MINUTES OF 274th MEETING OF CENTRAL LICENSING BOARD HELD ON 7th APRIL, 2020

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274thmeeting of the Central Licensing Board (CLB) was held on 7th April, 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. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar.	Member
2.	Dr. Muhammad Usman, Expert member Manufacturing of Drugs	Member
3.	Mr. Muhammad Israr, Law Expert, Ministry of Law & Justice Division.	Member
4.	Mr. Zeeshan Nazir , Deputy Director Representative Director (QA/LT), DRAP, Islamabad	Member
5.	Zakir Shah, Drug inspector, Department of Health, Govt of Khyber Pakhtunkhwa.	Member
6.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary/Member
7.	Mr. Nawaz Ahmed, Representative of PPMA.	Observer
8.	Mr.Nadeem Alamgir Representative of Pharma Bureau.	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), Dr. Muhammad Usman, AD (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 273rd meeting of the Central Licensing Board (CLB) which was held on **15thJanuary, 2020.**

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 Dow University of Health Sciences, Ojha Campus, Sparco Road of Main university Road, Karachi. **Section:** Biotech (Anti-Sera) Section	31-01-2020	Good	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Dr. Noor-Us-Saba, Director Biological, DRAP, Islamabad. 3. Sajjad Ahmed Abbasi FID, DRAP, Karachi .

***Recommendations of the panel**: -*

M/s Dow Institute of Health Sciences was visited and inspected on 31st January 2020 in compliance of DRAP's letter No.F.2-7/2012-Lic dated 10th January 2020. The manufacturing unit is pre-fabricated, purpose-built facility.

The Panel reviewed their overall documentation, SOPs, inspected Manufacturing Facility (static condition), Quality Control Lab & Stores and met with their technical persons, present at that time. Following are the observations:

i. The Panel observed that the premises of M/s Dow Institute of Health Sciences are constructed as per DRAP's approve Lay-out-plan.
ii. A very good level of sanitation, cleanliness & hygiene was noted.
iii. Technical personnel met during inspection were observed having prescribed qualification and experience and were well conversant regarding cGMP compliance, it was observed that the status of appointment of technical persons was on temporary/contract basis, however the management of the institute shown strong commitment to amend their recruitment policies and hire the full-time key technical persons before commencement of production activities of newly registered products as required by the Drugs (Licensing, Registering and Advertising) Rules, 1976.
iv. The HVAC system was found installed and observed in working condition during inspection.
v. Basic equipments required for production activities were seen available in the production facility, however the management informed that the installation qualification of the equipments will be performed within due course of time.
vi. Basic equipments required for tests/analyses were also seen available in the quality control laboratory.
vii. Separate equipments were present for R&D section.

Inspection was carried out using the generic inspection evaluation form based on

	Schedule B if the Drugs (Licensing, Registering and Advertising) Rules, 1976, additional guidance was obtained from Annex 3 of WHO TRS 996 2016 titled "**Manufacturing practices for biological products**". Based on our current understanding of risk assessment the Panel **recommends** the grant of **Drug Manufacturing License (By way of Formulation**) for inspected whole unit as dedicated **Biotech Unit** to be used exclusively for Anti-Sera production and other similar products indicated in section 9.3 of above mentioned TRs 996 i.e. anti sera, killed vaccine and other biological products indicating those made by rDNA techniques, toxoids and bacterial extracts may following inactivation be manufactured on the same premises provided that adequate decontamination and cleaning measures are implemented on the basis of QRM **Decision of the Central Licensing Board in 274th meeting** Perusal of record including panel inspection report shows that the firm fulfills the conditions for the grant of licence by way of formulation and by way of basic manufacture as well. Yet the Board observed that these are two distinct activities for which separate licences are required under the law, therefore, as per application of the firm the Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Dow University of Health Sciences, Ojha Campus, Sparco Road of Main university Road, Karachiwith following section: **Section:** Biotech (Anti-Sera) Section			
2.	M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, Plot No. A-79, S.I.T.E, Super Highway Industrial Area, Karachi **Section:** Empty Hard Gelatin Capsule Shells (Size 00,0,1,2,3)	02-01-2020	Good	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director E&M, DRAP, Karachi. 3. Federal Inspector of Drugs, Karachi. 4. Area Assistant Director, DRAP, Karachi.
	***Recommendations of the panel**: -* *In presence of the instructions continued in DRAP Islamabad letter No. F.2-3/2019-Lic Dated 26.09.2019, the panel thoroughly inspected & reviewed in detail their QA System, Production Facilities/System, QC Lab, Store, utilities & respective documents and found a satisfactory level of compliance. At the same plot, the firm also holds another DML No. 000516 (By way of Formulation) for the manufacturing of Soft Gelatine Capsule but in a well dedicated building, with separate technical persons, AHUs, Utilities and chemical lab. Based on the sated facts and keeping in view the current need of the country the panel recommends the grant of Drug Manufacturing Licence By way of (Semi Basic Manufacturing) for EHG Shells.*			

