MINUTES OF 273rd MEETING OF CENTRAL LICENSING BOARD HELD ON 15th JANUARY, 2020

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273rd meeting of the Central Licensing Board (CLB) was held on 15th January, 2020 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Prof. Dr Abdullah Dayo, Faculty of Pharmacy, University of Sindh, Jamshoro	Member
2.	Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar	Member
3.	Mr. Muhammad Israr, Law Expert, Ministry of Law & Justice Division.	Member
4.	Dr. Muhammad Usman, Expert member Manufacturing of Drugs	Member
5.	Dr. Munawar Hayat, Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
6.	Syed Abdul Saleem, Chief Inspector of Drugs, Department of Health, Government of Balochistan, Quetta	Member
7.	Dr. Hafsa Karam Ellahi, Representative Director (QA/LT), DRAP, Islamabad	Member
8.	Zakir Shah, Drug inspector, Department of Health, Govt of Khyber Pakhtunkhwa.	Member
9.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
10.	Mr Saleem iqbal and Ms. Mahwish Representatives of PPMA.	Observer
11.	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer
12.	Mr. Kamran Anwar, Representative PC&DA	Observer

The meeting started with the recitation of verses from the Holy Qura'an. The Chairman Central Licensing Board welcomed the honorable members and participants of the meeting. He stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes. The Central Licensing Board discussed and decided that initial draft minutes of the meeting would be prepared by concerned sections of Divisions and counter verified by the Secretary, Central Licensing Board before submitting to the members of the Board. Mr. Ayyaz Ahmed, Deputy Director (Licensing), Mr. Abdul Sattar Sohrani, Deputy irector (Quality Control) , Mr. Zeeshan Nazir, Deputy Director (Quality Assurance), Mr. Arslan Tariq, Assistant Director (QC),Mr. Sanaullah Babar Assistant Director (QC) Mr. Muhammad Yaqoob AD

(Lic.), Mr. Muhammad Usman, AD (Lic), Mr. Farman Ali Bozdar Assistant Director (Lic), and Ms. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 271st MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 272nd meeting of the Central Licensing Board (CLB) which was held on 17th October, 2019.

A. DRUG LICENSING DIVISION

Item-II: **GRANT OF NEW DRUG MANUFACTURING LICENSES.**

Following cases have been forwarded by the respective panel of experts for grant of new Drug Manufacturing Licenses. Same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s D. Haans Pharma (Pvt) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK. **Sections (04)** 1) Oral Liquid Section-I (Vet). 2) Oral Liquid Section-II (Vet). 3) Oral Powder Section-I (Vet). 4) Oral Powder Section-II (Vet).	**12-12-2019**	**Good**	1. Prof. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (Lic), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad. 4. Assistant Director (Lic), DRAP, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s D.Haans Pharma (Pvt)			

	Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK for the grant of Drug Manufacturing License (Formulation) for the following sections namely; 1) Oral Liquid Section-I (Vet). 2) Oral Liquid Section-II (Vet). 3) Oral Powder Section-I (Vet). 4) Oral Powder Section-II (Vet). **Decision of the Central Licensing Board in 273rd meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s D.Haans Pharma (Pvt) Ltd., Plot No. 9/A, Industrial Estate, Bhimber, AJK with following sections: **Sections (04)** 1) Oral Liquid Section-I (Vet). 2) Oral Liquid Section-II (Vet). 3) Oral Powder Section-I (Vet). 4) Oral Powder Section-II (Vet).			
2	M/s Enzon Pharma Labs (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore. **Sections (03)** 1) Large Volume Parenteral (LVP) (General) Section. 2) Small Volume Parenteral (SVP) (General) Section. 3) Ampoule (LDPE) (General) Section.	**05-12-2019 & 12-12-2019**	**Good**	1) Dr. Ikram-ul- Haq, Member Central Licensing Board. 2) Dr. Munawar Hayat, Chief Drugs Controller, Punjab. 3) Ms. Ufaq Tanveer Federal Inspector of Drugs, Lahore. 4) Ms. Anam Saeed, Assistant Director, Lahore.
	Recommendations of the panel: - "Keeping in view the approval of site and building, layout plan approved by DRAP, Islamabad and the facilities like building, HVAC system, machinery & equipments, instruments and personnel, documentation, Quality Control, Microbiological Lab, water			

	treatment and testing facilities, the panel of inspectors **recommended** grant of Drug Manufacturing License M/s Enzon Pharma Labs (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore for the following sections. 1) Large Volume Parenteral (LVP) (General) Section. 2) Small Volume Parenteral (SVP) (General) Section. 3) Ampoule (LDPE) (General) Section." **Decision of the Central Licensing Board in 273rd meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Enzon Pharma Labs (Pvt) Ltd, 5-Km, Off Raiwind Manga Road, Lahore with following sections: **Sections (03)** 1) Large Volume Parenteral (LVP) (General) Section. 2) Small Volume Parenteral (SVP) (General) Section. 3) Ampoule (LDPE) (General) Section			
3	M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M2-Pharma Zone, 26-km Lahore Sharikpur Road, Lahore **Sections (04)** 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) General Dry Powder Injection Section (Pre-Lyophilized) Vial.	**09-12-2019 & 20-12-2019**	**Good**	1) Dr. Ikram-ul- Haq, Member Central Licensing Board. 2) Dr. Munawar Hayat, Chief Drugs Controller, Punjab. 3) Mrs. Majida Mujahid, Federal Inspector of Drugs, Lahore. 4) Ms. Uzma Barkat, Assistant Director, Lahore.
	Recommendations of the panel: - "In the light of inspection conducted by the panel and based on the findings, the panel of inspectors **recommends** grant Of Drug Manufacturing License by way of formulation of			

	M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M-2, Pharm Zone, 26-KM, Lahore Sharaqpur Road, Sheikhupura for following sections:-" 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) General Dry Powder Injection Section (Pre-Lyophilized) Vial. **Decision of the Central Licensing Board in 273rd meeting** The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Variant Pharmaceuticals (Pvt) Ltd, Plot No. 5, M2-Pharma Zone, 26-km Lahore Sharikpur Road, Lahore with following sections: **Sections (04)** 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) General Dry Powder Injection Section (Pre-Lyophilized) Vial.			
4	M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi. **Name of Sections/Facility (19).** **Ground Floor. Dedicated Facility.** 1) Dry Suspension (Cephalosporin) 2) Capsule Section (Cephalosporin) 3) Dry Vial Section (Cephalosporin) 4) Penem Injection Section	**12-12-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (QA/LT), DRAP, Islamabad. 3. Area FID-II, DRAP, Islamabad.

	5) Ware House. **First Floor.** 1) Tablet Section (General). 2) Capsule Section (General). 3) Sachet Section (General). 4) Cream Section (General). 5) Ointment Section (General). 6) Lotion Section (General). 7) Dry Vial Section (General). **Second Floor.** 1) Ampoule Section SVP (General). 2) Infusion Section (General). 3) Hydrocortisone Injection (Steroid). 4) Soft Gel Capsule General. 5) Quality Control Lab. 6) Microbiology Lab.			

Recommendations of the panel: -

"Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi for the grant of Drug Manufacturing License for the following sections as of today;

Ground Floor

1.	Dry Suspension (Cephalosporin)	2.	Capsule Section (Cephalosporin)

	Dedicated Facility.		**Dedicated Facility.**
3.	Dry Vial Section (Cephalosporin) **Dedicated Facility.**	4.	Penem Injection Section **Dedicated Facility.**
5.	Ware House.	6.	Ware House.
First Floor			
1.	Tablet Section (General).	2.	Capsule Section (General).
3.	Sachet Section (General).	4.	Cream Section (General).
5.	Ointment Section (General).	6.	Lotion Section (General).
7.	Dry Vial Section (General)		
Second Floor			
1.	Ampoule Section SVP (General).	2.	Infusion Section (General).
3.	Hydrocortisone Injection (Steroide).	4.	Soft Gel Capsule General.
5.	Quality Control Lab.	6.	Microbiology Lab.

Decision of the Central Licensing Board in 273rd meeting

The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi with following sections:

Ground Floor			
1.	Dry Suspension (Cephalosporin) **Dedicated Facility.**	2.	Capsule Section (Cephalosporin) **Dedicated Facility.**
3.	Dry Vial Section (Cephalosporin) **Dedicated Facility.**	4.	Penem Injection Section **Dedicated Facility.**
5.	Ware House.	6.	Ware House.
First Floor			
1.	Tablet Section (General).	2.	Capsule Section (General).
3.	Sachet Section (General).	4.	Cream Section (General).
5.	Ointment Section (General).	6.	Lotion Section (General).
7.	Dry Vial Section (General)		
Second Floor			
1.	Ampoule Section SVP (General).	2.	Infusion Section (General).

3.	Hydrocortisone Injection (Steroide).	4.	Soft Gel Capsule General.
5.	Quality Control Lab.	6.	Microbiology Lab.

Item- III: **GRANT OF ADDITIONAL SECTIONS/ REVISION/AMENDMENTS ETC.**

The respective panel of experts for grant of additional sections has forwarded following cases. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection / Type of License	Ranking/ Evaluation	Inspection Panel Members
1	M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-KM, Ferozepur Road, Lahore. DML No. 000736 (Formulation). **Section (01):** 1) Liquid Injection (General) (Vet).	**07-10-2019**	**Good**	1.Dr. Farzana Chaudhary, Member, Appellate Board. 2.Syed Shahid Nasir, Member, Appellate Board. 3.Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
	Recommendations of the Panel. The panel of inspectors **recommends** the grant of additional new Liquid Injection (General) (Veterinary) Section subject to the firm (M/s Evergreen Pharmaceuticals, License to manufacture by way of formulation No. 000736), fulfilling all the deficiencies (Annex-I) highlighted by the panel during the two visits as mentioned in the CAPA submitted by the firm (Annex-II). The firm should inform the area FID about all the corrective measures for further action by the authorities. **Decision by the Central Licensing Board in 272nd meeting** The Board considered and decided to defer the case for verification of CAPA by the area Federal Inspector of Drugs. **Proceedings of Licensing Division**			

	Licensing Division intimated the decision of Central Licensing Board to Area Federal Inspector of Drugs vide letter dated 7th November 2019. **Recommendation of the FID** Area Federal Inspector of Drugs inspected the firm on 14th November, 2019 to verify the CAPA submitted by the firm and the **conclusion** of the report is as under: "In view of rectification / compliance of the observation / short coming which were pointed out during the previous inspection dated 07-10-2019, the observation are rectified / complied, of letter No. F. 1-31/2010-Lic (Vol-I) dated 07-11-2019, the observation are rectified / complied, therefore the previous recommendation of report dated 07-10-2019, may be considered for the grant of additional new Liquid Injection (General) (Veterinary) Section M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-KM, Ferozepur Road, Lahore under DML No. 000736". **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of one additional section in the name of M/s Evergreen Pharmaceuticals, 69-70/B, Main Glaxo Town, Industrial Estate, 20-KM, Ferozepur Road, Lahore. License No. 000736 as under: **Section (01)** 1. Liquid Injection (General) (Veterinary)			
2	M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore. DML No. 000461 (Formulation). **Section (01):** 1) Capsule (General).	26-06-2019 & 16-09-2019	**Good**	1.Dr. Farzana Chaudhary, Member, Appellate Board. 2.Mr. Munawar Hayat, Chief Drugs Controller, Punjab. 3.Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore.
	Recommendations of the Panel. "Keeping in view the manufacturing facility like building, HVAC system, sanitation, production			

	Machinery, Equipment in Quality Control Laboratory, testing facilities, the technical personnel met and the review of documentation, the panel of inspectors **recommended** the renewal of Drug Manufacturing License by way of formulation to M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore for Tablet Section (General) and the panel of inspectors also **recommended** the grant of following additional section / expansion. Capsule Section (General)." **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of one additional section in the name of M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore. DML No. 000461 (Formulation). as under: **Section (01)** 1. Capsule (General).			
3	M/s Zafa Chemie, Raiwind Manga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore. DML No. 000589 (Basic Manufacture). **API (06):** 1) Cefixime Trihydrate (BP) 2) Cefradine (BP) 3) Ofloxacin(BP) 4) Levofloxacin (USP) 5) Moxifloxacin (BP) 6) Montelukast Sodium/ (BP). **Manufacturing Facility (10):** 1) Building No. 1 (Multipurpose(General)) 2) Building No. 2 (Multipurpose (General))) 3) Building No. 3 (Multipurpose (General)))	**23-10-2019**	**Good**	1. Dr. Ikram Ul Haq, Member, Central Licensing Board. 2. Dr. Farzana Chaudhary, Expert Member. 3. Ms. Ufaq Tanveer Federal Inspector of Drugs, Lahore.

	4) Building No. 4-A (Penicillin) 5) Building No. 4-B (Cephalosporin) 6) Building No. 5 (Paracetamol) 7) Building No. 6 (Multipurpose (General))) 8) Building No. 7 (Multipurpose (General))) 9) Building No. 8 (Multipurpose(General))) 10) Quality Control Laboratory & Microbiology Laboratory.			

Recommendations of the Panel.

"Keeping in view the above observation, the evaluation of premises, equipments documentation materials, personnel of production, quality Control and EHS, validations, sanitation & hygiene, environment and utilities, layout of manufacturing facility and infrastructure available for manufacturing, the panel **recommend** the grant of revised layout and following additional APIs, to M/s Zafa Chemie, Raiwind Manga Bypass Near Sunder Industrial Estate, Mouza Bahikot, Tehsil & Distt Lahore".

1) Cefixime Trihydrate (BP)
2) Cefradine (BP)
3) Ofloxacin(BP)
4) Levofloxacin (USP)
5) Moxifloxacin (BP)
6) Montelukast Sodium/ (BP)".

Decision by the Central Licensing Board in 273nd meeting

The Board considered and approved the grant of following additional APIs and manufacturing facility in the name of M/s Zafa Chemie, Raiwind Manga Bypass, Near Sundar Industrial Estate, Mouza Bhaikot, Tehsil & District Lahore. DML No. 000589 (Basic Manufacture).

APIs (06)

1) Cefixime Trihydrate (BP)
2) Cefradine (BP)
3) Ofloxacin(BP)

	4) Levofloxacin (USP) 5) Moxifloxacin (BP) 6) Montelukast Sodium/ (BP) **Manufacturing Facility (10):** 1) Building No. 1 (Multipurpose(General) 2) Building No. 2 (Multipurpose (General) 3) Building No. 3 (Multipurpose (General) 4) Building No. 4-A (Penicillin) 5) Building No. 4-B (Cephalosporin) 6) Building No. 5 (Paracetamol) 7) Building No. 6 (Multipurpose (General) 8) Building No. 7 (Multipurpose (General) 9) Building No. 8 (Multipurpose(General) 10) Quality Control Laboratory & Microbiology Laboratory".			
4	M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, NIZ, Rawat, Rawalpindi. DML No. 000892 (Formulation) **<u>Sections (03)</u>** 1) Dry Powder Injection Section (Cephalosporin). 2) Dry Powder for Suspension Section (Cephalosporin). 3) Capsule Section (Cephalosporin).	**12-12-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Deputy Director (Lic), DRAP, Islamabad. 3. Area FID-II, DRAP, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, NIZ, Rawat, Rawalpindi for the grant of Additional Sections namely; 1. Dry Powder Injection Section (Cephalosporin). 2. Dry Powder for Suspension Section (Cephalosporin).			

