MINUTES OF 283rd MEETING OF CENTRAL LICENSING BOARD HELD ON 28th OCTOBER, 2021

==*=*=*

283rd meeting of the Central Licensing Board (CLB) was held on 28th October, 2021 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad. Dr Hafsa Karam Ellahi, Representative Division of Quality Assurance and Laboratory Testing Division/Member Central Licensing Board, Drug Regulatory Authority of Pakistan, Islamabad presided the meeting in the absence of Chairman as provided under Rule 8(8) of the Drugs (Licensing, Registering &Advertising) Rules, 1976. Following members attended the meeting:-

S.No	Name & Designation	Status
1	Mr. Muhammad Shoaib Ansari, Chief Inspector of Drugs, Government of Sindh, Karachi	Member
2	Mr Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
3	Mr. Mohammad Yunas Khattak, Chief Inspector of Drugs, Bannu Government of Khyber Pahtunkwa	Member
4	Mr Abdul Hameed Rao, Drug Controller, Government of Punjab, Lahore	Member
4	Mr. Manzoor Ali Bozdar, Addl Director, Drug Regulatory Authority of Pakistan, Islamabad	Secretary/ Member
5	Ms Mahvash Tariq Siddiqi, Representative of PPPMA	Observer
6	Mr Iftikhar Hussain, Representative of PPPMA	Observer
7	Mr.Nadeem Alamgir Representative of Pharma Bureau.	Observer

The meeting started with the recitation of Holy verses. The Chairperson 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 thereof. The Central Licensing Board considered, discussed and decided cases on merit. Secretary Licensing Board presented the agenda before the Board. Mr. Abdullah Bangash, AD (Lic), Ms. Zunaira Faryad, AD (Lic), Mr. Sanaullah Babar, AD (QC) and Mr. Adil Saeed, AD (QA) DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

Item-I **CONFIRMATION OF THE MINUTES OF 281ST MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 282nd meeting of the Central Licensing Board (CLB) which was held on 31st August, 2021.

A. DRUG LICENSING DIVISION

Item-I: **GRANT OF NEW DRUG MANUFACTURING LICENSE.**

The respective panel of experts for grant of Drug Manufacturing License 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 Pasteur & Fleming Pharma, Plot No. P-70-A Phase-III Road No. 4 Industrial Estate, Hattar	25-08-2021 (Formulation)	Good	i. Prof. Dr. Jamshed Ali Khan, Expert Member, ii. Area Federal Inspector of Drugs, DRAP, Peshawar, iii. Syed Adnan Ali Shah, AD, DRAP, Peshawar. However, the inspection was carried out by following members i. Prof. Dr. Jamshed Ali Khan, Expert Member, ii. Area Federal Inspector of Drugs, DRAP, Peshawar, iii. Mr. Adnan Shaidullah, AD, DRAP, Peshawar.

RECOMMENDATIONS:

Based on documentation reviewed, technical/management people met, personnel / materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab and allied facilities including HVAC system, the panel is of the view that the firm has established good facility in accordance with GMP guidelines and unanimously recommended grant of Drug Manufacturing License to the firm from for following mentioned five sections;

i. Tablet (Hormone)
ii. Tablet (General)
iii. Capsule (General)
iv. Dry Powder Suspension (General)
v. Cream/Ointment Section (General).

Decision of the Central Licensing Board in 283rd meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Pasteur & Fleming Pharma, Plot No. P-70-A Phase-III Road No. 4 Industrial Estate, Hattar on the recommendations of the panel of experts for the following sections:

Sections (05)

i. Tablet (Hormone)
ii. Tablet (General)
iii. Capsule (General)
iv. Dry Powder Suspension (General)

	v. Cream/Ointment Section (General). The Board also decided to issue advisory to the Federal Inspector of Drugs to carry and conduct the inspections by the panel as constituted by the Board. In case of unavoidable circumstances, panel may be changed with the approval of appropriate forum.			
2.	M/s JHK Pharma (Pvt) Ltd, Khushal Khan Khattak Mazar Road, AkoraKhattak, District Nowshera	20-10-2021 (Formulation)	Good	1. Mr. Zahid khan, Chief Drug Inspector, Peshawar. 2. Additional Director (E&M), DRAP, Peshawar. 3. Area Federal Inspector of Drugs, DRAP, Peshawar.
	RECOMMENDATIONS: Based on documentation reviewed, technical/management people met, personnel / materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiological lab, distill water system with continuous loop system, and allied facilities including HVAC system, the panel is of the view that the firm has established good facility in accordance with GMP guidelines and unanimously **recommended** grant of Drug Manufacturing License to the firm from for following mentioned four sections; i. Intravenous Infusion-LVP (General) ii. Intravenous Infusion-LVP (General Antibiotic) iii. Quality Control Lab iv. Warehouse **<u>Decision of the Central Licensing Board in 283rd meeting</u>** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s JHK Pharma (Pvt) Ltd, Khushal Khan Khattak Mazar Road, Akora Khattak, District Nowshera on the recommendations of the panel of experts for the following sections as per approved lay out plan for the following section: **<u>Sections (02)</u>** 1. Intravenous Infusion-LVP (General) 2. Intravenous Infusion-LVP (General Antibiotic)			
3.	M/s Ashrafsons Pharmaceuticals (Pvt) Ltd, Plot No.40, Road R-2, Industrial Estate GadoonAmazai, District Swabi	21-10-2021 (Formulation)	Good	1. Mr. Zahid khan, Chief Drug Inspector, Peshawar. 2. Area Federal Inspector of Drugs, DRAP, Peshawar 3. Syed Adnan Ali Shah, Assistant Director, DRAP, Peshawar.
	RECOMMENDATIONS: Keeping in view the above, the panel unanimously recommends the grant of Drug Manufacturing License (Formulation) for following sections to M/s Ashrafsons Pharmaceuticals (Pvt) Ltd, Plot No.40, Road R-2, Industrial Estate GadoonAmazai, District Swabi, Khyber PakhtunKhwa; i. Small Volume Parenteral (SVP)			

	ii. Large Volume Parenteral (LVP) - (Line-I only) **Decision of the Central Licensing Board in 283rd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Ashrafsons Pharmaceuticals (Pvt) Ltd, Plot No.40, Road R-2, Industrial Estate Gadoon Amazai, District Swabi on the recommendations of the panel of experts for the following sections: **Sections (02)** i. Liquid Injectable Infusion (SVP) LDPE(General) ii. Liquid Injectable Infusion (LVP) LDPE - (General)			
4.	M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala. **Sections (03):** **i.** Tablet (General). **ii.** Capsule (General). **iii.** Dry Powder Injection (Cephalosporin) section.	**25-08-2021**	**Good**	1. Dr. Zaka Ur Rehman, COO, PDTRC. 2. Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "Firm has established new unit. Panel has thoroughly inspected the unit, evaluated the documents revealed by the firm. Various technical aspects were discussed with the management of the firm at length. Details of equipment of production and quality control department and list of technical staff duly signed by the firm management are attached with this report for perusal of Central Licensing Board. On the basis of description mentioned above, documentation revealed and submitted by the firm, physical panel inspection of the unit; Panel has **recommended** the facility M/s AGM Pharmaceuticals, Eminabad Road, Khan Payara, Gujranwala for grant of Drug manufacturing License for Tablet (General) section, Capsule (General) section and Dry Powder Injection (Cephalosporin) section." **Decision of the Central Licensing Board in 283rd meeting** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s AGM Pharmaceuticals, Eminabad Road, GT Road, Gujranwala on the recommendations of the panel of experts for the following sections: **Sections (03)** i. Tablet (General) ii. Capsule (General) iii. Dry Powder Injection (Cephalosporin)			

5	M/s University of Veterinary and Animal Sciences, (UVAS) Ravi Campus, Pattoki, District Kasur	23-08-2021	**N/A**	1) Dr. Zaka Ur Rehman COO, PDTRC, Lahore. 2) Federal Inspector of Drugs, DRAP, Lahore. 3) Assistant Director, Lahore.

Recommendations of the panel:

"Panel has thoroughly evaluated the various documents in connection with production, Quality Control and Quality Assurance System of the unit. Panel also inspected the plant and discussed various technical aspects at length with the technical staff intended to be involved in production of vaccine and also discussed the protocols and production design of FMD vaccine intended to be manufactured. After thorough evaluation of documents provided by the management and inspection of the unit panel was of the view that UVAS has made lot of progress to obtain the manufacturing License for Veterinary vaccine, however some up-gradation and improvements were still required. Panel has given some advises for further up-gradation as mentioned above in the report. Management has sought some time to comply the observations. Managing Director TCBP-FMD, UVAS Ravi campus, Pattoki submitted in his comments that up-gradations advised shall be fulfilled within on e month (signed comments enclosed). Under the explained circumstances mentioned above in the report: panel was of the view that facility of Training Center for Biologics Production (TCBP-FMD), UVAS, Ravi Campus, Pattoki was not completely ready at present. Therefore, panel concluded that re-inspection required to be conducted upon complete compliance of the advises given above in the report.

Decision of the Central Licensing Board in 283rd meeting

The Board considered the case and decided to re-inspect the firm as recommended by the panel.

6	M/s Wallace Pharma Evolutions, Kala Wala Stop, 20-km, Lahore Jaranwala Road, Lahore.	**17-09-2021**	**N/A**	1) Mr. Munawar Hayat, Director, DTL, Lahore. 2) Dr. Zia Husnain, FID, DRAP, Lahore. 3) Ms. Uzma Barkat, AD, DRAP, Lahore.

First Inspection report by the panel of experts

1. Dr Zaka ur rehman, COO, PDTRC, Lahore
2. Ms. Majida Mujahid, FID, Lahore
3. Mr. Ajmal Sohail Asif, FID, Lahore

Reference to DRAP Islamabad's letter No. F.1-21/2015-Lic, dated 28.01.2021, the inspection of the firm M/s Wallace Pharmaceuticals, situated at Kala Wala Stop, 20 Km Lahore Jaranwala Road, Lahore, for grant of Drug Manufacturing License by way of formulation was conducted on 15.02.2021 and 08.07.2021 by the panel.

2. Panel inspected the firm on 15.02.2021 and noted that at that time firm was under construction and even boundary wall was not erected, therefore, the panel deferred the

Inspection on request of management of the firm.

3 Now as per request of the management, panel again visited firm on 08.07.2021. At the time of inspection Mr. Arshad, Director/Partner, Mr. Muhammad Tahir, Director/Partner and Mr. Muhammad Arshad Production manager were present. Panel started inspection and noted certain critical observation, however Mr. Arshad, Director of the firm showed distrust on the panel and did not allowed to continues inspection and said that he wants to change the panel as he thinks panel is biases against firm.

Second Inspection report by the panel of experts

1. Mr. Munawar Hayat, Director, DTL, Lahore.
2. Dr. Zia Husnain, FID, DRAP, Lahore.
3. Ms. Uzma Barkat, AD, DRAP, Lahore.

1.2 Brief History of Last Inspection

Another panel conducted the inspection of the firm on 15-02-2021 and 08-07-2021 as per available record. As per previous report firm was under construction as observed by the then panel on 15-02-2021 hence inspection was deferred and subsequently inspection was conducted on 08-07-2021. Report was forwarded vide letter No. F.1-78/2021-FID-111/10267 dated 08-07-2021.

2. OBSERVATIONS

2.1 Premises

The premises was a purposely built unit. It was a single-story building with AHUs installed on the rooftop. The firm has layout approval for general, psychotropic, penicillin and carbapenem sections but only the penicillin and carbapenem sections were fully constructed and ready for inspection as informed by the company's team. However, it was noted by the inspection panel that major changes had been done in the facility when inspected in the light of the approved layout plan. The company did not have layout approval for those changes. The carbapenem section was not completely dedicated as the access to QC laboratory was through this section. Moreover, RO plant, for supply to all areas, was also installed in this section. Space constraint was found in some areas of production and stores which is elaborated in detail in later part of the report.

2.1.1 Entries

Two male change rooms were established close to the boundary wall of the plot. One for entry in to the Carbapenem section and the other for entry in to the Penicillin area. Change rooms were provided with necessary facilities like cross-over bench, shoe racks, cabinets, etc. Air curtains were installed at the entrances and found functional at the time of inspection.

2.1.2 Warehouses

The firm had provided separate storage areas for storage of raw materials, packing material and finished goods in Carbapenem and penicillin areas. However, the receiving area for rawmaterial and packaging material was common in both carbapenem and penicillin area. Separate rejected and recall area was not provided.

2.1.2.1 Raw Material Store (Carbapenem Area)

Changes had been done by the firm in the facility from that approved in the layout plan. Receiving bay as approved in the layout plan was not existing. Air curtain was provided at the receiving point. The entry point was not shaded and it was very close to the boundary wall of the plot. Therefore, the passage between the raw material entry and the boundary wall was insufficient for movement of a vehicle for material loading and unloading. Dedusting area was not provided with necessary facilities for dedusting and no power supply was available in that room. A small open red rack was placed in the dedusting area for rejected materials. The firm was advised to provide facility for storage of rejected material under lock and key. The quarantine area as approved in the layout plan was actually divided into two areas, quarantine and sampling. There was no facility of maintenance of temperature and humidity in the quarantine area. In the layout plan, dispensing area and rejected area was given within the raw material store. But actually, there was a dispensing booth placed (without any control) within the released area of the raw material store and a passage was constructed connecting the packing material store and the quarantine area. Air conditioner was installed in the raw material store.

No relevant documentation and no SOPs related to material management and control

were available.

2.1.2.2 Packing Material Store (Carbapenem Area)

The firm had provided racks for storage of packing material. There was no facility of maintenance of storage conditions in the packing material store.

2.1.2.3 Finished Goods Store (Carbapenem Area)

A room was provided with racks for storage of finished goods. There was no HVAC system, air conditioner or any temperature/humidity maintenance mechanism in this store. No temperature/humidity monitoring device was given. It was advised to the management of the firm to maintain storage condition in the dispatch area also, seal the openings under the dispatch door, prevent the entry of sunlight through the glass door and provide shed outside the dispatch door.

2.1.2.4 Raw Material Store (Penicillin Area)

Air curtain was provided at the receiving bay. Yellow racks were placed and there was no facility for dedusting. The entry point was not shaded and sunlight was entering from the door. It was very close to the boundary wall of the plot. Therefore, the passage between the raw material entry and the boundary wall was insufficient for movement of a vehicle for material loading and unloading. An open red rack was placed in the quarantine area for rejected materials. The quarantine area was an elongated room and space was found insufficient for easy movement of man and material. The firm was advised to provide facility for storage of rejected material under lock and key.

Sampling booth was placed in the room. No weighing balance and sampling tools were given. There was no system of air control in that room. A dispensing room was also given. In that room a dispensing booth was placed. It was of such a size that the raw material container cannot be placed inside the booth. No weighing balance was available in the dispensing booth. Dispensing tools were not provided. The dispensing room had HVAC air supply but did not have any air return/exhaust duct.

Raw material released area was given in which racks were provided for storage of

released raw materials.

No relevant documentation and no SOPs related to material management and control were available.

2.1.2.5 Packing Material Store (Penicillin Area)

The finn had provided racks for storage of packing material. It was advised to maintain storage condition in the packing material store.

2.1.2.6 Finished Goods Store (Penicillin Area)

A room was provided with racks for storage of finished goods. It was advised to maintain storage condition in the released and dispatch area, seal the openings under the dispatch door, prevent the entry of sunlight through the glass door and provide shed outside the dispatch door.

2.1.3 Production Areas

The entry into the production area was through a corridor provided with HVAC system However, an air conditioner with open drain was also installed in the corridor which the panel advised to be removed.

2.1.3.1 Injection Section (Carbapenem)

The firm had provided separate material and personnel entry. A small double door hatch was installed for material entry in to the filling area. Firm was advised to install differential pressure monitoring device for material entry room. The personnel entry was through three buffers. Differential pressure monitoring devices were not installed between buffers A semiautomatic single nozzle filling machine under LFC was placed in the filling room in which each vial has to be manually placed under the nozzle for filling. A three headed sealing machine was placed in the same room without any physical separation which may pose a risk of particulate contamination Curtains were not given around the LFC and LFC was not checked by the firm as polythene wrap covering was still on it. Moreover, the area and filling machine was not appropriate for aseptic processing as there will be a lot of manual intervention from the facility provided. The firm 's team stated that rubber stoppers and seals will be manually placed in the vials and then vials will be transferred to sealing machine in trays. Clean room class was unknown as HVAC qualification had not been done. All the doors in

this section were not smooth. They were of SS and glass frame work and ridges and recesses were present. Windows were also not flushed. No filters were installed in the HVAC ducts, inlet and return. Ducts were not properly sealed and sunlight could be seen from the inlet diffuser and its duct.

For transfer of vials from cool zone to the filling room, no transfer trolley with HEPA filter was available.

Vial washing area as given in layout had been changed to RO plant by the firm. This location of RO plant was not approved in the layout plan. The company's team informed that this RO plant will supply water to both Penicillin and Carbapenem sections. In the vial washing area, double door autoclave, double door hot air sterilizer, RO water storage tank and open vial washing machine was installed. Vial washing machine was not placed under the LFC.

No machine and equipment was qualified and calibrated as informed by the company 's team.

2.1.3.2 Capsule Section (Penicillin)

The capsule section was provided with mixing room and capsule filling room equipped with double cone mixer and semi-automatic encapsulation machine. The mixing room was common for capsule and dry powder suspension area. Firm was advised to provide a pass box for material transfer between the mixing room and encapsulation room. Working space constraint was observed in the encapsulation room. HVAC system was provided. Manometers were installed. A blistering room was also provided where blistering machine was installed.

2.1.3.3 Dry Powder Suspension Section (Penicillin)

De-cartoning and bottle blowing area was given where a bottle blowing machine was installed. Air return/exhaust was not provided in these rooms. Hatch was not provided for transferring of bottles to the suspension filling room.

This section comprised of a mixing room where double cone mixer was installed, in process quarantine room and a filling room. A single nozzle filling machine was provided and cap sealing machine without physical segregation was given.

Manometers were installed to monitor differential pressure between the buffer and mixing room and buffer and filling room. One manometer was found faulty.

2.1.3.4 Dry Powder Injection Section (Penicillin)

In process quarantine area shown in the layout was changed to Vial decartoning area by the firm. There was no air return in this area. Entry to vial washing area was through a buffer (shown as decartoning room in the layout plan). Vial washing machine, double door sterilizer and autoclave was installed in the washing area. Working space constraint was seen in vial washing area. Installation of machinery was not as shown in the layout plan. Only RO water supply was given in this area. Machinery was not qualified/calibrated.

The firm had provided separate material and personnel entry. A small double door hatch was installed for material entry in to the filling area. This hatch seemed insufficient in size for material transfer. Firm was advised to install differential pressure monitoring device for material entry room. The personnel entry was through three buffers. Differential pressure monitoring devices were not installed between buffers. A semi-automatic single nozzle filling machine under LFC was placed in the filling room in which each vial has to be manually placed under the nozzle for filling. A three headed sealing machine was placed in the same room without any physical separation which may pose a risk of particulate contamination. Curtains were not given around the LFC and LFC was not checked by the firm as polythene wrap covering was still on it. Moreover, the area and filling machine was not appropriate for aseptic processing as there will be a lot of manual intervention from the facility provided. The firm 's team stated that rubber stoppers and seals will be manually placed in the vials and then vials will be transferred to sealing machine in trays Clean room classification was unknown as HVAC qualification had not been done. All the doors in this section were not smooth and not GMP compliant. They were of SS and glass framework and ridges and recesses were present on which powder may accumulate. Windows were also not flushed. No filters were installed in the HVAC ducts, inlet and return.

For transfer of vials from cool zone to the filling room, no transfer trolley with HEPA filter was available.

In process quality control lab was not provided. The firm was advised to provide the same.

2.1.3.5 Packing Area

Packing hall in penicillin area was provided with one conveyor belt for manual packing. Stools were also provided for workers. A rack was also provided. Overprinting area was not given.

2.1.4 Quality Control Laboratory

The firm had provided a QC laboratory having a wet-chemistry laboratory and instrument room, stability chamber room and retained sample room.

The QC lab was not well equipped. UV/Vis Spectrophotometer, HPLC, pH meter, moisture analyzer and weighing balance were provided in the instrument room. In the wet chemistry lab, only water batch, ultrasonicator and melting point apparatus was provided. Most of the equipment was old/refurbished. None of the equipnlent were calibrated and qualified. Two stability chambers were also provided.

The firm did not have many important testing equipment like FTIR, polarimeter, conductivity meter, atomic absorption spectrometer, Karl Fischer moisture analyzer, dissolution apparatus and disintegration apparatus. No glassware was provided

In the retained sample area, there was no provision of temperature/humidity maintenance and control.

The firm had established a microbiology lab comprising of media preparation room and sterility room. Entry to sterility room was through three buffers. The microbiology lab was not well equipped. Hot incubator, cool incubator, oven and an LFC cabinet was provided. No other equipment and apparatus like colony counter, microscope, glassware, stirrer, etc for microbiological testing was available. Proper biosafety cabinet was also not provided

2.2 Quality Assurance Department

Quality assurance department was not established. No quality assurance personnel were appointed.

2.3 Documentation

The company's team could not present any document to the inspection panel on demand. No

SOPs, work instructions, calibration and qualification documents were available.

2.4 Personnel

Mr Muhammad Arshad introduced himself as Production In charge and Mr. Aftab Alam introduced himself as Quality Control In charge of the company. The team did not have experience of penicillin manufacturing. No Quality Assurance in charge, Microbiologist or any other technical person was available.

2.5 Validation & Qualification

Equipment and machinery qualification protocols of production machinery and lab equipment were not available. Qualification report of HVAC system and water treatment system were not available

2.6 Safety Measures

Firm had provided emergency exit and fire extinguishers. However, firm was advised to provide smoke detectors, fire alarms and firefighting system in the facility.

2.7 Utilities

2.7.1 HVAC System

The firm had installed HVAC system in the unit. The system was provided with fifteen (15) air handling units as informed by the company's team. However, the team could not elaborate as to which AHU supplied to which area, types of filters and dehumidification system. No relevant documentation was available. Filters were not installed in the supply and return ducts. The AHU area on the roof top could not be visited and physically inspected due to lack of accessibility to that area. A broken bamboo ladder was given which was highly unsafe.

2.7.2 Water Purification System

The firm had installed a water treatment plant within the carbapenem area. Water purification was through double pass reverse osmosis. Storage tank was given. No further details/documents of the water treatment plant were available. The firm had not provided any distillation unit for the production of WFI which is required for container closure final rinse of sterile parenteral preparations as per standard guidelines.

2.8 Waste Management

No system for waste management was defined by the firm.

3. CONCLUSION & RECOMMENDATION

In the light of the inspection conducted by the panel and based on the findings detailed above in which several critical and major shortcomings were noted, the panel of

inspectors DOES NOT recommend grant of drug manufacturing license by way of formulation of M/S Wallace Pharma Evolutions, Kala Wala stop, 20km Lahore Jaranwala Road.

The panel of inspectors also suggests that:

i. The firm may get the revised layout plan approved by the concerned quarter in DRAP,
   Islamabad.
ii. The Competent Authority may constitute a new panel for re-inspection of the firm when the firm is ready for inspection after overcoming the shortcomings.

Reply of the Firm

The firm M/s. Wallace Pharma Evolutions, Lahore made a request for sharing of the report as improvements may be made. Accordingly, Inspection report was shared and reply of M/s. Wallace Pharma Evolutions, is as under;

The firm has submitted observation against their inspection report issued by Additional Director (I DRAP, Lahore. Mr. Arshad Mehmood, Managing Director of M/s Wallace Pharma Evolutions inf that the inspection of their firm was conducted on 17th September, 2021 wide DRAP Islamabad let F.1-21/2015-Lic, for the following sections.

i. Dry Powder Injection Section (Penicillin)
ii. Capsule Section (Penicillin)
iii. Dry Powder Suspension Section (Penicillin)
iv. Injection Section (Carbapenem)

In this regard they address the points highlighted in the inspection report given by the inspection te Detail of which are given below,

A. Reply against the Brief History of Last Inspection (1.2)
In this paragraph we agree with the all points except that the report was sent to DRAP on 8th July, It was a false claim as Firm didn't send any report to DRAP as claimed in Report.

B. Reply against the Premises Observations (2.1)
The Panel clearly mentioned that the building was purposefully built as per layout plan and it's a s story building and HVAC has been installed on the first floor. But Major changes have been done guidance of the previous panel.
We would like to state that we have constructed building as per approved layout plan, the previous illegally misguided us and advised many changes in the layout plan. Now the other panel having objection on the new changes advised by the previous panel specially Area FID Mr. Ajmal Sohail. forcefully directed us to follow his directions not the directions of the licensing section. They com rejected the approved layout plan approved by licensing section. So he directed to go for changes according to his own mind and unwantedly we have to make changes according to the instruction Ajmal Sohail FID.

Now this panel is not agreed with the changes and rejecting the changes we made under advice of Ajmal Sohail. We are unable to understand which the competent authority is? Mr. Ajmal Sohail F the previous panel, made advises which resulted the firm heavy loss.
Now this panel Is again advising differently from the approved Layout plan and also against the gi advice by Mr Ajmal Sohail (FID). meee guide us.

C. <u>Reply against the Entries Observations (2.1.1)</u>
The Panel clearly mentioned that the entries have been constructed according to approved layout p and nothing was wrong about that. So the panel clearly accepted that, so the panel clearly accepted But again panel mentioned the misleading sentence that entries are near to the boundary walls. We like to state sadly that entries were constructed according to approved layout plan, and was purpos constructed near from the boundary wall. The entries are always near to boundary wall as Human resource come from the outer boundary gate and it is strange how Panel biasedly added this point Observations part.