	Decision of the Central Licensing Board in 274th meeting The Board considered and approved the grant of Drug Manufacturing License by way of Semi Basic Manufacture in the name of M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, Plot No. A-79, S.I.T.E, Super Highway Industrial Area, Karachi with following section: **Section:** Empty Hard Gelatin Capsule Shells (Size 00,0,1,2,3)

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 Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, North Western Industrial Zone, Port Qasim, Karachi DML No. 000901 (Semi-Basic Manufacture). **Name of API's(02)** **1.** Chloroquine Phosphate (USP) **2.** Hydroxychloroquine Sulphate (USP).	**04-04-2020**	**Good**	1.Director CDL, Karachi 2.Additional Director E&M, DRAP, Karachi. 3.Federal Inspector of Drugs, Karachi.
	Recommendations of the panel**: -* *Based on area inspected, the people met and the documents reviewed and findings of the inspection and availability of relevant machinery and equipment required for the production and quality control testing of the products namely, Chloroquine Phosphate (USP) and Hydrochloroquine Sulphate (USP) and positive intention of the management of the M/s. Carryfor Pharmaceutical (Pvt) Ltd, to produce the both of the referred APIs (in this current critical medical situation related to the Corona Virus and requirement of these both APIs) on priority basis soon after obtaining due approval from DRAP Islamabad, panel recommends the grant of following additional API's in large public interest:* ***1. *Chloroquine Phosphate (USP)* **2.** *Hydroxychloroquine Sulphate (USP).* **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional API in the name of M/s Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, North Western Industrial Zone, Port Qasim, Karachi with following API: **Name of API's(02)**			

	1. Chloroquine Phosphate (USP) **2.** Hydroxychloroquine Sulphate (USP).			
2	M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District Sheikhupura DML No. 000649 (Semi Basic Manufacture) **Name of API's(09)** 1. Gabapentin Granules (Surge Specs) 2. Mannitol Granules (Surge Specs) 3. Potassium Chloride Granules (Surge Specs) 4. Vitamin-B1 Pellets (Surge Specs) 5. Pregabalin Pellets (Surge Specs) 6. Dexlansoperazole Pellets (Surge Specs) 7. Fenovirate Pellets (Surge Specs) 8. Nicotinamide Pellets (Surge Specs)	**04-07-2019**	-	1. Dr. Mahmood Ahmad, Ex. Dean IUB. 2. Mr. Shahid Nasir, Member Expert 3. Ms. Majida Mujhahid, Federal Inspector of Drugs, DRAP, Lahore. 4. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: - *The firm has complete set up to manufacture of pilot scale batch of their 09 API's.* *Keeping in view the above observations, the infrastructure, machinery, capacity and technical staff and Dissolution Real / Accelerated stability studies were carried out by firm and result of both cases were satisfactory.* *The panel **recommend** the grant of registration of aforementioned 09 APIs for manufacturing (By way of Semi-Basic Manufacture) under Drug Manufacturing License No. 000649.* ***Decision by the Central Licensing Board in 271st meeting*** *The Board considered and approved the grant of following APIs in the name of M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District Sheikhupura subject to condition that pharmacopoeial reference of API or product would be mentioned against each API which ever would be available in official books. In case no pharmacopoeial reference is available then manufacturer's specification would be allowed and mentioned.* ***Name of API's(09)*** *1. Gabapentin Granules* *2. Mannitol Granules* *3. Potassium Chloride Granules* *4. Vitamin-B1 Pellets* *5. Pregabalin Pellets*			