	3. Capsule Section (Cephalosporin). **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of Three (03) additional sections in the name of M/s Invictus Pharmaceuticals, Plot No. 21 & 26, Street No. NS-2, RCCI, NIZ, Rawat, Rawalpindi. DML No. 000892 (Formulation) as under: **Sections (03)** 1) Dry Powder Injection Section (Cephalosporin). 2) Dry Powder for Suspension Section (Cephalosporin). 3) Capsule Section (Cephalosporin).			
5	M/s Chemiworld (Pvt) Ltd, 97-J, Hayatabad Industrial Estate, Peshawar. DML No. 000579 (Basic Manufacture). **Name of APIs (02).** 1) Iron Sucrose Complex. 2) Iron Protein Succinylate..	**11-10-2019 & 05-11-2019**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Member CLB. 2. Director DTL, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: - "The panel after detailed inspection of the firm concluded that the firm has adequate facility for the production and testing of Iron Sucrose complex and **recommends** the grant of Iron Sucrose Complex API only to the firm. However the firm shall market the API after conduction of successful stability studies which is already under process". **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of One (01) additional APIs in the name of M/s Chemiworld (Pvt) Ltd, 97-J, Hayatabad Industrial Estate, Peshawar. DML No. 000579 (Basic Manufacture) as under: 1) Iron Sucrose Complex. The Board considered and did not approved the grant of API namely Iron Protein Succinylate.			
6	M/s ICI Pakistan Limited, S-	**19-12-019**	**Good**	1. Mr. Abdullah Dayo Member

	33, Hawkes Bay Road, Karachi. DML No. 000006 (Formulation) **Section (01):** 1) Liquid Syrup(General) (Revised)			Central Licensing Board. 2. Chief Drug Inspector - Sindh 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - The panel visited and verified the Liquid Syrup (General) section- Expansion reviewed the relevant documents and LOP, met with their technical persons. The panel observed the area found neat/cleaned, machines were installed appropriately the workers were found working with proper dress, the HVAC system found installed and installed. Based on stated observations the panel **recommends** grant of expansion of third line of 'Liquid General Section'. **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of following Section in the name of M/s ICI Pakistan Limited, S-33, Hawkes Bay Road, Karachi.DML No. 000006 (Formulation) as under: **Sections (01)** 1) Liquid Syrup(General) (Revised)			
7	M/s Abbott Laboratories Pakistan Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi DML No. 000001 (Formulation) **Facility** 1) Raw Material Store (amendments)	8-11-2019	Good	1. Mr. Abdullah Dayo Member Central Licensing Board. 2. Additional Director (E&M) Karachi . 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: -			

	The premises of above mentioned area was visited and related documents were reviewed. The panel observed that fume hood was installed in center of the room while it was in corner in approved layout plan via letter No. F. 2-5/2003-Lic (vol-III) dated 31st October 2018. In response to panel observation, firm submit a letter to revise the location of fume hood in layout plan to the division of Licensing via letter No. Nil dated 21st November,2019. In view of above, the panel **recommends** the grant of amendments in Raw Material Store i.e installation of fume hood for de-cartooning subject to necessary revision of approved layout plan." **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of following Section in the name of M/s Abbott Laboratories Pakistan Ltd, Opposite Radio Pakistan Transmission Center, Hyderabad Road, Landhi, Karachi DML No. 000001 (Formulation) as under: **Facility** **1)** Raw Material Store (Revised)			
8	M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur. DML No. 000429 (Semi Basic Manufacture) **API(02):** 1) Additional enzymatic process line for penicillin: i. Amoxicillin Trihydrate (By enzymatic process). ii. Ampicillin Trihydrate (By enzymatic process).	**02-09-019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Dr. Munawar Hayat, CDC, Punjab, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - "Keeping in view the findings of the inspection, technical people met and the documents reviewed, the panel **recommends** the grant of addition of enzymatic process line for synthesis of Penicillin (Amoxicillin Trihydrate and Ampicillin Trihydrate.".			

	Decision by the Central Licensing Board in 273nd meeting The Board considered and approved the grant of following in the name of M/s Citi Pharma (Pvt) Ltd, 3-Km, Head Balloki Road, Phool Nagar, District Kasur.DML No. 000429 (Semi Basic Manufacture) as under: **API(02):** 1) Additional enzymatic process line for penicillin: i. Amoxicillin Trihydrate (By enzymatic process). ii. Ampicillin Trihydrate (By enzymatic process).			
9	M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sunder Industrial Estate, Lahore. DML No. 000872 (Formulation **Section (01):** 1) Soft Gelatin Capsule.	04-12-2019	Good	1. Dr. Haleem Khan, Chairman Pharmacy Department, F.C University. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - "Keeping in view the facilities like building, HVAC, machinery, equipments, instruments, personnel, documentation and quality Control, testing facilities, the panel of inspectors is of the opinion to **recommend** the grant of additional section to M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sunder Industrial Estate, Lahore for the following section only: 1) Soft Gelatin Capsule section ." **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of one (01) additional section in the name of M/s Pharmasol (Pvt) Ltd, Plot No. 549, Sunder Industrial Estate, Lahore. DML No. 000872 (Formulation as under: **Section (01):** 1) Soft Gelatin Capsule.			
10	M/s British Pharmaceuticals,	**19-08-019**	**Good**	1. Dr. Farzana Ch, Member,

	23-Km Sheikhupura Road, Lahore. Drug Manufacturing License No. 000729 (Formulation) **Section (03):** 1) Capsule Section (General) (New) 2) Dry Powder Section (General) (New). 3) Tablet Section (General) (New).	**&** **27-12-019**		Technical Expert. 2. Mr. Shahid Nasir, Quality Control Expert. 3. Dr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 4. Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel: -

The firm has made a number of improvements, which were pointed out during previous inspections regarding installation of new machines/equipments. Improvements in process flow, improvements in documentation system. Keeping in view the improvements made by the firm, and commitments for future improvement, the members of the panel are of opinion to **recommend** the grant of new production sections as well as renewal of Drug Manufacturing License (000729) by way of Formulation for the following sections:

1) Liquid Syrup/Suspension (Existing section).
2) Capsule Section (General) (New)
3) Dry Powder Section (General) (New).
2) Tablet Section (General) (New).

<u>Decision by the Central Licensing Board in 273nd meeting</u>

The Board considered and approved the grant of three (03) additional sections in the name of M/s British Pharmaceuticals, 23-Km Sheikhupura Road, Lahore. Drug Manufacturing License No. 000729 (Formulation) as under:

Sections (03):

	1) Capsule Section (General) (New) 2) Dry Powder Section (General) (New). 3) Tablet Section (General) (New).			
11	M/s Medizan Pharmaceuticals, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad. **Section (01).** 1.Psychotropic (Tablet) Section (in place of Quinolones Tablet Section).	**09-01-2020**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Additional Director (QA/LT), DRAP, Islamabad. 3. Area FID-II, DRAP, Islamabad.
	"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **Recommended** the approval of following additional (new) section of M/s Medizan Pharmaceuticals, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad 1. Tablet Section (Psychotropic). **Decision by the Central Licensing Board in 273nd meeting** The Board considered and approved the grant of One (01) additional section in the name of M/s Medizan Pharmaceuticals, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad Drug Manufacturing License No. 000572 (Formulation) as under: **Section (01).** 1) Tablet Section (Psychotropic) (in place of Tablet Section (Quinolones)).			
12.	M/s Sclife Pharma (Pvt Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi. DML No. 000837 (by way of Formulation) **Sections (05).** i. Dry Powder Inhaler (General)-New ii. Sachet Section	10-01-2020	Good	1. Mr. Abdullah Dayo Member Central Licensing Board. 2. Chief Drug Inspector, Karachi. 3. Area Federal Inspector of Drugs, DRAP, Karachi.

	(General)-Relocated iii. Capsule section (General)-Relocated iv. Raw Material Store-Amendment v. WIP room-Relocated			

Recommendations of the panel: -

The section are built, relocated and made amendments as per layout plan approved by DRAP authorities Islamabad vide DRAP letter No. F.2-4/11-lic. Dated 9th December 2019. Necessary utilities, machineries and equipments as required under the guidelines are seen available onsite. Necessary documents relating to QC, QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and found satisfactory.

Based on the above stated facts the panel recommends the following:

i. Dry Powder Inhaler (General)-New
ii. Sachet Section (General)-Relocated
iii. Capsule section (General)-Relocated
iv. Raw Material Store-Amendments
v. WIP room-Relocated

Decision by the Central Licensing Board in 273nd meeting

The Board considered and approved the grant of following sections in the name of M/s Sclife Pharma (Pvt Ltd, Plot No. FD-57/58-A2, Korangi Creek Industrial Park (KCIP), Karachi. DML No. 000837 (by way of Formulation) as under:

Sections/Facility(05)

i. Dry Powder Inhaler (General)-**New**
ii. Sachet Section (General)-**Revised**
iii. Capsule section (General)- **Revised**
iv. Raw Material Store- **Revised**
v. WIP room- **Revised**

Item-IV: **GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE.**

Following cases have been forwarded by the respective panel of experts for grant of Renewal of Drug Manufacturing Licenses. The same are placed before the Board for its consideration/decision, please.

S #	Name of the firm	Date of Inspection	Ranking/ Evaluation	Inspection Panel Members
1	M/s McOLSON Research Laboratories (Pvt) Ltd, 26-Km, Lahore- Sharikpur Road, District Sheikhupura. DML No. 000664 (Formulation). **Period**: Commencing on 15-06-2019 ending on 14-06-2024.	**24-10-2019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Dr. Munawar Hayat, CDC, Punjab, Lahore. 3. Mrs. Majida Mujahid, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - Keeping in view the improvements made by the firm, implementation, of the GMP commitment for future improvement, the member of the panel are opinion to **recommend** the grant of Renewal of Drug Manufacturing License 000664 by way of formulation for the following section". 1) Capsule Section (Cephalosporin) 2) Dry Powder Suspension (Cephalosporin) 3) Dry Powder Injection Section (Cephalosporin). 4) Tablet Section (General) 5) Capsule Section (General) **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000664 (Formulation) in the name of M/s McOLSON Research Laboratories (Pvt) Ltd, 26-Km, Lahore-			

<table>
<tr><td></td><td colspan="4">Sharikpur Road, District Sheikhupura on the recommendations of the panel of experts for the further period of five years Commencing on 15-06-2019 ending on 14-06-2024 for following sections:-
1) Capsule Section (Cephalosporin)
2) Dry Powder Suspension (Cephalosporin)
3) Dry Powder Injection Section (Cephalosporin).
4) Tablet Section (General)
5) Capsule Section (General)</td></tr>
<tr><td>2</td><td>M/s Hamaz Pharmaceuticals (Pvt) Ltd, 13-Km, Lutafabad Bosan Road, Multan.

DML No. 000427 (Formulation).

Period: Commencing on 01-04-2016 ending on 31-03-2021.</td><td>29-08-2019</td><td>Good</td><td>1. Dr. Ikram Ul Haq, Member Central Licensing Board.
2. Director Drug Testing Laboratory, Multan.
3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore.
4. Assistant Director, DRAP, Lahore.</td></tr>
<tr><td></td><td colspan="4">Recommendations of the panel:
Based upon the physical inspection of the unit, evaluation and review of the documentation during inspection, discussion with the technical staff and review of the production facilities, building, equipments, quality control and quality Assurance, the panel of the opinion to recommend the Renewal of Drug Manufacturing License 000427 by way of Formulation to M/s Hamaz Pharmaceuticals (Pvt) Ltd. 13-Km, Boan Road, Lutufabad, Multan for the following section".
1) Tablet Section (General & Antibiotic)
2) Capsule Section (General & Antibiotic)
3) Dry Powder Suspension (General)
4) Oral liquid Section (General)
5) Liquid Injection (Ampoule & Vial) (General) section.
6) Sachet Section (General)
7) Cream Section (General)
8) Capsule Section (Cephalosporin)</td></tr>
</table>

	9) Dry Powder suspension (Cephalosporin) 10) Dry Powder for Injection (Cephalosporin) 11) Dry Powder suspension (Penicillin) 12) Capsule section (Penicillin) 13) Tablet Section (Penicillin) **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000427 (Formulation) in the name of M/s Hamaz Pharmaceuticals (Pvt) Ltd, 13-Km, Lutafabad Bosan Road, Multan on the recommendations of the panel of experts for the further period of five years Commencing on 01-04-2016 ending on 31-03-2021 for following sections:- 1) Tablet Section (General & Antibiotic) 2) Capsule Section (General & Antibiotic) 3) Dry Powder Suspension (General) 4) Oral liquid Section (General) 5) Liquid Injection (Ampoule & Vial) (General) section. 6) Sachet Section (General) 7) Cream Section (General) 8) Capsule Section (Cephalosporin) 9) Dry Powder suspension (Cephalosporin) 10) Dry Powder for Injection (Cephalosporin) 11) Dry Powder suspension (Penicillin) 12) Capsule section (Penicillin) 13) Tablet Section (Penicillin)			
3	M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore. DML No. 000461 (Formulation). **Period**: Commencing on 05-08-2017 ending on 04-08-2022.	**26-06-2019 & 16-09-2019**	**Good**	1.Dr. Farzana Chaudhary, Member, Appellate Board. 2.Mr. Munawar Hayat, Chief Drugs Controller, Punjab. 3.Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore.