D. <u>Reply against the Warehouses Observations (2.1.2)</u>
The panel mentioned that the receiving bay of carbapenem and Penicillin section are common. We completely deny the misleading statement as there's no common receiving bay for both section. T sections are located at different positions. And it can be verified from the approved layout plan too Again it's a fake misleading observation which shows the biased approach of panel members.

E. <u>Reply against the Raw Material Store Carbapenem Area Observations (2.1.2.1)</u>
We totally disagree with the observations pointed out. As panel has clearly mentioned that the sep room has been constructed for Carbapenem. But they have mentioned that firm don't have any rej room, and they are advised to make Rejection room.
The panel mentioned that there was a small red rack for rejected area. We would like to state that t enough for rejection as this is injectable area and there is no further dispensing in injectable area. I material comes in complete packing whether it's 1kg, 2kg or whatever. No dispensing is made in a injectable area, whose material is sterile and in sterile containers. Even there's no need of separate dispensing room, although we have provided the dispensing booth that is the requirement. Still it i pertinent to mention that there's no need of dispensing of carbapenem material. This is injectable a panel must know if they are not biased and aware to the legal requirements, technically there is no of open dispensing of the Dry Injectable Carbapenem material that is in sterile form. As all sterile containers goes directly from Raw Material store to the filling area. So for sampling of the injectab sterile containers, there is a separate pouch that is attached with every container for sampling. So t no need of separate sampling room as well that is again wrong advice from the panel to make a sep sampling room. There is a separate small pouch for samples that first material is placed in quarant and the sample that already been attached with the container is sent to the QC. When QC passes th sample, then container is shifted to the raw Material store.
So technically speaking there's no any need of separate sampling room still separate sampling and dispensing booth have been provided. So that's clearly illegal, biased and non-technical approach panel which can be clearly understood.
So we disagree with the observation raised by the panel. Separate Raw Material store is present th according to approved layout plan.

Moreover we would like to clear the position regarding the concern raised by panel that there's a v small area towards the raw material store. We would first like to mention that the Carbapenem qua usually 1kg, 5kg or maximum 10kg or 20kg which can be even carried by the human resource him but having said that we would like to mention that there's enough place for any vehicle movement

and that can be verified. Again this is biased and very illegal approach from the panel. We legally technically disagree with this point.

F. <u>Reply against the Packin: Material Store Carbapenem Area Observations (2.1.2.2)</u>

The Panel mentioned that there's no facility of maintenance of storage condition in packing materi store. We would like to mention that we have installed AC there, and if any arrangements are requ there we are ready to install this but this is again minor and ignorable observation as we have insta AC for maintenance of temperate and humidity in Packing Material Store.

And again this is pertinent to mention that there's no any aluminum foil that needs temperature for maintenance in Packing Material Store. Packing material store only contains unit cartons and mast cartons, which is in my opinion doesn't need any specific storage condition according to Drug act.

G. <u>Reply against the Finished Good Store Carbapenem Area Observations (2.1.2.3)</u>

In Finished Good Store, there are pellets are available there and AC are installed there, if any othe arrangements are required, we can be advised accordingly.

H. <u>Reply against the Production Area Observations (2.1.3)</u>

In Production area, we would like to thanks the panel that they acknowledged the HVAC facility a production area is according to approved layout plan. But again panel stated there was open AC in there that was in corridor along with HVAC, if it's DRAP Requirement we can remove Extra Ac f there. But having said that it is pertinent to mention that HVAC is installed there.

I. <u>Reply against the Inspection Section Carbapenem Observations (2.1.3.1)</u>

In the filling and Sealing area of Carbapenem Injection section, the panel has agreed about the pro entries in production area but their observations are differential pressure monitoring devices are no installed between buffers. It is very strange that they have mentioned such a small thing, in my opi material entry room. There is big need of installation of Differential pressure gauges because there material entry not the human entry. And there is also a hash window installed there so proper buff there, only monitoring guage is yet to be installed there which can be installed before the productio started which will at least take around 18 months onwards as we have to go for 6 month stability a then we have our files in que and then issuance of minutes and registration letter will take time so this will take 18 months. So these are such a minor things to mention as observation.

Furthermore it was mentioned that there's a Semi-Automatic Machine and LFC was also there but was no Polythene wrap there, in this regard panel mentioned that Semi-Automatic machine is not suitable for injectable section and so on they're recommending this section.

We would like to request that if Semi-Automatic machines are not approved by DRAP, then acros board a clear advisory should be issued with the technical justification that everyone should remov Semi-Automatic filling machine. As 90% of companies in Pakistan are using this machine and als panel has approved a lot of firms inspection who have Semi-Automatic filling machine. And all th machines are qualifying cGMP requirements.

All these Injections are sent in the market after the proper approval of QC department if the vials a steriled how QC department can pass it without complying the International requirements.

I strongly disagree with the panel on this point and would like to ask that on which technical groun they are recommending to not using the Semi-Automatic filling machine.

There are a lot of companies using the same machine and same officer's visits these Pharma comp on daily basis, but no objection was raised there. So again that's a biased approach and our reques ask the panel that why they have written this as in GMP and inspection requirements, there is no g specs in the Drug Act. The only requirement is that machines should be there which are complying sterile area and sterile products. And sterility only can be judged through the quality control tests r

the naked eye of an individual. So I completely disagree with the recommendation of panel regard
Semi-Automatic, and if there is any requirement a proper SRO should be issued for all companies
mentioning the law which is not allowing us to use Semi-Automatic filling machine.
Again I would disagree with the point of the panel that there were ridges and recesses present on t
doors. I can provide the pictures and videos right now to the board, that there were excellent SS d
available there. Even the same panel have approved Aluminum doors of other firms and we have S
doors and the reason known best to them. And again I would mention reason must know better to
as why they are having objection on SS doors and there are no Ridges there as these are not handm
but by machines.
Panel further mentioned that ducts were not properly sealed and sunlight could be seen from the in
diffuser. We disagree with this, maybe panel doesn't know that the Glue for Sealing of the ducts a
transparent. Not pure transparent but sometimes light can be seen from it. It doesn't mean that it's
but the Sealing Glue is white and little bit light can be seen from it. Again we're unable to underst
why this minor point is also added as Observation.
Panel mentioned that no transfer trolley was available there. We would like to mention that there's
need of transfer trolley there's because our sterilizer is directly opening in the filling and cooling a
and trays are placed in SS Racks there for certain period of cooling time there. So there's no need
for carrying trolley from cooling area to the filling area. These are taken by the human source. Stil
human are there for carrying trays there. Again this is not a GMP requirement for the sterile area.
We have all the required equipment in washing area according to layout plan, and we have steriliz
installed, autoclave and washing machine there. But they mentioned that RO Plant has been install
the firm will supply to both Carbapenem and Penicillin section. What is wrong with this point, Sep
Water Plant is arranged for all separate sections? Not at all.
If water is qualifying to the GMP requirement and there are SS Pipes for supply to certain area,
technically there is no harm in it. There is no international regulations against it, again that's an ill
observation. The Panel also mentioned that washing area was converted in RO Plant, Not at all. Th
a separate room for RO Plant and this Separate RO Plant was constructed as per the instruction of
previous panel.

J. <u>Reply against the Capsule Section Pencillin Observations (2.1.3.2)</u>
In this section report, panel has tried it best to raise any observation but Panel got almost failed in
but still they mentioned that there's a common mixing room for capsule and dry suspension. But it
pertinent to mention that this common mixing room has been approved by licensing section. Agai
illogical observation beside that they have accepted that all the other things are provided.
As they have accepted that all the things are present in Capsule section Penicillin it is difficult to
understand why they have not given approval to Capsule section penicillin. There's no apparent re
For this beside their biased approach.

K. <u>Rely against the Dry Suspension Section Penicillin Observations (2.1.3.3)</u>
In this section panel has accepted that all the things are according to Layout plan, machines are pr
installed for filling and sealing, HVAC are also installed. But monometer was faulty, they didn't n
that Monometer wasn't present there but only one was faulty. They were only having negative app
that they were just trying to point negative things as much as possible.
But still in Dry Suspension area, they had nothing to mention that on which basis they have ceased
give approval of Dry Suspension section Penicillin. Again we disagree with this biased and negati
approach.

L. <u>Reply against the Dry Inspection Section Penicillin Observations (2.1.3.4)</u>
In this section unfortunately the cut paste approach was adopted by the individual who wrote this

and very strange that no other member noticed this. The same observations they have mentioned th there's space constrain in vial washing area and machines were not placed according to the approv layout plan. In the vial washing area there's no approval of the location so the machines are placed according to user friendly and according to GMP requirement. There's no specific plan mentioned layout and that can be verified from the approved layout plan. We are unable to understand the app of panel that without any observation, there are bundle of observations which are even strong enou refuse the grant of DML. They were focusing on use of Semi-Automatic filling machine again, in regard we would like to bring this into notice of honorable board that semi-automatic machine is u majority of companies since 70 years in Pakistan for sterile production of the products and same p have given approval of several companies in Lahore region. Other details are already mentioned al We are disagree with all these recommendation and request the board to approve the section as alr we have faced huge losses.

M. <u>HVAC SYSTEM (2.7.1)</u>

In HVAC paragraph, panel has acknowledged that 15 HVAC System has been provided to all the sections, but the panel was unable to verify that whether HVAC system was installed there as there broken bamboo there so panel couldn't climb there. We disagree as the proper Ladder was availab there and any person could go there for inspection but despite this Panel themselves mention in the whole report about all the sections that they inspected all the differential monitoring guage, and so they themselves are accepting that the system was there then on this basis they needed to check it b going up. But we are not denying the need of inspection but on this basis as this is not a very high building just a single storey building and everyone can see all the 15 units by standing on the gate factory. So again this is nothing to mention here that they have already accepted that all the section HVAC system installed and differential pressure was there. So again we disagree as we are unable understand that why no one went up and inspected the HVAC system.

N. <u>Reply against the Quality Control Department Observations (2.1.4)</u>

In Quality Control department the panel accepted that we have all the separate rooms for Instrume room, chemistry and Microbiology and then further they mentioned that QC was not well equippe That's strange as they themselves mentioned HPLC, Uvi spectrometer and other required equipme why they were saying it was not well equipped. Further they said there's no Atomic Absorption th strange that this couldn't be the ground to refuse a firm Grant of DML. The other observation they mentioned were FTIR, conductive meter, polarimetry, all three things were shown to Mr Munawar the member of panel at his residence after consultation with him.

We requested you can see the FTIR, Dissolution apparatus, conductive meter and polarimeter at th factory or we can show you at your office. But he asked our person to come at his home and show instrument there, the person went there and shown Mr Munawar Hayat all the instruments and he a that he will give approval. We don't know what happened next day, reason is unknown why repor sent to DRAP without even informing any representative of the firm. .

So concluding all these facts we would like to request the board to approve the license of the firm facilitate the growth of Pharma Industry and to maintain the decorum of justice in the DRAP.

<u>Decision of the Central Licensing Board in 283rd meeting</u>

The Board considered the facts and observed that firm submitted application for grant of Drug Manufacturing License while the firm was not yet ready for inspection as evident from the first

	inspection report.The Board also observed that language used against panel members is devoid of norms and professionalism.The Board was alos informed that Mr. Munwar Hayat has already shown his inability to participate all panel inspections wherein he was nominated and he had been replaced with other expert in all inspections. The Board, therefore, decided to re-inspect the firm and constituted the following panel of experts for the inspection of the firm : i. Additional Director (QA/LT) DRAP, Islamabad. ii. Dr. Zia Husnain, FID, DRAP, Lahore. iii. Miss. Uzma Barkat, AD, DRAP, Lahore.			
7	M/s Med Asia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate (SIZ), **Risalpur**.	11.10.2021 (Formulation)	Good	i. Prof. Dr. Muhammad Saeed, Expert Member, ii. Area Federal Inspector of Drugs, DRAP, Peshawar, iii. Syed Adnan Ali Shah, AD, DRAP, Peshawar.

It is submitted for information that application for renewal of DML M/s Med Asia Pharmaceuticals (Pvt) Ltd. Risalpur, for the period **11/07/2020 to 12/07/2025** was submitted on **24/03/202**1 after the expiry of the DML No. 0000690 (Formulation). The Central Licensing Board in its 280th meeting held on 26-27th April, 2021, considering the facts on the record and after thread bare deliberation decided that as the application for renewal of DML No. 000690 (Formulation) of M/s Med Asia Pharmaceuticals (Pvt) Ltd., Risalpur is made after the expiry of the period of validity of License, therefore, Drug Manufacturing License DML No. **000690** (Formulation) was no more valid and stands cancelled. The Firm submitted application for regrant of DML and panel was constituted, accordingly.

RECOMMENDATIONS:

Based on documentation reviewed, technical/management people met, personnel / materials / processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab and allied facilities along with written commitment to procure FTIR within Six month the panel unanimously recommends **re-grant** of Drug Manufacturing License to the firm from for following mentioned three sections;

i. Tablet (General)
ii. Capsule (General)
iii. Oral Dry Suspension (General)

Decision of the Central Licensing Board in 283rd meeting

The Board considered the facts and approved the **grant a fresh**Drug Manufacturing License by way of Formulation in the name of M/s Med Asia Pharmaceuticals (Pvt) Ltd, Plot No. 7, Nowshera Industrial Estate (SIZ), **Risalpur** on the recommendations of the panel of experts for the following sections:

Sections (03)

i. Tablet (General)
ii. Capsule (General)
iii. Oral Dry Powder Suspension (General)

8	M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura.	**26-08-2021**	**Unsatisfac tory**	1. Dr. Zaka Ur Rehman, COO, PDTRC. 2. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Mr. Akbar Ali, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "The panel of Inspectors **does not recommend** the grant of Drug Manufacturing License by way of Formulation to M/s ICU Pharmaceuticals, Khewat No. 13/13, Khatooni No. 57/66, Mouza Mirpur Kehna, Tehsil Sharakpur, District Sheikhupura. **Decision of the Central Licensing Board in 283rd meeting** The Board considered the facts and decided to re-inspect the firm as provided under the rules.			

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 Eterna Pharma (Pvt) Ltd., Plot No.99,100,101&198-C, Sector D1, Old Industrial Estate, Azad Jammu & Kashmir. DML No.000923 (Formulation) **Sections (04):** 1. Oral Dry Powder-II (General) 2. Oral Dry Powder Section (Penicillin) 3. Powder for Injection (Penicillin) 4. Liquid for Injection (Penicillin)	**14-10-2021** (Formulation)	**Good**	1. Additional Director (QA/LT), DRAP, Islamabad. 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Muhammad Sarfraz, Assistant Director, DRAP, 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 4 additional sections by way of formulation to M/s Eterna Pharma (Pvt) Ltd., Plot No.99,100,101&198-C, Sector D1, Old Industrial Estate, Azad Jammu & Kashmir (by way of formulation); 1. Oral Dry Powder-II (General) 2. Oral Dry Powder Section (Penicillin) 3. Powder for Injection (Penicillin) 4. Liquid for Injection (Penicillin) **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Eterna Pharma (Pvt) Ltd., Plot No.99,100,101&198-C, Sector D1, Old Industrial Estate, Azad Jammu & Kashmir under DML No.000923 (Formulation)on the recommendations of the panel of experts. **Section / facility (04):** 1. Oral Dry Powder-II (General) 2. Oral Dry Powder Section (Penicillin) 3. Dry Powder Injection (Penicillin) 4. Liquid Injectable (Penicillin)			
2	M/s News Pharma, Plot No. 42, Sunder Industrial Estate, Lahore. DML No. 000775 (Formulation) **Section (01):** 1. Oral Liquid (General) Section.	**28-07-2021**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Government of the Punjab, Lahore. 2. Mrs. Majida Mujahid, FID, DRAP, Lahore. 3. Ms. Mahwish Jamil Butt, AD, DRAP, Lahore.
	Recommendations of the panel: "Keeping in view the facilities like building, HVAC system, machinery & equipment, instruments, personnel, documentation, quality control and testing facilities panel of inspectors **recommends** is of the opinion to recommend the grant of following new section to M/s News Pharma, 42-Sundar Industrial Estate, Lahore: i. Oral Liquid General Section. **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of following additional sections in the name of			

	M/s News Pharma, Plot No. 42, Sunder Industrial Estate, Lahore. under DML No.000775 (Formulation)on the recommendations of the panel of experts. **Section / facility (01):** i. Oral Liquid General Section.			
3	M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3 National Industrial Zone, Rawat. DML No.000518 (Formulation) **Section (01):** 1. Sachet (General) Section.	**14-09-2021**	**Good**	1) Additional Director (Bio) DRAP, Islamabad. 2) Federal Inspector of Drugs, DRAP, Islamabad. 3) Deputy Director (Lic) DRAP, Islamabad.
	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** for the grant of **additional section namely Sachet (General)** along with Renewal of Drug Manufacturing License No. 000518 by way of Formulation for the following sections of M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3 National Industrial Zone, Rawat, Rawalpindi. i. Tablet (General) (Renewal) ii. Tablet (Psychotropic) (Renewal &Regularization) iii. Cream/Ointment Section (General) (Renewal) iv. Dry Powder for Suspension (Cephalosporin) (Renewal) v. Dry Powder for Injection (Cephalosporin) (Renewal) vi. Capsule Section (Cephalosporin)(Renewal) vii. Capsule Section (General)(Renewal) viii. Ampoule Section (General) (Renewal)) ix. QC Lab & Microbiology. x. Stores / Warehouses." **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of following additional sections in the name of M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3 National Industrial Zone, Rawat under DML No.000518 (Formulation)on the recommendations of the panel of experts. **Section / facility (01):** 1. Sachet (General)			
4	M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North West Industrial Zone, Port Qasim Authority Karachi. DML No. 000842 (Formulation)	**23-06-2021**	**Good**	1) Mr. Shoaib Ansari, CDI, Sindh 2) Mr. Sajjad Ahmed Abbasi, DD CDL, Karachi 3) Federal Inspector of Drugs, DRAP, Karachi.

	Section (02): **1.** Injectable Ampoule BF (Steroid) – **New** **2.** Capsule (General) **- New**			

Recommendation of panel:

Based on the areas inspected, the people met and considering commitment of the firm for continuous upgradation and improvement the panel recommends as follows:

(1) The renewal of DML No. 000842 of M/s Hudson Pharma (Pvt) Ltd for 4 sections namely:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Plastic Ampoules (BFS) Section*	*2*	*Cream/ointment/Gel/Lotion (General) Section*
3.	*Capsule DPI (Steroidal) Section*	*4*	*Eye/Ear/Nasal Drops (General) Section*

(2) The grant of additional sections namely:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Plastic Ampule (Steroid)*		*Capsule (General) Section*

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of following additional sections in the name of M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North West Industrial Zone, Port Qasim Authority Karachi under DML No.000842 (Formulation)on the recommendations of the panel of experts.

Section / facility (01):

1. Injectable Ampoule BF (Steroid)- **New**
2. Capsule (General) Section - **New**

5	M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi.	**23-09-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mst. Sidra Yasmeen AD, DRAP, Karachi.

	DML No. 000040 (Formulation) Sections : 1. Dry Powder Injection (General) – **New.**			

"In compliance to instructions contained in DRAP Islamabad letter No.F.2-14/2004-Lic (Vol-II) dated 23 June, 2021, the constituted panel under the given TORs inspected in details the entire premises of M/s. Zafa Pharmaceutical Laboratories, L-4/1, A&B, Block-21, Federal B Industrial Area, Karachi on 23/09/2021. The panel found the facility purposefully designed as per approved lay out plan and capable enough to provide better cleaning, maintaining appropriate sanitization. During the detail inspection the panel further observed good practices in production, QC lab and in stores with respect to GMP documents. An appropriate level of QA System was seen in place. The firm has enough technical persons in each section. HVAC system was seen in good working conditions and validated. Overall an appropriate level of GMP compliance was noted in place. Based on the stated facts and the attitude of the firm towards continuous improvements, the panel unanimously recommends the grant of renewal of DML No.000040 for the following sections along with Regularization of amendments undertaken by them as per approved design :

Sr. No	**Name of Sections**	**Sr. No**	**Name of Sections**
Regularization/Renewal of following sections			
Building - I			
i.	Tablet (General)- I	ii.	e Ophthalmic Drops (General)
iii.	Liquid Syrup (General)	iv.	Capsule (General)
v.	Dry Powder Suspension (General)	vi.	Cream/Ointment (Steroid)
vii.	nal Preparation (Dusting Powder)	viii.	t (General)- II
ix.	Liquid Injection (General)	x.	Nasal Drops (General)
Building II			
i.	Liquid Ampoule SVP (General).	ii.	Aerosol Section.
iii.	Cream/Ointment (General)	iv.	Tablet Section (General) – III.
v.	Liquid Ampoule (General)- I	vi.	Liquid Ampoule (General)- II
vii.	Sachet (General)	viii.	**********

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of following additional sections in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi. under DML No.00040 (Formulation)on the recommendations of the panel of experts.

Section / facility (01):

1. Dry Powder Injection (General)- **New**

<table>
<tr><td>6</td><td>M/s Mediflow Pharmaceuticals (Pvt) Ltd, Plot No. ID-100, Sector 30, Korangi Industrial Area, Karachi.

DML No.000822 (Formulation)

Section (01) :

1. Large Volume Parental (General) – Revised.</td><td>04-08-2021</td><td>Good</td><td>1) CDI, Govt of Sindh.
2) Federal Inspector of Drugs, DRAP, Karachi.
1. Mr. Affan Ali, AD, CDL, Karachi.</td></tr>
<tr><td></td><td colspan="4"><u>Recommendations of the panel:</u>

“Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection and vision of the management for exports, panel recommends the grant of renewal of the drug manufacturing license by the way of formulation and regularization of the additional section as mentioned below:
<table><tr><td>Sr #</td><td>Name of Section</td></tr><tr><td>1.</td><td>Large Volume Parenteral</td></tr></table>
<u>Decision of the Central Licensing Board in 283rd meeting</u>

The Board considered and approved the grant of following section in the name of M/s Mediflow Pharmaceuticals (Pvt) Ltd, Plot No. ID-100, Sector 30, Korangi Industrial Area, Karachi. under DML No.000822 (Formulation)on the recommendations of the panel of experts

<u>Section / facility (01):</u>

Liquid Injectable (LVP) (General) – Revised.</td></tr>
<tr><td>7</td><td>M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone, Port Qasim Authority Karachi

DML No. 000588 (Formulation)

Facility (s) :

1. Penicillin Facility – Revised.
2. Quality Control Laboratory – Revised

API(s)/Pallets (19):

1. Aceclofenac Pallets – In House Specs
2. Clopidogrel Pallets – In House Specs –
3. Cyclobenzaprine HCL</td><td>16-09-2021</td><td>Good</td><td>1) Dir. Abdullah Dayo, Expert Member.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Ms. Krishan Das, AD DRAP, Karachi.</td></tr>
</table>

	Pallets **In House Specs** 4. Domperidone Pallets **In House Specs** 5. Doxycycline Pallets **In House Specs** 6. Ferrous Sulphate Pallets **In House Specs** 7. Fexofenadine HCL Pallets **In House Specs** 8. Folic Acid Pallets **In House Specs** 9. Itopride Pallets **In House Specs** 10. Ketoprofen Pallets **In House Specs** 11. Memantine Pallets **In House Specs** 12. Naproxen Pallets **In House Specs** 13. Nitroglycerine Pallets **In House Specs** 14. Rabeprazole Sodium Pallets **In House Specs** 15. Tizanidine Pallets **In House Specs** 16. Venlafaxine HCL Pallets **In House Specs** 17. Secnidazole Taste Masked Granules **In House Specs** 18. Additional Process flow for manufacturing of Cefixime Trihydrate 19. Cephalexin USP.			
	<u>Recommendations of the panel:</u> *"M/S. Saakh Pharma (Pvt.) Ltd. Situated at Plot No. C-7/1, North Western Industrial Zone Port Qasim Bin Qasim Town, Karachi inspected is by the panel on 16th Sep 2021 in compliance to the directions contained in DRAP, Islamabad Letter No. F.2-5/2001-Lic. (Vol-IV) dated 2nd April, 9th and 17th August 2021in connection with renewal of Drug Manufacturing License No. 000588 (By of Semi Basic). Following are the observation:* *1. The panel inspected the firm in detail including al 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 required for the production and test/analysis of the products being manufactured. Necessary documents relating to QC, QA and HVAC and other utilities were also seen in place.* *2. Based on the people met, documents reviewed and observations made during the inspections, the panel recommends the grant of renewal of Drug manufacturing License No. 000588 (By way of Semi Basic), grant of additional API and regularization/amendments of*			

Master Layout plan as per DRAP, Islamabad Letter No.F.2-5/2001-Lic (Vol-IV) dated 2" April, 9"' August and 17" August 2021; for following sections:

S.No.	*Name of Section*
1.	*Penicillin*
2.	*Cephalosporins*
3.	*General*
4.	*TasteMasking& Pelletization*

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of following revised facilities & additional API's in the name of M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone, Port Qasim Authority Karachi under DML No.000588 (Semi-Basic Manufacture) on the recommendations of the panel of experts

Section / facility (04):

S. No.	*Name of Section*
1.	*Penicillin (revised)*
2.	*Cephalosporins*
3.	*General*
4.	*Taste Masking& Palletization*
5.	*Quality Control (Revised)*

1. Aceclofenac Pallets – **In House Specs**
2. Clopidogrel Pallets – **In House Specs –**
3. Cyclobenzaprine HCL Pallets **In House Specs**
4. Domperidone Pallets **In House Specs**
5. Doxycycline Pallets **In House Specs**
6. Ferrous Sulphate Pallets **In House Specs**
7. Fexofenadine HCL Pallets **In House Specs**
8. Folic Acid Pallets **In House Specs**
9. Itopride Pallets **In House Specs**
10. Ketoprofen Pallets **In House Specs**
11. Memantine Pallets **In House Specs**
12. Naproxen Pallets **In House Specs**
13. Nitroglycerine Pallets **In House Specs**
14. Rabeprazole Sodium Pallets **In House Specs**
15. Tizanidine Pallets **In House Specs**
16. Venlafaxine HCL Pallets **In House Specs**
17. Secnidazole Taste Masked Granules **In House Specs**
18. Additional Process flow for manufacturing of Cefixime Trihydrate
19. Cephalexin USP.

