs.2381 9.50	Rs.25782.77	Rs.40949.77	Rs.34329.64/5ml vial	Rs.34329.64/5ml vial	Rs.39415.51/5ml vial	Rs.39415.57/5ml vial	Rs.39415.51/5 ml vial

10. The appellant did not raise any objection on finding of the DPC. The appellant has changed its demanded price to Rs.55383 per 5ml vial in appeal before this Board as compared to demanded price at the time of submission of application under hardship category@Rs.45840 5ml vial.
11. The price of the product was fixed by the Ministry of Health (defunct) on the basis of merit and Suit No.188 of 2013 was disposed of by the Hon'ble Sindh High Court vide Order dated 22-01-2019. Every chemical entity/molecule has its own properties and the appellant has not produced any evidence to prove superiority of its drug as compare to others. Therefore, its price fixation does not fall under para 4 of 2018 Policy. Further, Venofer was not considered as NCE while its price fixation under hardship category. Its price was determined under para 9 of 2018 Policy. In case of Feronjet, price was determined in 2013 and not related with the price of product of the appellant.
12. The appellant has misconceived the provision of SRO 34(I)/2019. Increase under this SRO was allowed due to devaluation of Pak Rupee against US$ and not to increase MRP of the drug at par with other drugs.
13. The Board noted that MRP of the product was determined on the basis of evidence produced by the Appellant after considering provision of 2015 Policy. The Appellant never applied for increase in MRP under 2018 Policy.
14. **The Board, after hearing arguments and perusing record of the case decided to refer the appeal to the Registration Board to clarify the status of the product as new chemical entity or otherwise**."

Copy of registration letter submitted by the firm reveals that product was registered by Registration Board in its 182nd meeting vide letter No. F.3-1/2004-Reg-I (M-182) dated 12-01-2005.

It is pertinent to mention that Registration Board grants registration of a drug product in either of following category and not as a New Chemical Entity.

- Generic drug (me too)
- Patented Drug
- New combination/ dosage form/ new drug molecule

Registration Board in *290th meeting decided to refer the case to DBER for complete evaluation in light of decision of Appellate Board.*

New Chemical Entity:

> *"A new chemical entity (NCE) is, according to the U.S. Food and Drug Administration, a drug that contains no *active moiety that has been approved by the FDA in any other application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act"*
>
> **an active moiety is the part of a molecule or ion – excluding appended inactive portions – that is responsible for the physiological or pharmacological action of a drug substance.*

Worldwide two (2) types of ATG marketed are:

i. Polyclonal antibodies derived from rabbit; rATG**(Grafalon& Thymoglobulin)**
ii. Polyclonal antibodies derived from horse; eATG**(Atgam)**

Parameter	Grafalon	Thymoglobuline
Some approval details worldwide	Austria: agreement date 26.11.1999	Austria: agreement date 18.12.1995 Registration in Australia 18 July 2008 EMA Approval; 18/03/2013
FDA orphan designation:	Prevention of graft versus host disease (GVHD) Dated 03/26/2010	Induction treatment to prevent rejection and to minimize maintenance immunosupression in pediatric liver transplant recipients Dated: 09/26/2006

As per record, which further may be verified from PER Division, is as under;

Sr. No.	Reg. No.	Name of Product	Manufacturer	Importer
1.	011055	Thymoglobuline (Anti Human) Injection	'Pasture Merieux France	Sind Medical Store Karachi
2.	069513	Thymoglobulin ® Vial	Genzyme Polyclonals S.A.S. France.	Scitech Health (Pvt) Limited, Karachi
3.	083176	Thymoglobuline (Powder for concentrate for solution for infusion)	M/s Genzyme Polycolonals S.A.S, 23 boulevard Chambaud de la Bruyere, 69007 Lyon- France	Sanofi-Aventis Pakistan Limited Karachi

Decision: Registration Board deferred the case and advised DBER to check the registration status of Thymoglobulin Injection (Reg. No. 011055) registered in name of M/s Sind Medical Store, Karachi.

3. Cancellation of registration of Cerebrolysine Injection (Registration No.000691) imported by Bio Pharma, Multan;

Division of Biological Drug Division received a complaint from Mr. Rana Yasir Arfat, Section Officer, Government of Pakistan, Prime Minister's Public Affairs and Grievances Wing, Ministry of Parliamentary Affairs, Cabinet Block, Islamabad. The details of complaint are as under;

Mr. Tanveer Ahmed Khan (Chartered Accountant) filed a complaint against the drug **Cerebrolysine Injection (Registration No.000691) manufactured from Pig Brain Extract**, Registration holder indenter M/s Bio Pharma, Multan, 97 A/1, gulgasht Colony, Multan, Pakistan and stated as under*;*

"This is to bring to your notice about the serious and heinous crime being done in Islamic Republic of Pakistan by importing and marketing the above drug from Austria which contains Pig Brain Extract which is absolutely Haram and prohibited criminal act according to the Constitution of Pakistan.