	Recommendations of the Panel. "Keeping in view the manufacturing facility like building, HVAC system, sanitation, production Machinery, Equipment in Quality Control Laboratory, testing facilities, the technical personnel met and the review of documentation, the panel of inspectors **recommends** the renewal of Drug Manufacturing License by way of formulation to M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore for Tablet Section (General) and the panel of inspectors also **recommend** the grant of following additional section / expansion. Capsule Section (General)." **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No000461 (Formulation) in the name of M/s Alfalah Pharma (Pvt) Ltd, 12-Km, Sheikhupura Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 05-08-2017 ending on 04-08-2022 for following section:- 1. Tablet Section (General)			
4	M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore- Sheikhupura Road, Lahore. DML No. 000532 (Formulation). **Period:** Commencing on 26-01-2019 ending on 25-01-2024.	**31-10-2019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Mr. Munawar Hayat, Chief Drugs Controller, Punjab. 3. Mrs. Majida Mujahid, Federal Inspector of Drugs, Lahore.
	Recommendations of the panel: - "The firm has made a number of improvement which were pointed out during previous inspections regarding installation of new machine/equipment. Improvements in process flow, improvement in documentation system and addition in installation of safety equipment. Keeping in view, the improvements made by the firm, implementation of the GMP and commitment for future improvement, the member of the panel are of opinion to **recommend** the grant of renewal of Drug Manufacturing License (00532) by way of formulation for the following sections:- 1) Tablet (General)			

	2) Tablet (Non Penicillin Antibiotics) 3) Capsule 4) Liquid Injectable 5) Eye Drops. 6) Eye / Ear Drops (Steroidal). 7) Topical Preparation. 8) Ophthalmic Ointment" **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence 000532 (Formulation) in the name of M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore-Sheikhupura Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 26-01-2019 ending on 25-01-2024 for following sections:- 1) Tablet (General) 2) Tablet (Non Penicillin Antibiotics) 3) Capsule 4) Liquid Injectable 5) Eye Drops. 6) Eye / Ear Drops (Steroidal). 7) Topical Preparation. 8) Ophthalmic Ointment"			
5	M/s Popular Chemical Works (Pvt) Ltd, 9-Km, Lahore Sheikhupura Road, Lahore. DML No. 000076 (Formulation). **Period**: Commencing on 30-08-2015 ending on 29-08-2020.	**29-05-2019**	**Good**	1. Dr. Ikram Ul Haq, Member Central Licensing Board. 2. Mr. Asim Rauf, Additional Director, DRAP, Lahore. 3. Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore. 4. Ms. Uzma Barkat, Assistant Director, DRAP, Lahore.

	Recommendations of the Panel. "During inspection some points were discussed with the management and advised for improvement and the management agreed. Keeping in view the manufacturing facility like, building, HVAC system, sanitation, production machinery, equipment in Quality Control and Microbiology Laboratory. Testing facilities, technical personnel met and documentation, the panel of inspectors recommends the renewal of Drug Manufacturing License by way of Formulation to M/s Popular Chemical Works (Pvt) Ltd, 9.f Km, Sheikhupura Road, Lahore for the followings sections: 1) Tablet section (General& Psychotropic). 2) Capsule section (General). 3) Oral Liquid section (General). 4) Liquid Injectable Ampoule section (General). 5) Dry Powder Suspension section (Penicillin). 6) Capsule section (Penicillin)" **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence 000076 (Formulation) in the name of M/s Popular Chemical Works (Pvt) Ltd, 9-Km, Lahore Sheikhupura Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 30-08-2015 ending on 29-08-2020 for following sections:- 1) Tablet section (General& Psychotropic). 2) Capsule section (General). 3) Oral Liquid section (General). 4) Liquid Injectable Ampoule section (General). 5) Dry Powder Suspension section (Penicillin). 6) Capsule section (Penicillin)"			
6	M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi. DML No. 000639 (Formulation) **Period**: Commencing on 19-06-2018 ending 18-06-2023.	**25-11-2019 & 25-11-2019**	**Good**	1. Dr. Muhammad Usman, Member, CLB. 2. Abdul Sattar Sohrani, Deputy Director (QC-I), DRAP, Islamabad. 3. Khalid Mahmood, FID-II, DRAP, Islamabad.

Recommendations of the panel: -

Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended** M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Road, Rawat, Rawalpindi for the grant of Drug Manufacturing License No. 000639 (Formulations) w.e.f. 19th June, 2018.

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence 000639 (Formulation) in the name of M/s Biogen Pharmaceuticals, 8-KM, Chakbeli Khan Road, Rawat, Rawalpindi on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 ending 18-06-2023 for following sections:-

i. Oral Liquid (General) Vetarinary
ii. Oral Powder (General) Vetarinary
iii. Liquid Injection (Vial) (General) Section Vetarin ary
iv. Tablet (General) Section (Human)
v. Cream/Ointment/Gel (General) Human

7	M/s. Nabi Qasim Industries Private Limited, 17/24, Korangi Industrial Area, Karachi DML No. 000105 (formulation) **Period**: Commencing on 12-07-2019 ending 11-07-2024	**04-12-2019**	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Additional Director (E&M)/ Area Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

Based on the people met, documents reviewed and considering the observation made during the inspection including huge exports to about fourty one counties of the world, panel recommends the renewal of Drug Manufacturing License for the following sections

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Capsule (ceph)	ii.	Oral dry powder suspension (Ceph)

	iii.	Lyophilized vial (General)	iv.	Tablet (General)
	v.	Capsule (General)	vi.	Sachet (General)
	vii.	Liquid syrup(General)	viii.	Cream/Ointment (General)
	ix.	Ear Drops/Topical solution	x.	Eye Drops
	xi.	Dry Powder (General/Antibiotic)	xii.	Enema
	xiii.	Tablet Harmone	xiv.	Harmone (Vaginal Tablet/Gel)

The panel has not submitted any recommendations regarding renewal of Licensed section with the title Tablet (Cephalosporin).

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence 000105 (formulation) in the name of M/s. Nabi Qasim Industries Private Limited, 17/24, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 12-07-2019 ending 11-07-2024 for following sections:-

Sr. No	**Name of Sections**	**Sr. No**	**Name of Sections**
i.	Capsule (ceph)	ii.	Oral dry powder suspension (Ceph)
iii.	Lyophilized vial (General)	iv.	Tablet (General)
v.	Capsule (General)	vi.	Sachet (General)
vii.	Liquid syrup(General)	viii.	Cream/Ointment (General)
ix.	Ear Drops/Topical solution	x.	Eye Drops
xi.	Dry Powder (General/Antibiotic)	xii.	Enema
xiii.	Tablet Harmone	xiv.	Harmone (Vaginal Tablet/Gel)

The Borad decieded to seek clarification from the panel regarding not recommending the renewal of Licensed section namely Tablet (Cephalosporin).

8	M/s Sami Pharmaceuticals (Pvt) Ltd , Plot No F-129, S.I.T.E Karachi	**05-11-2019**	**Good**	1. Dr. Ghulam Sarwar, Member DRB. 2. Chief Drug Inspector,

	Drug Manufacturing License No. 000731 (By way of Repacking) **Period**: 20-06-2016 to 19-06-2021			Sindh 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the management's commitment for continues improvement, existing technical staff and facilities provided; the panel recommends Grant of Renewal of Drug Manufacturing License No. 000731 (By Way of Repacking) to the firm M/s. Sami Pharmaceuticals (Pvt) Ltd situated at Plot no. F-129, S.I.T.E, Karachi. As per DRAP, Islamabad letter No. F.2-2/10-Lic dated 17th September 2019." **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000731 (By way of Repacking) in the name of M/s Sami Pharmaceuticals (Pvt) Ltd , Plot No F-129, S.I.T.E Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 20-06-2016 ending 19-06-2021.			
9	M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi Drug Manufacturing License No. 000642 (By way formulation) **Period**: 05-09-2018 to 04-09-2023	**21-11-2019**	**Good**	1. Dr. Abdulah Dayo, Member CLB. 2. Additional Director (E&M), DRAP, Karachi 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Based on the stated observations, the panel recommends the renewal of following sections:			

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)

iii.	Liquid Ampoule (General)	iv.	Oral dry powder suspension (General)	
v.	Cream/Ointment/Gel (General)	vi.	Ophthalmic Drops (General)	

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000642 (By way formulation) in the name of M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 05-09-2018 ending 04-09-2023 for following sections:-

Sr. No	Name of Sections	Sr. No	Name of Sections
i.	Tablet (General)	ii.	Capsule (General)
iii.	Liquid Ampoule (General)	iv.	Oral dry powder suspension (General)
v.	Cream/Ointment/Gel (General)	vi.	Ophthalmic Drops (General)

10	M/s AGP Limited, D-109, S.I.T.E Karachi Drug Manufacturing License No. 000044 (Formulation) **Period**: 15-07-2019 to 14-07-2024	**07-11-19**	**Good**	1. Dr. Abdulah Dayo, Member CLB. 2. Director DTL, Sindh Karachi 3. Area Federal Inspector of Drugs, DRAP, Karachi.

Recommendations of the panel: -

Keeping in view overall GMP compliance and intend towards improvement, panel unanimously recommend the renewal of DML No. 000044 and regularization of Manufacturing facility of M/s. AGP Limited, Plot No. D-109, S.I.T.E Karachi.

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000044 (Formulation) in the name of M/s AGP Limited, D-109, S.I.T.E Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 15-07-2019 ending 14-07-2024.

11	M/s Sapient Pharma, 123/S Industrial Area, Kot Lakhpat, Lahore. Drug Manufacturing License No. 000207 (Formulation) **Period**: Commencing on 09-02-2016 ending on 08-02-2021.	**19-09-2019 & 18-11-2019**	**Good**	1. Dr. Farzana Chowdhary, Member. 2. Ms. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the panel: -

In view of above inspection proceedings and facilities checked such as company, profile building machinery material, management, personnel, documentation and quality control testing, etc, the panel **recommends** the renewal of Drug Manufacturing License to M/s Sapient Pharma, 123/S, Industrial Estate, Kot Lakhpat, Lahore by way of formulation for the following sections only:-

1) Oral Liquid Section.
2) General Tablet Section.
3) Cream/Ointment Section.
4) External Preparation Section.
5) Ear Drop Section.
6) Suppository Section".

In addition to this it was observed that the area of the firm was 2 Kanal 4 Marlas, however the management of the firm informed that the adjacent land of 2 Kanal 1 Marla was purchased by the firm and now the total area is 04 Kanal 05 Marla as per requirement of Drugs Act 1976/DRAP Act 2012,. The panel advised the firm to submit documents of acquired land for regularization to Licensing Division, DRAP, Islamabad.

Decision by the Central Licensing Board in 273rd meeting

The Board considered and defferred the renewal of Drug Manufacturing Licence No. 000207 (Formulation) in the name of M/s Sapient Pharma, 123/S Industrial Area, Kot Lakhpat, Lahore.for seeking clarification regarding minimum area of establishment in the light of observation of the panel.

12	M/s British Pharmaceuticals,	**19-08-2019**	**Good**	1. Dr. Farzana Ch, Member.

	23-Km Sheikhupura Road, Lahore. Drug Manufacturing License No. 000729 (Formulation) **Period**: Commencing on 22-06-2016 ending on 21-06-2021.	**&** **27-12-2019**		2. Mr. Shahid Nasir, Quality Control Expert. 3. Dr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 4. Mrs. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendations of the panel: - The firm has made a number of improvements, which were pointed out during previous inspections regarding installation of new machines/equipments. Improvements in process flow, improvements in documentation system. Keeping in view the improvements made by the firm, and commitments for future improvement, the members of the panel are of opinion to **recommend** the grant of new production sections as well as renewal of Drug Manufacturing License (000729) by way of Formulation for the following sections: 1) Liquid Syrup/Suspension (Existing section). 2) Capsule Section (General) (New) 3) Dry Powder Section (General) (New). 4) Tablet Section (General) (New). **Decision by the Central Licensing Board in 273rd meeting** The Board considered and approved the renewal of Drug Manufacturing Licence No. 000729 (Formulation) in the name of M/s British Pharmaceuticals, 23-Km Sheikhupura Road, Lahore. on the recommendations of the panel of experts for the further period of five years Commencing on 22-06-2016 ending on 21-06-2021. 1) Liquid Syrup/Suspension			
13	M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sunder Industrial Estate, Lahore. Drug Manufacturing License No. 000782 (Formulation)	**20-09-2019** **&** **21-11-2019**	**Good**	1. Dr. Farzana Ch, Expert. 2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 3. Ms. Ufaq Tanveer, Federal Inspector of Drugs, DRAP, Lahore.

	Period: Commencing on 03-02-2019 ending on 02-02-2024.			4. Ms. Anam Saeed, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: - The panel inspections of the firm M/s Horizon Healthcare (Pvt) Ltd, Plot No. 27, Sunder Industrial Estate, Lahore were conducted on 20-09-2019 & 21-11-2019 for grant of renewal of Drug Manufacturing License. All the areas were inspected in detail including stores, production areas, Quality Control, HVAC, water treatment etc and documents were reviewed which were found satisfactory. *But it was noticed during visit that the firm had obtained approval of their revised layout plan in August, 2018 and the building was partially constructed according to the revised layout plan while rest of the areas (including warehouse & some areas of tablet and capsule section) were not in line with the approved layout.* The firm applied for this revision in DRAP Islamabad on 13-12-2019 and submit copy in this office. So, the panel members are of the opinion that the renewal of DML is subject to the condition of approval/ regularization of their existing layout from DRAP Islamabad. **Decision by the Central Licensing Board in 273rd meeting** The Board considered and defferred the renewal of Drug Manufacturing Licence No. 000782 (Formulation) in the name of M/s Horizon Healthcare (Pvt) Ltd, Plot No. 33, Sunder Industrial Estate, Lahore.till regularizaiton /approval Layout plan and verification by Area FID .			
14	M/s Remington Pharmaceutical Industries (Pvt) Ltd, 18-Km Multan Road, Lahore. Drug Manufacturing License No. 000061 (Formulation) **Period**: Commencing on 19-06-2018 ending on 18-06-2023.	**12-06-2019 & 17-07-2019 & 30-09-2019**	**Good**	1. Dr. Farzana Ch, Expert Member. 2. Syed Shahid Nasir, Expert Member. 3. Dr. Zaka ur Rehman, Secretary Punjab Pharmacy council, Lahore. 4. Ms. Uzma Barkat, Federal Inspector of

				Drugs, DRAP, Lahore.

Recommendations of the panel: -

"The firm was directed to get the existing layout plan approved /regularization from DRAP, Islamabad without fail.