8	M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha DML No. 000465 (Formulation) **Section (01):** **1.** Capsule (General) **- New**	**10-09-2021**	**Good**	4) Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
	Recommendation of panel : *On the basis of inspection, M/s Well Care Pharmaceuticals situated at A-7 Punjab Industrial Estate, Lahore Road, Sargodha is **recommended** for the grant of additional section as mentioned above, under DML No. 000465.* **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of following section in the name of M/s Well Care Pharmaceuticals, A/7, P.S.I.E Sargodha under DML No.000465 (Formulation) on the recommendations of the panel of experts **Section / facility (01):** **1.** Capsule (General) **- New**			
9	M/s The Searle Company Limited, F-319. S.I.T.E. Karachi DML No. 000016 (Formulation) **Section (01):** 1. Tablet (General)**&**Packaging Section- Expansion (Mezzanine Floor) 2. Tablet (General) - Revised	**08-10-2021**	**Good**	1. Dr. AbullahDayo, Expert Member. 2. FID, DRAP, Karachi. 3. Mr. Krishan Das, AD, DRAP, Karachi.
	Recommendation of panel: Based on the stated observations the panel unanimously recommends the grant of changes/expansions/revision of sections made as per approved design for following sections under DML No. 000016 by way for formulation: 1. Tablet (General) Section & Packaging Section Expansion-Mezzanine Floor. 2. Tablet (General) Section revised (Granulation suit, Dispensing Booth, Cold Room, WIP Room, Blistering & Packaging Hall)-Mezzanine Floor. **Decision of the Central Licensing Board in 283rd meeting**			

	The Board considered and approved the grant of following section in the name of M/s The Searle Company Limited, F-319. S.I.T.E. Karachi under DML No.000016 (Formulation) on the recommendations of the panel of experts **Section / facility (02):** 1. Tablet (General) **&**Packaging Section- Expansion (Mezzanine Floor) 2. Tablet (General) - Revised			
10	M/s OBS Pakistan (Pvt) Ltd, C-14, Manghopir Road, SITE Karachi. DML No. 000012 (Formulation) **Section (01):** 1. Liquid vial SVP (Steroid) – Revised	**08-10-2021**	**Good**	2. Dr. Najam us saqib, Additional Director , DRAP, Karachi 3. FID, DRAP, Karachi. 4. Mr. Krishan Das, AD, DRAP, Karachi.
	Recommendations of the panel: *Based on the above stated facts & observations and keeping in view the attitude of the firm towards continuous investment and improvements for better GMP compliance, the panel unanimously decided to recommend the grant of amendments in Liquid Vial SVP (Steroid) under DML No. 000012 by way of formulation.* Panel was given mandate for *grant of amendments in Liquid Vial SVP (Steroid) & for grant of amendments in Research & Development Lab but in the recommendations panel has mentioned recommendation regarding grant of amendments in Research & Development Lab.* **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of following section in the name of M/s OBS Pakistan (Pvt) Ltd, C-14, Manghopir Road, SITE Karachi under DML No.000012 (Formulation) on the recommendations of the panel of experts **Section / facility (01):** 1. Liquid vial SVP (Steroid) – **Revised**			
11	M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Plot No.134-B&135-B, Nowshera Industrial Estate, Risalpur DML No.000691 (Formulation)	**22-09-2021** **Formulation**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Expert member 2. Federal Inspector of Drugs, DRAP, Peshawar. 3. Syed Adnan Ali Shah, AD, DRAP, Peshawar.

Recommendations of the panel:

Based on documentation reviewed, technical/management people met, materials/processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm is operating at satisfactory level of GMP compliance and unanimously ***recommends****grant of renewal of Drug Manufacturing License to the firm from 03.08.2020 for following mentioned four sections alongwith* ***grant of additional following new*** *four sections;*

Ser	***Name of Section (Additional New Sections)***
1	*Powder Injectable (Cephalosporin)*
2	*Capsule (Cephalosporin)*
3	*Oral Dry Suspension (Cephalosporin)*
4	*Tablet-II (General)*

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of following sections in the name of M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Plot No.134-B&135-B, Nowshera Industrial Estate, Risalpur under DML No.000691 (Formulation) on the recommendations of the panel of experts

Section / facility (04):

Ser	***Name of Section (Additional New Sections)***
1	*Powder Injectable (Cephalosporin) -* ***New***
2	*Capsule (Cephalosporin) –* ***New***
3	*Oral Dry Suspension (Cephalosporin) -* ***New***
4	*Tablet-II (General) -* ***New***

12.	M/s Medera Pharmaceuticals, Plot No. 2, St No. N-4, National Industrial Zone, Rawat. **Sections (03):** 1. Lotion (General). 2. Capsule Section (Cephalosporin). 3. Dry Powder for Suspension (Cephalosporin).	**21-10-2021 & 26-10-2021**	**Good**	1. Additional Director (QA & LT), DRAP, Islamabad. 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Hasan Afzaal, AD, DRAP, Islamabad.

Recommendations of the panel:

"Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommends** the approval for the Grant of three new Sections namely Lotion Section (Ground floor), Capsule (Cephalosporin) Dry powder for suspension (Cephalosporin) (Basement) along with Renewal of Drug Manufacturing License No. 000714 by way of formulation for the following sections of M/s Medera Pharmaceuticals (PVT) Limited, Plot No. 2, St # N-4, National Industrial Zone, Rawat.

i. Tablet (General) (Renewal)
ii. Cream/Ointment Section (Genera) Renewal
iii. Cream/Ointment Section Steroidal Renewal
iv. Dry Powder for Oral Suspension (General) (Renewal)
v. Capsule Section (General)(Renewal)
vi. Capsule Section (Cephalosporin) (New) (Basement)
vii. Dry Powder for Suspension (Cephalosporin) (New) (Basement)
viii. Lotion Section General (New) Ground Floor.
ix. Q.C Lab & Microbiology Lab.
x. Stores / Warehouses"

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of following sections in the name of M/s Medera Pharmaceuticals, Plot No. 2, St No. N-4, National Industrial Zone, Rawat. under DML No.000714 (Formulation) on the recommendations of the panel of experts

Section / facility (03):

1. Lotion (General) – **New**
2. Capsule (Cephalosporin) - **New**
3. Dry Powder Suspension (Cephalosporin)- **New**

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

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 Pulse Pharmaceuticals (Pvt) Ltd, MozayBadoke, Raiwind Road (SuaAasil Road), Lahore. DML No.000564 (Formulation) Period: Commencing on 31-12-2019 ending on 30-12-2024.	**04-102021**	**Good**	1. Dr. Mehmood Ahmed, Member. 2. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Mr. Munawar Hayat, Director, DTL, Lahore. 4. Aisha Irfan, FID, DRAP, Lahore.

Recommendations of the panel:

"In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery / equipment, material, management, air handling water treatment system, personnel and documentation etc the panel recommends **the renewal of Drug Manufacturing License and regularization** to the following sections / warehouse to M/s Pulse Pharmaceuticals (Pvt) Ltd, MozayBadoke, Raiwind Road (SuaAasil Road), Lahore by way of formulation:

1. Tablet (General) Section.
2. Tablet (Quinolone) Section.
3. Oral Dry Powder Suspension (Cephalosporin).
4. Tablet (Psychotropic) Section.
5. Capsule (Cephalosporin) Section.
6. Capsule (General) Section.
7. Dry Powder Injection (Cephalosporin) Section.
8. Liquid Injection Ampoule.
9. Injectable Ampoule (General) Section (Revised).
10. Warehouse (Revised).

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000564 by way of formulation in the name of M/s Pulse Pharmaceuticals (Pvt) Ltd, Mozay Badoke, Raiwind Road (Sua Aasil Road), Lahore on the recommendations of the panel of experts for the period Commencing on 31-12-2019 ending on 30-12-2024 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:-

Sections (09):

1. Tablet (General) Section.

	2. Tablet (Quinolone) Section. 3. Oral Dry Powder Suspension (Cephalosporin). 4. Capsule (Cephalosporin) Section. 5. Capsule (General) Section. 6. Dry Powder Injection (Cephalosporin) Section. 7. Liquid Injection Ampoule. 8. Injectable Ampoule (General) Section (Revised). 9. Warehouse (Revised).			
2	M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot No.30, Phase-I & II, Industrial Estate, Hattar. DML No.000374 (Formulation) Tenure: Commencing on 17-11-2020& ending on 16-11-2025	**01-09-2021**	**Good**	iv. Prof. Dr. Jamshed Ali Khan, Expert Member, v. Area Federal Inspector of Drugs, DRAP, Peshawar, vi. Syed Adnan Ali Shah Afridi, AD, DRAP, Peshawar. However, the inspection was carried out by following members iv. Prof. Dr. Jamshed Ali Khan, Expert Member, v. Area Federal Inspector of Drugs, DRAP, Peshawar, 1. Mr. Adnan Shaidullah, AD, DRAP, Peshawar.

<u>Recommendations of the panel:</u>

Based on documentation reviewed, technical/management people met, materials/processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm is operating at satisfactory level of GMP compliance and unanimously **recommends** grant of renewal of Drug Manufacturing License to the firm from 17.11.2020 for following sections;

Ser	Name of Section		Name of Section
1.	Capsule (General)	6.	Injectable Vial (Cephalosporin)
2.	Tablet (General)	7.	Sachet (General)

3.	Tablet Section (Psychotropic)	8.	Cream/Ointment (General)	
4.	Dry Powder Suspension (Cephalosporin)	9.	Liquid Syrup (General)	
5.	Capsule (Cephalosporin)	----------		

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000374 by way of formulation in the name of M/s Bloom Pharmaceuticals (Pvt) Ltd, Plot No.30, Phase-I & II, Industrial Estate, Hattar on the recommendations of the panel of experts for the period Commencing on 17-11-2020 & ending on 16-11-2025for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:-

Section (09)

Ser	Name of Section		Name of Section
1.	Capsule (General)	6.	Injectable Vial (Cephalosporin)
2.	Tablet (General)	7.	Sachet (General)
3.	Tablet Section (Psychotropic)	8.	Cream/Ointment (General)
4.	Dry Powder Suspension (Cephalosporin)	9.	Liquid Syrup (General)
5.	Capsule (Cephalosporin)	----------	

The Board also decided to issue advisory to the Federal Inspector of Drugs to carry and conduct the inspections by the panel as constituted by the Board. In case of unavoidable circumstances, panel may be changed with the approval of appropriate forum.

3	M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Industrial Estate, Hayatabad, Peshawar. DML No.000388 (Formulation) **Sections (09):** 1. Capsule (General) 2. Tablet (General) 3. Tablet Section (Psychotropic) 4. DryPowder Suspension	**07-09-2021 & 22-10-2021**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Expert Member 2. Mr. Saleem Khan, DG Drugs, Peshawar, KPK 3. Area Federal Inspector of Drugs, DRAP, Peshawar.

	(Cephalosporin) 5. Capsule (Cephalosporin) 6. Injectable Vial (Cephalosporin) 7. Sachet (General) 8. Cream/Ointment (General) 9. Liquid Syrup (General) Tenure: Commencing on 26-06-2019 & ending on 25-06-2024			

Recommendations of the panel:

Based on the areas inspected, the people met, documents reviewed, the intension towards further improvements and the corrective and preventive action taken, the firm is considered to be operating at good level of compliance with cGMP guide lines as per drug act, 1976 and rules framed there under.

As per manufacturing / testing equipment installed in the production, quality control, utilities, engineering as well as the cGMP compliance status of the firm, the panel unanimously **recommended the grant of renewal** of DML No.000388by way of formulation.

The panel also verified the regularization of layout plan as directed by DRAP vide letter No.F.3-7/92-Lic (Vol-II) dated 08th July, 2021.

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000388 by way of formulation in the name of M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Industrial Estate, Hayatabad, Peshawar on the recommendations of the panel of experts for the period Commencing on 26-06-2019 & ending on 25-06-2024 for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:-

Sections (08):

1. Capsule (General)
2. Tablet (General)
3. Dry Powder Suspension (Cephalosporin)
4. Capsule (Cephalosporin)
5. Injectable Vial (Cephalosporin)
6. Sachet (General)
7. Cream/Ointment (General)
8. Liquid Syrup (General)

4	M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542/ A-B, Sunder Industrial Estate, Lahore. DML No. 000800 (Formulation) Period: Commencing on 19-09-2019 & ending on 18-09-2024.	**02-07-2021 & 03-08-2021**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mrs. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Mehwiah Jamil Butt, Assitant Director, DRAP, Lahore
	Recommendations of the panel: Keeping in view the manufacturing facilities like building, functional HVAC system, installed Production machinery in the respective sections & availability of Quality Control equipments, instruments, Technical & experienced personnels, having adequate documentation, regarding production, QA, quality control, microbiology lab and purified water production and testing facilities, the panel of inspectors **recommends** the grant of Renewal of DML to M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542/ A & B Sunder Industrial Estate, Lahore bearing Lic No. 000800 in respect of its approved following four Sections:- 1. Liquid Injection (Veterinary) (General). 2. Liquid Injection (Veterinary) (General Antibiotic). 3. Oral Liquid (Veterinary) (General & General Antibiotics). 4. Powder (Veterinary) (General & General Antibiotics). **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of renewal of DML No. 000800 by way of formulation in the name of M/s Izfaar Pharmaceuticals (Pvt) Ltd, 542/ A-B, Sunder Industrial Estate, Lahore the recommendations of the panel of experts for the period Commencing on 19-09-2019 & ending on 18-09-2024. for the following section: - **Section (04)** 1. Liquid Injection (Veterinary) (General). 2. Liquid Injection (Veterinary) (General Antibiotic). 3. Oral Liquid (Veterinary) (General & General Antibiotics). 4. Powder (Veterinary) (General & General Antibiotics).			
5	M/s Bayer Pakistan (Pvt.) Ltd, 108, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore. DML No. 000243 (Formulation) Period: Commencing on 18-11-2019 & ending on 17-11-2024.	**28-09-2021**	**Very Good**	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab. 2. Ms. Aisha Irafan, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Uzma Barkat, Assitant Director, DRAP, Lahore.

	Recommendations of the panel: "In view of above inspection proceedings and facilities verified, such as company profile, building, production, in-process controls, quality control testing, machinery/equipment, material, management, air handling, water treatment system, personnel and documentation e.t.c the panel **recommends** the renewal of Drug Manufacturing License and regularization of layout plan of the following sections/warehouse, quality control laboratory and microbiology to M/s. Bayer Pakistan (Pvt.) Ltd., 108-Industrial Estate, Kot Lakhpat, Lahore by way of Formulation: 1. Semi Solid Cream/Ointment (Steroid/Non-Steroid) Section (Renewal & Regularization) 2. Tablet (Hormone) Section (Renewal & Regularization) 3. Injectable (Ampoule) (Hormone) Section (Renewal & Regularization) 4. Tablet (Psychotropic) Section (Renewal) 5. Warehouse (Renewal & Regularization) 6. Quality Control Laboratory & Microbiology (Renewal & Regularization)". It is pertinent to mention here that the firm got their layout plan regularized for Cream/Ointment (Steroid) Section, however, panel has recommended the renewal and regularization of both Cream Ointment (Steroid/**Non-Steroid**) section. **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of renewal of DML No. 000243 by way of formulation in the name of M/s Bayer Pakistan (Pvt.) Ltd, 108, Quaid-E-Azam Industrial Estate, Kot Lakhpat, Lahore the recommendations of the panel of experts for the period Commencing on 18-11-2019 & ending on 17-11-2024. for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:- **Section (06)** 1. Semi Solid Cream/Ointment (Steroid) Section (Renewal & Regularization) 2. Tablet (Hormone) Section (Renewal & Regularization) 3. Injectable (Ampoule) (Hormone) Section (Renewal & Regularization) 4. Tablet (Psychotropic) Section (Renewal) 5. Warehouse (Renewal & Regularization) 6. Quality Control Laboratory & Microbiology (Renewal & Regularization).			
6	M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggian Bypass Road, Lahore. DML No. 000676 (Formulation) Period: Commencing on 09-12-2019 & ending on 08-12-2024.	**12-07-2021**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drugs Controller, Punjab. 2. Dr. Farzana Chaudhary, Expert Member. 3. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.

	Recommendations of the panel: "The panel of inspectors **recommends** the renewal of DML beaing No.000676 issued in favour of M/s Hoover Pharmaceuticals (Pvt) Ltd, located at Plot No.16, Zain Park Industrial Area, Saggian bypass Road, Lahore in respect to all approved sections." As per available record of Licensing Division, the firm possess following sections: i. Capsule (General). ii. Cream/Ointment (General). iii. Tablet (General) iv. Cream/Ointment (Steroid). v. External Liquid (General). vi. Oral Dry Powder Suspension (General). vii. Oral Liquid (General). viii. Sachet (General). **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of renewal of DML No. 000676 by way of formulation in the name of M/s Hoover Pharmaceuticals (Pvt) Ltd, Plot No. 16, Zain Park Industrial Area, Saggian Bypass Road, Lahore the recommendations of the panel of experts for the period Commencing on 09-12-2019 & ending on 08-12-2024. for the following section: - **Section (08)** 1. Capsule (General). 2. Cream/Ointment (General). 3. Tablet (General) 4. Cream/Ointment (Steroid). 5. External Liquid (General). 6. Oral Dry Powder Suspension (General). 7. Oral Liquid (General). 8. Sachet (General).			
7	M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3 National Industrial Zone, Rawat. DML No.000518 (Formulation). Period: Commencing on 22-06-2021 & ending on 21-06-2026.	**14-09-2021**	**Good**	1. Additional Director (Bio) DRAP, Islamabad. 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Deputy Director (Lic) DRAP, Islamabad.

	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** for the grant of additional section namely Sachet (General) along with Renewal of Drug Manufacturing License No. 000518 by way of Formulation for the following sections of M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3 National Industrial Zone, Rawat, Rawalpindi. i. Tablet (General) (Renewal) ii. Tablet (Psychotropic) (Renewal &Regularization) iii. Cream/Ointment Section (General) (Renewal) iv. Dry Powder for Suspension (Cephalosporin) (Renewal) v. Dry Powder for Injection (Cephalosporin) (Renewal) vi. Capsule Section (Cephalosporin)(Renewal) vii. Capsule Section (General)(Renewal) viii. Ampoule Section (General) (Renewal)) ix. QC Lab & Microbiology. x. Stores / Warehouses." **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of renewal of DML No. 000518 by way of formulation in the name of M/s Gray's Pharmaceuticals, Plot No. 2, Street No. N-3, National Industrial Zone, Rawat on the recommendations of the panel of experts for the period Commencing on 22-06-2021 & ending on 21-06-2026for the following sections subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:- **Sections (09):** 1. Tablet (General) (Renewal) 2. Cream/Ointment Section (General) (Renewal) 3. Dry Powder for Suspension (Cephalosporin) (Renewal) 4. Dry Powder for Injection (Cephalosporin) (Renewal) 5. Capsule Section (Cephalosporin)(Renewal) 6. Capsule Section (General)(Renewal) 7. Ampoule Section (General) (Renewal)) 8. QC Lab & Microbiology. 9. Stores / Warehouses.			
8	M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North West Industrial Zone, Port Qasim Authority Karachi. DML No. 000842 (Formulation) **Period:** Commencing on 25-08-2021 & ending on 24-08-2026.	**23-06-2021**	**Good**	1) Mr. Shoaib Ansari, CDI, Sindh 2) Mr. Sajjad Ahmed Abbasi ,DD CDL, Karachi 3) Federal Inspector of Drugs, DRAP, Karachi.
	Recommendations of the panel: *Based on the areas inspected, the people met and considering commitment of the firm for*			

	continuous upgradation and improvement the panel recommends as follows: *(1) The renewal of DML No. 000842 of M/s Hudson Pharma (Pvt) Ltd for 4 sections namely:* ***Sr #*** | ***Name of Section*** | ***Sr. #*** | ***Name of Section*** *1.* | *Plastic Ampoules (BFS) Section* | *2.* | *Cream/ointment/Gel/Lotion (General) Section* *3.* | *Capsule DPI (Steroidal) Section* | *4.* | *Eye/Ear/Nasal Drops (General) Section* *(2) The grant of additional sections namely:* ***Sr #*** | ***Name of Section*** | ***Sr. #*** | ***Name of Section*** *1.* | *Plastic Ampule (Steroid)* | *2.* | *Capsule (General) Seciton* **<u>Decision of the Central Licensing Board in 283rd meeting</u>** The Board considered and approved the grant of renewal of DML No. 000842 by way of formulation in the name of M/s Hudson Pharma (Pvt) Ltd, Plot No. D-93, North West Industrial Zone, Port Qasim Authority Karachi the recommendations of the panel of experts for the period Commencing on 25-08-2021 & ending on 24-08-2026. for the following section: - **<u>Section (04)</u>** 1. Plastic Ampoules (BFS) Section 2. Cream/ointment/Gel/Lotion (General) Section 3. Capsule DPI (Steroidal) Section 4. Eye/Ear/Nasal Drops (General) Section			
9	M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi. DML No. 000040 (Formulation) **Period:** Commencing on 20-05-2020 & ending on 29-05-2025.	**23-09-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mst. Sidra Yasmeen AD, DRAP, Karachi.

Recommendations of the panel:

"In compliance to instructions contained in DRAP Islamabad letter No.F.2-14/2004-Lic (Vol-II) dated 23 June, 2021, the constituted panel under the given TORs inspected in details the entire premises of M/s. Zafa Pharmaceutical Laboratories, L-4/1, A&B, Block-21, Federal B Industrial Area, Karachi on 23/09/2021. The panel found the facility purposefully designed as per approved lay out plan and capable enough to provide better cleaning, maintaining appropriate sanitization. During the detail inspection the panel further observed good practices in production, QC lab and in stores with respect to GMP documents. An appropriate level of QA System was seen in place. The firm has enough technical persons in each section. HVAC system was seen in good working conditions and validated. Overall an appropriate level of GMP compliance was noted in place. Based on the stated facts and the attitude of the firm towards continuous improvements, the panel unanimously recommends the grant of renewal of DML No.000040 for the following sections along with Regularization of amendments undertaken by them as per approved design :

Sr. No	Name of Sections	Sr. No	Name of Sections
Regularization/Renewal of following sections			
Building - I			
xi.	Tablet (General)- I	xii.	Sterile Ophthalmic Drops (General)
xiii.	Liquid Syrup (General)	xiv.	Capsule (General)
xv.	Dry Powder Suspension (General)	xvi.	Cream/Ointment (Steroid)
xvii.	External Preparation (Dusting Powder)	xviii.	Tablet (General)- II
xix.	Liquid Injection (General)	xx.	Nasal Drops (General)
Building II			
ix.	Liquid Ampoule SVP (General).	x.	Aerosol Section.
xi.	Cream/Ointment (General)	xii.	Tablet Section (General) – III.
xiii.	Liquid Ampoule (General)- I	xiv.	Liquid Ampoule (General)- II
xv.	Sachet (General)	xvi.	**********

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000040 by way of formulation in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi the recommendations of the panel of experts for the period Commencing on 20-05-2020 & ending on 29-05-2025 for the following section: -

Section (24)

Sr. No	Name of Sections	Sr. No	Name of Sections
Regularization/Renewal of following sections			

	Building - I			
	i.	Tablet (General)- I	ii.	e Ophthalmic Drops (General)
	iii.	Liquid Syrup (General)	iv.	Capsule (General)
	v.	Dry Powder Suspension (General)	vi.	Cream/Ointment (Steroid)
	vii.	nal Preparation (Dusting Powder)	viii.	t (General)- II
	ix.	Liquid Injection (General)	x.	Nasal Drops (General)
	Building II			
	xvii.	Liquid Ampoule SVP (General).	xviii.	Aerosol Section.
	xix.	Cream/Ointment (General)	xx.	Tablet Section (General) – III.
	xxi.	Liquid Ampoule (General)- I	xxii.	Liquid Ampoule (General)- II
	xxiii.	Sachet (General)	xxiv.	**********

10	M/s Mediflow Pharmaceuticals (Pvt) Ltd, Plot No. ID-100, Sector 30, Korangi Industrial Area, Karachi. DML No.000822 (Formulation) Period: Commencing on 23-06-2020 & ending on 22-06-2025.	**04-08-2021**	**Good**	3) CDI, Govt of Sindh. 4) Federal Inspector of Drugs, DRAP, Karachi. 5) Mr. Affan Ali, AD, CDL, Karachi.