	6. *Lansoprazole Pellets (USP 41)* 7. *Dexlansoprazole Pellets* 8. *Fenovirate Pellets* 9. *Nicotinamide Pellets* *In the light of the decision of the board the grant of Lansoprazole pellets (USP41) was issued to firm, because it was approved with compendia specs Now the firm has submitted that specification/monograph of rest of the above mentioned API's will be manufactured/tested in accordance with Surge's Specification (Manufacturer Specs) .* *Submitted for consideration of the board* **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional API in the name of M/s Surge Laboratories (Pvt) Ltd, 10-Km, Faisalabad Road, Bikhi, District Sheikhupura in the light of recommendations of Committee at (Item IV case 4): **Name of API's(08)** 1. Gabapentin Granules (Surge Specs) 2. Mannitol Granules (Surge Specs) 3. Potassium Chloride Granules (Surge Specs) 4. Vitamin-B1 Pellets (Surge Specs) 5. Pregabalin Pellets (Surge Specs) 6. Dexlansoperazole Pellets (Surge Specs) 7. Fenovirate Pellets (Surge Specs) 8. Nicotinamide Pellets (Surge Specs)			
3	M/s PharmEvo (Pvt) Ltd, Plot No. A-29 North Western Industrial Zone, Port Qasim, Karachi DML No. 000504 (Formulation) **Name of Additional Section (03)** 1. Packaging Material Warehouse. (Revised) 2. Quality Control Laboratory. (Revised) 3. Quality Control Laboratory. (Cephalosporin)-New	**13-02-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi .
	Recommendations of the panel: - *Based on Area inspected people met, documents rewived and export volume of the firm panel recommends approval of layout plan for following sections,* 1. Packaging Material Warehouse. (Revised) 2. Quality Control Laboratory. (Revised)			

	3. Quality Control Laboratory. (Cephalosporin)-New **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional sections in the name of M/s PharmEvo (Pvt) Ltd, Plot No. A-29 North Western Industrial Zone, Port Qasim, Karachi: **Name of Additional Section (03)** 1. Packaging Material Warehouse. (Revised) 2. Quality Control Laboratory. (Revised) 3. Quality Control Laboratory. (Cephalosporin)-New			
4	M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi DML No. 000267 (Formulation) **Name of Additional Section (02)** 1. Quality Control Laboratory. (Revised) 2. Relocation of Microbiology Laboratory & Sampel retention room from1st floor to 2nd floor .	**29-01-2020**	**Good**	1. Director DTL, Sindh Karachi 2. Additional Director E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi .
	Recommendations of the panel: - *During details inspection the panel observed that firm has scientifically and as per approve layout plan modified and redesigned their microbiology as well as Quality Control Lab for retaining a better level of compliance. The panel reviewed in detailed their current approved designed, HVAC design, area qualification and found an optimal level of cGMP compliance. The lab areas have been provided with separate change rooms. QC Lab has been provided with latest technology 10HPLC with 21 CFR Compliance and other necessary equipments. The newly constructed micro lab was satisfactory equipped and well qualified. Based on the above stated observation panel recommends the current changes/amendments may be approved. ,* **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional Sections in the name of M/s Martin Dow Limited, Plot No. 37, Sector 19, Korangi Industrial Area, Karachi **Name of Additional Section (02)** 1. Quality Control Laboratory. (Revised) *2.* Relocation of Microbiology Laboratory & Sampel retention room from1st floor to 2nd floor .			
5	M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi	**24-01-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Chief Drug Inspector Sindh,

	DML No. 000136 (Formulation) **Name of Sections (05)** 1. Warehouse on ground floor of Plot No. 14. (Regularization) 2. Warehouse on first floor of Plot No. 14. (Regularization) 3. PM Store at Plot No. 43. (Regularizaton) 4. Amendments in change room of cephalosporin section 5. QC Lab, QA PD Facilities (New)			Karachi. 3. Area FID, DRAP, Karachi .
	Recommendations of the panel: - *During the detailed inspection the panel physically inspected in detail their entire production areas, newly developed QC Lab, QA & PD facilities and stores. The facilities ere found constructed as per approved design and have been provided with required necessary machineries equipment and adequate facilities. Based on observations, panel recommends as follows.* 1. QC Lab, QA PD Facilities (New) *Panel Also recommends that the following changes/amendments made in the design for attaining a better level of compliance may be regularized/approved as per prevailing policy.* 1. Warehouse on ground floor of Plot No. 14. (Amendments) 2. Warehouse on first floor of Plot No. 14. (Amendments) 3. PM Store at Plot No. 43. (Amendments) 4. Amendments in change room of cephalosporin section **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional sections in the name of M/s Hilton Pharma (Pvt) Ltd, Plot No. 13-14 & 43, Sector 15, Korangi Industrial Area, Karachi **Name of Sections (05)** 1. Warehouse on ground floor of Plot No. 14. (Regularization) 2. Warehouse on first floor of Plot No. 14. (Regularization) 3. PM Store at Plot No. 43. (Regularizaton) 4. Amendments in change room of cephalosporin section 5. QC Lab, QA PD Facilities (New)			
6	M/s Tabros Pharma (Pvt) Ltd, Plot No. L-20/B, Sector 22, F. B Industrial Area, Karachi DML No. 000106 (Formulation) **Name of Sections (05)** 1. Cream /Ointment/ Gel (General) 2. Dry Powder Suspension	**28-02-2020**	**Good**	1. Prof. Dr. Abdullah Dayo, Member, CLB Karachi 2. Additional Director E&M), DRAP, Karachi. 3. Area FID, DRAP, Karachi.