In the light of the inspection conducted by the panel and based on the findings, the panel of inspectors recommends Grant of renewal of Drug Manufacturing License by way of formulation of M/s Remington Pharmaceutical Industries (Pvt) Ltd, Lahore for the following section,"

i. Tablet Section (General & Antibiotics)

ii. Dry Powder Suspension Section (General& Antibiotics)

iii. Capsule Section (General & Antibiotics)

iv. Sachet Section General.

v. Oral Liquid Section (General) Syrup/Suspension.

vi. Eye, Ear & Nose Drops Section (General & Steroid) Solution/ Suspension

vii. Eye Ointment Section (General & Steroid)

viii. Ear, Nose & Throat Section (General & Steroid) Solution/ Suspension (Ear Drops/ Nasal Spray)

ix. Skin Ointment/Cream/Lotion Section (General & Steroid)

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000061 (Formulation) in the name of M/s Remington Pharmaceutical Industries (Pvt) Ltd, 18-Km Multan Road, Lahore on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 ending on 18-06-2023 for following secions:-

i. Tablet Section (General & Antibiotics)

ii. Dry Powder Suspension Section (General& Antibiotics)

iii. Capsule Section (General & Antibiotics)

iv. Sachet Section General.

	v. Oral Liquid Section (General) Syrup/Suspension. vi. Eye, Ear & Nose Drops Section (General & Steroid) Solution/ Suspension vii. Eye Ointment Section (General & Steroid) viii. Ear, Nose & Throat Section (General & Steroid) Solution/ Suspension (Ear Drops/ Nasal Spray) ix. Skin Ointment/Cream/Lotion Section (General & Steroid) The borad also decided to advise the firm for regularization of layout plan of existing facility as recommended by the panel.			
15.	M/s Espoir Pharmaceuticals PCSIR KLC, PCSIR Laboratories Complex, Shahrah-e-Drsalim-uz-zamanSiddique, ,Off University Road KLC, Karachi Drug Manufacturing License No. 000754 (By way formulation) **Period**: Commencing on 05-10-2017 ending on 04-10-2022	**19-12-2019**	**Good**	1. Dr. Abdulah Dayo, Member CLB. 2. Additional Director E&M, DRAP Karachi 3. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Keeping in view the status of observation, current compliance status the panel recommends the resumption of production activates and renewal of DML by way of formulation for following sections: a) Liquid Syrup b) Tablet (General) c) Sachet d) Capsule (General) e) Dry Powder Suspension			

	Decision by the Central Licensing Board in 273rd meeting The Board considered and approved the renewal of Drug Manufacturing Licence No. 000754 (By way formulation) in the name of M/s Espoir Pharmaceuticals PCSIR KLC, PCSIR Laboratories Complex, Shahrah-e-Drsalim-uz-zamanSiddique, ,Off University Road KLC, Karachi on the recommendations of the panel of experts for the further period of five years Commencing on 05-10-2017 ending on 04-10-2022 for following secions:- 1. Liquid Syrup 2. Tablet (General) 3. Sachet 4. Capsule (General) 5. Dry Powder Suspension The borad alos decided to resume the production of the firm as per recommendation of the panel of experts.			
16.	M/s Ahson Drug Company, T/1 SITE, Tando Adam ,Sindh. Drug Manufacturing License No. 000138 (By way formulation) Tenure 17-12-2014 to 16-12-2019	**14-10-2019**	**Good**	1. Dr. Abdullah Dayo, Member CLB. 2. Chief Drug Inspector, Sindh. 3. Additional Director E&M, DRAP Karachi 4. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - Based on the people met, documents reviewed and observations made during the inspection and intention of the management towards export, the panel recommends :- A- The renewal of their DML No. 000138 (By way of Formulation) for following sections : 1. Syrup (General) 2. Tablet (General) 3. Dry Powder Suspension 4. Capsule (General) 5. Ointment (General) 6. Sterile Area (vial/ampoule)			

	7. Eye Drops 8. Ointment (sterile) B- The panel also advises to the management to submit the layout plan to the DRAP authorities for regularization purposes. **Decision by the Central Licensing Board in 273rd meeting** The borad also decided to advise the firm for regularization of layout plan of existing facility as recommended by the panel.			
17	M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore. DML No. 000493(Formulation) **Period**: Commencing on27-02-2017ending on26-02-2022	**12-06-2019**	**Satisfactory / Average** (w.r.t. Liquid repacking and external preparation sections) **Un-satisfactory (**w.r.t all other sections**)**	1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 4. Dr. Akbar Ali, Assistant Director, DRAP, Lahore.
	Case Background:- Panel Inspection report dated 26-11-2018 was received from DRAP, Lahore for renewal of Drug Manufacturing License with following recommendations of the panel. **Recommendations of the panel: -** The Panel of inspectors **does Not Recommend** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore. **Decision by the Central Licensing Board in 267th meeting** The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. **Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**			

	The Show Cause notice dated 29th January, 2019 was issued to M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore. The firm has replied to show cause notice and the firm has requested to provide sufficient time to explain their position in writing. **A letter of Personal hearing has been issued on 19-02-2019** **Decision by the Central Licensing Board in 269th meeting** Mr . Arjumand Bhutta, Director of the company appeared before the Board and contended that almost most of the shortcomings have been rectified as advised during the panel inspection and report recived with Showcause Notice. He further contended that period of one month is required to rectify rest of the shortcomings as reported in the report. The Board after hearing the representative of the firm decided to give one month period to the firm. The company shall submit request for re-inspection of the unit once rectification are made and accordingly a panel would be constituted to conduct inspection for consideration of the Board. Meanwhile Licence of the company shall remain suspended. **Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.** The Licensing Division issued Drug Manufacturing License suspension letter dated 13-03-2019. The firm submitted compliance report and request for re-inspection. Following panel of experts were constituted dated 06-05-2019. 1. Dr. Ikram-ul-Haq, Member CLB. 2. Mr. Jamil Anwar, Secretary PQCB, Punjab, Lahore. 3. Area Federal Inspector of Drugs, DRAP, Lahore. 4. Area Assistant Director, DRAP, Lahore. Inspection report has been received from DRAP, Lahore with following recommendations of the panel. **Recommendations of the panel: -** The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd in respect of Liquid repacking and external preparation sections only. The Panel of Inspectors **does not recommend** the renewal in respect of all other sections. The Panel further recommends suspension of production in all the section which are not recommended for renewal till the rectification of shortcoming and GMP compliance.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

In the meanwhile the firm has informed that they improved of working of HVAC system as per instruction by Panel of inspectors which conducted firms inspection on 12-06-2019. The firm has requested for re-inspection.

Decision by the Central Licensing Board in 271st meeting

The Board considered and approved the renewal of Drug Manufacturing Licence No. 000493 (Formulation) in the name of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore,on the recommendations of the panel of experts for the further period of five years commencing on 27-02-2017 and ending on 26-02-2022for following sections:

Sections

1. Liquid Repacking
2. External Preparation Sections

Moreover, the Board did not approve rest of sections on the recommendation of the panel of experts;

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Licensing Division issued Drug Manufacturing License to the firm for Liquid Repacking and External Preparation Sections 04-10-2019. The firm requested for re-inspection. Following panel of experts were constituted dated 07-11-2019.

1. Dr. Ikram-ul-Haq, Member CLB.
2. Secretary PQCB, Punjab, Lahore.
3. Area Federal Inspector of Drugs, DRAP, Lahore.
4. Area Assistant Director, DRAP, Lahore.

Ms. Majida Mujahid was nominated in place of Dr. Ikram-ul-Haq, Member CLB as he has gone aboard due to his personal commitments vide letter dated 20-12-2019.

Inspection report has been received from DRAP, Lahore with following recommendations of the panel.

*"he panel of Inspectors **Recommends** the renewal of Drug manufacturing License bearing No.000493 issued in favor of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga off Rawind Road, Lahore in respect of Oral Liquid section and Tablet (General) section only, The panel of inspectors **Does not Recommend** the renewal in*

	respect of all the sections situated at first floor i,e Tablet (Antibiotic),Capsule, cream/ointment and oral dry powder suspension sections, which are not recommended for renewal till the rectification of shortcomings and GMP compliance". **<u>Decision by the Central Licensing Board in 273rd meeting</u>** 1. The Board considered and approved the renewal of Drug Manufacturing Licence No. 000493 (Formulation) in the name of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore on the recommendations of the panel of experts for the further following sections i. Oral liquid Section General ii. Tabelt section General 2. The Borad did not approved the renewal of Secions namely Tablet (Antibiotic),Capsule, cream/ointment and oral dry powder suspension sections, on the recommendation of panel of Experts / Inspector till the rectification of shortcomings and GMP compliance the production shall remain suspended till rectification made and verified by the panel constituted by the Board. 3. The board also decieded to advise the firm for regularization of layout plan for better GMP compliance. .

ITEM – V MISC CASES

Case No.1 **CHANGE OF MANAGEMENT OF M/S AMSON VACCINES & PHARMA (PVT) LTD, 154, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD**

M/s Amson Vaccines & Pharma (Pvt) Ltd., 154, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000393 (By way of formulation) has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form 29	**Outgoing Management**	**New Management as per Form 29**
1. Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5. 2. Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 3. Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7.	Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5.	1.Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 2.Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7. 3.Mr. Abbas Khan S/o Dilawar Khan CNIC No. 16101-9382481-7.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Amson Vaccines & Pharma (Pvt) Ltd., 154, Industrial Triangle, Kahuta Road, Islamabad under DML No. 000393 by way of Formulation as under ;

Previous Management as per Form 29	**Outgoing Management**	**New Management as per Form 29**
1. Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5. 2.Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 3.Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7.	1.Mr. Dilawar Khan S/o Roshan Khan, CNIC No. 161019-288045-5.	1. Syed Saleem Asghar S/o Asghar Ali Sagheer, CNIC No. 37405-0386356-5. 2.Mr. Shamim Ahmed Khan S/o Abdul Majeed Khan CNIC No. 37405-9227345-7. 3.Mr. Abbas Khan S/o Dilawar Khan CNIC No. 16101-9382481-7.

Case No.2 **CHANGE OF MANAGEMENT OF M/S MEDWELL PHARMACEUTICALS, 1-KM, TERBELLA ROAD, LAWRENCEPUR, FAQIRABAD.**

M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur, Faqirabad, under DML No. 000699 (By way of formulation) has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Previous Management	Outgoing Management	New Management
1. Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2. Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3. Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1.Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2.Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3.Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1. Syed Mansoor Ali Shah S/o Syed Mehmood Ali Shah CNIC No. 37485-7498787-9. 2. Mr. Umer Hayat Khan S/o Qamar Hayat Khan CNIC No. 35201-0568913-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management M/s Medwell Pharmaceuticals, 1-Km, Terbella Road, Lawrencepur, Faqirabad, under DML No. 000699 by way of Formulation as under;

Previous Management	Outgoing Management	New Management
1. Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2. Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3. Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1. Mr. Jvaied Iqbal Chishti S/o Abdul Hameed CNIC No. 37406-6558480-7. 2.Mr. Shabeer Ahmad S/o Shamsuddin CNIC No. 38403-7945363-1. 3.Mr. Mohammad Munir S/o Shamsuddin CNIC No. 38403-4474939-7.	1. Syed Mansoor Ali Shah S/o Syed Mehmood Ali Shah CNIC No. 37485-7498787-9. 2. Mr. Umer Hayat Khan S/o Qamar Hayat Khan CNIC No. 35201-0568913-5.

Case No.3 **CHANGE OF MANAGEMENT OF M/S TRIGON PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Trigon Pharmaceuticals (Pvt) Ltd, 8-Km, Thokar Raiwind road, Lahore, under DML No. 000342 by way of Formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-29	Added Management as per Form-29	New Management as per Form-29
1. Mr. Shahid Munir S/o Muhammad Munir Khan CNIC No. 35202-2938966-1. 2. Mr. Khalid Munir S/o Muhammad Munir Khan CNIC No. 35202-6378136-7. 3. Mr. Muhammad Irshad S/o Muhammad Shafi CNIC No. 35202-1660976-3.	1.Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5. 2.Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9.	1. Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9. 2. Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Trigon Pharmaceuticals (Pvt) Ltd, 8-Km, Thokar Raiwind road, Lahore, under DML No. 000342 by way of Formulation as under;

Previous Management as per Form-29	Added Management as per Form-29	New Management as per Form-29
1. Mr. Shahid Munir S/o Muhammad Munir Khan CNIC No. 35202-2938966-1. 2. Mr. Khalid Munir S/o Muhammad Munir Khan CNIC No. 35202-6378136-7. 3. Mr. Muhammad Irshad S/o Muhammad Shafi CNIC No. 35202-1660976-3.	1. Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5. 2.Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9.	1. Mr. Muhammad Safder S/o Ch. Muhammad Shafi CNIC No. 36501-3646813-9. 2. Mr. Rizwan Ahmed Khan S/o Muhammad Khan, CNIC No. 36302-5064463-5.

Case No.4 **CHANGE OF MANAGEMENT OF M/S PERFECT PHARMA (PVT) LTD, LAHORE.**

M/s Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore, under DML No. 000469 by way of Formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Previous Management as per Form-29	Retire Management as per Form-29	Management as per Form-29
1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Salman Shafi S/o Muhammad Jameel Akhtar CNIC No. 42101-4318679-9. 2. Mr. Farhan Jawed S/o Jawed Iqbal CNIC No.42201-0699080-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Perfect Pharma (Pvt) Ltd, 5-Km, Manga Road, Raiwind, Lahore, under DML No. 000469 by way of Formulation as under;

Previous Management as per Form-29	Retiring Management as per Form-29	New Management as per Form-29
1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Aijaz Ahmad S/o Malik Muhammad Hussain CNIC No. 35202-6647750-3. 2. Mr. Asad Aijaz Malik S/o Aijaz Ahmad CNIC No. 35202-8924661-3-9. 3. Mr. Azhar Aijaz S/o Aijaz Ahmad CNIC No. 35202-2884870-9.	1. Mr. Salman Shafi S/o Muhammad Jameel Akhtar CNIC No. 42101-4318679-9. 2. Mr. Farhan Jawed S/o Jawed Iqbal CNIC No.42201-0699080-5.

Case No.5 **CHANGE OF MANAGEMENT OF M/S STANDPHARM PAKISTAN (PVT) LTD, 20-KM FEROZEPUR ROAD, LAHOR**

M/s StandPharm Pakistan (Pvt) Ltd, 20-Km Ferozepur Road, Lahore under DML No. 000051 (Formulation) has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Previous management As per Form-1A	Added New Management	New Management As per Form-1A & Form-29
1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7	1. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7	1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7 4. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s StandPharm Pakistan (Pvt) Ltd, 20-Km Ferozepur Road, Lahore under DML No. 000051 (Formulation) as under;

Previous management As per Form-1A	Added New Management	New Management As per Form-1A & Form-29
1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7	1. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7	1. Mr. Farooq Ahmed Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2645836-7. 2. Mr. Abdul Quddos Alvi S/o Abdul Ghafoor Alvi CNIC No. 35202-2647942-3. 3. Mr. Munir Ahmed S/o Mushtaq Ahmad, CNIC No. 35200-1550943-7

		4. Mr. Tahir Mustafa Ahmed S/o Mushtaq Ahmad CNIC No. 35202-8036372-7

Case No.6 **CHANGE OF NAME / TITLE AND MANAGEMENT OF UNLICENSED PHARMACEUTICALS UNIT M/S M&J PHARMACEUTICALS, PLOT NO.L 28, STREET NO. SS-2, RCCI, INDUSTRIAL ESTATE, RAWAT, RAWALPINDI.**

M/s M&J Pharmaceuticals, Plot No. 28, Street No. SS-2, RCCI, Industrial Estate, Rawat, Rawalpindi has submitted request for Change of Name / Title and management of unlicensed Pharmaceutical Unit with fee of Rs.10,000/-. The pre-requisite documents of the change of name / title and management are as under: -

i. Change of Name/Title.