Recommendations of the panel:

"Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection and vision of the management for exports, panel recommends the grant of renewal of the drug manufacturing license by the way of formulation and regularization of the additional section as mentioned below:

Sr #	***Name of Section***
1.	*Large Volume Parenterals*

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000822 by way of formulation in the name of M/s Mediflow Pharmaceuticals (Pvt) Ltd, Plot No. ID-100, Sector 30, Korangi Industrial Area, Karachi the recommendations of the panel of experts for the period Commencing on 23-06-2020 & ending on 22-06-2025 for the following section: -

Section (02)

1. Liquid Injectable (LVP)

11	M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone, Port Qasim Authority Karachi DML No. 000588 (Formulation) **Period**: Commencing on 29-03-2021 & ending on 28-03-2026.	**16-09-2021**	**Good**	4) Dir. Abdullah Dayo, Expert Member. 5) Federal Inspector of Drugs, DRAP, Karachi. 6) Ms. Krishan Das, AD DRAP, Karachi. 1)

Recommendations of the panel:

"M/S. Saakh Pharma (Pvt.) Ltd. Situated at Plot No. C-7/1, North Western Industrial Zone Port Qasim Bin Qasim Town, Karachi inspected is by the panel on 16th Sep 2021 in compliance to the directions contained in DRAP, Islamabad Letter No. F.2-5/2001-Lic. (Vol-IV) dated 2nd April, 9th and 17th August 2021in connection with renewal of Drug Manufacturing License No. 000588 (By of Semi Basic). Following are the observation:

1. The panel inspected the firm in detail including al 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 required for the production and test/analysis of the products being manufactured. Necessary documents relating to QC, QA and HVAC and other utilities were also seen in place.

2. Based on the people met, documents reviewed and observations made during the inspections, the panel recommends the grant of renewal of Drug manufacturing License No. 000588 (By way of Semi Basic), grant of additional API and regularization/amendments of Master Layout plan as per DRAP, Islamabad Letter No.F.2-5/2001-Lic (Vol-IV) dated 2" April, 9"" August and 17" August 2021; for following sections:

S.No.	*Name of Section*
1.	*Penicillin*
2.	*Cephalosporins*
3.	*General*
4.	*TasteMasking& Pelletization*

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000588 by way of formulation in the name of M/s Saakh Pharma (Pvt) Ltd, Plot No. C-7/1, North Western Industrial Zone, Port Qasim Authority Karachi the recommendations of the panel of experts for the period commencing on 29-03-2021 & ending on 28-03-2026 for the following section:

Section (04)

	1. *Penicillin* *2. Cephalosporin* *3. General* 4. *Taste Masking & Pelletization*			
12	M/s Karachi Chemical Industries (Pvt) Ltd, Plot No. F/25, Estate Avenue, S.I.T.E Karachi. DML No. 000048 (Formulation) Period: Commencing on 01-06-2021 & ending on 31-05-2026.	**12-10-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendations of the panel:

*"*In compliance to the instructions contained in DRAP Islamabad letter No.F.2-25/84-Lic (Vol-I) dated 06 September, 2021, a detailed panel inspection of Ms. Karachi Chemical Industries (Private) Limited, F/25, Estate Avenue, SITE, Karachi was carried out on 12/10/2021 under the given TORs. Mr. Saboor Ahmed MD of the firm, Hafiz Ghulam Haider Production Manager and other technical persons from respective departments assisted during the course of inspection. Followings are detailed observations and recommendations of the visit:

1. The firm was found built as per approved design, wherein an appropriate flow of men and materials is given. The premises was found suitably designed to minimize the chances of contamination and cross contamination into the products. Dedicated sections of penicillin, cephalosporin and cream ointment are kept well segregated with separate entries, separate machines and separate HVAC system. A separate dispensing booth has also been provided for steroidal cream/ointment section as required under policy.

2. An appropriate level of sanitation and worker hygiene was noted amid dynamic working conditions, along with respective log books and necessary working SOPs found in place and practiced accordingly. Workers and other technical staff were adequately trained with required qualification and experience.

3. QC lab was satisfactorily equipped and necessary SOPs and other documents were also in place. QA was noted engaged in IP testing, line clearance, validation, calibration, training and other necessary activities for better safety of products well in line to approved SOPs.

4. Well defined and spacious stores are also given and found appropriate level of practices in stores. All utilities are also suitably provided and monitored as per SOPs in place. HVAC was seen in place in all sections and found well operated and monitored. Documents in this regard like air balancing, monitoring devices and relevant documents were well in place.

Based on the above stated observation the panel unanimously recommends the grant of renewal of DML No. 000048 by way of formulation and regularization of existing approved lay out plan for the following sections for the next five years:

Sr #	*Name of Section*	*Sr. #*	*Name of Section*
1.	Warehouse (General)	*2.*	Quality Control Laboratory
3.	Tablet (General)	*4.*	Capsule (General)
5.	Liquid External Preparation	*6.*	Ointment (General)
7.	Liquid (General)	*8.*	Sachet Section (General)
9.	Dry Powder Suspension (Penicillin)	*10.*	Capsule (Penicillin)
11.	Warehouse (Penicillin)	*12.*	Dry Powder Suspension (Cephalosporin)
13.	Capsule (Cephalosporin)	*14.*	Warehouse (Cephalosporin)
15.	Repacking Section	*16.*	**********

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000048 by way of formulation in the name of M/s Karachi Chemical Industries (Pvt) Ltd, Plot No. F/25, Estate Avenue, S.I.T.E Karachi the recommendations of the panel of experts for the period commencing on 01-06-2021 & ending on 31-05-2026 for the following section:

Section (16)

Sr #	*Name of Section*	*Sr. #*	*Name of Section*
1.	Warehouse (General)	*2.*	Quality Control Laboratory
3.	Tablet (General)	*4.*	Capsule (General)
5.	Liquid External Preparation	*6.*	Ointment (General)
7.	Liquid (General)	*8.*	Sachet Section (General)
9.	Dry Powder Suspension (Penicillin)	*10.*	Capsule (Penicillin)
11.	Warehouse (Penicillin)	*12.*	Dry Powder Suspension (Cephalosporin)
13.	Capsule (Cephalosporin)	*14.*	Warehouse (Cephalosporin)
15.	Repacking Section	*16.*	**********

13	M/s Kohs Pharmaceuticals (Pvt) Ltd, Plot No. P/8, SITE, Hyderabad. DML No. 000132 (Formulation) Period : Commencing on 07-10-2020 & Ending on 06-10-2025	**28-09-2021**	**Good**	2. Dr. AbullahDayo, Expert Member. 3. FID, DRAP, Karachi. 4. Mr. Krishan Das, AD, DRAP, Karachi.

Recommendation of panel :

Based on the people met, area visited and commitment of the management for continuous improvement and advises of the panel members, the panel is of the view to recommend as follows:

i. Renewal of Drug Manufacturing License No. 000132 (By way of Formulation) to the firm M/s Kohs Pharmaceuticals (Pvt) Ltd, situated at plot No. P/8, S.I.T.E, Hyderabad for following sections namely:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Liquid (General)*	*2.*	*Tablet (General)*
3.	Capsule (General)	*4.*	**********

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000132 by way of formulation in the name of M/s Kohs Pharmaceuticals (Pvt) Ltd, Plot No. P/8, SITE, Hyderabad the recommendations of the panel of experts for the period commencing on 07-10-2020 & Ending on 06-10-2025for the following section:

Section (03)

1. *Liquid (General)*
2. *Tablet (General)*
3. Capsule (General)

14	M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Plot No.134-B&135-B, Nowshera Industrial Estate, Risalpur DML No.000691 (Formulation) Tenure: Commencing on 03-08-2020 & ending on 02-08-2025	**22-09-2021** **Formulation**	**Good**	1. Prof. Dr. Jamshed Ali Khan, Expert member 2. Federal Inspector of Drugs, DRAP, Peshawar. 3. Syed Adnan Ali Shah, AD, DRAP, Peshawar.

Recommendations of the panel:

Based on documentation reviewed, technical/management people met, materials/processes flow and detailed physical inspection of the stores, section wise manufacturing facilities, quality control lab, microbiology lab and allied facilities, the panel is of the view that the firm is operating at satisfactory level of GMP compliance and unanimously ***recommendsgrant of renewal of Drug Manufacturing License*** *to the firm from 03.08.2020 for following mentioned four sections along with grant of additional following new four sections;*

Ser	Name of Section (Existing)
1.	Tablet (General)
2.	Tablet Section (Quinolone)
3.	Capsule (General)
4.	Oral Liquid Syrup (General)

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000691 by way of formulation in the name of M/s Rock Pharmaceutical Laboratories (Pvt) Ltd, Plot No.134-B&135-B, Nowshera Industrial Estate, Risalpur the recommendations of the panel of experts for the period commencing on 03-08-2020 & ending on 02-08-2025 for the following section:

Section (03)

1. *Tablet (General)*
2. *Tablet Section (Quinolone)*
3. *Capsule (General)*
4. *Oral Liquid Syrup (General)*

15	M/s Arsons Pharmaceutical Industries (Pvt) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defense Road, Lahore. DML No.000514 (Formulation). Period: Commencing on 23-06-2018 & ending on 22-06-2023.	**29-09-2021**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mrs. Majida Mujahid, FID, DRAP, Lahore. 3. Ms. Ufaq Tanveer Butt, AD, DRAP, Lahore.

Recommendations of the panel:

"Keeping in view the facilities like Building, HVAC System, Equipment, Instruments, Machinery, Personnel. Documentation, Quality Control and testing Facilities, the Panel of inspectors is of the opinion to **recommend** the Renewal of Drug Manufacturing License No. 000514 by way of formulation to M/s. Arsons Pharmaceuticals (Pvt.) Ltd., 205-k.m. Defence Road, Off 22-k.m. Multan Road, Lahore only for the following sections:

1. Tablet Section (General) (1st floor)
2. Tablet Section (Psychotropic) (1st floor)
3. Capsule Section (General) (1st floor)
4. Cream/Ointment/Gel Section (Ground floor)"

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000514 by way of formulation in the name of M/s Arsons Pharmaceutical Industries (Pvt) Ltd, 22-Km, Multan Road, Off 2.5-Km, Defense Road, Lahore the recommendations of the panel of experts for the

	period commencing on 23-06-2018 & ending on 22-06-2023 for the following section subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020 in respect of *Tablet (Psychotropic)*:- **Section (04)** 1. Tablet Section (General) (1st floor) 2. Tablet Section (Psychotropic) (1st floor) 3. Capsule Section (General) (1st floor) 4. Cream/Ointment/Gel Section (Ground floor)			
16	M/s Medera Pharmaceuticals, Plot No. 2, St No. N-4, National Industrial Zone, Rawat. DML No. 000714 (Formulation). Period: Commencing on 15-06-2021 & ending on 14-06-2026.	21-10-2021 & 26-10-2021	Good	1. Additional Director (QA & LT), DRAP, Islamabad. 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Hasan Afzaal, AD, DRAP, Islamabad.
	Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommends** the approval for the Grant of three new Sections namely Lotion Section (Ground floor), Capsule (Cephalosporin) Dry powder for suspension (Cephalosporin) (Basement) along with Renewal of Drug Manufacturing License No. 000714 by way of formulation for the following sections of M/s Medera Pharmaceuticals (PVT) Limited, Plot No. 2, St # N-4, National Industrial Zone, Rawat. i. Tablet (General) (Renewal) ii. Cream/Ointment Section (Genera) (Renewal) iii. Cream/Ointment Section Steroidal (Renewal) iv. Dry Powder for Oral Suspension (General) (Renewal) v. Capsule Section (General)(Renewal) vi. Capsule Section (Cephalosporin) (New) (Basement) vii. Dry Powder for Suspension (Cephalosporin) (New) (Basement) viii. Lotion Section General (New) Ground Floor. ix. Q.C Lab & Microbiology Lab. x. Stores / Warehouses" **Decision of the Central Licensing Board in 283rd meeting** The Board considered and approved the grant of renewal of DML No. 000714 by way of formulation in the name of M/s Medera Pharmaceuticals, Plot No. 2, St No. N-4, National Industrial Zone, Rawat the recommendations of the panel of experts for the period commencing on 15-06-2021 & ending on 14-06-2026for the following section: **Section (10)** 1. Tablet (General) (Renewal) 2. Cream/Ointment Section (Genera) (Renewal)			

	3. Cream/Ointment Section Steroidal (Renewal) 4. Dry Powder for Oral Suspension (General) (Renewal) 5. Capsule Section (General)(Renewal)			
17	M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. L-1B, Block 22, Federal B Industrial Area, Karachi. DML No. 000513 (Formulation) Period : Commencing on 22-06-2018 & Ending on 21-06-2023	**21-10-2021**	**Good**	4. Dr. Abullah Dayo, Expert Member. 5. FID, DRAP, Karachi. 6. Mr. Krishan Das, AD, DRAP, Karachi.

Recommendation of panel :

Based on the above stated observations the panel unanimously recommends thegrant of renewal of DML No. 000513 by way of formulation for the next five years for following sections:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet (General)*	*2.*	*Capsule (General)*
3.	Eye Ointment (Sterile)	*4.*	*Liquid Syrup (General)*
5.	Dry Powder Suspension (General)	*6.*	*Liquid Injection (Biotech)*
7.	Cream Ointment (General)	*8.*	*Sterile Liquid Injection (Biotech)*
9.	Sterile Dry Powder Injection (General)	*10.*	*Sterile Ampoule LDPE (BFS)*

The panel was given mandated for inspection of the firm for renewal of DML No. 000513 (Formulation) and regularization in the light of approved layout plan , however, panel has only recommended the grant of renewal of DML and the recommendation of the panel regarding regularization of facility are not mentioned.

Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the grant of renewal of DML No. 000513 by way of formulation in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. L-1B, Block 22, Federal B Industrial Area, Karachi the recommendations of the panel of experts for the period commencing on 22-06-2018 & Ending on 21-06-2023for the following section:

Section (10)

1. Tablet (General)
2. Capsule (General)
3. Eye Ointment (Sterile)
4. Liquid Syrup (General)
5. Dry Powder Suspension (General)

	6. Liquid Injection (Biotech) 7. Cream Ointment (General) 8. Sterile Liquid Injection (Biotech) 9. Sterile Dry Powder Injection (General) 10. Sterile Ampoule LDPE (BFS)			
18	M/s Sanofi Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi. DML No. 000368 (Basic Manufacture) Period : Commencing on 30-10-2020 & Ending on 29-10-2025. Facility : Haemaccel Infusion	**15-09-2021**	**Good**	1. Dr. Abullah Dayo, Expert Member. 2. FID, DRAP, Karachi. 3. Mr. Affan Ali, AD, CDL, Karachi.
	Recommendation of panel : Based on the people met, documents reviewed and observation made during the inspection, panel recommends the renewal of DML and regularization of the Haemaccel manufacturing facility. **<u>Decision of the Central Licensing Board in 283rd meeting</u>** The Board considered and approved the grant of renewal of DML No. 000368 by way of Basic Manufacture in the name of M/s Sanofi Aventis Pakistan Limited, Plot No. 23, Sector 22, Korangi Industrial Area, Karachi the recommendations of the panel of experts for the period commencing on 30-10-2020 & Ending on 29-10-2025for the following section: **<u>Section (01)</u>** 1. Haemaccel Infusion			

ITEM-V MISCELLANEOUS CASES

Case No. 1 **CHANGE OF MANAGEMENT OF M/S PULSE PHARMACEUTICALS (PVT) LTD, MOZAY BADOKE, RAIWIND ROAD (SUA AASIL ROAD), LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000564 BY WAY OF (FORMULATION).**

M/s Pulse Pharmaceuticals (Pvt) Ltd, MozayBadoke, Raiwind Road (SuaAasil Road), Lahore DML No.000564 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed fee. The detail of management of the firm is as under;

Previous Management as per Form-29.	New Management as per Form-29.
1.Mr. Muhammad Hussain Mehdi S/o Hussain Mehdi, CNIC No. 44107-2040792-9. 2.Mariam Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-4563314-2. 3.Mrs. Ambreen Javid W/o Javid Iqbal, CNIC No. 35202-3660452-8. 4.Fatima Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-1985141-8. 5.Mr. Javid Iqbal S/o Muhammad Iqbal, CNIC No. 35202-9644935-9.	1.Mr. Muhammad Hussain Mehdi S/o Hussain Mehdi, CNIC No. 44107-2040792-9. 2.Mariam Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-4563314-2. 3.Fatima Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-1985141-8.

Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of management of M/s Pulse Pharmaceuticals (Pvt) Ltd, Mozay Badoke, Raiwind Road (Sua Aasil Road), Lahore DML No. 000564 by way of Formulationas undersubject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

Previous Management as per Form-29.	New Management as per Form-29.
1. Mr. Muhammad Hussain Mehdi S/o Hussain Mehdi, CNIC No. 44107-2040792-9. 2. Mariam Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-4563314-2. 3. Mrs. Ambreen Javid W/o Javid Iqbal, CNIC No. 35202-3660452-8. 4. Fatima Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-1985141-8. 5. Mr. Javid Iqbal S/o Muhammad Iqbal, CNIC No. 35202-9644935-9.	1. Mr. Muhammad Hussain Mehdi S/o Hussain Mehdi, CNIC No. 44107-2040792-9. 2. Mariam Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-4563314-2. 3. Fatima Hussain Mehdi D/o Hussain Mehdi, CNIC No. 44107-1985141-8.

CASE NO. 2 CHANGE OF MANAGEMENT OF M/S AULTON PHARMACEUTICALS, PLOT NO.84/1, BLOCK A, PHASE V, INDUSTRIAL ESTATE, HATTAR.

M/s Aulton Pharmaceuticals, Plot No.84/1, Block A, Phase V, Industrial Estate, Hattar under DML No. 000828 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Partnership Deed	New management as per Partnership Deed
1. Muhammad ArifJaved S/o Muhammad Ismail CNIC No.915062-145277-9. 2. Mrs. ShaziaJaved W/o Muhammad ArifJaved CNIC No.61101-2634862-4.	1. Muhammad ArifJaved S/o Muhammad Ismail CNIC No.915062-145277-9. 2. Mrs. ShaziaJaved W/o Muhammad ArifJaved CNIC No.61101-2634862-4. 3. Aamir Karim S/o Fazal Karim, CNIC No.61101-6722947-5. 4. Muhammad Ali Khan S/o Ajab Khan CNIC No.13302-0515218-5.

Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of management of M/s Aulton Pharmaceuticals, Plot No.84/1, Block A, Phase V, Industrial Estate, Hattar under DML No. 000828 by way of Formulationas under;

Previous management as per Partnership Deed	New management as per Partnership Deed
1. Muhammad Arif Javed S/o Muhammad Ismail CNIC No.915062-145277-9. 2. Mrs. Shazia Javed W/o Muhammad Arif Javed CNIC No.61101-2634862-4.	1. Muhammad Arif Javed S/o Muhammad Ismail CNIC No.915062-145277-9. 2. Mrs. Shazia Javed W/o Muhammad Arif Javed CNIC No.61101-2634862-4. 3. Aamir Karim S/o Fazal Karim, CNIC No.61101-6722947-5. 4. Muhammad Ali Khan S/o Ajab Khan CNIC No.13302-0515218-5.

CASE NO. 3CHANGE OF MANAGEMENT OF M/S SIAM PHARMACEUTICAL, PLOT NO. 217, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD.

M/s Siam Pharmaceutical, Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000374 by way of formulation has submitted request for change in management of the firm as per Form-29 with prescribed Fee Challan of Rs.50,000/-. The detail of management of the firm is as under;

Previous management as per Partnership Deed	New management as per Partnership Deed
1.Mr. Faisal Muzamil S/o Muzammil Hussain CNIC # 37405-4805522-3 2.Mr. Rashid Muzamil S/o Muzammil Hussain CNIC # 61101-5136210-3 3.Mr. Asim Muzamil S/o Muzammil Hussain CNIC # 37405-6158148-7 4.Mr. Qasim Farooq S/o Ansar Farooq CNIC # 37405-5587025-9 5.Mr. Mehrban Ali S/o Sheikh Sultan CNIC # 61101-4842050-7	1. Mr. Abdul Hafeez S/o Khursheed Ahmad CNIC # 36302-5010906-1 2. Mr. Kamran Rasheed S/o Abdul Rasheed CNIC # 35201-3140240-7 3. Mr. Muhammad Asif S/o Muhammad Faiz CNIC # 35202-69833391-3 4. Mr. Sadiq Hussain S/o Muhammad Khan Khan CNIC # 17301-1298527-9 5. Mr. Qasim Farooq S/o Ansar Farooq CNIC # 37405-5587025-9 6. Mr. Shahid Mehmood S/o Irshad Ahmad CNIC # 33100-8311735-9

Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of management of M/s Siam Pharmaceutical, Plot No. 217, Industrial Triangle, Kahuta Road, Islamabad, under DML No. 000374 by way of Formulationas under:

Previous management as per Partnership Deed	New management as per Partnership Deed
1. Mr. Faisal Muzamil S/o Muzammil Hussain CNIC # 37405-4805522-3 2.Mr. Rashid Muzamil S/o Muzammil Hussain CNIC # 61101-5136210-3 3.Mr. Asim Muzamil S/o Muzammil Hussain CNIC # 37405-6158148-7 4.Mr. Qasim Farooq S/o Ansar Farooq CNIC # 37405-5587025-9 5.Mr. Mehrban Ali S/o Sheikh Sultan CNIC # 61101-4842050-7	1. Mr. Abdul Hafeez S/o Khursheed Ahmad CNIC # 36302-5010906-1 2. Mr. Kamran Rasheed S/o Abdul Rasheed CNIC # 35201-3140240-7 3. Mr. Muhammad Asif S/o Muhammad Faiz CNIC # 35202-69833391-3 4. Mr. Sadiq Hussain S/o Muhammad Khan Khan CNIC # 17301-1298527-9 5. Mr. Qasim Farooq S/o Ansar Farooq CNIC # 37405-5587025-9 6. Mr. Shahid Mehmood S/o Irshad Ahmad CNIC # 33100-8311735-9

CASE NO. 4 CHANGE OF MANAGEMENT OF M/S E-PHARM LABORATORIES KARACHI

M/s E-Pharm Laboratories, A-40, Road No. 1, S.I.T.E Super Highway, Industrial Area North Karachi, DML No. 000598 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee as under: -

Existing Management as per Per Partnership Deed	New Management as Per Revised Partnership Deed
1. Mr. Muhammad Ilyas S/o Muhammad Ismail CNIC No. 42201-7031549-1. 2. Mr. Atif Ilyas S/o Muhammad Ilyas CNIC No. 42201-3302151 3. Mr. Asad Ilyas S/o Muhammad llyas CNIC No. 42201-2189824-7	1. Mr. Atif Ilyas S/o Muhammad Ilyas CNIC No. 42201-3302151 2. Mr. Asad Ilyas S/o Muhammad Ilyas CNIC No. 42201-2189824-7

Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of management of M/s E-Pharm Laboratories, A-40, Road No. 1, S.I.T.E Super Highway, Industrial Area North Karachi, DML No. 000598 by way of Formulationas under;

Existing Management as per Per Partnership Deed	New Management as Per Revised Partnership Deed
1. Mr. Muhammad Ilyas S/o Muhammad Ismail CNIC No. 42201-7031549-1. 2. Mr. Atif Ilyas S/o Muhammad Ilyas CNIC No. 42201-3302151 3. Mr. Asad Ilyas S/o Muhammad llyas CNIC No. 42201-2189824-7	1. Mr. Atif Ilyas S/o Muhammad Ilyas CNIC No. 42201-3302151 2. Mr. Asad Ilyas S/o Muhammad Ilyas CNIC No. 42201-2189824-7

CASE NO. 5 CHANGE OF TITLE & MANAGEMENT OF M/S OBS PAKSITAN (PVT) LTD, KARACHI.

M/s OBS Pakistan (Pvt) Ltd, Plot No.C-14, Manghopir Road, S.I.T.E Karachi under .DML No. 000012 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee as under:-

Current Title of the firm.	Current Title of the firm.
M/s OBS Pakistan (Pvt) Ltd, Plot No.C-14,Manghopir Road, S.I.T.E Karachi.	M/s Searle Pakistan Limited, Plot No.C-14,Manghopir Road, S.I.T.E Karachi.

Sr. No	Existing Management	New Management as per Form- A (SECP)
1.	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1
2.	Miss. Faiza Naeem W/o Mr. Naeem IdressAllahwala CNIC No. 42201-0540338-0	Mr. Zubair RazzakPalwala S/o AbdulRazzak Palwala CNIC No. 42201-50807803.
3.	Mr. Mudassir Habbib Khan S/o Mr. Musharaf Zaman Khan CNIC No. 42000-0528026-1	Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.
4.	Mr. Hammad Bin Kafeel S/o Mr. Kafeel Ahmed CNIC No. 42101-1938271-9	Mr. MobinAlam S/o Muhammad Aziz Alam CNIC No. 42301-4675803-3
5.	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim-ud-Din CNIC No. 42101-7618398-1	Ms. FareenNaz Qureshi D/o Muhammad Hassan Azwar CNIC No. 42301-0763444-4.
6.	Mr. Tariq Moin-ud-din S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Tahir Ahmed S/o Mr. Maqbool Ahmed CNIC No. 42201-0169711-5
7.	**********	Mr. Muhammad Zubar Haider Shaikh S/o Haider Buksh Shaikh CNIC No. 42301-9578130-3

Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of Title & management of M/s OBS Pakistan (Pvt) Ltd, Plot No.C-14, Manghopir Road, S.I.T. E Karachi under DML No. 000012 by way of Formulationas under;

Current Title of the firm.	Current Title of the firm.
M/s OBS Pakistan (Pvt) Ltd, Plot No.C-14, Manghopir Road, S.I.T.E Karachi.	M/s Searle Pakistan Limited, Plot No.C-14, Manghopir Road, S.I.T.E Karachi.