	(General) 3. Capsule (General) 4. Sachet (General) 5. Tablet (General)			
	Recommendations of the panel: - *Panel Also recommends that the following layout plan ammendmts in following sections.* 1. Cream /Ointment/ Gel (General) 2. Dry Powder Suspension (General) 3. Capsule (General) 4. Sachet (General) 5. Tablet (General) **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional sections in the name of M/s Tabros Pharma (Pvt) Ltd, Plot No. L-20/B, Sector 22, F. B Industrial Area, Karachi: **Name of Sections (05)** 1. Cream /Ointment/ Gel (General) 2. Dry Powder Suspension (General) 3. Capsule (General) 4. Sachet (General) 5. Tablet (General)			
7.	M/s Ferozsons Laboratries Ltd, Amangarh, Nowshera,**Khyber Pakhtunkhawa.** DML No. 000038 (Formulation) **Section (06)** 1. Tablet Section (General). 2. Tablet Section (General). 3. Ointment/Cream/Gel Section (General) 4. Bottle filling area for Tablets and Capsules. 5. Raw Material Store. 6. Packaging material store.	25-02-2020	**Very Good**	i) Dr. Jamshed Ali Khan, Member CLB. ii) Additional Director (E&M), DRAP, Peshawar. iii) Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: - "As per manufacturing facilities installed in the newly established two additional tablet general sections and in the additional cream/ointment/gel sections, the HVAC system installed, available facilities for quality control, microbial testing and environment monitoring, interactions made with qualified staff of the firm and keeping in view the quality assurance and quality assurance and quality management system as well as the cGMP compliance status of the firm, the panel unanimously recommends the grant of following additional/amended sections/areas to the firm M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera vide DML No.000038 (Formulation). **Ground Floor**			

	1. Tablet Section (General). 2. Ointment/Cream/Gel Section (General) 3. Bottle filling area for Tablets and Capsules. 4. Raw Material Store. **First Floor** 5. Packaging material store. The panel also recommends grant of following additional section to the firm as well. **Ground Floor** 1. Tablet Section (General)." **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional sections in the name of M/s Ferozsons Laboratries Ltd,Amangarh, Nowshera, **Khyber Pakhtunkhawa.**: **Name of Sections (05)** **Ground Floor** 1. Tablet Section (General). 2. Ointment/Cream/Gel Section (General) 3. Bottle filling area for Tablets and Capsules. 4. Raw Material Store. **First Floor** 5. Packaging material store. The panel also recommends grant of following additional section to the firm as well. **Ground Floor** 6. Tablet Section (General)."			
8.	M/s Sayyed Pharmaceutical Industries (Pvt) Ltd., Plot No.67/2, Phase-3, Industrial Estate, Hattar DML No. 000697 (Formulation) **Section (06)** 1. Tablet Section (Psychotropic).	18-03-2020	**Good**	i) Prof. Dr. Jamshed Ali Khan, University of Peshawar, Peshawar. ii) Additional Director (E&M), DRAP, Peshawar. iii) Area Federal Inspector of Drugs, DRAP, Peshawar.
	Recommendations of the panel: - "In compliance to Licensing Division, DRAP Islamabad letter No.F.3-6/2006-Lic (Vol-I) dated 27-01-2020, the constituted panel on 18-03-2020 conducted inspection of the firm M/s Sayyed Pharmaceutical Industries (Pvt) Ltd., Plot No.67/2, Phase-III, Industrial Estate, Hattar for the grant of addional tablet Psychotropic Section. The panel observed that the section has been established as per approved layout plan. The requisite machinery were found installed in separate rooms. The section has been provided with HVAC system. Separate receiving bay, quarantine, released area and dispensing facilities available in the section. An in-process quarantine provided and a blistering machine is also installed in a separate room. The firm has an independent quality control laboratory, equipped with the required instruments for testing/analysis of the raw			