Previous Name	**New Name**
M&J Pharmaceuticals.	Pharmonix Pharmaceuticals.

ii. Change of Management.

S.#.	**Old Management.**	**New Management.**
1.	i. Naraish Perkash. ii. Roop Chand.	i. Muhammad Waqas Ali S/o Muhammad Azmat Ali, CNIC No. 17301-1520035-9. ii. Amjad Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-3056252-3. iii. Muhammad Ishaq Badshah S/o Muhammad Azmat Ali, CNIC No.16102-4145509-5.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of title of M/s M&J Pharmaceuticals as under;

Previous Name	**New Name**
M&J Pharmaceuticals.	Pharmonix Pharmaceuticals.

The Board considered and endorsed the change of management of Pharmonix Pharmaceuticals as under;

S.#.	**Old Management.**	**New Management.**
1.	i. Naraish Perkash. ii. Roop Chand.	i. Muhammad Waqas Ali S/o Muhammad Azmat Ali, CNIC No. 17301-1520035-9. ii. Amjad Ali Zeb S/o Muhammad Aurangzeb, CNIC No. 42201-

		3056252-3. iii. Muhammad Ishaq Badshah S/o Muhammad Azmat Ali, CNIC No.16102-4145509-5.

Case No.7. <u>CHANGE OF MANAGEMENT OF M/S ICI PAKISTAN LTD, 32/2A, PHASE-III, INDUSTRIAL ESTATE, HATTAR.</u>

M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Previous management as per Form-29 of S.E.C.P.	Retiring Management as per Form-29 of S.E.C.P	Current management as per Form-A & Form-29 of S.E.C.P.
1. Mr. Asif Jooma CNIC No.42301-3175078-7 . 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1.Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Kamal A Chinoy CNIC No. 42301-1401852-5. 6. Mr. Jawed Yunus Tabba CNIC No. 42201-21111104-7. 7. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 8. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7.

<u>Decision by the Central Licensing Board in 273rd meeting:</u>

The Board considered and endorsed the change of management of M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363 by way of formulation as under;

Previous management as per Form-29 of S.E.C.P.	Retiring Management as per Form-29 of S.E.C.P	New management as per Form-A & Form-29 of S.E.C.P.
1. Mr. Asif Jooma CNIC No.42301-3175078-7 . 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1.Mr. Saboor Ahmad CNIC No.35202-2339737-9.	1. Mr. Asif Jooma CNIC No.42301-3175078-7. 2. Mr. Muhammad Ali Tabba CNIC No.42201-6464247-3. 3. Mr. Muhammad Sohail Tabba CNIC No.42000-0568372-5. 4. Mr. Muhammad Abid Ganatra CNIC No.42201-5355492-7. 5. Mr. Kamal A Chinoy CNIC No. 42301-1401852-5. 6. Mr. Jawed Yunus Tabba CNIC No. 42201-

		21111104-7. 7. Amina Abdul Aziz Bawany CNIC No. 42000-3004991-0. 8. Khawaja Iqbal Hassan CNIC No. 42301-8986425-7.

Case No.8. CHANGE OF TITLE OF M/S ICI PAKISTAN LTD, 32/2A, PHASE-III, INDUSTRIAL ESTATE, HATTAR.

M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363 by way of Formulation has submitted request for change of title of the firm as per Form-29 along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

Current Title of firm.	Proposed title of Firm.
M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.	M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of title of M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar under DML No. 000363 by way of Formulation as under;

Current Title of firm.	New title of Firm.
M/s Cirin Pharmaceuticals (Pvt) Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.	M/s ICI Pakistan Ltd, 32/2A, Phase-III, Industrial Estate, Hattar.

Case No.9 CHANGE OF MANAGEMENT OF M/S MEDITECH, PESHAWAR.

M/s Meditech, Peshawar, under DML No. 000544 By way of Formulation has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

Current Management as per Sole proprietor	Incoming management as per Partnership Deed	New Management as per Form-H & Partnership Deed
1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3.	1. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5	1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3 2. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Meditech, Peshawar, under DML No. 000544 By way of Formulation as under;

Current Management as per Sole proprietor	Incoming management as per Partnership Deed	New Management as per Form-H & Partnership Deed
1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3.	1. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5.	1. Mr. Nadeem Shahzad Nawaz S/o Haji Abdul Rasheed CNIC No.17301-9554612-3 2. Mr. Naeem Shahzad S/o Abdul Rasheed CNIC No. 173015-276733-5

Case No. 10. <u>CHANGE OF MANAGEMENT OF M/S PHARMATEC PAKISTAN (PRIVATE) LIMITED, D-86/A, SITE, KARACHI.</u>

M/S Pharmatec Pakistan (Private) Limited, D-86/A, SITE, Karachi under DML No. 000024 (By way of formulation) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Existing Management as per Form 29 (year 2016)	Retiring Management	New Management as per Form 29 (year 2019)
1.Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2.Mr. Pervez Hayat Noon	1.Mr. Pervez Hayat Noon	1 Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2. Mr. Qazi Zia Uddin S/O Mr. Qazi Qamar Uddin CNIC No. 42201-0704198-1

<u>Decision by the Central Licensing Board in 273rd meeting:</u>

The Board considered and endorsed the change of mangement of M/S Pharmatec Pakistan (Private) Limited, D-86/A, SITE, Karachi under DML No. 000024 By way of Formulation as under;

Existing Management as per Form 29 (year 2016)	Retiring Management	New Management as per Form 29 (year 2019)

1.Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2.Mr. Pervez Hayat Noon	1.Mr. Pervez Hayat Noon	1 Dr. Shahida Qaisar W/o Qazi Qamar Uddin CNIC No. 42201-0704198-1 2. Mr. Qazi Zia Uddin S/O Mr. Qazi Qamar Uddin CNIC No. 42201-0704198-1

Case No. 11. <u>CHANGE OF MANAGEMENT OF M/S RAY PHARMA (PVT) LTD, PLOT NO S-58, S.I.T.E KARACHI</u>

M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi under Drug Manufacturing License No. 000642 (By way formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	**Existing Management**	**Retiring Management**	**Existing Management**
1.	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1	Ms. Nadia Abbas Rahimtoola	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1
2.	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7	Mr. Mustafa Jaffar	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7
3.	Mr. Aly Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-9497690-3	Mr. Stephen Christopher Smith	Mr. Aly Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-9497690-3
4.	Mr. Hassan Maqbool	********	Mr. Hassan Maqbool

	Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1		Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1
5.	Ms. Nadia Abbas Rahimtoola	********	Mr. Shahab Bilal S/o Sajjad Haider CNIC NO. 42201-0592770-7
6.	Mr. Mustafa Jaffar	********	Mr. Muhammad Habib Abbas Rahimtoola S/o Abbas Farouq Rahimtoola CNIC NO. 42000-1868817-3
7.	Mr. Stephen Christopher Smith	********	********

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Ray Pharma (Pvt) Ltd, Plot No S-58, S.I.T.E Karachi under Drug Manufacturing License No. 000642 By way of Formulation as under;

Sr. No	Existing Management	Sr. No	Retiring Management	Sr. No	Existing Management
1.	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1	1.	Ms. Nadia Abbas Rahimtoola	1	Mr. Farouq Habib Rahimtoola S/o Habib Ibrahim Rahimtoola CNIC NO. 42000-0447756-1
2.	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7	2.	Mr. Mustafa Jaffar	2	Mr. Abbas Farouq Rahimtoola S/o Farouq Habib Rahimtoola CNIC NO. 42000-0447648-7
3.	Mr. Aly Farouq Rahimtoola S/o Farouq	3.	Mr. Stephen Christopher Smith	3.	Mr. Aly Farouq Rahimtoola S/o Farouq

	Habib Rahimtoola CNIC NO. 42000-9497690-3				Habib Rahimtoola CNIC NO. 42000-9497690-3
4.	Mr. Hassan Maqbool Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1		********	4.	Mr. Hassan Maqbool Rahimtoola S/o Maqbool HH Rahimtoola CNIC NO. 42201-0432772-1
5.	Ms. Nadia Abbas Rahimtoola		********	5.	Mr. Shahab Bilal S/o Sajjad Haider CNIC NO. 42201-0592770-7
6.	Mr. Mustafa Jaffar		********	6.	Mr. Muhammad Habib Abbas Rahimtoola S/o Abbas Farouq Rahimtoola CNIC NO. 42000-1868817-3
7.	Mr. Stephen Christopher Smith		********		********

Case No. 12. <u>CHANGE OF MANAGEMENT OF M/S BOSCH PHARMACEUTICALS (PVT) LTD, PLOT NO 221, SECTOR 23, KORANGI INDUSTRIAL AREA KARACHI</u>

M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 221, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000350 (By way formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	Existing Management	Incoming Management	New Management
1.	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7

2.	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1	Ms. Farzana Faisal	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1
3.	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3	********	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3
4.	Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3	********	Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO. 42201-2340655-3
	********	********	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s Bosch Pharmaceuticals (Pvt) Limited, Plot No. 221, Sector 23, Korangi Industrial Area, Karachi under Drug Manufacturing License No. 000350 (By way formulation as under;

Sr. No	Existing Management	Incoming Management	New Management
1.	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3	Mr. Ahmed Nasib S/o Muhibuddin CNIC NO. 42201-5957504-7
2.	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1	Ms. Farzana Faisal	Mr. Farhan Chawla S/O Mohiuddin Chawla CNIC NO. 42201-8008212-1
3.	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3	********	Mr. Sheikh Mohiuddin Chawla S/O Sheikh Muhammaddin chawla CNIC NO. 42201-2175782-3
4.	Mr. Zakraria Nasib S/O Mr. Ahmed	********	Mr. Zakraria Nasib S/O Mr. Ahmed Nasib CNIC NO.

	Nasib CNIC NO. 42201-2340655-3		42201-2340655-3
	********	********	Mr. Ambia Nasib S/O Mr. Ahmed Nasib CNIC No. 42201-2245655-3

Case No. 13. <u>CHANGE OF MANAGEMENT OF M/S OBS PAKISTAN (PRIVATE) LIMITED, C-14, MANGOPIR ROAD, S.I.T.E KARACHI</u>

M/s OBS Pakistan (Private) Limited, C-14, Mangopir Road, S.I.T.E Karachi under Drug Manufacturing License No. 000012 (By way formulation)) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	**Existing Management**	**Interim Management**	**New Management**
1.	Mr. Tarek Khan	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1
2.	Dr. Jehanzeb Akram	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2	Miss. Faiza Naeem W/o Mr. Naeem Idress Allahwala CNIC No. 42201-0540338-0
3.	**********	Ms. Nusrat Munshi D/o Alauddin Munshi CNIC NO. 42301-7644816-8	Mr. Mudassir Habbib Khan S/o Mr. Musharaf Zaman Khan CNIC No. 42000-0528026-1
4.	**********	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim Uddin CNIC No. 42101-7618398-1	Mr. Hammad Bin Kafeel S/o Mr. Kafeel Ahmed CNIC No. 42101-1938271-9
5.	**********	Mr Muhammad Arif Mian S/o Mian	Mr. Mirza Anjum Fahim S/o Mr. Mirza

		Muhammad Ali CNIC No. 37405-2992199-9	Fahim-ud-Din CNIC No. 42101-7618398-1
6.	**********	Mr. Muhammad Arsalan Batla S/o Muhammad Younus Batla CNIC No. 42201-7571901-7	Mr. Tariq Moin-ud-din S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the change of management of M/s OBS Pakistan (Private) Limited, C-14, Mangopir Road, S.I.T.E Karachi under Drug Manufacturing License No. 000012 By way of Formulationas under;

Sr. No	Existing Management	Interim Management	New Management
1.	Mr. Tarek Khan	Mr. Tariq Moinuddin Khan S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1
2.	Dr. Jehanzeb Akram	Ms Adeela Tariq Khan W/o Tariq Moinuddin Khan CNIC No. 42301-0683642-2	Miss. Faiza Naeem W/o Mr. Naeem Idress Allahwala CNIC No. 42201-0540338-0
3.	**********	Ms. Nusrat Munshi D/o Alauddin Munshi CNIC NO. 42301-7644816-8	Mr. Mudassir Habbib Khan S/o Mr. Musharaf Zaman Khan CNIC No. 42000-0528026-1
4.	**********	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim Uddin CNIC No. 42101-7618398-1	Mr. Hammad Bin Kafeel S/o Mr. Kafeel Ahmed CNIC No. 42101-1938271-9
5.	**********	Mr Muhammad Arif Mian S/o Mian Muhammad Ali CNIC No. 37405-2992199-9	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim-ud-Din CNIC No. 42101-7618398-1
6.	**********	Mr. Muhammad	Mr. Tariq Moin-ud-

		Arsalan Batla S/o Muhammad Younus Batla CNIC No. 42201-7571901-7	din S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1

CASE NO. 14. <u>CORRECTION IN CHANGE OF MANAGEMENT OF M/S JAENS PHARMACEUTICAL INDUSTRIES (PVT) LTD, LAHORE</u>

M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation has submitted request for change in management of the firm as per Form-A with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;-

Previous Management as per Form-1A	**Restring Management**	**New Management as per Form-A**
1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. 5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.

<u>Decision by the Central Licensing Board in 271st meeting:</u>

The Board considered and endorsed the change of management of M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation as under ;

Previous Management as per Form-1A	Restring Management	New Management as per Form-A
1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. 5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board

It is pertinent to mention here that in the minutes of 271st meeting of CLB, the name of one Director was mistakenly written as Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal instead of Mr. Nasim Iqbal S/o Muhammad Iqbal.

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the correction in change of management of M/s Jaens Pharmaceutical Industries (Pvt) Ltd, 28-Km, Lahore Sheikhupura Road, Lahore under DML No. 000352 by way of formulation as under;

Previous Management as per Form-1A	Restring Management	New Management as per Form-A

1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Muhammad Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9. 5. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Muhammad Arshed S/o Ch. Rehmat Ulllah CNIC No. 42201-1618716-7.	1. Mr. Syed Javed Ali S/o Syed Mehboob Ali CNIC No. 35404-5847754-5. 2. Mr. Muhammad Naeem Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604954-7. 3. Mr. Nasim Iqbal S/o Muhammad Iqbal CNIC No. 35201-1604953-5. 4. Mr. Muhammad Nasib S/o Haji Lal Din CNIC No. 611017-770893-9.