Sr. No	Existing Management	New Management as per Form- A (SECP)
1.	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1	Mr. Munis Abdullah S/o Mr. Rashid Abdullah CNIC No. 42201-9982517-1
2.	Miss. Faiza Naeem W/o Mr. Naeem IdressAllahwala CNIC No. 42201-0540338-0	Mr. Zubair RazzakPalwala S/o AbdulRazzak Palwala CNIC No. 42201-50807803.
3.	Mr. Mudassir Habbib Khan S/o Mr. Musharaf Zaman Khan CNIC No. 42000-0528026-1	Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9.
4.	Mr. Hammad Bin Kafeel S/o Mr. Kafeel Ahmed CNIC No. 42101-1938271-9	Mr. MobinAlam S/o Muhammad Aziz Alam CNIC No. 42301-4675803-3
5.	Mr. Mirza Anjum Fahim S/o Mr. Mirza Fahim-ud-Din CNIC No. 42101-7618398-1	Ms. FareenNaz Qureshi D/o Muhammad Hassan Azwar CNIC No. 42301-0763444-4.
6.	Mr. Tariq Moin-ud-din S/o Mr. K A Moin-ud-din CNIC No. 42301-0725070-1	Mr. Tahir Ahmed S/o Mr. Maqbool Ahmed CNIC No. 42201-0169711-5
7.	**********	Mr. Muhammad Zubar Haider Shaikh S/o Haider Buksh Shaikh CNIC No. 42301-9578130-3

CASE NO.6 <u>CHANGE OF MANAGEMENT OF M/S CITY PHARMACEUTICAL LABORATORIES, KARACHI</u>

M/s City Pharmaceutical Laboratories, 12-A, I-5, Sector 5, New Survey No. 276, Korangi Industrial Area Karachi, DML No. 000723 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee as under: -

Existing Management	New Management/Director as per Partnership deed
1. Mr. Muhammad Taufeeq S/o Qasim Ahmed 2. Mr. Gul Muhammad Kodvani S/o Qasim Ahmed 3. Mr. Muhammad Farooq Kodvani. S/o Qasim Ahmed	1. Mr. Muhammad Taufeeq S/o Qasim Ahmed CNIC No. 42301-0853346-3.. 2. Mr. Gul Muhammad Kodvani S/o Qasim CNIC No. 42301-0629879-1. 3. Mr. Muhammad Farooq Kodvani S/o

4. Mr. Muhammad Sohail S/o Qasim Ahmed	QasimKodvani CNIC No. 42301-3224533-1.

Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of management of M/s City Pharmaceutical Laboratories, 12-A, I-5, Sector 5, New Survey No. 276, Korangi Industrial Area Karachi, DML No. 000723 by way of Formulationas under;

Existing Management	**New Management/Director as per Partnership deed**
1. Mr. Muhammad Taufeeq S/o Qasim Ahmed 2. Mr. Gul Muhammad Kodvani S/o Qasim Ahmed 3. Mr. Muhammad Farooq Kodvani. S/o Qasim Ahmed 4. Mr. Muhammad Sohail S/o Qasim Ahmed	1. Mr. Muhammad Taufeeq S/o Qasim Ahmed CNIC No. 42301-0853346-3.. 2. Mr. Gul Muhammad Kodvani S/o Qasim CNIC No. 42301-0629879-1. 3. Mr. Muhammad Farooq Kodvani S/o Qasim Kodvani CNIC No. 42301-3224533-1.

CASE NO. 7 CHANGE OF MANAGEMENT OF M/S THE SEARLE COMPANY LIMITED LAHORE

M/s The Searle Company Limited, 32-km, Multan Road, Lahore under DML No. 000647by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under:-

EXISTING MANAGEMENT	**NEW MANAGEMENT as per Form 29**
1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. Rashid Abdullah S/o Abdullah A. Razzaq CNIC No. 42201-1132967-1. 3. Mr. Hussain Lawai S/o Haji Moosa CNIC No. 914000-140464-5. 4. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 5. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803.	1. Mr. Munis Abdullah S/o Rashid Abdullah CNIC No. 42201-9982517-1 2. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 3. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7. 4. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 5. Mrs. Shaista Khaliq Rehman W/o Syed Saqdiq Abdur Rehman CNIC No. 43201-8797867-2. 6. Mr. Mufti Zia Ul Islam S/o Taus Khan CNIC

6. Mr. Ayaz Abdullah S/o Shahid Abdullah CNIC No. 42201-8726172-1. 7. Mr. Asad Abdullah S/o Shahid Abdullah CNIC No. 42201-8964822-9.	No. 42000-0467228-3. 7. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-5080780-3.

Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of management of M/s The Searle Company Limited, 32-km, Multan Road, Lahore under DML No. 000647 by way of Formulationas under subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020;

EXISTING MANAGEMENT	NEW MANAGEMENT as per Form 29
1. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 2. Mr. Rashid Abdullah S/o Abdullah A. Razzaq CNIC No. 42201-1132967-1. 3. Mr. Hussain Lawai S/o Haji Moosa CNIC No. 914000-140464-5. 4. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 5. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-50807803. 6. Mr. Ayaz Abdullah S/o Shahid Abdullah CNIC No. 42201-8726172-1. 7. Mr. Asad Abdullah S/o Shahid Abdullah CNIC No. 42201-8964822-9.	1. Mr. Munis Abdullah S/o Rashid Abdullah CNIC No. 42201-9982517-1 2. Mr. Adnan Asdar Ali S/o Asdar Ali CNIC No. 42301-1091664-3. 3. Dr. Atta ur Rehman S/o Jamil ur Rehman CNIC No. 42000-3123678-7. 4. Mr. S. Nadeem Ahmed S/o S. Mumtaz Ahmed CNIC No. 42301-0859989-9. 5. Mrs. Shaista Khaliq Rehman W/o Syed Saqdiq Abdur Rehman CNIC No. 43201-8797867-2. 6. Mr. Mufti Zia Ul Islam S/o Taus Khan CNIC No. 42000-0467228-3. 7. Mr. Zubair Razzak Palwala S/o Abdul Razzak Palwala CNIC No. 42201-5080780-3.

CASE NO. 8. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S IPP,SWAT

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research*

Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s IPP (Pvt) Ltd., Swat DML No.000244 (Formulation) on dated 13-05-2019 as the firm has never submitted CRF.

In response to Show Cause Notice the firm has responded vide letter No. IPP2/07/19 dated 02/07/2019 which is reproduced as under;

"In Continuation to your Letter No. F3-10/2011-Lic 27/06/2019 dated 13 May 2019. Dispatched on 26 june 2019 Received on 27/6/2019.

Regarding this connection We have already provided Audit report to office of the statistical officer DRAP.

Also a photo copy of the Audit reports/ financial statement for the year June 30/2016 June 30/17 and June 30/2018 is also enclosed here with for your office proceeding and recordpurpose

Thanking you and assuring you the best of our cooperation at all time."

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Waseem Jawad Partner of the firm appeared before the Board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

Accordingly, a personal hearing letter was issued to the firm on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Waseem Javed, Managing Director appeared before the Board. He argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and

considering case background decided to suspend the Drug Manufacturing License 000244(by way of formulation) ofM/s IPP (Pvt) Ltd., Swat 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 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Meanwhile, the firm M/s IPP, Swatsubmitted NOC (CRF) valid till 31-12-2021 issued by Budget & Account Division, DRAP

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000244 (Formulation)ofM/s IPP (Pvt) Ltd., Swat.

CASE NO. 9 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S IPP,ISLAMABAD.

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s IPP, Islamabad DML No. 000370 (Formulation) on dated 14-05-2019 as the firm but firm has not submitted CRF till 2019

In response to Show Cause Notice, the firm has responded vide letter No. IPP/05/19 dated 02/05/2019 which is reproduced as under;

> *"With references to your letter # 1-16/94-Lic (vol-l) dated 14th May 2019 received on 21st May, 2019. this is you that have NOC regarding above mention that our account is up to 30-6-216. Photo copy of NOC issued by you is attached for ready reference.*
> *It is therefore requested to please amend your record. we are also attaching the receipt CRF regarding 2017 2018.*
>
> *Thanking you and assuring you best of our co-operation at all the time."*

Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Ms. Rukhsana Partner /Director of the firm appeared before the board and contended that problem of license ownership is resolved and would submit report within one month. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Accordingly, a personal hearing letter was issued to the firm on 25-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Ms. RukhsanaJaved CEO appeared before the Board. She argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000370(by way of formulation) of M/s IPP, 34, Industrial Triangle, Kahuta Road, Islamabad 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 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Meanwhile, the firm, M/s IPP (Pvt) Ltd, Islamabadsubmitted NOC (CRF) valid till 31-12-2021 issued by Budget & Account Division, DRAP.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000370 (Formulation)ofM/s IPP, 34, Industrial Triangle, Kahuta Road, Islamabad.

CASE NO. 10. NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S DELTA PHARMA (PVT) LTD., RISALPUR

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above-mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Delta Pharma (Pvt) Ltd., Risalpur DML No. 000446 (formulation) dated 25-09-2020 but as per available record in licensing Division, the firm has not submitted CRF till date. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Ashfaq Paracha CEO of the firm and Mr. Musa Ashfaq appeared before the board and contended that firm will submit NDC of CRF. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

Accordingly, a personal hearing letter was issued to the firm on 24-08-2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Musa Ashfaq, Director appeared before the Board. He argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000446(by way of formulation) of M/s Delta Pharma (Pvt) Ltd., Plot No. 09, Nowshera Industrial Estate (SIZ), Risalpur 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 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

The firm, M/s Delta Pharma (Pvt) Ltd., Plot No. 09, Nowshera Industrial Estate (SIZ), Risalpur submitted NOC (CRF) valid till 31-12-2021 issued by Budget & Account Division, DRAP.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the implementation of decision regarding suspension of the Drug Manufacturing License No.000446 (Formulation)ofM/s Delta Pharma (Pvt) Ltd., Plot No. 09, Nowshera Industrial Estate (SIZ), Risalpur.

CASE NO. 11 CORRECTION IN NAME OF LICENSED SECTION OF M/S VISION PHARMACEUTICALS (PVT) LTD, PLOT NO. 22-23, INDUSTRIAL TRIANGLE, KAHUTA ROAD.

M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad has requested for correction in the covering letter for renewal of DML.

It is submitted for information that renewal of M/s Vision Pharmaceuticals (Pvt) Ltd, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad {(DML No. 000517 (Formulation)} w.e.f. 01-04-2019 was presented and approved in 278th meeting of CLB held on 10th-11th Dec, 2020 for following sections, accordingly;

1. Tablet (General)
2. Capsule General
3. Sachet (General)
4. Oral Dry powder Suspension (General)
5. Sterile Dry Powder Injectable Vial (General)
6. Liquid Infusion (SVP) (Blow Fill Seal Technology)
7. Liquid Ampoule (General)
8. Liquid Injectable Vial SVP (General)
9. Dry Power injection (Steroid).

It is submitted that in the inspection report for renewal of DML submitted by Area FID, DRAP Islamabad, both LVP and SVP Parenteral were mentioned. However, but name of the Section *"Large Volume Parenteral (General)"* was inadvertency not mentioned in the agenda of 278th meeting of CLB and same was reflected in the decision (minutes) of the said meeting.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and approved the renewal of Drug Manufacturing License for Liquid Injectable (LVP) (General) Section.

Case No. 12 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S WAHABSONS PHARMA (PVT) LTD., 4-KM, BUNNER ROAD, BARIKOT, SWAT.

M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat had applied for renewal of DML No. 000533 by way of formulation for the period of 27-01-2019 to 26-01-2024 on 30-10-2018.

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 17th December, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form-1A alongwith enclosure/Flags/Annexure.
2. Class (es) of Drugs.
3. Dosage(s) forms of drugs.
4. Name(s) of registered drug(s).
5. Detail of management at the time of previous renewal and present renewal.
6. Updated Form-29 from S.E.C.P. attested alongwith CNIC's of all Directors.
7. Approved layout plan.
8. Proof of licensed sections from Central Licensing Board.
9. Detail of section wise equipment and machinery for manufacture and QC Lab.
10. Approval letter of QC Incharge in case of change then submit required documents as per checklist (attached) alongwith prescribed fee.

The firm submitted their reply on 09th January, 2019. After evaluation of the submitted documents, a final reminder was issued on 29th May, 2019 to the firm with following shortcomings: -

1. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
2. Names/detail of Directors of firm on firm's letter head alongwith attested CNIC copies of all directors (at this renewal and at previous renewal).
3. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
4. Proposed QC Incharge Ms. Seema Mughal does not fulfill the requirements of Rule-16 of Drugs (Licensing, Registering & Advertising) Rules, 1976 in terms of required experience, therefore, submit documents of new proposed QC Incharge.
5. Detail of all licensed sections on firms letter head alongwith approval letter(s) of all sections issued from CLB.

The firm submitted their reply to Final Reminder on 15th July, 2019 and following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Form-1A dully signed and attested by the management of firm alongwith all enclosures.
2. Form-29 and Form-A for year 2019 (certified true copy) issued by S.E.C.P. alongwith prescribed fee for change of management (if management is changed).
3. Approval letter(s) of all sections issued from CLB.

Proceedings and Decision by the Central Licensing Board in 276th 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), and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat Drug

Manufacturing Licence No 000533 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Accordingly, a Show-Causenotice was served to the firm dated 25-09-2020. But no reply has been received from the firm till to date. Now a personnel hearing letter issued to the firm on 08-10-2020.

Proceedings and Decision by the Central Licensing Board in 277th meeting:

No person appeared on behalf of the firm. The Board deliberated the case and decided to afford final opportunity for personal hearing to the firm in the next meeting of the Central Licensing Board before taking decision.

Accordingly, a personal hearing letter was issued to the firm on 19th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Zeeshan Ahmed Admin Officer of the firm appeared before the board and contended that the documents are already submitted to the division of Drug Licensing. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000533 (by way of formulation) of M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat till fulfillment of codal formalities/submission of required documents 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 ofRule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the board for ratification.

The firm submitted shortcoming documents which were are evaluated and the application for renewal of DML was found complete as per Form-1A. In compliance to the decision of the CLBorders regarding resumption of production/ ceasing of suspension orders were issued accordingly.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considered and ratified the decision of the Secretary, Central Licensing Board regarding resumption of production and ceasing of suspension orders in the name of M/s Wahabsons Pharma (Pvt) Ltd., 4-Km, Bunner Road, Barikot, Swat.

CASE NO. 13. GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000734 OF M/S SATURN PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Saturn Pharmaceuticals (Pvt) Ltd, Lahore under Drug Manufacturing License No. 000734 submitted application for renewal of DML for the period **15/06/2021 to 14/06/2026** after the validity of DML i.e. on 19th September, 2021. Therefore, DML No. 000734 (Formulation) M/s Saturn Pharmaceuticals (Pvt) Ltd, Lahore under Drug Manufacturing License No. 000734, is no more valid

It pertinent to mention that as per Rule 5 (6) of Drug (L, R & A) Rule, 1976 "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". Furthermore, Rule 5(3) states that "If the application for renewal of the license is made after the expiry of the period of the validity of the license, it shall be treated as a fresh application for the grant of a license."

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to M/s Saturn Pharmaceuticals (Pvt) Ltd, Lahore in the next meeting of the Board.

CASE NO. 14 CHANGE OF TITLE/NAME OF SECTION OF M/S SHAIGAN 14-KM, ADYALA ROAD, POST OFFICE DAHGAL, RAWALPINDI UNDER DML NO000333 (FORMULATION).

M/s Shaigan 14-KM, Adyala Road, Post Office Dahgal, Rawalpindi has requested for change of title/name of section from "Lyophilized Injection Vial (Steroidal) Hormone" to "Lyophilized Injection Vial (Steroidal)" section.

It is submitted for information that section "Lyophilized Injection Vial (Steroidal) Hormone" was granted to M/s Shaigan 14-KM, Adyala Road, Post Office Dahgal, Rawalpindi in 272nd meeting of Central Licensing Board held on 17th October, 2019

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after threadbare deliberation decided to advise the firm to get their layout plan approved prior to grant of Lyophilized Injection Vial (Steroidal) section.

Case No.15 SURRENDER OF LICENSED SECTION OF M/S AKSON PHARMACEUTICAL (PVT) LTD, PLOT NO. 9-B/1&2, STREET NO. D-1, OLD INDUSTRIAL ESTATE, MIRPUR AZAD KASHMIR

M/s. Akson Pharmaceutical (Pvt) Ltd, Plot No. 9-B/1&2, Street No. D-1, Old Industrial Estate, Mirpur Azad Kashmir has requested for surrender of following sections

1. Capsules (Cephalosporin)
2. Dry Powder Suspension (Cephalosporin)
3. Injectable Powder (Cephalosporin)

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after threadbare deliberation acceded the request of the firm with the direction to intimate future utilization of withdrawn facility.

CASE NO. 16 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000830 OF M/SSKIMS PHARMACEUTICALS,10-B, VALUE ADDITION CITY, KHURRIANWALA, FAISALABAD.

M/s Skims Pharmaceuticals,10-B, Value Addition City, Khurrianwala, Faisalabad had applied for renewal of DML No. 000830 by way of formulation for the period of 03-12-2020 to 02-12-2025. 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 January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Classes of Drugs, dosage form of drugs, name of drugs registered / approved.
ii. Section wise detail of machinery for manufacture.
iii. Up to date nothing due certificate regarding CRF from STO.
iv. CNIC's copies of all directors.
All documents should be duly attested.

The firm submitted their reply on 21st January, 2021. After evaluation of the submitted documents, final reminder was issued on 10th February, 2021 to the firm with following shortcomings: -

i. Up to date Nothing Due Certificate regarding CRF from STO.

The case was placed before the Central Licensing Board in its 282nd meeting of Central Licensing Board held on 31st August, 2021. The Board decided that:-

Proceedings and Decision by the Central Licensing Board in 282nd 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000830 (by way of formulation) of M/s Skims Pharmaceuticals,10-B, Value Addition City, Khurrianwala, Faisalabad may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In response above mentioned decision firm has submitted No Objection Certificate in response to this Division's Show Cause Notice issued on 28th September, 2021.The application for renewal of Drug Manufacturing License for the period from 03-12-2020 to 02-12-2025 is now complete.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000830 (Formulation)of M/s Skims Pharmaceuticals,10-B, Value Addition City, Khurrianwala, Faisalabad.

CASE NO.17 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000482 OF M/S SEAGULL PHARMA, TOWER POINT BEG COLONY GOJRA ROAD, JHANG.

Case Background:

M/s Seagull Pharma, Tower Point Beg Colony Gojra Road, Jhang had applied for renewal of DML No. 000482 by way of formulation for the period of 19-12-2020 to 18-12-2025. 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 30th December, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management with CNICs of all directors.
ii. Proof of licensed sections from CLB.
iii. Up-to-date nothing due certificate regarding CRF from STO.
iv. Submit classes of drugs, dosage form of drugs, name of registered / approved drugs.
All documents should be duly attested.

The firm submitted their reply on 4th February, 2021. After evaluation of the submitted documents, final reminder was issued on 5th April, 2021 to the firm with following shortcomings: -

For Renewal of DML.

i. Up-to-date nothing due certificate regarding CRF from STO.
ii. Classes of drugs, dosage form of drugs, list of registered / approved drugs, if any, please.
All documents should be duly attested.

The firm submitted their reply on 22nd April, 2021 in response to this Division's Final Reminder. After evaluation of the submitted documents, the application of Renewal of Drug Manufacturing License is still deficient for following documents: -

i. Up-to-date nothing due certificate regarding CRF from STO.

The case was placed before the Central Licensing Board in its 282nd meeting of Central Licensing Board held on 31st August, 2021. The Board decided that:-

Proceedings and Decision by the Central Licensing Board in 282nd 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000482 (by way of formulation) of M/s Seagull Pharma, Tower Point Beg Colony Gojra Road, Jhang may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In response to above mentioned decision firm has submitted No Objection Certificate in response to this Division's Show Cause Notice issued on 28th September, 2021 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License for the period from 19-12-2020 to 18-12-2025 is now complete.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000482 (Formulation)ofM/s Seagull Pharma, Tower Point Beg Colony Gojra Road, Jhang.

CASE NO. 18 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000437 OF M/S RAZEE THERAPEUTICS (PVT) LTD, 48-KM,LAHORE KASUR ROAD, KASUR.**

M/s Razee Therapeutics (Pvt) Ltd, 48-Km, Lahore Kasur Road, Kasur had applied for renewal of DML No. 000437 by way of formulation for the period of 06-09-2019 to 05-09-2024. 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 30th September, 2019:-

i. Updated Nothing Due Certificate regarding CRF from STO (R&D), DRAP, Islamabad.
ii. Section approval letters of Oral Liquid (General), Tablet (General) and Capsule (General) Sections, if not available, apply for regularization of layout plan.
iii. Prescribed fee of Rs. 50,000/- for change of management as there is change in management of the firm.
iv. Duly attested CNIC copy of all Directors / CEO.
v. Certified true copy of Form-29 (Attestation by SECP).

Firm has submitted their reply and scrutiny of application for renewal of Drug Manufacturing License following observation has been still observed and final reminder had issued to the firm on 25th February, 2020 with following observation has been observed:-

i. Section approval letters of Oral Liquid (General), Tablet (General) and Capsule (General) Sections, if not available, apply for regularization of layout plan.
ii. Attested CNIC copies of all Directors CEO.
iii. Latest Certified true copy of Form-29 (Attestation by SECP).

In response to final reminder firm has submitted proof of following section approval from Central Licensing Board.

i. Dry Powder Injectable (Vial) (Cephalosporin),
ii. Dry Power for suspension (Cephalosporin),
iii. Capsule (Cephalosporin),
iv. Liquid Vial (General),
v. Liquid Ampoule (General)

However, the firm did not rectify following shortcoming;

i. Attested CNIC copies of all directors
ii. Latest certified true copy of Form-29 by SECP (In original)

Proceedings and Decision by the Central Licensing Board in 283rd 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000437by way of formulation of M/s Razee Therapeutics (Pvt) Ltd, 48-Km, Lahore Kasur Road, Kasur may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 19 CHANGE OF MANAGEMENT OF M/S SEATLE (PVT) LTD, 45-KM, MULTAN ROAD, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000481 BY WAY OF (FORMULATION).

M/s Seatle (Pvt) Ltd, 45-KM, Multan Road, Lahore, had applied for renewal of DML No. 000481 by way of formulation on 06-08-2020 for the period of 29-09-2020 to 28-09-2025. 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 5th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

For Renewal of DML.

i. Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
ii. Attested CNIC's copies of all Directors.
iii. Latest Certified true copy of Form-29 (Attestation by SECP).
iv. Evidence of Lotion Section (Steroidal).
v. Evidence of Gel, Lotion, Liquid, Solution Section (General).
vi. Up-to-date nothing due certificate regarding CRF from STO.

For Production Incharge (Mr. Toqueer Ahmad).

i. Appointment letter.
ii. Job acceptance letter by the appointee.
iii. Resignation letter of appointee from the previous firm or promotion letter from same firm.
iv. Experience Certificate as under Drugs (Licensing, Registering and advertising) Rules, 1976 not less than 06 years.

All documents should be duly attested.

On scrutiny of application for change of management following observations has been noted Firm has changed their management several times without endorsement of Central Licensing Board. :-

A letter was issued to the firm on 9th June, 2021 with following observations: -

> "In your application for the change of management it is observed that your firm has changed their management several times without endorsement of Central Licensing Board. You are required to clarify your position for not submitting required documents in time. Moreover, submit certified true copy of consolidated Form-29 attested by SECP for new management".

In response to above mentioned letter Firm has submitted certified true copy of Form-29 attested by SECP for current management. Furthermore, firm has submitted assurance in future that they will get timely endorsement from CLB against change in management and to follow DRAP protocol and SOPs. The detail of current management is as under: -

New management as per Form-29 at Page 195-212/Corr Dated 10th June, 2021.
1. Ali Akhai S/o M. JavedAkhai CNIC No.42000-3326827-5. 2. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 422010-556944-9. 3. Mr. Muqtadir Muhammad Ali Jawad S/o Shafiq Ahmed CNIC No. 42201-5392112-5. 4. Syed Dawood S/o Syed Fashiuddin Ahmed CNIC No. LB9262870.

It is submitted that on scrutiny of reply of the firm in response to this division's letter dated 9th June, 2021 it is observed that firm has not provided consolidated Form-29 for previous changes in management; moreover, firm has not submitted date wise break-up of the management and their tenure, on letter head and entire data submitted by the firm is difficult to comprehend. They have changed the management almost ten times without endorsement of CLB, the detail is as under:

S.#	Change of management.	Page No.	Status	Fee
1.	As per Form-29 dated 24-12-2020.	Page 117/Corr.	Management changed without endorsement of Central Licensing Board.	Requisite Fee required.
2.	As per Form-29 dated 01-10-2019.	Page 118/Corr.	-do-	-do-
3.	As per Form-29 dated 12-01-2017.	Page 128/Corr.	-do-	-do-
4.	As per Form-29 dated 08-05-2017.	Page 126/Corr.	-do-	-do-
5.	As per Form-29 dated 04-08-2017.	Page 136/Corr.	-do-	-do-
6.	As per Form-29 dated 15-05-2017.	Page 165/Corr.	-do-	-do-
7.	As per Form-29 dated 25-04-2017.	Page 167/Corr.	-do-	-do-
8.	As per Form-29 dated 06-01-2017.	Page 169/Corr.	-do-	-do-
9.	As per Form-29 dated 23-05-2016.	Page 171/Corr.	-do-	-do-
10.	As per Form-29 dated 02-09-2014.	Page 141/Corr.	-do-	-do-

Proceedings and Decision by the Central Licensing Board in 282nd meeting:

"The Board considered and after deliberations decided to seek the prescribed fee and consolidated Form-29 & Form-A issued by the SECP".