	materials, in-process of bulks and finished products. Competent technical staff employed to supervise production and quality control activities. Keeping in view all the above mentioned facilities provided by the firm in their newly established section and the overall GMP compliance status of the firm, the panel unanimously recommends the grant of following additional section to M/s Sayyed Pharmaceutical Industries (Pvt) Ltd., Plot No.67/2, Phase-3, Industrial Estate, Hattar under Drug Manufactureing License No.000697 (Formulation). 1. Tablet Section (Psychotropic)" **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional sections in the name of M/s Sayyed Pharmaceutical Industries (Pvt) Ltd., Plot No.67/2, Phase-3, Industrial Estate, Hattar.: **Name of Sections (01)** 1. Tablet Section (Psychotropic)"			
9.	M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, **Islamabad.** DML No. 000795 (by way Formulation). **Sections/Facility (04):** 1) Tablet Section (General) – Revised. 2) Capsule Section (General) – Revised. 3) Sachet Section (General) – Revised. 4) Cream & Ointments Section (General) – Re-location.	07-02-2020	**Good**	4. Prof. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad. 5. Dr. Hafsa Karam Elahi, Additional Director (QA/LT), DRAP, Islamabad. 6. Babar Khan, Area Federal Inspector of Drugs, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts on record and the people met/interviewed during the visit, the panel unanimously verified the up-gradation as per approved revised/relocated layout plan and **recommended the approval** for the following sections of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad. 1. Tablet Section (General) – Revised. 2. Capsule Section (General) – Revised. 3. Sachet Section (General) – Revised. 4. Cream & Ointments Section (General) – Re-location." **Decision of the Central Licensing Board in 274th meeting** The Board considered and approved the grant of Additional sections in the name of M/s Herbion Pakistan (Pvt) Ltd., Industrial Triangle, Kahuta Road, Islamabad.: **Sections/Facility (04):**			

	1. Tablet Section (General) – Revised. 2. Capsule Section (General) – Revised. 3. Sachet Section (General) – Revised. 4. Cream & Ointments Section (General) – Re-location.			
10.	M/s Rotex Pharma (Pvt) Ltd, Plot No.206 & 207, Industrial Triangle, Kahuta Road, **Islamabad**. DML No. 000651 (by way Formulation). **<u>Section (01)</u>** 1. Biotech rDNA Vial Section. 2. Biological – Non-rDNA Vial Section. 3. Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form). 4. Restructuring/Extension of QC as per approved layout.	28-01-2020	**Good**	1. Dr. Noor Us Saba, Director, Biological Division, DRAP, Islamabad. 2. Mr. Ayyaz Ahmad, Deputy Director (Licensing Division), DRAP, Islamabad. 3. Babar Khan, Area Federal Inspector of Drugs, Islamabad.
	Recommendations of the panel: - "Keeping in view the above facts on record and the people met during the visit, the panel unanimously recommended the approval of following additional sections of Rotex Pharma (Pvt) Ltd., Plot # 206-207, Industrial Triangle, Kahuta Road, Islamabad. 1. Biotech rDNA Vial Section. 2. Biological – Non-rDNA Vial Section. 3. Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form). 4. Restructuring/Extension of QC as per approved layout." **<u>Decision of the Central Licensing Board in 274th meeting</u>** The Board was informed that Biotech rDNA vial section and non rDNA vials sections have filling and sealing areas only. The Board considered and approved the grant of Additional sections in the name of M/s Rotex Pharma (Pvt) Ltd., Plot # 206-207, Industrial Triangle, Kahuta Road, Islamabad**.**: **<u>Sections/Facility (04):</u>** 1. Biotech rDNA Vial Section. (filling and sealing) 2. Biological – Non-rDNA Vial Section. (filling and sealing) 3. Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form). 4. Restructuring/Extension of QC as per approved layout."			
11.	M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur road, Lahore. DML No. 000395(Formulation)	13-02-2020	**Good**	1. Dr. Zaka ur Rehman, Drug Controller Govt. of Punjab. 2. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.

	Section (02) 1. Cream / Ointment (General) Section. 2. Tablet (Narcotics / Psychotropic) Section.			3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.

Recommendations of the Panel.