Case No. 15. <u>CORRECTION IN CHANGE OF MANAGEMENT OF M/S SAMI PHARMACEUTICALS (PVT) LTD, F-129, SITE, KARACHI</u>

M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik	********	Mr. Abdul Salam S/O

	W/O Yaseen Malik CNIC NO. 42301-4246934-6		Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. Shohaib Shamim S/O Shamim Ahmed CNIC No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-07079872-3

Decision by the Central Licensing Board in 271st meeting:

The Board considered and endorsed the change of management of M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) as under ;

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	********	Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. Shohaib Shamim S/O Shamim Ahmed CNIC

			No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-07079872-3

Decision by the Central Licensing Board in 271st meeting:

The Board considered and endorsed the change of management of M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 (By way of Re-packing) as under ;

Sr. No	Existing Management	Retiring Management	New Management
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	********	Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. **Shoaib** Shamim S/O Shamim Ahmed CNIC No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O

			Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-**0709872**-3

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board

It is pertinent to mention here that in the minutes of 271st meeting of CLB, the name of one Director was mistakenly written as Mr. Shohaib Shamim instead of Shoaib Shamim and CNIC of one of the director Mr. Zubair Shamim was mentiond as 42201-07079872-3 instead of 42201-0709872-3

Decision by the Central Licensing Board in 273rd meeting:

The Board considered and endorsed the correction in change of management of M/s Sami Pharmaceuticals (Pvt) ltd, F-129, SITE, Karachi under DML No. 000731 by way of Re-packing as under;

Sr. No	**Existing Management**	**Retiring Management**	**New Management**
1.	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	Mr. Shamim Ahmed S/o Sheikh Muhmmad Rafi CNIC No. 42201-0709868-7
2.	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3	********	Mr. Junaid Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-3
3.	Mrs. Nafees Yaseen Malik W/O Yaseen Malik CNIC NO. 42301-4246934-6	********	Mr. Abdul Salam S/O Zikr-ur-Rehman CNIC No. 42201-6555398-5
4.	********	********	Mr. Shoaib Shamim S/O

			Shamim Ahmed CNIC No. 42201-0709871-7
5.	********	********	Mr. Owais Shamim S/O Shamim Ahmed CNIC No. 42201-0709876-5
6.	********	********	Mr. Muhammad yaseen Malik S/o Hameed eid Muhammad CNIC No.42301-0668555-7
7.	********	********	Mr. Zubair Shamim S/o Shamim Ahmed CNIC No.42201-0709872-3

Case No. 16 <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MYRTLE PHARMA, KARACHI</u>

M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone,Bin Qasim Karachi, had applied for renewal of DML No. 000722 by way of formulation for the period of 22-06-2016 t21-06-2021.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 01-02-2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i) Form-1A duly attested and signed by owner/ Director of firm alongwith all attested enclosures.
ii) Detail of management on firm's letter head alongwith attested CNIC copies of Partners or Sole proprietor at present renewal and at the time of previous renewal of DML.
iii) Approval Complete set of duly attested documents for proposed Production Incharge and Quality Control Incharge as (per check list)..

The firm submitted their reply on 07th March 2017. After evaluation of the submitted documents, Final reminder was issued on 17th May 2018. to the firm to submit following shortcomings: -

1. Undertaking on stamp paper of Proposed Quality Incharge & Production Incharge
2. Attested copy of CNIC and academic degree along with Registration Certificate issued from Pharmacy Council of proposed Production Incharge Mr. Rana Akram (dully attested).
3. Experience certificates of proposed Production Incharge.
4. Relevant experience certificates in testing of drugs of 10 years of Proposed Quality Incharge.
5. **All documents should be duly attested.**

No reply is received from the firm till date and application for renewal of DML is still incomplete as of today.

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone, Bin Qasim Karachi, Drug Manufacturing Licence No 000722 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

A show cause notice Dated : 16th October 2019 was issued to the firm. The reply of show cause notice is received from the firm M/s Myrtle Pharma, Karachi wherein firm has stated that due to sudden death of the father of Deputy Chief Executive Ms. Arhama Nasim and subsequent stoppage of activities due to the absence of any male family member who could took over the responsibility immediately, she has recently involved in the company matters and has requested to give some time (at least two months) to fulfill required information.

The firm is also called for Personal Hearing vide letter Dated : 16th October 2020.

Decision by the Central Licensing Board in 273rd meeting

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case for giving final opportunity to the firm to plead his case.

Case No. 17. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S. KALIGON AGRO INDUSTRIES (PVT) LTD, BALUCHISTAN

1	M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan DML No. 000277 (Formulation) **Period**: 11.02.2016 to 10.02.2021	**20.12.2018**	**Good**	i.Dr. Ghulam Sarwar Member DRB. ii. Additional Director (E&M), DRAP, Karachi. iii. Area Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: - *M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Tehsil Hub, Lasbella, Baluchistan was inspected by the panel members in compliance to DRAP's letter No. F.4-3/86-Lic (Vol-II) dated 31st October, 2018. The panel reviewed their overall documentation, inspected Manufacturing Facility, Quality Control Lab & Store and met with their technical persons. Following are the observations:* 1. *The panel observed the premises constructed as per DRAP's* ***approved*** *LoP.* 2. ***As per record, at the time of grant of license. M/s Kaligon Agro Industries was situated at industrial area under Hub industrial Trading Estate (HITE), however at present, M/s. Kailgon Agro Industries is not covered under the said industrial estate i.e. HITE. However, the management of firm is planning to shift the facility from current site to another suitable site and submitted the affidavit*** *(enclosed as Annex-E).* 3. *An appropriate level of sanitation, cleanliness & workers hygiene was noted.* 4. *Personnel met during inspection were observed having prescribed*			

qualification and experience and were well conversant regarding GMP compliance.

5. *Basic equipment required for tests/analysis of the registered products seen in place and in operational condition.*

Based on the stated observations, the panel recommends the grant of renewal of their DML no. 000277 By way of Formulation (subject to approval of location of the facility by the Central Licensing Board) for following sections, for the next five years.

1. ***Dry Powder (VET)***
2. ***Liquid / Suspension (VET)***
3. ***Tablet (VET)***

However, the panel does not recommend the renewal of Injection Section (as it does not comply with the GMP requirement) until the UP-gradation with necessary arrangements as required for parenteral drugs production.

Decision by the Central Licensing Board in 270th meeting

The Board considered the case and afer thread bare deliberation decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Liquid vial Section (Human General) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain suspended in liquid vial injection (Human General) till decision by CLB .

The Board also d**effered the case for** the renewal of Drug Manufacturing Licence No. 000277 (Formulation) in the name of M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan for seeking clarification from Area FID regarding exact location of the firm.

The Show cause notice dated 18th July, 2019 was issued to the firm but no reply is received. The firm is called for the personal hearing vide letter dated, 04th September, 2019.

Decision by the Central Licensing Board in 270th meeting

	The Board considered the case and afer thread bare deliberation decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Liquid vial Section (Human General) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain suspended in liquid vial injection (Human General) till decision by CLB . The Board also d**effered the case for** the renewal of Drug Manufacturing Licence No. 000277 (Formulation) in the name of M/s Kaligon Agro Industries (Pvt) Ltd, 849-Pathra, Hub Chowki Road (RCD), Lasbella, Baluchistan for seeking clarification from Area FID regarding exact location of the firm. **The Show cause notice dated 18thJuly, 2019 was issued to the firm but no reply is received. The firm is called for the personal hearing vide letter dated, 04th September, 2019.** **<u>Proceedings and Decision by the Central Licensing Board in 271st meeting:</u>** No person appeared on behalf of the firm the Board decided to seek clarification from the Federal Inspector of Drugs, Drug Regulatory Authority, Quetta @ Karachi and to serve final opportunity to firm before taking final decision. The reply of the firm is received in which firm has stated that no show cause notice has been received to this office as mentioned in proceeding and Decision paras of the minutes issued. Representative of the firm visited DRAP office Islamabad on 1st July 2019 and during the visits it was communicated that certain clarification regarding manufacturing plant location has been asked from the area FID. With regard to the location of M/s Kalgon Agro Industries is located in general area HITE, Baluchistan, where certain other manufacturing facilities are also constructed and operational (Google image is attached vide Annexure A) All basic industrial amenity connections have been provided by the Government Department i.e, Electricity, Water, Gas, Road infrastructure and Sanitation/Sewerage. The situation adjacent with the factory premises is clear from the populated area as construction of the manufacturing facility is in the center of the available space of 16940 Square yards Area (approximately 3.5 Acres). (Google image is attached vide Annexure B)

	It is highlighted that No Objection Certificate for establishment of Manufacturing Plant was issued from Government of Baluchistan, Industries Department vide BOI (IND) 3-10-75 Dated 25 Feb 1981 (Copy enclosed). Subsequently, Drug Manufacturing license was issued from Ministry of Health, Pakistan on fulfilling all departmental requirements vide DML 000277 (copy enclosed) and renewals were accorded. Efforts to keep the area as per the sensitive requirements of drug manufacturing is always the priority of the management and same was already acknowledge by the inspection team and endorsed in the visit report. It is also highlighted that the delay in obtaining license renewal is causing severe financial constraint on the management, which is further effecting the desired expansion requirement. In view of above, following is submitted for consideration:- Renewal of license may be issued at the earliest. In future letter may be send on office address of M/s. Kailgon Agro Industries at " C-8 Ruqia Square Block 14 F.B Area Karachi" as management is always available to clarify all the requirement of your Esteemed Office as and when intimated. Also a clarification letter is received from Mr. Sajjad Ahmed Abbasi, Area FID, Quetta wherein he has stated that the site location of M/s. Kailgon Agro industries is not covered under the hub, However the firm obtained NO Objection Certificate with certain conditions, for establishment of the facility on 25 February, 1981 (Copy of NOC is enclosed). Another NOC was issued by Health Division, Ministry of Health, Government of Pakistan on 27 October, 1985 (copy enclosed). In addition, the management of firm has also submitted the affidavit for shifting of said facility to designated industrial area (the affidavit has already been submitted along with the panel inspection report: te copy is enclosed). The firm is called for personal hearing vide letter Dated : 08th January,2020.

Decision by the Central Licensing Board in 273rd meeting

No person appeared on behalf of the firm. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case as the letter of personal hearing was not delivered on right address.

Case No. 18. M/s REHMAT PHARMA, LAHORE.

A copy of letter is received from Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has considered the case of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore in its 206th meeting held on 23rd May, 2019 and Provincial Quality Control Board decided to recommend the **cancellation** of the Drug Manufacturing License of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore to Central Licensing Board, DRAP, Islamabad due to violation of non-compliance / violation of Schedule B-II (GMPs) of Drug (L, R & A) Rule 1976 and manufacturing for sale of Drugs under unhygienic conditions. Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**.

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts and report of PQCB Punjab on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing Licence No 000476 of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore, may not be cancelled by Central Licensing Board on the recommendation of Punjab Quuality Control Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 5th December, 2019 was issued to M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore,

The firm replied to Show Cause Notice which is reproduced is as under:

S.No.	Objections	Observation	Stances
2.	Water Treatment / Reverse Osmosis Plant was out of order, dirty and dusty.	Water Testing is not performed as per requirement. (TDS and Microbial count is not performed).	We are doing water testing as per requirements. Relevant proof / documents are attached at page number 1, as for Microbial Count (we are not operating injectable

			section). Page # 1 –1 – C
3.	Heating, ventilation air conditioning (HVAC) system was found out of order in all areas where installed	Neither operational, nor validation conducted.	HVAC is operational Page # 2
4.	Standards manufacturing procedures (SMPs) of products were not available.	Partially complied requiring further improvements.	Now fully complied with as we have made improvements regarding manufacturing procedures (SMPs) as per instructions given by the inspection team. Relevant documentary proof is attached at Page # 3 – 85
5.	Log books record of production machinery and quality control instruments were not being maintained.	Partially complied	Log books are being maintained properly, relevant documents are attached at page number 86 – 133
6.	HEPA (High Efficiency Particulate Air) filter were not installed in sampling as well as dispensing hoods furthermore their differential pressures were not being maintained.	DOP test not performed	DOP test is performed for Dispensing Hood HEPA Filter. Page # 134 – 134 – C
7.	Identification test of active pharmaceutical ingredients for each container were not being performed	FTIR available but not working.	FTIR is working properly, documentary proof is attached at Page # 135 – 173.
8.	Officers and workers were found walking in the production area in their	The company claimed that training of the staff has been conducted in	We trained our staff about proper gowning necessity in the production area of

	street clothes without following prescribed gowning techniques.	this regard however training record is not available.	pharmaceuticals. Record for the training with documentary proof is attached Page # 174 – 181
9.	Environmental monitoring, temperature humidity etc. was not being carried out.	Partially complied	Now fully complied with documentary proof is attached at Page # 182 – 201.
10	Vender validation / qualifications were not performed.	Not complied	SOP is prepared and qualification has been done with venders. Documentary proof is attached at Page # 202 – 230.
15.	Production process and quality control testing methods were not validated.	Not complied	Validation of production processes and quality control methods have been done and are been done continuously. Documentary proof is attached at Page # 232 – 416.
18.	Product recall system was not available	SOP developed but mock exercise was not carried out to verify the system.	We did mock exercise just after few days of last inspection. Documentary proof is attached at Page # 417 – 423.
20.	Complaint Register, Procedure for complaints handling, CAPA (Corrective and preventive action) and change control system were not prepared and initiated.	Not complied.	Complaint register is prepared, procedure for complaints handling, CAPA and change control system is prepared. Documentary proof is attached at Page # 424 – 444.
22.	Qualification / Calibration of the jacketed vessel with mixer 200 kg RPM-01,	Not complied	Now complied with. The required calibration had been done.

	silverson mixer 100 Liter, an SS RO container RPM-05 manufactured by Haji Aslam Engineering was not done.		Documentary proof is attached at Page # 445.
23.	Paint work on the walls, floors and roof was eroded.	Not complied	Overall new paint in all areas has been applied. Page # 446.
24.	Electric thermometers were not calibrated.	Not complied	All of the electric thermometers of all areas has been calibrated. Certificates are attached Page # 447 – 456.
27.	Temperature and humidity of raw material store was 29.2 C and 52 % respectively.	Partially complied	Temperature and humidity of raw material store is now in range, documentary proof is attached at Page # 182 – 201.
28.	Standard Operating Procedures (SOP) for de-dusting area, quarantine area were not available, Log record in quarantine and rejected area were not maintained. 30.4C temperature with 50% humidity was recorded in quarantine are.	SOPs not available.	SOPs are prepared for De-Dusting are and Quarantine are, Documentary proof is attached at Page # 457 – 468.
30.	Famotidine 40mg Film Coated Tablet 1* 10s batch number FT – 091 manufactured on ……. Was found in quarantine area without ensuring	Partially complied	Now fully complied with as Temperature of quarantine area is maintained and is checked on daily basis. Documentary proof is attached at Page # 182 – 201.

	storage conditions at temperature 31.3C and 59% humidity.		
31.	Compendia testing as per pharmacopeial monographs was not employed to test / analyze raw materials. Intermediates and finished products.	Partially complied	Now fully complied with as we are performing compendia testing as per pharmacopeial monographs, documentary proof is attached at Page # 469 – 515.
32.	Procedure for self-inspection and or quality control audit were not established.	Not complied.	Now complied with as Both procedure for self-inspection and quality control audit have been established. Documentary proof is attached at Page # 516 – 534.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr . Bashir Ahmad (CEO), Mr. Shoukat Joya (Advocate) andMr. Sajjad Bashir appeared before the Board and pleaded that they have rectified the observations pointed out during the inspection by the officials of Govt. of Punjab. Howover, upon enquiring they admitted that they were purchasing the core tablet of Ferrous sulphate from unknown source and only the process of tablet coating was being done in the industry .Since, it is heinous crime therefore, the Board after hearing the representative of the firm decided to cancel the Drug Manufacturing License No. 000476 (Formulation) of M/s Rehmat Pharma, 10-Km, Sheikhupura Road, Lahore on the recommendation of Punjab Quality Control Board under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 19 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CITI PHARMA (PVT) LTD, LAHORE.**

01	M/s Citi Pharma (Pvt) Ltd, 3-km, Head Balloki Road, Bhai Pheru, Distt Kasur. DML No. 000512 (Formulation) **Period**: Commencing on 26-06-2018 ending on 25-06-2023. **Sections** 1. Oral Liquid (General) 2. Tablet (General) 3. Capsule (General) sections 4. Oral Dry Powder Suspension Section 5. Capsule Sections	**19-03-2019**	**Good** (w.r.t Oral Liquid, Tablet & Capsule Sections) **Unsatisfactory** (w.r.t. Oral Powder Suspension & Capsule Ceph. Sections)	5. Dr. Farzana Chowdhary, Expert. 6. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore. 7. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 8. Mr. Shahrukh Ali, Assistant Director, DRAP, Lahore.