In response to Central Licensing Board's decision firm has submitted relevant fee for change of management. Detail of the management is a under;

Previous management as per Form-29	New management as per Form-29.
1. Mr. Khalid Khan S/o Abdul Hameed Khan CNIC No. 6110117552121. 2. Mr. Muqtadir Muhammad Ali Jawad S/o Shafiq Ahmed CNIC No. 42201-	1. Mr. Ali Akhai S/o M. JavedAkhai CNIC No.42000-3326827-5. 2. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 422010-556944-9.

5392112-5. 3. Mr. JavedAkhai S/o A. Sattar Akhai CNIC No. 4200016582011 4. Mr. Rizwan Omar S/o Omar A Muhammad CNIC No. 4220136095277.	3. Mr. Muqtadir Muhammad Ali Jawad S/o Shafiq Ahmed CNIC No. 42201-5392112-5. 4. Syed Dawood S/o Syed Fashiuddin Ahmed CNIC No. LB9262870.

Proceedings &Decision of the Central Licensing Board in 283rd meeting:

The Board considered and accepted for record the change of management of M/s Seatle (Pvt) Ltd, 45-KM, Multan Road, Lahore subject to submission of NOC from Ministry of Narcotics in the light of Ministry of Narcotic Control, Islamabad's letter No. 5-8/2012-Policy-I dated 06/11/2020 and Division of Controlled Drugs, DRAP, Islamabad's Letter No.5-4/2020-CD date 10/11/2020.

Previous management as per Form-29	New management as per Form-29.
1. Mr. Khalid Khan S/o Abdul Hameed Khan CNIC No. 6110117552121. 2. Mr. Muqtadir Muhammad Ali Jawad S/o Shafiq Ahmed CNIC No. 42201-5392112-5. 3. Mr. Javed Akhai S/o A. Sattar Akhai CNIC No. 4200016582011 4. Mr. Rizwan Omar S/o Omar A Muhammad CNIC No. 4220136095277.	1. Mr. Ali Akhai S/o M. Javed Akhai CNIC No.42000-3326827-5. 2. Mr. Javed Ghulam Muhammad S/o Ghulam Muhammad CNIC No. 422010-556944-9. 3. Mr. Muqtadir Muhammad Ali Jawad S/o Shafiq Ahmed CNIC No. 42201-5392112-5. 4. Syed Dawood S/o Syed Fashiuddin Ahmed CNIC No. LB9262870.

CASE NO. 20 APPROVAL OF QUALITY CONTROL INCHARGE OF M/S PAKHIEM INTERNATIONAL PHARMA (PVT) LTD, LAHORE.

The firm, M/s Pakheim International Pharma (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore has submitted application for approval of proposed Quality Control Incharge Muhammad Ishfaque. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

1. Attested copy of CNIC of appointee.
2. Attested copy of academic degrees, as under Drugs (Licensing, Registering and Advertising) Rules, 1976.
3. Attested copies of Experience Certificate as under Drugs (Licensing, Registering & Advertising Rules), 1976.
4. Attested copy of Resignation / retirement of earlier QC Incharge.
5. Attested copy of Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
6. Undertaking as wholetime employee on stamp paper as per check list (Notarized), signed by both appointee and management.

Accordingly, a shortcoming letter was issued to the firm on 16th November, 2020 to rectify above mentioned shortcoming. In response to this Division's letter firm has submitted their reply upon evaluation of submitted documents shortcoming has been still observed and a final reminder was issued to the firm on 7th January, 2021 with following observations:-

1. Copy of CNIC of appointee.
2. Copy of academic degrees, as required under Drugs (Licensing, Registering and Advertising) Rules, 1976.
3. Copies of Experience Certificate as under Drugs (Licensing, Registering & Advertising Rules), 1976.
4. Copy of Resignation / retirement of previous QC Incharge.
5. Resignation or termination letter of appointee from the previous firm.

Meanwhile the firm has submitted application for approval of another QC Incharge Syed Muhammad Ali Zaidi instead of Mr. Muhammad Ishfaque. Upon evaluation of application for approval of proposed QC Incharge as per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

i. Resignation letter of earlier Quality Control Incharge.

The case was placed before the Central Licensing Board in its 282nd meeting of Central Licensing Board held on 31st August, 2021. The Board decided that:-

Proceedings and Decision by the Central Licensing Board in 282nd 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 License No 000492(by way of formulation) of M/s Pakheim International Pharma (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore may not be suspended or cancelled by Central Licensing Board".

In response to Show Cause Notice dated 7thOctober, 2021 firm has submitted required documents of proposed Quality Control Incharge Syed Muhammad Ali Zaidi and was approved, accordingly.

A letter of personal hearing is to be served to the said firm for 283rd meeting of Central Licensing Board schedule to be held on 28th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Hafeez Tehseen (Pant Manager) & Mr. Ali Zaidi (Quality Control Incharge) of the firm appeared before the Board and contended that all the documents have been submitted in Licensing Division. The Board considering the facts on the record and after hearing representative of the firm decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000492 (Formulation)of M/s Pakheim International Pharma (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore.

CASE NO. 21 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000814 OF M/S PCP LABORATORIES, 98-KM, AKHTARABAD, DISTRICT OKARA.

M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara had applied for renewal of DML No. 000814 by way of formulation for the period of 23-06-2015 to 22-06-2020. 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 5th October, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present, if any change apply for change of management.
ii. Partnership deed alongwith CNIC's of all partners.
iii. Detail of premises including layout plan.
iv. Proof of licensed sections from CLB.
v. Approval letter of Quality Control Incharge in case of change than submit required documents as per check list.
vi. Form 1A as per prescribed format.
vii. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

For Production Incharge (Mr. Rehmat Jamil).

i. Copy of appointment letter of appointee.
ii. Copy of job acceptance letter by the appointee.
iii. Readable copy of registration certificate from pharmacy council.
iv. Copy of resignation letter of earlier Production Incharge.
v. Copy of resignation letter of appointee from previous firm.
vi. Undertaking as whole-time employee on stamp paper signed by both appointee & management.

All documents should be duly attested.

The firm submitted their reply after evaluation of the submitted documents, final reminder was issued on 3rd March, 2021 to the firm with following shortcomings: -

For Renewal of DML.

i. Detail of management at the time of previous renewal and at present, in case of any change apply for change of management.
ii. Partnership deed alongwith copies of CNIC of all partners.
iii. Detail of premises including layout plan.
iv. Proof of licensed sections from CLB.
v. Approval letter of Quality Control Incharge, in case of change, submit required documents as per check list.
vi. Form 1A as per prescribed format.
vii. Up-to-date nothing due certificate regarding CRF from STO.

All documents should be duly attested.

No reply is received from the firm as of today and the application for renewal of DML No. 000814 (Formulation) is still deficient of above-mentioned documents.

The case was placed before the Central Licensing Board in its 282nd meeting of Central Licensing Board held on 31st August, 2021. The Board decided that:-

Proceedings and Decision by the Central Licensing Board in 282nd 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, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000814 (by way of formulation) of M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976".

In response to Show Cause Notice dated 28th September, 2021 firm has submitted their reply. The Firm also submitted for change of management. However following shortcoming is not rectified so for;

i. Compete Legal Documents for management are not provided.

A letter of personal hearing is to be served to the said firm for 283rd meeting of Central Licensing Board schedule to be held on 28th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Adeel Shahzad, IR & Compliance Manager and Ms. Aden Naseem Khan, HOD Regulatory, of the firm appeared before the board. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000814 by way of Formulation of M/s PCP Laboratories, 98-Km, Akhtarabad, District Okara till fulfillment of codal formalities 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the board for ratification.

CASE NO. 22 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000364 OF M/S SPECTRUM LABORATORIES (PVT) LTD, 8-KM, RAIWIND ROAD, LAHORE.

Case background.

M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore had applied for renewal of DML No. 000364 by way of formulation for the period of 16-09-2020 to 15-09-2025. 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 2nd December, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

For Renewal of DML.

1. Class of Drugs as per requirement of Form 1A.

2. Detail of management at the time of previous renewal and at present.
3. Latest Certified true copy of Form-29 (Attestation by SECP).
4. Up to date nothing due certificate regarding CRF from STO.
   All documents should be duly attested.

The firm submitted their reply on 28th December, 2021. After evaluation of the submitted documents, final reminder was issued on 28th January, 2021 to the firm with following shortcomings: -

i. Consolidated Form-29 or Form-A alongwith detail of all directors (attested by SECP / latest certified true copy).

The case was placed before the Central Licensing Board in its 282nd meeting of Central Licensing Board held on 31st August, 2021. The Board decided that:-

Proceedings and Decision by the Central Licensing Board in 282nd 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000364 (by way of formulation) of M/s Spectrum Laboratories (Pvt) Ltd, 8-Km, Raiwind Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Firm has submitted the Form-29 and Form-A in response to this Division's Show Cause Notice dated 28th September, 2021 for renewal of Drug Manufacturing License No. 000364 (by way of Formulation) for the period 16-09-2020 to 15-09-2025. However, SECP attested the documents with following remarks:-

"Certified to be true copy of the document filed by the company owner this office accepts no responsibility as to the correctness of the details and given in the document".

Accordingly, personal hearing letter was issued to the firm on 20/10/2021

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Shafique-ur-Rehman, CEO, appeared before the Board and submitted certified true copy of Form-29 issued by the SECP. The Board after hearing the representative of the firm and considering case background decided to cease the operation of show cause notice to the firm.

CASE NO. 23 APPROVAL OF PRODUCTION AND QUALITY CONTROL INCHARGE OF M/S ORTA LABORATORIES (PVT) LTD, 24-KM, MULTAN ROAD, OFF DEFENCE ROAD, MOHALANWAL, NEAR BAHRIA TOWN BRIDGE, LAHORE.

The firm M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, Lahore has submitted application for approval of proposed Production and Quality Control Incharge. The application was evaluated as per Drug (licensing, Registering & advertising) Rules 1976 and found some deficiencies and shortcomings has conveyed to firm. Firm has submitted their reply, after evaluation of the submitted documents, final reminder was issued on 10th February, 2021 to the firm with following shortcomings: -

For Production Incharge (Mr. Atta Ur Rehman).

1. Job acceptance letter by appointee.
2. Resignation letter of appointee from previous firm and also mention name of firm.

For Quality Control Incharge (Mr. Muhammad Ziaqat).

1. Resignation letter of earlier QC Incharge.
2. Resignation letter of appointee from previous firm.

All documents should be duly attested.

Meanwhile the firm has submitted application for approval of another QC Incharge Omer Mahmood instead of Mr. Muhammad Ziaqat. Upon evaluation of application for approval of proposed QC Incharge per Drug (licensing, Registering & advertising) Rules 1976 and found following shortcomings;

For QC Incharge (Omer Mahmood).

i. Readable copy of CNIC.
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than six years.
iii. Undertaking of whole-time employee on stamp paper signed by both Management & QC Incharge (Notarized).

The case was placed before the Central Licensing Board in its 282nd meeting of Central Licensing Board held on 31st August, 2021. The Board decided that:-

Proceedings and Decision by the Central Licensing Board in 282nd 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 License No 000075 (by way of formulation) of M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, Lahoremay 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 was issued to the firm on 28th September, 2021.

The firm replied to Show Cause Notice and filed new application for approval of Ms. Bushra Karamat as Production Incharge but application is still short of following documents:

For Production Incharge (Ms. Bushra Karamat):

i. Valid registration certificate from Pharmacy Council.
ii. Undertaking as Whole-time employee.
iii. Resignation of earlier Production Incharge.
iv. Copy of CNIC

Documents should be duly attested.

For QC Incharge (Omer Mahmood):

i. Readable copy of CNIC.
ii. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 not less than six years.

Documents should be duly attested.

A letter of personal hearing was issued to the firm on 28th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Omer Mehmood, Quality Control Manager, Mr. Muneeb Nawaz and Mr. Maqsood Ahmad, HOD Accounts of the firm appeared before the board. The documents presented before the Board were not readable which were communicated to the persons appeared on behalf of the firm. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000075by way of Formulation M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohalanwal, Near Bahria Town Bridge, Lahore till fulfillment of codal formalities/submission of required documents 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. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 24 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S ALI INDUSTRIES, LAHORE.

M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore had applied for renewal of DML No. 000222 by way of Formulation for the period of 24-10-2018 to 23-10-2023 on 16-10-2018.

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 November, 2018 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Properly filled, signed & stamped Form-1A as per format.
ii. Detail of management at the time of previous renewal and at present if any change, prescribed fee of Rs. 50,000/ alongwith proper application for change of management.
iii. CNIC Copies of all Partners.
iv. Copy of partnership deed issued by the Registrar of firm.
v. Proof of Sections approved by CLB, if not available, apply for regularization of layout plan.
vi. Approval letters of technical staff.
vii. All documents should be duly attested.

The firm replied to this letter on 24th February, 2020 but application was incomplete with following shortcomings and reminder letter was issued on 18th August, 2020 to the firm for completion of application:

i. Copy of partnership deed.
ii. Copy of final sale deed.
iii. Copy of CNIC Copies of all participants mentioned in provisional sale deed.
iv. Copy of succession certificate as mentioned in provisional sale deed
v. **All documents should be notarized.**

The firm replied to reminder on 4th September, 2020 and application for renewal of DML is still incomplete with following documents being deficient.

i. Copy of final sale deed.
ii. Copy of succession certificate as mentioned in provisional sale deed
iii. All documents should be notarized.

Proceedings and Decision by the Central Licensing Board in 277th 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) and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of for renewal of DML No. 000222 by way of formulation of M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore may not be rejected or Drug Manufacturing License 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 was issued to M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahore on 12th November, 2020.

The firm replied but application is still deficient of following documents:

i. Copy of final sale deed.
ii. All documents should be notarized.

A letter of Personal hearing has been issued on 17th August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

No person appeared on behalf of the firm. The Board decided to serve final opportunity to the firm for the sake of fair trial and justice.

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

A letter of Personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Aif Siddique, CEO of the firm appeared before the Board.He contended that he has not got registry of the property in his name due to his personal reasons which he could not disclose to the Board. He further contended that he may be given one month time for submission of required documents. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000222by way of Formulation M/s Ali Industries, 239/C, Sunder Industrial Estate, Lahoretill

fulfillment of codal formalities/submission of required documents 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the board for ratification.

CASE NO. 25 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FARMIGEA PAKISTAN (PVT) LTD, LAHORE.

M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore had applied for renewal of DML No. 000471 by way of Formulation for the period of 02-03-2020 to 01-03-2025 on 24-02-2020.

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 1st September, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

The firm did not reply and reminder letter was issued on 3rd February,2021 to the firm for completion of application.

The firm did not reply to reminder and application for renewal of DML is still incomplete with following documents being deficient.

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

Proceedings and Decision by the Central Licensing Board in 282nd 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 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000471 (by way of formulation) of M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) 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 was issued to M/s Farmigea Pakistan (Pvt) Ltd, 4.5-Km, Raiwind Manga Road, Lahore on 28th September, 2021.

The firm **did not reply** and application is still deficient of following documents:

i. Detail of management at the time of previous renewal & at present, if any change, apply for change of management.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of all Directors.
iv. Approval letter of sections approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letter of Production Incharge.

A letter of Personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

No person appeared on behalf of the firm. The Board decided to serve final opportunity to the firm for the sake of fair trial and justice.

CASE NO.26 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FERROZA INTERNATIONAL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore had applied for renewal of DML No. 000389 by way of Formulation for the period of 26-06-2021 to 25-06-2026 on 23-06-2020.

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 01-09-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal, if any change, apply for change of management with proper application and prescribed fee.
iii. Duly attested CNIC copies of all Directors.
iv. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letters of Production Incharge and Quality Control Incharge.

The firm did not reply and reminder was issued on 08-10-2020 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of management at the time of previous renewal, if any change, apply for change of management with proper application and prescribed fee.
iii. Duly attested CNIC copies of all Directors.
iv. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
v. Approval letters of Production Incharge and Quality Control Incharge.
vi. Documents should be duly attested.

The firm replied to reminder on 27-10-2020 but application for renewal of DML is still incomplete with following documents being deficient.

i. Latest certified true copy of Form-29 duly attested by SECP (Original).
ii. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
iii. Complete set of duly attested documents (as per checklist except CNIC & experience certificates) of proposed Production Incharge and Quality Control Incharge along with prescribed fee.
iv. Documents should be duly attested.

Moreover, it is pertinent to mention here that the firm has been carrying out production activities without approved Quality Control Incharge since 2015 and without approved Production Incharge since 2013 as reflected in certificates submitted by the firm.

Proceedings and Decision by the Central Licensing Board in 282nd 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, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000389 (by way of formulation) of M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur 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 was issued to M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore on 30th September, 2021.

The firm **did not reply** and application is still deficient of following documents:

i. Latest certified true copy of Form-29 duly attested by SECP (Original).
ii. Sections approval letters approved by CLB, if not available, apply for regularization of layout plan.
iii. Complete set of duly attested documents (as per checklist except CNIC & experience certificates) of proposed Production Incharge and Quality Control Incharge along with prescribed fee.
iv. Documents should be duly attested.

Moreover, it is pertinent to mention here that the firm has been carrying out production activities without approved Quality Control Incharge since 2015 and without approved Production Incharge since 2013 as reflected in certificates submitted by the firm.

A letter of Personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Usman Khalid, Director of the firm appeared before the board. The Board after perusal of record and facts decided to suspend the Drug Manufacturing License No 000389 by way of Formulation M/s Ferroza International Pharmaceuticals (Pvt) Ltd, 33-Km, Ferozepur Road, Lahore till fulfillment of codal formalities/submission of required documents 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the board for ratification.

CASE NO. 27SITE VERIFICAATION AND SITE APPROVAL OF M/S DUAA PHARMA,

M/s Duaa Pharma, **Khewat No. 1131, 1200 Khasra No. 1201, Tehsil Fateh Jang, District Attock** submitted application for site verification of proposed plot. After application was completed by the firm, area FID was requested to conduct site inspection of proposed plot and submit report regarding suitability of plot for establishment of pharmaceutical unit.

The FID submitted inspection report which is reproduced below:

The inspection was conducted on 07-07-2021. Report of Inspection of this site is described as under as per format laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976.

Requirement as laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976	**Observation(s) by the Inspector**
1. Location and surroundings: -	**1. Location and surroundings: -**
1.1 Location: The premises shall be located preferably in an industrial area and in any case not in any residential or commercial area.	**1.1 Location:** The premises of **M/s Duaa Pharma, Khewat No 1131,1200 Khasra No 1201, Tehsil Fateh Jang,District Attock** which is an unclassified area. The site is near from residential area of the village KhairiMorat.
1.2 Surroundings: Premises shall be situated in an environment that, when considered together with measures to protect the manufacturing process, presents minimum risk of causing any contamination of materials or products. It shall be away from filthy surroundings and shall not be adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of soot, dust or smoke which may contaminate the drugs being manufactured or adversely affect their quality. Existing units shall keep the surroundings under their control to be clean.	**1.2 Surroundings:** Premises/Plot (at present) is situated in a clean & open environment near to residential and un classified area. although at present away from filthy surroundings and is not adjacent to an open sewerage, drain, public lavatory or any factory which produces a disagreeable or obnoxious odor or fumes or large quantities of soot, dust or smoke (causing unsuitability of surrounding) which could contaminate the drugs being manufactured or adversely affect their quality.The firm is responsible in future for the same measures to avoid any contamination which may affect the quality of product to be manufactured in the unit.

1.3 Size The size of the plot shall not be less than **2000 square yards**.	**1.3 Size** Total area of the plot is17120 square feet =**1902.22 square yards** = 3.2 kanals (as mentioned in the copy registry provided by the firm. (copy attached) • **The area is less than the prescribe area.**

2. Other Observations noted by the inspector(s):

2.1 The plot is of irregular shape at the time of inspection, at present, **in-front** of the site there is a street road and open area having residential area of KhiariMorat village. **at the back** there is an agricultural field/land, side by side a house attached with the plot on **the right is** the mosque **& left side** there is also an agricultural field/land. There is a house in the nearby vicinity.
(The sketch of the plot and its adjoining area is attached with report).

2.2 The Registry of Possession of Plot is in the name of Syed NajumulHusnain S/O Munir Shah.

2.3 Mr. Syed Najam -ul- Husnain c/o M/S Duaa Pharma Located at Khewat No 1131,1200 Khasra No 1201, Tehsil Fateh Jang, District Attock was present at the site and accompanied during the visit.

2.4 The undersigned observed a mosque and residence adjacent to the right side and back side respectively in the present site.

3. Conclusion and Recommendations:

The location under consideration is **"not suitable"** to establish a pharmaceutical unit as per requirements laid down under paragraph 1 of Section 1 of Schedule "B" (SRO 470(1)/98 dated 15-5-1998 under rule 16 (a) of the Drugs (Licensing, Registering and Advertisement) Rules, 1976 at present.

Decision of the Central Licensing Board in 282nd meeting

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm M/s Duaa Pharma, **Khewat No. 1131, 1200 Khasra No. 1201, Tehsil Fateh Jang, District Attock** in the upcoming meeting of the Board.

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

A letter of personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Syed Najmul Husnain Shah, CEO and Ms. Samaha Kazmi, Manager of the firm appeared before the Board. The admitted before the Board that existing area of the plot is less that the required area. The Board after hearing representative of the firm and perusal of facts decided to reject the proposed site for establishment of Pharmaceutical unit.

CASE NO. 28 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S KOHINOOR INDUSTRIES, SAHIWAL.

M/s Kohinoor Industries, 159-160/B, Small Industrial Estate, Sahiwal had applied for renewal of DML No. 000197 by way of Formulation for the period of 25-10-2020 to 24-10-2025 on 24-08-2020. 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 25-09-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Classes of Drugs.
iii. Section approval letters of External Preparation & Repacking sections approved by CLB, if not available, apply for regularization of layout plan.
iv. Detail of Machinery in all Production departments.
v. Approval letter of Quality Control Incharge, if not already approved, submit complete application along with prescribed fee.
vi. Detail of equipment in Laboratory (Quality Control and Microbiology).

The firm did not reply and reminder letter was issued on 05-05-2021 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Classes of Drugs.
iii. Section approval letters of External Preparation & Repacking sections approved by CLB, if not available, apply for regularization of layout plan.
iv. Detail of Machinery in all Production departments.
v. Approval letter of Quality Control Incharge, if not already approved, submit complete application along with prescribed fee.
vi. Detail of equipment in Laboratory (Quality Control and Microbiology).

Reply to reminder was received on 04-06-2021 and application for renewal of DML is still incomplete with following documents being deficient.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Approval letter of Quality Control Incharge, if not already approved, submit complete application along with prescribed fee.

Proceedings and Decision by the Central Licensing Board in 282nd 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, Rule 16, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000197 (by way of formulation) of M/s Kohinoor Industries, 159-160/B, Small Industrial Estate, Sahiwal 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 was issued to M/s Kohinoor Industries, 159-160/B, Small Industrial Estate, Sahiwal on 28th September, 2021.

The firm **replied**but application is still deficient of following documents:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Approval letter of Quality Control Incharge, if not already approved, submit complete application along with prescribed fee (The firm has submitted approval letter of Mr. Naveed, however, in the Form-1A earlier submitted by the firm Ms. Shama was Quality Control Incharge of the firm).

A letter of Personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Haroon Shahid, Managing Partner of the firm appeared before the Board. He asked two-week time for completion of application. The Board after hearing representative of the firm and threadbare deliberation decided to suspend the Drug Manufacturing License No 000197 by way of Formulation M/s Kohinoor Industries, 159-160/B, Small Industrial Estate, Sahiwal till fulfillment of codal formalities/submission of required documents 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO.29 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S LAWRENCE PHARMA (PVT) LTD, LAHORE.

M/s Lawrence Pharma (Pvt) Ltd, 10.5-Km, Sheikhupura Road, Lahore had applied for renewal of DML No. 000322 by way of Formulation for the period of 19-10-2020 to 18-10-2025 on 15-06-2020. 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 13-08-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Approval letters of Production Incharge and Quality Control Incharge, if not already approved, submit their complete application alongwith prescribed fee.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Duly attested CNIC copies of owner / partners.
iv. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.
v. Proof of sections/section approval letters approved by CLB, if not available, apply for regularization of layout plan.
vi. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
vii. Documents should be duly attested.

The firm replied to this letter on 08-09-2020 and reminder was issued on 28-09-2020 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO, DRAP, Islamabad.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Copy of Form-29 for year 2015 issued & attested by SECP, if any change in management since 2015, apply for change of management alongwith prescribed fee of Rs. 50,000/-.

iv. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.

The firm did not reply to reminder and application for renewal of DML is still incomplete with following documents being deficient.

i. Updated NDC regarding CRF from STO, DRAP, Islamabad.
ii. Latest certified true copy of Form-29 duly attested by SECP (original).
iii. Copy of Form-29 for year 2015 issued & attested by SECP, if any change in management since 2015, apply for change of management along with prescribed fee of Rs. 50,000/-.
iv. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.