Keeping in view the manufacturing facility like building, functional HVAC system, installed production Machinery in the respective sections &availability of Quality Control equipment, instruments, Technical & experienced personnel, having adequate documentation, regarding production, quality control, microbiology lab and Technical water production and testing facilities, the panel of inspectors **recommends** the grant permission for the production to M/s Don Valley Pharmaceuticals (Pvt) Ltd, License No. 000395 for the following two new additional section:

1. Cream / Ointment (General) Section.
2. Tablet (Narcotics / Psychotropic) Section.

Decision of the Central Licensing Board in 274th meeting

The Board considered and approved the grant of Additional sections in the name of M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km Main Ferozepur road, Lahore**.**:

Sections/Facility (04):

1. Biotech rDNA Vial Section.
2. Biological – Non-rDNA Vial Section.
3. Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form).
4. Restructuring/Extension of QC as per approved layout."

ITEM – IV MISC CASES

CASE NO. 1. CORRECTION IN CHANGE OF NAME OF M/S MEDIZAN PHARMACEUTICAL, ISLAMABAD.

1.	M/s Medizan Laboratories (Pvt) Ltd, 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)).

The title of the firm is Medizan Laboratories (Pvt) Ltd., Islamabad however, in the decision the name of the firm is mentioned as Medizan Pharmaceuticals. It is submitted that as per record of Licensing Division the name of the firm is M/s Medizan Laboratories (Pvt) Ltd., Islamabad therefore, the case is placed before the CLB for correction in the title / name of the firm regarding grant of additional section, please.

Decision of the Central Licensing Board in 274th meeting

The Board considered and approved the correction in the name of the firm as Medizan Laboratories (Pvt) Ltd., Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad

Case No. 2. <u>CORRECTION IN APPROVAL OF LAYOUT PLAN FOR REGULARIZATION UNDER DRUG MANUFACTURING LICENSE NO.000275 (FORMULATION) OF M/S BROOKES PHARMA (PVT) LIMITED, KARACHI</u>

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/sBrookes 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.	**********

M/s Brookes Pharma (Pvt) Ltd, Karachi, DML No. 000275(Formulation), had applied for regularization of layout plan of running facility for their following existing sections and same was recommended by the panel of experts: -

S.NO.	SECTION NAMES	S.NO	SECTION NAMES
1	Tablet (General) Section	12	In Process Quarantine
2	Dry Powder Suspension (General)	13	Cream/Ointment/Gel Section (General)
3	Raw Material Warehouse	14	Capsule Section (Pellet Mfg & Filling)
4	Topical Liquid (Spray) Solution	15	Capsule Powder Section (General)
5	Liquid Injection Section (Psychotropic)	16	Oral Liquid Syrup Section (General)
6	Packaging Material Store	17	Dry Powder Sachet (General)
7	Quality Control Laboratory	18	Oral Tablet Psychotropic Section
8	Liquid Injectable (SVP)	19	External Liquid Section (Pyodine) Manufacturing Filling & Packing.
9	Sterile Topical Solution (General)	20	Warehouse (Cephalosporin)
10	Ampoule Compact Line		
12	Injectable Section (Cephalosporin)		

However, in the agenda and then subsequently in the minutes of the 273rd meeting of the CLB the sections were mentioned as below:

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 Injectable (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			
15.	Small Volume Parentrals (General)Section	16.	Dry Suspension (Penicillin) Section
17.	Capsule Pallet Filling (General)Section	18.	Cream/Ointment section
19.	Injectable (Hormone) Section	20.	Ampoule Compact Line Section **(additional)**
21.	Tablet (Penicillin) Section	22.	Quality Control Laboratory
23.	Capsule (Penicillin) Section	24.	**********

Case is placed before the Central Licensing Board for correction and grant of regularization of following sections to M/s Brookes Pharma (Pvt) Ltd, Karachi, DML No. 000275(Formulation):

S.NO.	SECTION NAMES	S.NO	SECTION NAMES
1.	Tablet (General) Section	2.	In Process Quarantine
3.	Dry Powder Suspension (General)	4.	Cream/Ointment/Gel Section (General)
5.	Raw Material Warehouse	6.	Capsule Section (Pellet Mfg & Filling)
7.	Topical Liquid (Spray) Solution	8.	Capsule Powder Section (General)
9.	Liquid Injection Section (Psychotropic)	10.	Oral Liquid Syrup Section (General)
11.	Packaging Material Store	12.	Dry Powder Sachet (General)
13.	Quality Control Laboratory	14.	Oral Tablet Psychotropic Section
15.	Liquid Injectable (SVP)	16.	External Liquid Section (Pyodine) Manufacturing Filling & Packing.
17.	Sterile Topical Solution (General)	18.	Warehouse (Cephalosporin)
19.	Ampoule Compact Line	20.	Injectable Section (Cephalosporin)