Recommendations of the panel: -

The panel of inspectors **recommends** the renewal of DML bearing No. 000512 issued in favour of M/s Citi Pharma, (Pvt) Ltd, Lahore in respect of Oral Liquid (General) Tablet (General) & Capsule (General) sections only, The panel of inspectors **Does Not Recommend** the renewal in respect of Cephalosporin (Oral Dry Powder Suspension and Capsule Sections).

Decision by the Central Licensing Board in 270th meeting

1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000512 (Formulation) in the name of M/s Citi Pharma (Pvt) Ltd, 3-km, Head Balloki Road, Bhai Pheru, Distt Kasur on the recommendations of the panel of experts for the further period of five years commencing on 26-06-2018 and ending on 25-06-2023 in respect of Oral Liquid (General) Tablet (General) & Capsule

	(General) sections. 2. The Board considered and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for Cephalosporin (Oral Dry Powder Suspension and Capsule) Section may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain stopped/suspended in Cephalosporin (Oral Dry Powder Suspension and Capsule) Section till decision by CLB.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 26th September, 2019 was issued to M/s Citi Pharma (Pvt) Ltd, 3-km, Head Balloki Road, Bhai Pheru, Distt Kasur.

The firm replied to Show cause notice and stated that after renewal inspection and recommendation of the panel, Citi Pharma decided to shift the Cephalosporin facility to new block to fulfill aa dedication and segregation requirements. For this purpose, they submitted layout plan and got approval from DRAP and now they are in the phase of Civil work and hopefully will be ready for inspection within 6 months. The firm has requested to renew their License as per recommendation of panel and they will try to get approval of Cephalosporin facility as soon as possible and during this period will hold the production.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr . Zamir Ul Hassan, Director Operations of the firm appeared before the Board and contended that the firm is in the process of Civil work and will be ready for inspection within 6 months and they will with hold the production in Cephalosporin facility during this period. The Board after hearing the representative of the firm decided to suspend production in Cephalosporin facility till completion of new facility..

CASE NO. 20. M/S SAFINA PHARMACEUTICALS (PVT) LTD, LAHORE.

Drug Manufacturing License No. 000654 (Formulation) was issued to M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *"if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application".* But, in this case the application for renewal of DML for the period 30-01-2019 to 29-01-2024 has not been received till date. Therefore, DML No. 000654 (Formulation) M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore is no more valid.

Proceedings and Decision of Central Licensing Board in 271st meeting

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000654 by way of formulation M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore may not be declared cancelled.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 15th October, 2019 was issued to M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Muhammad Nadeem, CEO of the firm appeared before the Board. He contended that due to illness of his brother, the firm could not file application for renewal of DML.The Board after hearing the representative of the firm and after considering the facts on the record and thread bare deliberation observed that the Drug Manufacturing Licence 000654 by way of Formulation of M/s Safina Pharmaceuticals (Pvt) Ltd, 17-Km, Lahore Sheikhupura Road, Lahore as already expired after completion of the the tenure 30-01-2014 to 29-01-2019. Hence , stand cancelled under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs

(Licensing, Registering and Advertising) Rules, 1976. Manufacturing of drugs is prohibited and punishable offence under Section 23 and Section 27 and rules framed thereunder.

Case No. 21 APPROVAL OF PRODUCTION INCHARGE OF M/S GMP PHARMACEUTICALS, LAHORE.

M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore had applied for approval of Mr. Muhammad Iqbal as Production Incharge on 03rd January, 2019. The application for the was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 27th February, 2019.

1. Appointment letter
2. Job acceptance letter by the appointee.
3. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of Production Incharge (Not less than 10 years in relevant experience).
4. Resignation / retirement of earlier Production Incharge.
5. Undertaking as whole time employee on stamp paper duly signed by management and appointee.

6.Documents should be duly attested.

The firm submitted their reply on 15th March, 2019. After evaluation of the submitted documents, final reminder was issued on 17th May, 2019 to the firm with following shortcomings: -

1. CNIC copy of Production Incharge.
2. Undertaking as whole time employee on stamp paper duly signed by management and appointee.

3.Documents should be duly attested / notarized.

The firm has replied to Final reminder on 12th June, 2019with following shortcomings: -

1. Undertaking as whole time employee on stamp paper duly signed by management and appointee.
2. **Documents should be duly attested / notarized.**

In the meanwhile the firm appointed Mr. Dilawar Hussain as Production Incharge and applied on 18th July, 2019. The application is short of following documents:

i. Resignation / retirement of earlier Production Incharge (Mr. Muhammad Iqbal).
ii. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
iii. Undertaking as whole time employee on stamp paper.
iv. Documents should be duly attested.

Proceedings and Decision of Central Licensing Board in 271st meeting.

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule, 19 Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the DML No. 000815 by way of formulation of M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 15th October, 2019 was issued to M/s GMP Pharmaceuticals, 28-Km, Sheikhupura Road, Lahore.

The firm has replied to show cause notice and submitted the deficient documents in the application.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Zia ur Rehman, Director and Mr. Dilawar Hussain, Production Incharge of the firm appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 22 APPROVAL OF PRODUCTION INCHARGE OF M/S WELL CARE PHARMACEUTICALS, SARGODHA.

Ms. Nasreen Akhtar, approved Production Incharge of M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha, under Drug Manufacturing Licence No. 000465 by way of formulation had resigned w.e.f, 30-08-2018 and the firm was asked to apply for approval of new Production Incharge. The firm filed application for approval of new Production Incharge on 11th October, 2018.The application was evaluated and reminder for following shortcomings / deficiencies was issued to the firm on 30th November, 2018.

i. CNIC copy of appointee.
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years).
iii. Resignation / retirement of earlier Production Incharge.
iv. Undertaking as whole time employee on stamp paper.
v. All documents should be attested.

The firm submitted their reply on 5th December, 2018. The application is still short of following documents:

i. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 (Not less than 10 years).
ii. Registration certificate from Pharmacy council.

Proceedings and Decision by the Central Licensing Board in 272nd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing Licence No 000465 by way of formulation of M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha may not be suspended or cancelled by Central Licensing Board

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 8th November, 2019 was issued to M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha.

The firm replied to show cause notice and completed the application of application for approval of Production Incharge.

A letter of personal hearing has been issued to the firm on 8th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Malik Saeed, Managing Director of the firm appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice. The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

Case No. 23 SURRENDERING OF APPROVED SECTION M/S LEGACY PHARMACEUTICALS (PVT) LTD., PLOT NO. 111, INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR.

M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad, Peshawar, has submitted request for surrendering following two sections;

Section Name	Pharmacological Category (ies)	Remarks
Veterinary Liquid Syrup	General	According to the firm no registration has been granted in the section yet. No production activity is observed at the time of inspection. The firm intends to surrender the section
Veterinary Dry Powder	General	According to the firm no registration has been granted in the section yet. No production activity is observed at the time of inspection. The firm intends to surrender the section

Decision by the Central Licensing Board in 270th meeting

The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000632 (Formulation) in the name of M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the further period of five years Commencing on 19-06-2018 and ending on 18-06-2023for following sections:-

1 Tablet (General).
2 Capsule (General).
3 Tablet (Psychotropic).
4 Capsule (Cephalosporin).
5 Sachet General
6 Cream/Ointment (General).
7 Oral Liquid Syrup (General).
8 Dry Powder suspension (penicillin).
9 Dry Powder Suspension (General).
10 Tablets hormone
11 Dry Powder suspension (Cephalosporin).

The Board after perusal of recommendation of the panel of experts decided to issue show cause notices as to why following sections may not be cancelled under section 41 of the Drug Act 1976.

1. Veterinary Liquid Syrup.
2. Veterinary Dry Powder.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board

Accordingly, Show Cause Notice was issued to the firm on 3rd September, 2019. In compliance of the Decision of the Central Licensing Board the firm submitted their reply and place on the file. Accordingly, a letter for personal hearing is issued on 7th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Amin Ullah, Managing Director and Mr Umar Farooq Prodcution pharmacist of the firm appeared before the Board and pleaded that they are voluntarly surrendering the sections and would submit future plan for utility of the sections . The Board after hearing the representative of the firm acceded the request of the firm regarding cancellation of Veterinary Liquid Syrup section and Veterinary Dry Powder section.

Case No. 24 **SITE VERIFICATION OF M/S STEFANIE PHARMACEUICALS PLOT/BLOCK NO.69-B, LARGE INDUSTRIAL ESTATE, HAYATABAD, PESHAWAR .**

M/s Stefanie Pharmaceuticals, Peshawar vide their application dated Nil has forwarded a request for approval of site to establish a pharmaceutical unit located at Plot/Block No.69-B, Large Industrial Estate, Hayatabad, Peshawar. Accordingly Area FID, DRAP, Peshawar was directed vide letter dated 19th April, 2018 for verification of site. Area FID, DRAP, Peshawar, after visiting the site has forwarded site verification report of the said firm. The recommendation of the Area FID, DRAP, Peshawar is as under;

Size of the plot:

The management has already submitted "Transfer Lease" for the proposed site which shows it is 1.0 (one) Acres plot and dimensions are (370' 0 ½" X 115' 3") which measures about 44464.0 sq. Ft. However, the management has spared 150627.73 Sq. Ft for M/s Stefanie Health Care" and rest for "M/s Stefanie Pharmaceutical" i.e 28457.27 Sq. Ft. the rest for the offices i.e 944.00.

Location:

The proposed site is located at Hayatabad Industrial Estate, Peshawar, the boundaries are as under;

Surroundings:

On North side is Plot No.69B (M/s Oriental Enterprises).

On South side is Plot No.69C. (M/s Shanghai UPVC)

On East side is Plot No.70 and 70A (M/s United Rubber (Pvt) Ltd.)

On West side is Road S/3

Environment:

Smoke pollution is seen from in its surrounding (east side) as the

Rubber factory is emitting dense black fumes at the time of visit.

Conclusion:

As per requirement laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(I)/98 dated 15.05.1998) under rule 16(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976, the proposed premises is **not suitable** to construct a pharmaceutical unit as of today.

Sketch of plot and its adjoining area is attached as desired.

2. Meanwhile, another application is received from M/s Stefanie Pharmaceutical, Peshawar for re-inspection of the site alongwith prescribed fee of Rs.5,000/- and he has also submitted an affidavit wherein he has stated that he will install HVAC system in the building.

Decision by the Central Licensing Board in 272nd meeting:

The Board considered and decided to call the representative of the firm for personal hearing before taking final decision.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board

Accordingly, a letter for personal hearing was issued on 7th January, 2020.

Decision by the Central Licensing Board in 273rd meeting

Mr. Ehsan Ullah, CEO of the firm appeared before the Board.. The Board after hearing the representative of the firm decided to re-inspect the firm for site verification.

Case No. 25 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AVANT PHARMACEUTICALS (PVT) LTD, BALOCHISTAN

M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., Balochistan DML No. 000786 (Formulation)	**N/A**	**N/A**	i. Dr. Abdullah Dayo Member Central Licensing Board. ii. Additional Director (E&M), Karachi. iii. Area Federal Inspector of Drugs, DRAP, Karachi.

Period: Commencing on 03-02-2019 ending on 01-02-2024.			

Letter of FID: -

The firm, M/s Avant Pharmaceuticals (Pvt) Ltd., Baluchistan, vide their letter (copy enclosed) has informed that they are doing some renovation work at their facility and not ready for panel inspection.

It is therefore kindly requested to your good office that the necessary directions may kindly be passed to the undersigned in the light of Drugs (Licensing, Registering and Advertising) Rules, 1976, for further necessary action in this regard.

Decision by the Central Licensing Board in 271st meeting

The Board considered the letter of Federal Inspector of Drugs, Drug Regulatory Authority of Pakistan, Kararchi and attached letter of the firm M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., Balochistan wherein firm was doing renovation work with intimation of the Board and avoiding inspection for renewal of Drug Manufacturing Licence. The Board decided to suspend the production of drugs in manucaturing facility till renovation is made by the firm. The firm shall inform the Board for its readiness for inspection. The Board shall pass orders for inspection accordingly. The production shall remain suspend till final orders by the Board on the recommendations of the panel of experts.

The decision of the CLB was conveyed to the firm vide letter Dated : 16th October 2019.

Now firm has informed for readiness for renewal of the Drug Manufacturing License and has requested for constitution of the panel of experts.

Decision by the Central Licensing Board in 273rd meeting

The Board considered the facts and after threadbare deliberation constituted the following panel of experts to reinspect the firm for the purpose of renewal of DML No. 000786 (Formulation) of M/s Avant Pharmaceuticals (Pvt) Ltd., Plot M-28, H.I.T.E., Balochistan:

1. Dr. Abdullah Dayo Member Central Licensing Board.
2. Chief Drugs Inspector, Balochistan.
3. Area Federal Inspector of Drugs, DRAP, Quetta.

Case No. 26 **RENEWAL OF DML OF M/S HERBION PAKISTAN (PVT) LTD, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.**

M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad. DML No. 000795 (Formulation) **Period**: Commencing on 25-03-2019 ending on 24-03-2024. **Sections** 1. Syrup (General) 2. Plasters. 3. Capsules (General) 4. Tablets (General) 5. Creams/Ointment (General) 6. Sachet (General)	**21-05-2019**	**Good**	1. Professor Dr. Muhammad Usman, Member Central Licensing Board. 2. Deputy Director (QC), DRAP, Islamabad. 3. Area FID, DRAP, Islamabad. 4. Dr. Muhammad Usman, Assistant Director (Licensing), DRAP, Islamabad.