Proceedings and Decision by the Central Licensing Board in 282nd 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, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000322 (by way of formulation) of M/s Lawrence Pharma (Pvt) Ltd, 10.5-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 was issued to M/s Lawrence Pharma (Pvt) Ltd, 10.5-Km, Sheikhupura Road, Lahore on 28th September, 2021.

The firm replied to show cause notice on 25th October, 2021 but application is still deficient of following documents:

i. Latest certified true copy of Form-29 duly attested by SECP (original) without the stamp that SECP does not take responsibility of contents of Form.
ii. Section approval letters approved by CLB, if not available, apply for regularization of layout plan.

A letter of Personal hearing has been issued on 20th October, 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

No person appeared before the Board. The Board after threadbare deliberation decided to suspend the Drug Manufacturing License No 000322 by way of Formulation M/s Lawrence Pharma (Pvt) Ltd, 10.5-Km, Sheikhupura Road, Lahore till fulfillment of codal formalities/submission of required documents 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

CASE NO. 30 RENEWAL OF DRUG MANUFACTURING LICENCE No. 000147 (FORMULATION) BY M/S EROS PHARMACEUTICALS (PVT) LTD, KARACHI.

M/s Eros Pharmaceuticals (Pvt) Ltd, Plot No. 93-95, Sector 23, Korangi Industrial Area, Karachi, has applied for renewal of DML No. 000147 by way of formulation for the period commencing on 21-08-2020 and ending on 20-08-2025.

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 31st August, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Updated Certified True Copy of Form-29 & Form-A issued by SECP along with attested CNIC copies of all directors.
(ii) Application on Prescribed Form-1A signed by the current management / director of the firm.
(iii) Documents for approval of Proposed QC In charge Mr. Asif Hussain as already communicated vide letter dated 23-07-2020.
(iv) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB.
(v) Updated NDC of CRF.

Later on, no reply was received from the firm and a reminder letter was issued on 9th March, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976 to submit the above-mentioned documents for completion of the application for renewal of DML.

The firm has submitted their reply received on 16th June 2021 which is evaluated and application for renewal of DML is still found deficient of following shortcomings / deficiencies: -

i. Application is not submitted on Prescribed Form-1A.
ii. Updated Original Form-29 & Form-A issued by the SECP.
iii. Clarify the name/dosage form of section namely Antiseptic (General)
iv. Status regarding ready for inspection of licensed sections in the light of approved layout plan.

Proceedings and Decision by the Central Licensing Board in 282nd 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 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000147(by way of formulation) of M/s Eros Pharmaceuticals (Pvt) Ltd, Plot No. 93-95, Sector 23, Korangi Industrial Area, Karachimay not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In compliance to the decision of the CLB, show cause notice dated 30th September 2021 was issued. The reply/documents of the firm are submitted by the firm in response to the show cause notice which

are evaluated and the application for renewal of DML No. 000147 (Formulation) is still found deficient of following documents:

i. Application is not submitted on Prescribed Form-1A.
ii. Updated Original Form-29 & Form-A issued by the SECP.
iii. Clarify the name/dosage form of section namely Antiseptic (General)
iv. Status regarding ready for inspection of licensed sections in the light of approved layout plan.

The firm is also called for Personal Hearing vide letter dated 22nd October 2021.

Proceedings & Decision of the Central Licensing Board in 283rd meeting:

Mr. Asif Iqbal, Director of the firm appeared before the Board. The Board after hearing representative of the firm and threadbare deliberation decided to suspend the Drug Manufacturing License No 000147 by way of Formulation M/s Eros Pharmaceuticals (Pvt) Ltd, Plot No. 93-95, Sector 23, Korangi Industrial Area, Karachi till fulfillment of codal formalities/submission of required documents 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Afterwards, Secretary CLB may take decision and case may be placed before the board for ratification.

CASE NO. 31 RENEWAL OF DRUG MANUFACTURING LICENCE No. 000074 (FORMULATION) BY M/S KARACHI PHARMACEUTICAL LABORATORTIES, PLOT NO. S/54, HAWKES BAY ROAD, KARACHI.

M/s Karachi Pharmaceutical Laboratories,Plot No. S/54, Hawkes Bay Road,Karachi, has applied for renewal of DML No. 000074 by way of formulation for the period of 30-09-2020 to 29-09-2025 on 30th July 2020.

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 27th January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB of if not available then submit layout plan for regularization.
(ii) Undertaking on stamp paper regarding sole proprietor ship along with attested CNIC copy of Sole Proprietor.
(iii) Updated NDC of CRF.
(iv) Complete set of attested documents (as per checklist) for approval of QC In charge.

Later on, the firm submitted reply / documents which were evaluated and a reminder letter was issued on 5thMay, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Submit layout plan for regularization of manufacturing facility along with Prescribed fee as the firm does not possess the approval letters of licensed sections issued from the CLB.

(ii) Complete set of attested documents (as per checklist) for approval of QC In charge who fulfills the requirement of Rule 16 (e) of the Drugs (L,R&A) Rules, 1976 as the proposed QC In charge Ms. Seema Ashqeen possess the degree in B.SC Chemistry and does not fulfil the requirement of Rule 16 (e) of the Drugs (L,R&A) Rules, 1976 in terms of required qualification.

(iii) Updated NDC of CRF.

The firm has submitted their reply which is evaluated and application for renewal of DML is still found deficient of following shortcomings / deficiencies: -

i. Updated NDC of CRF issued from the statistical officer, DRAP, Islamabad.
ii. Complete set of attested documents **(as per checklist)** for approval of Mrs. Amna Mehboob as Proposed Production in charge along with prescribed fee.
iii. Proof of sections/approval letters of all sections issued by the Central Licensing Board or if not available then submit layout plan for regularization of manufacturing facility.
iv. Prescribed fee for change of QC In charge for approval of new proposed QC In charge Mr. Hasan Adil.

Proceedings and Decision by the Central Licensing Board in 282nd 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 , Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000074 (by way of formulation) M/s Karachi Pharmaceutical Laboratories, Plot No. S/54, Hawkes Bay Road, Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In compliance to the decision of the CLB, show cause notice dated 30th September 2021 was issued. The reply/documents of the firm are submitted by the firm in response to the show cause notice which are evaluated and the application for renewal of DML No. 000074 (Formulation) is still found deficient of following documents:

i. Updated NDC of CRF issued from the statistical officer, DRAP, Islamabad.
ii. Complete set of attested documents **(as per checklist)** for approval of Mrs. Amna Mehboob as Proposed Production in charge along with prescribed fee.
iii. Prescribed fee for change of QC In charge for approval of new proposed QC In charge Mr. Hasan Adil.

The firm is also called for Personal Hearing vide letter dated 22nd October 2021.

Proceedings and Decision of Central Licensing Board in 283rd meeting.

Managing Director of the Company forwarded prscription of the Doctor regaring his ailing condition and chest X- ray . The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

CASE NO. 32 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000081 (FORMULATION) OF M/S SPECIFIC RESEARCH LABORATORIES, KARACHI**

M/s Specific Research Laboratories, Plot No. S/21, Estate Avenue Road, S.I.T.E Karachi has filled/submitted application for renewal of DML No. 000081 (Formulation) for the period commencing on 30-09-2020 and ending on 29-09-2025.The application for the renewal of DML of the firm was evaluated and a letter dated 19th November 2020 was issued to the firm to submit following document for completion of application for renewal of DML.

i. Detail of licensed sections on firm's letter head along with approval letters issued from the CLB or if not available then submit layout plan for regularization.
ii. Approval letter of Q.C. In-charge Feryal Vali Mohammad and Production in-charge Mr. Mushtaq Noorwalaor if not available then submit complete set of attested documents (as per checklist) for approval.
iii. N.D.C of CRF (Updated) issued by statistical officer DRAP, Islamabad.
iv. Attested Section wise detail of machinery for manufacture & Quality control.
v. Names of drugs/products for grant of repacking along with prescribed fee and proof/approval letter of repacking section.
vi. Clarify the legal status of firm (whether sole proprietor ship or partnership) and submit Copy of Partnership deed duly notarized (in case of partnership firm) and undertaking on stamp paper (in case firm is sole-proprietorship firm) along with attested CNIC copy of sole proprietor /partner.

No reply was received from the firm and a Reminder dated 18th May 2021 was issued to the firm to submit the said documents but no reply/response is received from the firm and the application for renewal of DML is still deficient of above-mentioned documents.

Proceedings and Decision by the Central Licensing Board in 282nd 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, Rule 12, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000081(by way of formulation) of M/s Specific Research Laboratories, Plot No. S/21, Estate Avenue Road, S.I.T.E Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

In compliance to the decision of the CLB, show cause notice dated 30th September 2021 was issued. No reply/documents are submitted by the firm in response to the show cause notice

The firm is also called for Personal Hearing vide letter dated 22nd October 2021.

Proceedings and Decision of Central Licensing Board in 283rd meeting:

No representative of the of the firm appeared before the Board. It was informed to the Board that firm is in operational since last renewal and had failed to complete application for renewal second time. The Board considering the facts on the record and after thread bare deliberation decided to cancel Drug Manufacturing License No. 000081 by way of Formulation issued in the name of M/s Specific Research Laboratories, Plot No. S/21, Estate Avenue Road, S.I.T.E Karachi 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Case No. 33. <u>M/S GENOME PHARMACEUTICALS (PVT) LTD., HATTAR VIOLATION OF SECTION 34 OF THE DRUGS ACT, 1976 AND RULE 19 OF DRUGS (LICENSING, REGSITERING & ADVERTISING) RULES, 1976.</u>

M/s Genome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar licensed manufacture under Drug Manufacturing License (DML) No. 0000454. As per available record in the Drugs Licensing Division, DRAP, current management of the firm is as under;

Current management as per Form-A
1. Mr.Siraj-ud-Din S/o Syed Ghulam Bacha, CNIC No. 17301-1302453-3. 2. Mr. AbuzarFaizyRattu S/o MianRehmat Ullah Rattu, CNIC No. 37405-0371513-9. 3. Mr. Hazrat Ullah S/o Habib Ullah Jan, CNIC No.17301-1316990-9. 4. Mr. Faisal Zafar S/o Malik Muhammad Zafar, CNIC No.37405-6266706-9

A letter from M/s Genome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar is received through **Mr. Faisal Zafar and Mrs. Tehseen Zia** which is re-produced as under;

*"It is to bring in your kind notice that we are five shareholders in Genome Pharmaceuticals (Pvt) Ltd. The details of shareholding alongwith number of percentage held are mentioned below (**Form A from SECP as evidence is attached Annexure-A**)*

S.No.	***Name of Share holders***	***Number of shares held***	***Percentage of shares***
1.	*Mr. FaisalZafar*	*28,500,000*	*35.625%*
2.	*Mrs. Tehseen Zia w/o Faisal Zafar*	*13,500,000*	*16.875%*
3.	*Mr. Hazratullah*	*18,000,000*	*22.5%*
4.	*Mr. Sirajuddin*	*12,000,000*	*15%*
5.	*Mr. AbuzarFaiziRattu*	*8,000,000*	*10%*

Actually, we are facing severe conflicts in the internal management of company operations among shareholders for the last one year. Being a majority shareholder 52.5% collectively we are trying to resolve the issues as per business norms with dialogue and legally as well.

In fact, our board of director elections were due in October 2020 but due to bad intentions of other three shareholders including Ex. CEO

1. *Mr. Hazratullah*
2. *Mr. Sirajuddin*
3. *Mr.AbuzarFaizyRattu*

They took Oath to protect their rights only and made grouping against us, which is violation of SECP Act as well. The Ex. CEO Mr. AbuzarFaizyRattu had deliberately delayed the meeting to conduct the Board of director's election, therefore being a major

shareholders we decided to get help from SECP (Security Exchange Commission of Pakistan) and SECP issued a letter on 25th June, 2021 to Company Secretary to hold overdue EOGM(Extra Ordinary General Meeting)within 30 days and the Company secretary fixed the date to hold elections on 24th July, 2021 right in compliance but to create hurdles in execution of EOGM they took an illegal stay order from Civil court Islamabad and also filed the case in ?High court Islamabad at the same time. After that we succeeded top lift the stay order from Civil court Islamabad and held election on 24th July, 2021 successfully, furthermore, they were compelled to withdraw the case from Civil court Islamabad as well. ***(The copy of SECP Direction letter is attached as Annexure-B & Civil court order is attached as Annexure-C).***

As a result of elections only two directors 1. Mr. Faisal Zafar 2. Mrs. Tehseen Zia got elected un-opposed, as other three shareholders has not submitted their nomination to contest the election to company Secretary. ***(The evidence of EOGM form 28 SECP is also attached as Annexure-D)***

We had submitted EOGM minutes of the meetings on 29th July 2021 to SECP but just to create a dispute Mr. Abu ZarFaizyRattu also submitted their fake EOGM minutes of the meeting to SECP, which was returned to him 07th September 2021 from SECP because of "being inconsistent/contradictory vis-à-vis allied communication" basis. Moreover, SECP has declared only Mr. Faisal Zafar being the Authorized signatory of the company. ***(The SECP letter is also attached for your consideration as Annexure-E)***

Furthermore, due to defeat on legal grounds and ethical platforms now other three shareholders are doing un-ethical practices to create negative impact of the company, defame in the corporate sector, government institutions, private platforms and also creating hurdles in company day to day operations.

In addition, Mr. Hazratullah had given threat that he will lock the factory and we were compelled to submit and application at Hattar Police station to avoid this illegal act and to keep on record.

(The application is attached as evidence for your consideration as Annexure-F)

Similarly, Mr. Sirajuddin had taken company original factory property documents including registry, allotment letter and bank account cheque books from finance manager, hence, we had submitted an application at Airport Police Station Chaklala scheme iii, in this regard.

(The evidence is attached as Annexure-G)

Keeping in view the above stated facts their intentions are self-explanatory to destroy the company. Therefore, as a precaution we are submitting our apprehensions to your honorable authority in order to avoid any illegal act from their side to DRAP Pakistan.

We look forward to your cooperation in this regard."

A letter from M/s Genome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar is received through **Mr. Abu ZarFaizy, Mr. Hazrat Ullah and Mr. Sirajuddin** which is re-produced as under;

"We being Members/Directors of the Genome Pharmaceutical (Pvt) Ltd would like to draw your attention that we have some serious issue/disputes with one of the partner Mr. Faisal Zafar who has allegedly controlling everything by some fraudulent action

taken by him in the company documents, and we are observing some serious issues he is not full filling the requirement of law and that can lead to some quality issues and we have no access to any official record and he has submitted application against us in Hattar Police Station and Police Station Airport, Rawalpindi. In order to keep us away from the system and doing everything single handedly. So you are requested no to accept any change in the company documents and stop production until issue is not fully resolved.

Keeping in view that one petition C.O No.11/2021 in Islamabad High Court Islamabad is already pending."

Area FID, DRAP, Peshawar has also forwarded above letter of Mr. Abu ZarFaizy, Mr. Hazrat Ullah and Mr. Sirajuddin of M/s Genome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar and requested for necessary direction in the matter.

It is submitted for information that as per section 34 of Drugs Act 1976 regarding offences by companies, etc, is stated that: where the person guilty of an offence under this Act, is a company, corporation, firm or institution, every director, partner and employee of the company, corporation, firm or institution with whose knowledge or consent the offence was committed shall be guilty of the offence.

As the present Directors have created a dispute regarding the running the affairs of the company, it would be difficult to ascertain the names of accused if any complaint is received.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

Following Directors were afforded opportunity of personal hearing to reach at the right and just decision.-

Mr. Faisal Zafar, appeared before the Board and contended that company was established in 2008 with four Directors

1. Mr. Siraj-ud-Din S/o Syed Ghulam Bacha, CNIC No. 17301-1302453-3.
2. Mr. Abuzar Faizy Rattu S/o Mian Rehmat Ullah Rattu, CNIC No. 37405-0371513-9.
3. Mr. Hazrat Ullah S/o Habib Ullah Jan, CNIC No.17301-1316990-9.
4. Mr. Faisal Zafar S/o Malik Muhammad Zafar, CNIC No.37405-6266706-9

He further stated that he and his Mrs owned 45% shares at the time establishment of the company. He argued that he has purchased 7.5% shares from Syed Siraj ud Din in 2015 and now he holds majority shares.In written reply which he read out before the Board and stated that Writ is pending before the Honourable Lahore High Court, Rawalpindi Bench where in Honorable Court has issued Order to maintain the status quo. On a query, he replied that neither Drug Regulatory Authority nor Central Licensing Board are party to said Writ Petition.

He reiterated that Company has held election on 24th July, 2021 and has not elected Mr. Siraj-ud-Din, Mr. Abuzar Faizy Rattu and Mr. Hazrat Ullah as director therefore they are trying to blackmail and threaten the him. The submitted that in view of the stay order, matter may be kept in abeyance till final disposal of the petitions pending adjudication before the Honorable Court. On a further query, he admitted that previously two Directors of the Company were also jailed on misappropriation of the raw material of a drug. He futher stated that Genome Pharmaceutical (Pvt) Ltd. is a big company and it was not easy to re-appropriate accounts as well as import of raw materials and drugs manufactured which Ex-Director are demanding.

Mr. Hazratullah, appeared before the Board and contended that he hold 22.5% shares in the Company. He further stated that all share holders were working on trust and production was under the control of Mr. Faisal Zafar. He further stated that few months back when he was asked for audit of the company and accounts. He refused to show us documents rather than he Lodged an FIR against me. He further stated that if all matter are being run as per law than there should not be shyness in showing the accounts and all record of raw material imported/ purchased and drugs manufactured. He further showed his fears that previously two Directors were jailed and now I fears some mis-appropriation was carried out and being Director he would be held accountable.He stressed that he should be informed of the activities of company or company should be closed.

Mr. Sirajuddin, appeared before the Board and stated that he hold 22.5% shares since establishment of the Company. He stated that he had shares in other companies as well therefore, he was not interfering in the affairs of the manufacture and import of raw materials. He stated that he found change in behavior of the Mr. Faisal Zafar when we asked for the audit of Accounts and import, export and manufacture of drugs. He has not only denied us the access to documents and record but has filed an FIR against me as well. He stated that matter pertaining to shares is pending before the Honourable High Court which is filed by me and Court has passed orders of status quo on my request on the basis of Form 29 issued to the Company 2014against the illegal activity by Mr Faisal Zafar for transferring of my 7.5% shares. He further argued that we need assurance from the Board as well Mr. Faisal Zafar if company is being run as law and we may be given access for the audit of Accounts and import, export and manufacture of drugs. If no assurance is given it should be closed keeping in view previous record of the Company.

Mr. Abuzar Faizi Rattu, appeared before the Board and stated that he is holding 10% shares in the Company since its establishment. He was responsible for the regulatory affairs and Government institutions. He furthers stated that he came to know that medicines of our company are being exported

with seeking NOC from DRAP as required under the Law. He therefore, approached Mr Faisal zafar for the access to the documents and audit of Accounts and manufacturing record which he denied. To further his suspicion, he lodged FIR at two different police stations against two of the Directors. He argued that we do not take responsibility of quality of drugs/ medicines, no assurance is given for audit is carried.

The Board after hearing the Directors of the Company observed that Central Licensing Board has to do nothing with the shares of the Company. Without prejudice to the matter, the Central Licensing Board shall abide the decision of Honorable Court. The Board further observed that central Licensing Board shall not compromise on quality of drugs being manufactured and import and export of drugs as per law. The Board also observed that it is the prime responsibility of the Company under Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 continue to maintain conditions on the basis of which he was granted licence. The Board also observed the Form 29 issued in the name Company bears the stamp of the Security and Exchange Commission of the Pakistan (SECP) as under:-

> "Copy of this form is being issued on the request of applicant. However, this office does not take any responsibility of its genuineness as parties are in litigation in the Court and the matter is pending for adjudication."

The Board considering the statement of the Directors and above facts on record decided:

i. seek detail report from the Additional Director (E&M), Drug Regulatory Authority of Pakistan, Peshawar for the last five years with clear recommendations regarding import of raw material, manufacture of drugs andexport of drugs and samples of drugs takenand report thereof.

ii. to suspend the Drug Manufacturing Licence No. 0000454 (Formulation) of M/s Genome Pharmaceuticals (Pvt) Ltd., 16/1, Phase-IV, Industrial Estate, Hattar under Section41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till the detailed report by the Additional Director (E&M), Drug Regulatory Authority of Pakistan, Peshawar.

CASE NO. 34. <u>RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HARMANN PHARMACEUTICAL LABORATORIES (PVT) LTD, LAHORE.</u>

M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, 216-Km, Multan Road, Lahore had applied for renewal of DML No. 000145 by way of Formulation for the period of 09-01-2021 to 08-01-2026 on 07-12-2020.

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 15-01-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.
iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Duly attested CNIC copies of all Directors.
v. Status of regularized sections/facility whether the firm is ready for inspection or otherwise.

The firm did not reply to this letter and reminder letter was issued on 08-07-2021 to the firm for completion of application:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.
iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Duly attested CNIC copies of all Directors.
v. Status of regularized sections/facility whether the firm is ready for inspection or otherwise.

The firm replied to reminder on 12-08-2021 and intimated that their two Directors died due to Covid and they are in process of finalization of succession certificates from Court however, application for renewal of DML is still incomplete with following documents being deficient:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Prescribed fee of Rs.75,000/- and apply for change of management.
iii. Latest certified true copy of Form-29 duly attested by SECP (Original).
iv. Duly attested CNIC copies of all Directors.
v. Status of regularized sections/facility whether the firm is ready for inspection or otherwise.

Proceedings and Decision by the Central Licensing Board in 283rd 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 Drug Manufacturing License No 000145 by way of formulation of M/s Harmann Pharmaceutical Laboratories (Pvt) Ltd, 16-Km, Multan Road, Lahore may not be suspended or cancelled by the Central Licensing Board.

CASE NO. 35 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/s IPRAM INTERNATIONAL RAWAT.

M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat had applied for renewal of DML No. 000551 by way of Formulation for the period of 27-08-2019to 26-08-2024on 26-08-2019.

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 9thOctober, 2020under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

For Renewal of DML.

i. Form 1A duly signed and stamped by CEO of the firm along with annexure.
ii. Detail of management at the time previous renewal and present renewal.
iii. Proof of Licensed Section from CLB.
iv. Nothing due certificate regarding CRF from STO upto 2019.

For Change of Management.

i. Request for change of management on letter head of the firm.
ii. Fee Challan Rs.50,000/- retained by STO, DRAP, Islamabad.
iii. Revised / New partnership deed along with CNIC (s) copies of all directors.
iv. Form-C from registrar of firm.

The firm did not reply and Final reminder letter was issued on 26th October, 2020 to the firm for completion of application:

For Renewal of DML.

i. Form 1A duly signed and stamped by CEO of the firm along with annexure.
ii. Detail of management at the time previous renewal and present renewal.
iii. Proof of Licensed Section from CLB.
iv. Nothing due certificate regarding CRF from STO upto 2019.

For Change of Management.

i. Request for change of management on letter head of the firm.
ii. Fee Challan Rs.50,000/- retained by STO, DRAP, Islamabad.
iii. Revised / New partnership deed along with CNIC (s) copies of all directors.
iv. Form-C from Registrar of firms.

The firm replied to reminder on 10th November, 2020but the application for renewal of DML is still incomplete with following documents being deficient.

i. Nothing due certificate regarding CRF from STO.
ii. Proof of Licensed Section from CLB.

iii. Detail of management at the time previous renewal and present renewal.
iv. Request for change of management on letter head of the firm.
v. Prescribed fee of Rs.50,000/- for change of management.
vi. Duly attested Form-C from Registrar of firms, revised partnership deed and CNIC copies of all partners.

Proceedings and Decision by the Central Licensing Board in 279th 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 & Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000551(by way of formulation) of M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat may not be suspended or cancelled by the Central Licensing Board.

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

The Show Cause Notice was issued to M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat on 6th July, 2021.

The firm replied but application is still deficient of following documents:

i. Nothing due certificate regarding CRF from STO.
ii. Proof of Licensed Section from CLB.
iii. Detail of management at the time previous renewal and present renewal.
iv. Request for change of management on letter head of the firm.
v. Prescribed fee of Rs.50,000/- for change of management.
vi. Duly attested Form-C from Registrar of firms, revised partnership deed and CNIC copies of all partners.

Moreover, the firm has submitted an undertaking stating that Ch. Pervaiz Ahmed is sole proprietor of the firm but their regulatory representative submitted wrong documents of partnership deed.

A letter of Personal hearing has been issued on 17th August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Choudhary Pervaiz Ahmad, CEO of the firm and Mr. Nadeem Ahmad, Manager HR & Regulatory appeared before the Board. He contended that he had submitted that partnership deed has been submitted inadvertently and emphasized that he is sole proprietor of the firm. On quarry, he replied that partnership deed was prepared for other purposes which did not disclose. He further stated that matter has been taken up with Budget and Accounts for issuance of nothing due certificate as soon as certificate is issued he would submit the Secretariat. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000551(by way of formulation) of M/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat 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 till completion of codal formalities/submission of required documents. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

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

The firm submitted all deficient documents and application for renewal of DML is complete.

Proceedings and Decision of the Central Licensing Board in 283rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the decision of the Board for suspension of Drug Manufacturing License No.000551 (Formulation)ofM/s Ipram International, Plot No. 26, Street SS-3, National Industrial Zone, Rawat.