The said mentioned company committing crime against the constitution and supreme law of Quran and Sunnah by importing and selling the above drug in Islamic republic of Pakistan. The import of above drug causing heavy financial foreign currency loss to State Pakistan.

Enclosed hereby, please find evident details which are also available on the website of above drug manufacturer Ebewe Pharma A 4866, Unterach, Austria website, which is self-explanatory.

The above indenter deliberately escaped and maligned the facts of pig brain extract presence in the drug, and never disclosed its composition and defects at any stage of import, marketing or selling thus misleading different Government institutions like Customs, Ministry of Health and Drug Regulatory Authority of Pakistan.

Import & marketing of above Haram drug should be imposed immediate Bann, penalized by imposing heavy penalty and withdrawal of Registration from Ministry of Health. Also immediate action prayed for lifting of the stock available at chemists shops, whole sellers and importer/indenter stocks and inventories, for the sake of Religion and Health of the nation of Islamic Republic of Pakistan.

Hope immediate action will be taken against the above complaint."

It is submitted that Registration status in other Muslim Countries revealed that the product was also registered in UAE & Egypt.

Renewal section of PER division provided following document;

i. Latest renewal application submitted on 10th November 2015. (Submitted fee: 20,000/-)
ii. Approval of change of name of manufacturer dated 3rd May 2006.

The change of name of manufacturer was granted on 3rd May 2006& regarding a second change, a copy of approval letter submitted by the firm is dated 13th May 2010.

Further, Additional Director E&M Lahore was requested to provide import status of the product. Assistant Director (I&E) responded that **no import case of the *Cerebrolysin Injection* has been cleared from Lahore office for the last 10 years**.

All the related information was forwarded to Prime Minister Public Affairs Grievances Wing, Islamabad in response to received letter.

M/s Bio Pharma, Multan submitted a response reproduced as under;

1. *The product Cerebrolysin was registered from Ministry of Health of Pakistan keeping in view the Pig Brain Extract at time of registration.*
2. *Mostly imported biological products like heparin are also extracted from Pig source.*
3. *Pharmaceuticals formulations mostly consist of Ethanol (Alcohol).*
4. *Chondioitin sulfate is also extracted from insects.*
5. ***We have marketed Cerebrolysin actively, but now we are unable to continue due to higher forex rates & no increase in our product retail price**.*
6. *The manufacturer of Cerebrolysin (Ever Neuro Pharma is not bought by M/s Sandoz Ltd. Germany.)*
7. *We have already received Manufacturer change of name approval from DRAP."*

Decision: **Registration Board advised DBER to prepare the case to seek guidance from DRAP Authority for all such products which are manufactured from porcine source.**

4. **Change in address of importer of already registered veterinary biologicals applied by M/s Marush Pvt. Ltd., Lahore.**

The M/s Marush Pvt. Ltd. Lahore has applied for change of address for company head office as per following detail:

Previous Address	**New Address**
123-K Model Town Lahore	117-A, Ahmad Block, New Garden Town Lahore.

The request of the firm has been reproduced as under;

"As we have moved an application for change of address for company head office with challan payment, which is pending in your office.

Lahore DRAP office has directed us to get the change of address completed for release of upcoming shipment. Thanks to add this to tomorrow's additional agenda so that we don't have to wait till the next board meeting. Special thanks for your cooperation and understanding"

The list of products are mentioned below and the firm has submitted Fee of Rs.5000/- for each product. No other document has been provided.

Sr. No.	**Brand Name**	**Reg. No.**
1	Cevac FP L Vaccine	022790
2	Cevac LT L Vaccine	022791
3	Cevac ND IB K Vaccine	022792
4	Cevac EDS K Vaccine	022793
5	Cevac New K Vaccine	022794
6	Cevac ND IBD K Vaccine	022796
7	Cevac ND EDS K Vaccine	022797
8	Cevac ND IB IBD K Vaccine	022798
9	CevacND IB EDS K Vaccine	022799
10	Cevac NEW L Vaccine	022800
11	Cevac BI L Vaccine	023401
12	Cevac ND IB IBD EDS K Vaccine	023402
13	Cevac IBD L Vaccine	026449
14	Cevac BRON 120L Vaccine	027469
15	Cevac TRANSMUNE IBD Vaccine	039910
16	Cevac Broiler ND K Vaccine	039911
17	Cevac Gumbo L Vaccine	039913
18	Cevac MD Rispens	077532
19	Vectormune HVT NDV	079620
20	Circomune INJ.	081819
21	Vectormune HVT AIV	081819

Decision: 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.**

C. Division of Quality Assurance/Laboratory Testing

Old Cases of Quetta office:

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 was 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 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 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 production Incahrge
   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

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 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 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.

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 01.02.2006 and 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

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)(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.

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 Qulified 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.

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-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.**

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.