Decision of the Central Licensing Board in 274th meeting

The Board considered and approved the correction in the name of the sections of the firm as M/s Brookes Pharma (Pvt) Ltd as under

S.NO.	SECTION NAMES	S.NO	SECTION NAMES
1.	Tablet (General) Section	11	In Process Quarantine
2	Dry Powder Suspension (General)	12	Cream/Ointment/Gel Section (General)
3	Raw Material Warehouse	13	Capsule Section (Pellet Mfg & Filling)
4	Topical Liquid (Spray) Solution	14	Capsule Powder Section (General)
5	Liquid Injection Section (Psychotropic)	15	Oral Liquid Syrup Section (General)
6	Packaging Material Store	16	Dry Powder Sachet (General)
7	Quality Control Laboratory	17	Oral Tablet Psychotropic Section
8	Liquid Injectable (SVP)	18	External Liquid Section (Pyodine) Manufacturing Filling & Packing.
9	Sterile Topical Solution (General)	19	Warehouse (Cephalosporin)
10	Ampoule Compact Line	20	Injectable Section (Cephalosporin)

Case No. 3. <u>CORRECTION IN TITLE OF AJ MIRZA PHARMA (PVT) LTD, KARACHI PLOT NO. 44, SECTOR 27, KORANGI INDUSTRIAL AREA, KAACHI UNDER DRUG MANUFACTURING LICENSE NO. 000234 (FORMULATION),</u>

M/s AJ Mirza Pharma (Pvt) Ltd, Karachi Plot No. 44, Sector 27,Korangi Industrial Area, Kaachi, has stated that firm had applied for the change of management of company name/title from M/s Meredoa to M/s AJ Mirza Pharma (Pvt) Ltd. However, the DML issued to the firm with the title AJM Pharma Pvt Ltd where 'M' stands for Mirza which may probably not written as complete. Moreover, firm has also stated the firm is registered in SECP as AJ Mirza Pharma (Pvt) Ltd and has requested for correction in the title of the firm on the Drug Manufacturing License as AJ Mirza Pharma (Pvt) Ltd instead of AJM..

As per record of Licensing Division, DRAP the title/ name of the firm was approved by the Central Licensing Board in its 252nd meeting held on 15th March, 2017 as M/s AJM Pharma Pvt Ltd and same was mentioned on the DML at the time of renewal of DML NO. 000234 (Formulation) However on the previously submitted Form-29 and in the document of agreement of sale) the name of firm is mentioned as **M/s A.J. Mirza Pharma Private Limited,** therefore, case of firm regarding **correction in Change of Title** is placed before the Central Licensing Board for consideration, please.

<u>Decision of the Central Licensing Board in 274th meeting</u>

The Board considered and approved the correction in the name of M/s AJ Mirza Pharma (Pvt) Ltd, Karachi Plot No. 44, Sector 27,Korangi Industrial Area, Karachi as **M/s A.J. Mirza Pharma Private Limited,** Plot No. 44, Sector 27,Korangi Industrial Area, Karachi.

Item 4 **UNIFORMITY IN TESTING PROTOCOLS IN HOUSE SPECIFICATION AND RELEASE PATTERN FOR APIS AND PELLETS**

The CLB in its 264th meeting held on 19th July, 2018 constituted a committee on API comprising of the following members to make recommendations of the subject matter for the consideration of the Board;

1. Dr. Ikram U l Haq, Member CLB
2. Syed Muied Ahmad, Member CLB
3. Dr. Abdul Manan, Manufacturing Expert, M/s Pharmagen Ltd, Lahore
4. Mr. Abdul Aziz, Manufacturing Expert, M/s Vision Pharmaceuticals (Pvt) Ltd., Islamabad
5. Mr. Ayyaz Ahmad, Deputy Director (Licensing), DRAP, Islamabad – Member/Coordinator

The committee discussed the subject matter in detail in its meetings and submitted recommendations as under;

The committee deliberated and exhaustively discussed on the need of uniformity in testing protocols, in house specifications and release pattern for APIs and pellets according to the mandate given by the Central Licensing Board in its 264th meeting held on 9th July, 2018. The committee considered different aspects of the subject and gave the recommendations as under:

1) ***APIs included in Pharmacopoeias***
   - I. *If any APIs is included in Pharmacopoeias, the specifications and requirements given in the Pharmacopoeia should be followed.*
   - II. *In case of inclusion of APIs in more than one Pharmacopoeia priority should be given according to the specified rules.*
   - III. *If any firm intends to manufacture an API according to the more than one Pharmacopoeia specification it should submit data and provide testing facility according to the applied Pharmacopoeia.*
   - IV. *In consideration to the recommendation of the panel and discussion in the CLB the specifications of one or more than one pharmacopoeias will be approved by the Board.*