Recommendations of the panel: -

Keeping in view the facts on record, the panel unanimously ***recommends the approval of renewal of Drug Manufacturing License by way of Formulation DML N:000795 to*** M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Humak, Islambad for following two (2) sections only:

1. Syrup (General)
2. Plasters.

While the approval/renewal of sections namely capsules, Tablets, Creams/Ointment and sachet will be subject to completion of work and subsequent panel inspection and approval by Licensing Board. Hence, the panel did not recommend the renewal of aforementioned sections.

Decision by the Central Licensing Board in 270th meeting

1. The Board considered and **approved** the renewal of Drug Manufacturing Licence No. 000795 (Formulation) in the name of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad on the

recommendations of the panel of experts for the further period of five years commencing on 25-03-2019 and ending on 24-03-2024 in respect of Syrup(General) section.

2. The Board considered and alsodecided to issue **showcause notice** under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License for capsules, Tablet, Creams/Ointment Sections may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Meanwhile, production will remain **stopped/suspended** in capsules, Tablets, Creams/Ointment till decision by CLB.

The Board also decided to **refer** the mater of Plasters Section to MD&MC Division for further processing the case as the subject matter falls under the domain of MD&MC Division.

Accordingly, a Show Cause Notice dated 26th February, 2018 was issued to M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad as per decision of Central Licensing Board in its 270th meeting held on 23rd May, 2019. .

Accordingly, Show Cause Notice was issued to the firm on 4th September, 2019. In compliance of the Decision of the Central Licensing Board. The firm has submitted their reply and informed that they are ready for inspection. Chairman Central Licensing Board has been pleased to constitutes a panel of inspectors / experts for above sections.

Decision by the Central Licensing Board in 273rd meeting

The Board considered the facts and after threadbare deliberation decided to cease the operation of the showcause Notice issued to M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad.DML No. 000795 (Formulation).

Case No. 27 SUSPENSION OF LICENSES OF ABSCONDER ACCUSED PERSONS IN CASE NO. 42/2016, THE STATE VS M/S FRIENDS PHARMA (PVT) LTD & OTHERS.

Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta, directed the Licensing Division to provide information regarding accused persons namely Meheryab, Quality Control Manager and Ms. Shabana Malik, Production Manger of M/s Friends Pharma Pvt Ltd,

31-Km, Ferozepur Road, Lahore that whether they are registered/license-holder in any other company / firm by our office in case No. 42/2016 The State Vs M/s Friends Pharma Pvt Ltd, Lahore. Licensing Division informed the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta via letter dated 22nd May, 2019 that as per available record of Licensing Division, M/s Friends Pharma (Pvt) Ltd, 31-Km, Ferozepur Road, Lahore promoted Ms. Shabana Malik D/o Fazal Karim CNIC No. 35202-2380250-0 as Production Incharge w.e.f 18-04-2018 as per promotion letter and working on the same post till date. Mr. Meheryab S/o Muhammad Akram CNIC No. 35201-1676468-3 joined the firm as Quality Control Incharge w.e.f 07-07-2014 as per appointment letter and he resigned from his post w.e.f. 06-2015. Furthermore, Mr. Meheryab joined M/s Theramed Pharmaceutical (Pvt) Ltd, Lahore DML No. 00696 (formulation) as Quality Control Incharge w.e.f 06-02-2018 and working on the same post till date. Now, Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta ordered that the licenses of both the qualified persons i.e. Meheryab and Shabana Malik be suspended forthwith being the willful absconders of the Court as both are reluctant to appear the Court and concealing themselves in this connection, due to which Court has already declared them as proclaimed offenders.

Decision by the Central Licensing Board in 273rd meeting

The Board considering the orders of the Hon'ble Mr. Mehta Rajesh Nath Kohli Chairman Drug Court Balochistan, Quetta and after thread bare deliberation decided to serve Show Cause Notice to the accused persons namely Meheryab, Quality Control Manager and Ms. Shabana Malik, Production Manger of M/s Friends Pharma Pvt Ltd, 31-Km, Ferozepur Road, Lahore under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their approval as technical staff may not be cancelled.

Case No.28 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEGA PHARMACEUTICALS LTD LAHORE.

M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore had applied for renewal of DML No. 000537 by way of formulation for the period of 17-04-2019 to 16-04-2024 on 19-02-2019

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 06th March, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.
ii. Latest certified true copy of Form-29 (Attestation by SECP).
iii. Duly attested CNIC copies of all Directors.

The firm replied to this letter on 29th March, 2019. A Reminder letter was issued on 03rdJuly, 2019 of following shortcomings.

i. Latest certified true copy of Form-29 having complete detail of CEO/Directors of the firm (duly attested by SECP).
ii. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.

The firm has replied to Final Reminder on 23rd July, 2019 but the application for renewal of DML is still incomplete with following shortcoming:

i. Prescribed fee of Rs. 50,000/- for change of management.
ii. Latest certified true copy of Form-29 or Form-A mentioning detail of Directors (Attestation by SECP).

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore, Drug Manufacturing Licence No 000537 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 15th October, 2019 was issued to M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore.

The firm has replied to show cause notice and completed the application for renewal of DML.

Decision by the Central Licensing Board in 273rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to revoke the show cause notice issused to M/s Mega Pharmaceuticals Ltd, 27-Km, Raiwind Road, Lahore, Drug Manufacturing Licence No 000537 by way of Formulation. The Board also decided to issue warning to the firm to be careful in future.

Case No.29 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S AVENTEK PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000660 by way of formulation for the period of 27-03-2019 to 26-03-2024 on 27-02-2019

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 7th March, 2019 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

i. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management along with prescribed fee of Rs. 50,000/- for change of management.
ii. Nothing due certificate regarding CRF from STO (Updated).
iii. Section approval letters of all sections issued by Central Licensing Board, if not available, apply for regularization of layout plan along with prescribe fee of Rs. 5,000/- per each section.
iv. Latest certified true copy of Form-29 (Attestation by SECP).

v. CNIC copies of all Directors.

vi. Jab acceptance letter of proposed Quality Control Incharge.

vii. Undertaking as whole time employee on stamp paper signed by appointee and management. (Quality Control Incharge).

viii. Experience certificate from M/s Pulse Pharmaceuticals (Pvt) Ltd, Lahore of proposed Quality Control Incharge.

ix. Resignation / retirement of earlier Quality Control Incharge.

x. The proposed Production Incharge completed the degree of Pharm-D on 17th March, 2009 and her total post qualification experience is less than 10 years which does not fulfill the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) rules 1976 in term of relevant experience. You are, therefore, directed to submit complete set of duly attested documents of new proposed Production Incharge who fulfills the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) rules 1976 in terms of Qualification and relevant experience (as per Checklist).

xi. Documents should be duly attested.

The firm replied to this letter on 18th March, 2019. A Reminder letter was issued on 14th May, 2019 of following shortcomings.

i. Nothing due certificate regarding CRF from STO (Updated).

ii. Prescribed fee of Rs. 50,000/- for change of management as there seems to be change in management of the firm.

iii. Latest certified true copy of Form-29 (Attestation by SECP).

iv. Undertaking as whole time employee on stamp paper duly signed by appointee and management. (Quality Control Incharge and Production Incharge).

v. Appointment letter, academic degree of B. Pharm (Production Incharge).

vi. Registration certificate from Pharmacy council (Production Incharge).

vii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of Production Incharge (Not less than 10 years).

viii. Resignation / retirement of earlier (Production Incharge)..

ix. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Production Incharge).

x. Documents should be duly attested.

The firm did not reply to Final Reminder and application for renewal of DML is still incomplete.

Proceedings and Decision by the Central Licensing Board in 271st meeting:

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A), Rule 12 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore, Drug Manufacturing Licence No 000660 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.

The Show Cause notice dated 15th October, 2019 was issued to M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore.

The firm has replied to show cause notice and submitted the deficient documents in the application.

Decision by the Central Licensing Board in 273rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to revoke the show cause notice issused to M/s Aventek Pharmaceuticals (Pvt) Ltd, Plot No. 44-C, Sunder Industrial Estate, Lahore, Drug Manufacturing Licence No 000660 by way of Formulation. The Board also decided to issue warning to the firm to be careful in future.

Case No. 30. <u>APPROVAL OF LAYOUT PLAN FOR REGULARIZATION UNDER DRUG MANUFACTURING LICENSE NO.000044 (FORMULATION) OF M/S AGP LIMITED, D-109, S.I.T.E KARACHI.</u>

M/s AGP Limited, D-109, S.I.T.E Karachi , DML No. 000044 (Formulation), has applied for regularization of layout plan of running facility for their following existing sections: -

1. Tablet Section-I (Ceph).
2. Dry syrup Section (Ceph).
3. Capsule Section (Ceph).
4. Warehouse (Ceph).
5. Quality Control laboratory.

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1. Dr. Abdulah Dayo, Member CLB.
2. Director DTL, Sindh Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the above mentioned section.

Recommendations:-

Keeping in view overall GMP compliance and intend towards improvement, panel unanimously recommend the renewal of DML No. 000044 and regularization of Manufacturing facility of M/s. AGP Limited, Plot No. D-109, S.I.T.E Karachi.

<u>Decision by the Central Licensing Board in 273rd meeting</u>

The Board considered and approved regularization of of Lay out plan in the name of M/s AGP Limited, D-109, S.I.T.E Karachi , DML No. 000044 (Formulation) on the recommendation of the panel of experts for the following sections:-

1. Tablet Section-I (Ceph).
2. Dry syrup Section (Ceph).
3. Capsule Section (Ceph).
4. Warehouse (Ceph).
5. Quality Control laboratory.

Case No. 31 . APPROVAL OF LAYOUT PLAN FOR REGULARIZATION UNDER DRUG MANUFACTURING LICENSE NO.000275 (FORMULATION) OF M/S BROOKES PHARMA LIMITED, KARACHI

M/s Brookes Pharma (Pvt) Ltd, Karachi, DML No. 000275(Formulation), has applied for regularization of layout plan of running facility for their following existing sections: -

GROUND FLOOR			
Sr. No	**Name**	**Sr. No**	**Name**
1.	Tablet (General) Section.	8.	Capsule (General Antibiotic) Section.
2.	Capsule (General) Section.	9.	Dry Syrup (Cephalosporin) Section.
3.	Liquid Syrup (General) Section	10.	Capsule (Cephalosporin) Section.
4.	Liquid Injectbale (General) Section.	11.	Sachet (Cephalosporin) Section.
5.	Large Volume Parentrals (General) Section.	12.	Dry Powder Injectable (Cephalosporin) Section.
6.	Nasal Drop Section.	13.	Packing Material Store.
7.	Tablet Section (General Antibiotic) Section.	14.	Raw Material Store & Finished Goods Store.
FIRST FLOOR			
1.	Small Volume Parentrals (General)Section	2.	Dry Suspension (Pencillin) Section
3.	Capsule Pallet Filling (General)Section	4.	Cream/Ointment section
5.	Injectable (Hormone) Section	6.	Ampoule Compact Line Section **(additional)**
7.	Tablet (Pencillin) Section	8.	Quality Control Laboratory
9.	Capsule (Pencillin) Section	10.	**********

Accordingly, layout plan of firm was approved/regularized/authenticated and following panel was constituted to verify the above sections of firm as per approved layout plan.

1. Dr. Abdulah Dayo, Member CLB.
2. Additional Director (E&M), DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.

Accordingly, Panel has inspected the premises and verified the above mentioned section.

Recommendations:-

The panel inspected all the manufacturing sections, stores and QC Lab and found the facility as per approved layout plan. The facility has been provided with necessary utilities, machineries and equipment as required under the guidelines. Necessary documents relating to QC, QA, installation qualification of machines, HVAC and other utilities were also verified under the scope and noted an optimal level of compliance.

Based on the above stated facts the panel recommends the grant of regularization of sections as per Evaluation form."

Decision by the Central Licensing Board in 273rd meeting

The Board considered and approved regularization of of Lay out plan in the name of M/s Brookes Pharma (Pvt) Ltd, Karachi, DML No. 000275 (Formulation) on the recommendation of the panel of experts for the following sections:-

GROUND FLOOR			
Sr. No	**Name**	**Sr. No**	**Name**
1.	Tablet (General) Section.	8.	Capsule (General Antibiotic) Section.
2.	Capsule (General) Section.	9.	Dry Syrup (Cephalosporin) Section.
3.	Liquid Syrup (General) Section	10.	Capsule (Cephalosporin) Section.
4.	Liquid Injectbale (General) Section.	11.	Sachet (Cephalosporin) Section.
5.	Large Volume Parentrals (General) Section.	12.	Dry Powder Injectable (Cephalosporin) Section.
6.	Nasal Drop Section.	13.	Packing Material Store.
7.	Tablet Section (General Antibiotic) Section.	14.	Raw Material Store & Finished Goods Store.
FIRST FLOOR			
1.	Small Volume Parentrals (General)Section	2.	Dry Suspension (Pencillin) Section
3.	Capsule Pallet Filling (General)Section	4.	Cream/Ointment section
5.	Injectable (Hormone) Section	6.	Ampoule Compact Line Section

			(additional)
7.	Tablet (Pencillin) Section	8.	Quality Control Laboratory
9.	Capsule (Pencillin) Section	10.	**********

Case No. 32 **CHANGE OF LICENSED SECTION NAME OF M/S HUDSON PHARMA PVT) LIMITED, No. D-93, NORTH WESTERN INDUSTRIAL ZONE, PORT QASIM, KARACHI .**

M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North western Industrial zone, Port Qasim, Karachi under DML.No 000842(Formulation) has submitted requested for change of licensed section name from Capsule (General) section to Capsule DPI Steroidal Section.

Proceedings and Decision by the Central Licensing Board in 272nd meeting:

The Board considered the case and decided to seek verification of facility of separate dispensing booth for DPI steroidal products by the following panel:

1. Dr Abdullah Dayo, Member Central Licensing Board
2. Additional Director, DRAP, Karachi
3. Federal Inspector of Drugs of area, DRAP, Karachi

Panel Inspection report is received and recommendation are as follows:-

Based on the people met, documents reviewed and finding of inspection, panel hereby verify the existence of separate dispensing both available and installed for dispensing of steroidal products.

Decision by the Central Licensing Board in 273rd meeting

The Board considered the facts on record and after threadbare deliberation decided to approve the change of Licensed section name of M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North western Industrial zone, Port Qasim, Karachi under DML.No 000842(Formulation) from Capsule (General) section to Capsule (DPI Steroidal) Section.