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, 2008 informed 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 28th October 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 Bicolax B.No.4E009 labelled 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 28th May 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 their letter 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/17-08/2005 dated 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 26th August 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 Incahrge
   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, **challenged 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** with manufacturing date 12/04:

i. Production Incharge – Qamar ul Huda
ii. Quality Control Manager – Mrs Seema Ashaqeen
iii. Managing Director – Salim Ismail Patel

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.

Case No. 5:- MANUFACTURE AND SALE OF MISBRAND 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 24-11-2005 under 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. 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 for manufacturing 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

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**

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 27-03-2006 the 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 22-04-2006 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** with manufacturing date 07/05:

i. Production Incharge – Zafar Khursheed
ii. Quality Control Manager – Muhammad Irshad
iii. Managing Director – Saboor Ahmed

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.

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.

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.

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.

Case No. 09: CASES DECIDED BY BOARD FOR WHICH IMPLEMENTATION PART IS NOT TRACEABLE/PENDING.

Name of drug	Manufactured by	Declared by CDL as	Current Status of case	Decision of 291st Meeting of RB held on 02-04th September, 2019
1. Tabs. Zoflox **Batch No.** 89ZE	M/s Pharmatec Pakistan (Pvt) Ltd; Karachi	Substandard	Product was declared of Standard Quality by NIH (Appellate Lab) vide test report No. 127-M/2005 dated 20.12.2005.	The Registration Board considered the fact that the Tabs. Zoflox Batch No. 89ZE manufactured by M/s Pharmatec Pakistan (Pvt) Ltd., Karachi has been declared of **Standard** Quality by Appellate Laboratory i.e. NIH Islamabad vide test report No. 127-M/ 2005 dated 20.12.2005 therefore decided to **DROP** the case.
2. Susp. Erythromycin Estolate **Batch No.** 054785	M/s Pliva Pakistan (Pvt) Ltd; Hub	Substandard	Product was declared of Standard Quality by NIH (Appellate Lab) vide test report No. 014-M/2007 dated 04.04.2007.	The Registration Board considered the fact that the Susp. Erythromycin Estolate Batch No. 054785 manufactured by M/s Pliva Pakistan (Pvt) Ltd; Hub has been declared of **Standard** Quality by Appellate Laboratory i.e. NIH Islamabad vide test report No. No. 014-M/ 2007 dated 04.04.2007 therefore decided to **DROP** the case.
3. Tabs. Paracetamol **Batch No.** 1595	M/s Pakistan Pharmaceutical and chemical Hyderabad	Substandard	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.#004251) for 2 months, • Panel inspection of the firm for qualitative investigation of case.	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

			• 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 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.
4. 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 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.	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.
5. Isotop 20 mg Capsule	M/s Panacea Pharmaceuticals, Islamabad	Substandard	Case decided by Drug Registration Board in its 234th Meeting held on	The Registration Board considered the facts/available record of the case and after

Batch No. 003			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, 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**	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.

			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 CDL Karachi" That the-then ADC (QC) vide letter No. F. 3-46/2010-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 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 the market.	
6. 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 Narobe Infusion (Metronidazole) (Reg. 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**	The Registration Board considered the facts/ available record of the case & 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.

			petition was not 2587/2012 is being obtained from the Court, which will be processed accordingly. **That the parawise comments in the afore said writ petition was submitted on 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.**	
7. 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 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.

8. Susp. Eatone. **Batch No.** 1069	M/s PharmaWise Labs (Pvt) Ltd; Lahore.	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 decided to drop the Case as the report of the CDL Karachi s time barred and issues after eleven (11) months.	The Registration Board considered the fact that the case of Susp. Eatone Batch No. 1069 manufactured by M/s PharmaWise Labs (Pvt) Ltd; Lahore has already been **DROPPED** by the Registration Board in its 219th Meeting held on 20th August, 2009 on the ground that the report of the CDL Karachi is time barred and issues after eleven (11) months.
9. Susp. Amocilline DS **Batch No.** K229	M/s CCL Pharmaceutical (Pvt) Ltd; Lahore.	Substandard	The case was presented in 214th DRB held on 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	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.
10. Susp. Dolor **Batch No.** 440	M/s Adamjee Pharmaceutical, Karachi	Substandard	Case dropped in 214th DRB held on 29.10.2008 as the sample declared of "standard" quality by NIH. The same was communicated vide letter No. 03-304/07-QC	The Registration Board considered the fact that the Susp. Dolor Batch No. 440 manufactured by M/s Adamjee Pharmaceutical, Karachi has been declared of **Standard** Quality by Appellate Laboratory i.e. NIH Islamabad and the Board has already

			dated 20.11.2008	**DROPPED** the case in its 214th DRB held on 29.10.2008.
11. 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 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.
12. 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-	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

			then Deputy Director (QA) for its implementation.	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.
13. 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.
14. 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 (Reg. No. 039495) of the firm for a period 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 communicate the implementation of aforesaid Board's decision of the case.

			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 recommended to grant resumption of production.	• 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.

Meeting ended with vote of thanks to and from the Chair.

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