2) ***APIs not included in Pharmacopoeia***
   - i. *Any product not included in pharmacopoeias the manufacturer will provide along with application the following information, if applicable, along with procedure, justification and reference.*
     - a) *Identification, assay, potency limits, impurities, moisture contents degradation products and/or any other test. Documentary evidence shall be provided before marketing/sale of first batch.*
     - b) *The information provided by manufacturer may be scrutinized/evaluated by a committee of experts in test analysis/quality control constituted by CLB.*
     - c) *The board will decide to assign these specifications as manufacturer specification, innovator specifications or any other.*
     - d) *If the API becomes part of pharmacopoeia the manufacture will follow the specifications of that pharmacopoeia within sixty days of publication.*
     - e) *The manufacture will submit the undertaking that the API is not included any pharmacopoeia.*

3) ***Specifications, Testing protocols and release pattern for pellets***

I. *Pellets must be very clearly specified whether these are immediate release, delayed release, extended release, taste mask pellets or any other.*
II. *If any pellet containing API is included in Pharmacopoeia, the specifications and requirements for the finish product given in the Pharmacopoeia should be followed.*
III. *In case of inclusion of pellets containing API in more than one Pharmacopoeias priority should be given according to the specified rules.*
IV. *If any firm intends to manufacture any pellets containing API according to the more than one Pharmacopoeia specification it should submit data and provide testing facility according to the applied Pharmacopoeias.*
V. *In consideration to the recommendation of the panel and discussion in the CLB the specifications of one or more than one pharmacopoeia will be approved by the board.*

4) <u>Pellets containing API not included in Pharmacopoeia</u>

i. *Any product not included in any pharmacopoeia, the manufacturer will provide along with application the following information, if applicable, along with procedure, justification and reference.*
   a) *Identification, assay, potency limits, impurities, moisture contents performance test, degradation products and/or any other test.*
   b) *The information provided by manufacturer may be scrutinized/evaluated by a committee of experts in test analysis/quality control constituted by Central Licensing Board.*
   c) *The board will decide to assign these specifications as manufactures specification, innovator specifications or any other.*
   d) *If the pellets containing API becomes part of pharmacopoeia the manufacture will follow the specifications of that pharmacopoeia.*
   e) *The manufacture will submit the undertaking that the API is not included in any pharmacopoeia.*

5. The coordinator appreciated the great efforts and the time given by the Honorable members. The meeting ended with vote of thanks by the coordinator.

<u>Decision of the Central Licensing Board in 274th meeting</u>

The Board considered and approved the recommendations of the Committee. The Board also advised to circulate the recommendations to all API manufacturers for compliance of the recommendations.

Case No. 5. <u>GRANT OF ADDITIONAL API AT SAAKH PHARMA PRIVATE LTD., (000588).</u>

M/s Saakh Pharma Pvt. Limited is one of the prominent APIs manufacturer Company having adequate facility to manufacture approved APIs(products) at our factory bearing Plot No.C-7/1, N.W.I.Z. Port Qasim Authority, Karachi. We have ample variety of approved sections i.e. Penicillin, Cephalosporin, Palletization and Taste masking and General Section having necessary and mandatory machineries and Lab equipments to manufacture respective APIs.

Looking into the prevailing situation and dire need of Chloroquine Tablets to defeat corona virus pandemic in order to save lives of our peoples, we are intending to produce Hydroxychloroquine Sulfate USP in General Section of our existing unit situated at Plot No.C-7/1, N.W.I.Z. Port Qasim Authority, Karachi for onward supply to the manufacture Chloroquine Tablets. In this regard, we are enclosing herewith necessary available documents for grant of the above said additional (API) product.

Your are therefore, requested to waive the requirement of inspection and grant of said additional API/product enabling us to do the needful in the interest of Pakistan

Decision of the Central Licensing Board in 274th meeting

The Board considered and decided to complete the codal formalities and further approval of additional API Hydroxy chloroquine Sulfate USP by circulation.

Case No. 6 **ANY OTHER ITEM WITH THE PERMISSION OF THE CHAIR**

The Board deliberated and decided to hold further meetings in the wake of Corona virus by circulation to address the approval of Additional API and Sections or any other matter to meet emergency situation.

Meeting ended with the vote of thanks to the Chair.