CASE NO. 36. NON-COMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S MOON PHARMACEUTICALS, PLOT NO. 5, SS-4 ROAD, NATIONAL INDUSTRIAL ZONE, RAWAT UNDER DML NO. 000833 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> "(14) The Licensee shall by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above-mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing License may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Moon Pharmaceuticals, Plot No. 5, SS-4 Road, National Industrial Zone, Rawat on23rd September, 2020 as the firm has never submitted CRF. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

Mr. Sayed Hussain on behalf of the firm appeared before the board and contended that compliance is submitted before the Budget & Account, Division, DRAP Islamabad. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

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

A letter of Personal hearing has been issued on 17th August, 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Sayed Hussain, Accounts Officer, appeared before the Board. He argued that due to Covid-19 they could not pursue the case, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000833(by way of formulation) of M/s Moon Pharmaceuticals, Plot No. 5, SS-4 Road, National Industrial Zone, Rawat 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 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

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

Letter of suspension of DML was issued to the firm on 11th October, 2021.

Budget & Accounts Division, DRAP, Islamabad has issued Nothing Due Certificate valid upto 31-12-2021.

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the suspension of the Drug Manufacturing License No.000833 (Formulation) of M/s Moon Pharmaceuticals, Plot No. 5, SS-4 Road, National Industrial Zone, Rawat for further period and firm is allowed to resume the production.

CASE NO. 37 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000667(FORMULATION) OF M/S AXIS PHARMACEUTICALS, FAISALABAD.

M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad. DML No. 000667 (Formulation). **Period**: 10-06-2019 to 09-06-2024.	09-06-2020	**Good**	1. Dr Munawar Hayat, Chief Drugs Controller, Punjab 2. Dr. Farzana Chaudhary, Expert Member. 3. Mr Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
Recommendations of the panel: - "Based on the areas inspected, the technical people met and the documents reviewed and considering the findings of the inspection the panel verified a satisfactorily maintained facility in respect of Drug Manufacturing License (DML) and conformance of requirement of DML as per Drug (Licensing , Registering and Advertising) Rules, 1976 and capacity & capability of the firm in respect of manufacturing and quality control of all registered products and			

approved sections and newly applied section as per following list.

1. Tablet Section (General).
2. Capsule Section (General).
3. Dry Powder Sachet Section (General).
4. Oral Liquid Section (General).
5. Topical Semisolid (Cream / Ointment / Gel) Section (New section).

The Panel of Inspectors **recommends** the renewal of Drug Manufacturing License No. 000667and grant of new manufacturing section in favour of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad".

Decision of the Central Licensing Board in 275th meeting:

The Board considered and approved the grant of renewal of Drug Manufacturing License in the name of M/s Axis Pharmaceuticals (Pvt) Ltd, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad on the recommendations of the panel of experts for the period commencing on 10-06-2019 and ending on 09-06-2024 for the following sections:

1. Tablet Section (General).
2. Capsule Section (General).
3. Dry Powder Sachet Section (General).
4. Oral Liquid Section (General).

It is submitted that title of the firm was inadvertently written as "M/s Axis Pharmaceuticals (Pvt) Ltd" instead of correct title i.e, "M/s Axis Pharmaceuticals".

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation allowed the correction in title of the firm from M/s Axis Pharmaceuticals (Pvt) Ltd 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabadto M/s Axis Pharmaceuticals, 3-B, Value Additional City, 1.5-Km, Khurrianwala-Sahianwala Road, Faisalabad.

CASE NO.38. APPROVAL OF PRODUCTION INCHARGE OF M/S MEDLEY PHARMACEUTICAL, WAH CANTT.

M/s Medley Pharmaceutical, Plot No. 41/A, Punjab Small Industrial Estate, JhangBahtar Road, Wah Cantt had applied for approval of Production Incharge on 06-08-2018.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on13-09-2018 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Duly attested experience certificates as under Drugs (L, R & A) rules, 1976.
ii. Resignation of appointee from previous firm (Shawan Pharmaceuticals).

The firm replied to this letter on 12-03-2019 but application was incomplete and reminder letter was issued on 12-04-2019 to the firm for submission of following documents:

i. Duly attested experience certificates as under Drugs (L, R & A) rules, 1976.

ii. Resignation of appointee from previous firm (Shawan Pharmaceuticals).

Reply to reminder was received on 23-04-2019but application is still incomplete with following documents being deficient:

i. Duly attested experience certificates as under Drugs (L, R & A) rules, 1976.
ii. Resignation of appointee from previous firm (Shawan Pharmaceuticals).

Proceedings and Decision by the Central Licensing Board in 282nd 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 License No 000237 (by way of formulation) ofM/s Medley Pharmaceutical,Plot No. 41/A, Punjab Small Industrial Estate, JhangBahtar Road, Wah Cantt 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 was issued to M/s Medley Pharmaceutical, Plot No. 41/A, Punjab Small Industrial Estate, JhangBahtar Road, Wah Cantt on 18th October, 2021.

The firm replied to Show Cause Notice and submitted all deficient documents. Now, application for approval of Production Incharge is complete.

Proceedings and Decision of the Central Licensing Board in 283rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000237 (Formulation)ofM/s Medley Pharmaceutical, Plot No. 41/A, Punjab Small Industrial Estate, Jhang Bahtar Road, Wah Cant.

CASE NO. 39 APPROVAL OF QUALITY CONTROL INCHARGE & PRODUCTION INCHARGE OF M/S MEDPHARM RESEARCH LAB, LAHORE.

M/s Med Pharm Research Lab, 28-Km, Ferozepur Road, Lahore had applied for approval of Quality Control Incharge on 07-02-2020.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 02-03-2020 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Appointment letter.
ii. Job acceptance letter by the appointee.
iii. Copy of academic degree of M.Sc. Chemistry.
iv. Resignation/retirement of earlier Quality Control Incharge.
v. Document should be duly attested.

The firm did not reply and reminder letter was issued on 19-05-2021 to the firm for submission of following documents:

i. Appointment letter.
ii. Job acceptance letter by the appointee.
iii. Copy of academic degree of M.Sc. Chemistry.

iv. Resignation/retirement of earlier Quality Control Incharge.
v. **Document should be duly attested.**

Reply to reminder was received on 21-06-2021 but application is still incomplete with following documents being deficient:

i. Appointment letter.
ii. Job acceptance letter by the appointee.
iii. Copy of academic degree of M.Sc. Chemistry.
iv. Resignation/retirement of earlier Quality Control Incharge.
v. **Document should be duly attested.**

PRODUCTION INCHARGE:

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 23-01-2020 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Resignation / retirement of earlier Production Incharge.
ii. Resignation or termination letter of Production Incharge from the previous firm / promotion letter / transfer letter from the same firm.
iii. All Documents should be duly attested.

The firm did not reply and reminder letter was issued on 27-07-2021 to the firm for submission of following documents:

i. Resignation / retirement of earlier Production Incharge.
ii. Resignation or termination letter of Production Incharge from the previous firm / promotion letter / transfer letter from the same firm.
iii. All Documents should be duly attested.

The firm did not reply and application is still incomplete with following documents being deficient:

i. Resignation / retirement of earlier Production Incharge.
ii. Resignation or termination letter of Production Incharge from the previous firm / promotion letter / transfer letter from the same firm.
iii. All Documents should be duly attested.

Proceedings and Decision by the Central Licensing Board in 282nd 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 License No 000878 (by way of formulation) of M/s Med Pharm Research Lab, 28-Km, Ferozepur 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 was issued to M/s Med Pharm Research Lab, 28-Km, Ferozepur Road, Lahore on 28th September, 2021.

The firm replied to Show Cause Notice and submitted all deficient documents. Now, application for approval of Production Incharge & Quality Control Incharge is complete.

Proceedings and Decision of the Central Licensing Board in 283rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000878 (Formulation)ofM/s Med Pharm Research Lab, 28-Km, Ferozepur Road, Lahore.

CASE NO. 40 APPROVAL OF PRODUCTION INCHARGE OF M/S IQRA PHARMACEUTICALS, RAWAT.

M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, RCCI Industrial Estate, Rawat filed application of Mr. Arif Ullah Khan for approval as Production Incharge on 01-10-2020.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 13-10-2020 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Deposit Prescribed fee of Rs. 5000/- and original fee challan must be retained by STO, DRAP.
ii. CNIC copy of appointee.
iii. Registration certificate from Pharmacy Council.
iv. Resignation/ retirement of earlier Production Incharge.
v. Documents should be duly attested.

The firm did not reply to this letter and filed new application of Mr. Jamshaid Ali as Production Incharge on 05-07-2021. Application was evaluated and following deficient documents in the application were conveyed to the firm via reminder dated 10-08-2021:

i. Duly attested resignation of earlier Production Incharge and proposed Production Incharge from previous firm.

Reply to reminder was received on 01-09-2021 but application was still incomplete with following documents being deficient:

i. Duly attested resignation of earlier Production Incharge and proposed Production Incharge from previous firm.

Final Reminder dated 28-09-2021 was issued to the firm for completion of application. However, the firm has not replied and application is incomplete with following documents being deficient:

i. Duly attested resignation of earlier Production Incharge and proposed Production Incharge from previous firm.

Proceedings and Decision by the Central Licensing Board in 283rd 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 License No 000899(by way of formulation) of M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, RCCI Industrial Estate, Rawat may not be suspended or cancelled by Central Licensing Board .

CASE NO. 41 APPROVAL OF QUALITY CONTROL INCHARGE OF M/S BIO MARK PHARMACEUTICALS, LAHORE.

M/s Bio Mark Pharmaceuticals, Plot No. 527, Sunder IndustrialEstate, Lahore filed application for approval of Quality Control Incharge on 17-05-2021.

The application was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 11-06-2021 under Rule 16 of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Duly attested appointment letter, job acceptance letter & resignation of proposed Q.C Incharge from previous firm.

ii. Duly attested resignation of earlier Q.C Incharge.

iii. Duly notarized undertaking as whole-time employee on stamp paper duly signed by appointee & management.

The firm did not reply to this letter and filed new application of Ms. Rehana Kausar on 07-07-2021. Application was evaluated and following deficient documents in the application were conveyed to the firm via reminder dated 10-08-2021:

i. Complete set of duly attested documents (as per checklist, except undertaking) of proposed Q.C Incharge.

Reply to reminder was received on 13-09-2021 but application is still incomplete with following documents being deficient:

i. Appointment letter.

ii. Job acceptance letter.

iii. Resignation of earlier Q.C Incharge.

Documents should be duly attested.

Proceedings and Decision by the Central Licensing Board in 283rd 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 License No 000863 by way of Formulation of M/s Bio Mark Pharmaceuticals, Plot No. 527, Sunder Industrial Estate, Lahore may not be suspended or cancelled by Central Licensing Board .

CASE NO. 42 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S HANSEL PHARMACEUTICALS (PVT) LTD, LAHORE.

M/s Hansel Pharmaceuticals (Pvt) Ltd, Plot No.2, Pharma City, 30-Km, Multan Road, Lahore had applied for renewal of DML No. 000581 by way of Formulation for the period of 24-06-2020 to 23-06-2025 on 11-06-2020.

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 17-08-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Detail of machinery for Quality Control Laboratory.
iii. Latest certified true copy of Form-29 duly attested by SECP (original).
iv. Duly attested CNIC copies of all Directors.
v. Detail of management at the time of previous renewal of DML and at present, if any change, apply for change of management.

The firm replied to this letter on 11-09-2020 but application was incomplete and reminder letter was issued on 08-10-2020 to the firm for submission of following documents:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Latest certified true copy of Form-29 duly attested by SECP mentioning detail of all Directors.

The firm did not reply and application for renewal of DML is incomplete with following documents being deficient:

i. Updated NDC regarding CRF from STO (R&D) DRAP, Islamabad.
ii. Latest certified true copy of Form-29 duly attested by SECP mentioning detail of all Directors.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

Certified true copy of Form-29 and a copy of case in Honorable Lahore High Court against differential amount under Central Research Fund (CRF) was received in Licensing division prior to meeting. The Board considering the facts on the record and after thread bare deliberation decided to defer the case till decision by the Court.

CASE NO. 43 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BASEL PHARMACEUTICALS, MULTAN.

M/s Basel Pharmaceuticals, 227- Phase-II, Multan Industrial Estate, Multan had applied for renewal of DML No. 000726 by way of Formulation for the period of 21-06-2021 to 20-06-2026 on 16-06-2021.

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 08-07-2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.
iii. Legal status of the firm, if sole proprietor submit undertaking as whole proprietor on stamp paper.
iv. Duly attested CNIC of owner.
v. Section approval letters approved by CLB, if not available, submit layout plan apply for regularization.
vi. Name, class and dosage form of drugs being manufactured.
vii. Name and qualification of technical staff.
viii. Approval letters of Production Incharge and Quality Control Incharge.

The firm did not reply and reminder was issued on 28-09-2021 to the firm for submission of following documents:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management.
iii. Legal status of the firm, if sole proprietor, submit undertaking as whole proprietor on stamp paper.
iv. Duly attested CNIC of owner.
v. Section approval letters approved by CLB, if not available, submit layout plan apply for regularization.
vi. Name, class and dosage form of drugs being manufactured.
vii. Name and qualification of technical staff.
viii. Approval letters of Production Incharge and Quality Control Incharge.

The firm **did not reply** and application for renewal of DML is still incomplete.

In the meanwhile, Mr. Abdul Rashid Shaikh, FID, DRAP, Lahore has reported that he visited the premises of the firm on 30-09-2021 to check status of the firm on second time. Firm was found closed, no any activity was observed since long. Presently also found the premises closed and the building seems non-functional and closed since long and was in deplorable condition, no any person was present. In these conditions, it is not possible to maintain the conditions of manufacturing of Pharmaceuticals products (conditions of DML). So, he has suggested that personal hearing may be given to the management of the firm in this regard and then the DML may be cancel after codal formalities as per Drugs Act, 1976 and DRAP Act, 2012.

Proceedings and Decision by the Central Licensing Board in 283rd 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 DML No. 000726 by way of Formulation of M/s Basel Pharmaceuticals, 227- Phase-II, Multan Industrial Estate, Multan may not be suspended or cancelled by the Central Licensing Board.

CASE NO. 44. CHANGE OF MANAGEMENT OF M/S GREATER PHARMA, RAWAT.

The Central Licensing Board in its 279th Meeting held on 18th February, 2021 considered and endorsed the change of management of M/s Greater Pharma, Plot No. 35, Street No. SS-3, National Industrial Zone, RCCI, Rawat under DML No. 000896 by way of Formulation as under:

Previous Management	New Management as per Affidavit
1. Mr. Abdul Wadood Khan S/o Masood Khan CNIC No. 17301-0355625-1.	1. Mr. Muhammad Dawood S/o Haji Momeen CNIC No. 54201-2468331-5.

Accordingly**,** Decision of the Board was conveyed to the firm on 30th March, 2021.

Then, letters/complaints received from **Mr. Abdul Wadood Khan** which are reproduced as under:

"I am a sole owner of the factory "Greater Pharma" situated at Plot No.35, Street SS-3, Industrial Zone, Rawat Islamabad and a license has been issued by your worthy Office (copy Attached). Sir unluckily I was suffering from serious injuries and mental disability and was also in comma for long period due to road accident on 14-08-2020. When I came to normal life, surprisingly it reveals that my factory has been fraudantly transferred to Mr. M. Dawood via fake Deed Dated 15-01-2021 by my nearest relative namely Sajid Masood S/o Manzoor and they have illegally occupied my site factory and it's all machinery and items. Sir Mr. M. Dawood has been manufacturing the medicines/items without having any authority which is highly illegal and it may damage the public at large, thus it required attention of your worthy office. Furthermore, I did not attend any board meeting which is essential for granting permission or authority for manufacturing. It is therefore, requested, that stern action may kindly be taken against Muhammad Dawood or any other person if involved and manufacturing may discontinue in the interest of public at large."

&

"I have an accident on motorway 14th August 2020 along with wife, after accident I was admitted in RMI and North West hospital Hayatabad Peshawar. I was suffering, in comma disease and mentally abnormal. That time I was treated with Prof Tariq Hashim and Khalid mufti. All hospital evidence records with me in hospital.

1. *1 have submitted complaint in DRAP Islamabad two weeks ago. But I am waiting reply from DRAP.*
2. *I have already submitted complaint in Chairman NAB Islamabad for legal action.*
3. *My factory was rented to Mr. Daud through fraud agreement.*
4. *The Meezan Bank Hayatabad Peshawar through evidence Mr. Sajid Masood received all payment, ID CARD copy attaches in bank record.*
5. *The DRAP has taken decision without my presence, I have no physical visit to DRAP Islamabad, according to 1976 Rule regulation agreement is against rules, regulation and Director (Licensing) according to DRAP Rule and regulation agreement was not follow through DRAP Rules and regulation."*

Complaint of Mr. Abdul Wadood Khan was forwarded to the firm for their comments. **Reply of the firm** is as under:

"With ref of your letter dated 10/sep/2021, subjected justification and comments on complain of Mr. Abdul wadood. We here by justify the complaint as follows. I Muhammad Dawood CNIC NO 54201-2468331-5 (CEO) Greater pharmaceuticals Pvt Ltd plot 35, Street SS-3 Rawat Industrial zone Islamabd,

COMMENTS OF C.E.O

Abdul Wadood's complain is based on absolutely fake statement, he was in his own senses as per described with evidences as follow, his fake allegations are only based on malicious, he is just miss guiding the DRAP and doing a fraud complain and as well damaging the time and goodwill of DRAP,we have submitted all the required documents in DRAP, after the NOC of Abdul Wadood and many more documents DRAP have issued the change of management letter, on the bases of DRAP's said letter we applied for new sections approval, after the receiving of new approved map from DRAP we started construction, we have invested a huge amount on new sections construction, machinery HVAC system, equipments, market and many more, According to his statement majorly he have dispute with his own family and he is mixing up the dispute with our deal and confusing the DRAP,

FURTHER JUSTIFICATIONS WITH EVIDENCES AND WITNESSES

Mr. Abdul Wadood's accident and discharging date. According to his statement he had accident on 17 Aug 2020 as per his hospital reports, he was hospitalized for 15 days only, from dated 17 Aug 2020 to 2 Sep 2020 and he was discharged on 2 September 2020, he was ok and his own senses.

SALE AND PURCHASE

After 6 months of his accident Mr Abdul Wodood visited the Greater pharma to us, he was absolutely in his senses, then we matured the deal (agreement attached) and Agreement was signed personally by Mr Abdul. Wadood (pictures are attached for evidence) in the presence of following witnesses. Personal appearance of all following witnesses is absolutely possible if DRAP required.

1. *Mr. Naeem shah (Ex owner of Goodman Lab rawat)*
2. *Mr. Masood khan (Father of Abdul Wodood khan)*
3. *Mr. Waheedullah (Brother of Abdul Wadood)*
4. *Mr. Sajid Masood s/o Manzoor khan*
5. *Mr. Huzaifawodood (son of Abdul wodood khan)*
6. *Mr. Masood s/o (M. Dawood)*

Payments to Mr. Abdul wadood

We have paid the payment as per attached agreement to Mr. Abdul wadood by cheqs (cheq copies are attached) and Mr. Wodood personally received all the cheq (signed receipts are available) with his named title (Abdul Wadood khan) and he collected all the payment from banks. (Bank record is attached).

We are requesting to DRAP kindly do not entertain such kind of nonsense complains which have no legal documents, proofs and any evidences. And this is only based on malicious."

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to both parties in next meeting of the Board.

CASE NO. 45. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FRESH PHARMACEUTICAL, RAWAT.

M/s Fresh Pharmaceutical, Plot No.7, Street No. S-6, National Industrial Zone, Rawat had applied for renewal of DML No. 000827 by way of Formulation for the period of 07-10-2020 to 06-10-2025 on 08-10-2020.

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 29-10-2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976: -

i. Late Fee surcharge of Rs. 10,000/- as the application is two (02) days late.
ii. Properly filled, signed & stamped Form-1A (as per format) along with its all annexures.
iii. Detail of management, if any change, apply for change of management.
iv. Section approval letters of all sections approved by Central Licensing Board.
v. Approval letters of Production Incharge & Quality Control Incharge.
vi. Nothing due certificate regarding CRF from STO (Updated).
vii. Duly attested CNIC copies of all partners.
viii. Duly attested partnership deed.

The firm replied to this letter on 13-11-2020 but application was incomplete and reminder letter was issued on 04-01,2021 to the firm for submission of following documents:

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management along with proper application and prescribed fee.
iii. Legal status of the firm, if sole proprietor, Undertaking on stamp paper, if partnership firm, duly attested copy of partnership deed.
iv. Duly attested CNIC copies of owner/ partners.
v. Duly attested appointment letter, CNIC copy of appointee & Undertaking as whole-time employee on stamp paper.

Reply to reminder was received on 16-03-2021 and application for renewal of DML is still incomplete with following documents being deficient.

i. Nothing due certificate regarding CRF from STO (Updated).
ii. Detail of management, if any change, apply for change of management along with proper application and prescribed fee.
iii. Legal status of the firm, if sole proprietor, Undertaking on stamp paper, if partnership firm, duly attested copy of partnership deed.
iv. Duly attested CNIC copies of owner/ partners.
v. Duly attested CNIC copy of appointee.

Proceedings and Decision by the Central Licensing Board in 282nd 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, Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000827 (by way of formulation) of M/s Fresh Pharmaceutical, Plot No.7, Street No. S-6, National Industrial Zone, Rawat 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 was issued to M/s Fresh Pharmaceutical, Plot No.7, Street No. S-6, National Industrial Zone, Rawat on 28th September, 2021.

The firm replied to Show Cause Notice and submitted all deficient documents. Now, application for renewal of DML is complete.

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease theoperation of show cause notice in respect of Drug Manufacturing License No.000827 (Formulation) ofM/s Fresh Pharmaceutical, Plot No.7, Street No. S-6, National Industrial Zone, Rawat.

CASE NO. 46 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000727 (FORMULATION) OF M/S JASONS PHARMACEUTICALS, RAWAT.

Drug Manufacturing License No. 000727 (Formulation) was issued to M/s Jasons Pharmaceuticals, Plot No. 26, Street No. SS-2, National Industrial Zone, Rawat. 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. 75,00/- 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 of 22-06-2021 to 21-06-2026 has not been received till date.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to M/s Jasons Pharmaceuticals, Plot No. 26, Street No. SS-2, National Industrial Zone, Rawat.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to M/s Jasons Pharmaceuticals, Plot No. 26, Street No. SS-2, National Industrial Zone, Rawat.

CASE NO.47 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000384 (FORMULATION) OF M/S CEICIL LABORATORIES (PVT) LTD, LAHORE.

Drug Manufacturing License No. 000384 (Formulation) was issued to M/s Ceicil Laboratories (Pvt) Ltd, 21-Km, Ferozepur Road, Doolu Khurd, 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. 75,00/- 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 of 16-04-2021 to 15-04-2026 has not been received till date.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to M/s Ceicil Laboratories (Pvt) Ltd, 21-Km, Ferozepur Road, Doolu Khurd, Lahore.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to M/s Ceicil Laboratories (Pvt) Ltd, 21-Km, Ferozepur Road, Doolu Khurd, Lahore.

Case No. 49 **REQUEST FOR CHANGE OF TITLE OF SECTION OF M/S JASKAN PHARMACEUTICALS (PVT) LTD, LAHORE UNDER LICENSE NO. 000796 (FORMULATION).**

The Central licensing Board in its 279th meeting held on 18th February, 2021 approved Injectable (Vial) (General) section. Now,M/s Jaskan Pharmaceuticals (Pvt) Ltd, Lahore has requested to change the title of section to Injectable (Vial) (General) section **(LVP)** as the filling, capping & sealing machines installed in this section are designed to manufacture Large Volume Parenteral (LVP).

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation allowed the correction in title of Injectable (Vial) (General) section (LVP).

CASE NO. 50 **NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s AL-KEMY PHARMACEUTICALS, HYDERABAD UNDER DRUG MANUFACTURING LICENSE NO. 000131 (FORMULATION).**

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under: -

> **Decision by the Central Licensing Board in 269th meeting:**
>
> "The Board considered the case and decided to serve show cause notice to the above-mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing License may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Al-KemyPharmaceuticals Hyderabadon23rd September, 2020 but firm has not submitted the CRF since year 2014. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person appeared before the board on behalf of the firm. The Board after perusal of record and facts decided to defer the case for giving final opportunity to the firm.

NDC of CRF Updated is still not received from the firm.
The firm is also called for Personal Hearing vide letter dated 17th August 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Faraz Ahmed, Managing Director appeared before the Board. He argued that he had submitted required documents with Budget and Accounts Division, therefore, they may be given time for submission of required document. The Board after hearing the representative of the firm and considering case background decided to suspend the Drug Manufacturing License 000131 (by way of formulation) ofM/s Al-Kemy Pharmaceuticals Hyderabad 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 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Before issuance of letter/decision of the CLB, Updated NDC of CRF was received from the Budget & Accounts Division, DRAP Islamabad, therefore, orders of the suspension were not issued.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000131 (Formulation)of M/s Al-Kemy Pharmaceuticals Hyderabad.

CASE NO. 51. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/s BLISS INDUSTRIES (PVT) LTD, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000086 (FORMULATION).

The Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> *"(14) The Licensee shall by the 30th June and the 31st December each year, Whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."*

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit. The decision of the Central Licensing Board is as under:-

Decision by the Central Licensing Board in 269th meeting:

"The Board considered the case and decided to serve show cause notice to the above mentioned firms under Section 41 of the Drugs Act, 1976 red with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their Drug manufacturing Licence may not be suspended till settlement of Central Research Fund".

. In the light of Central Licensing Board's decision a Show Cause Notice was issued to M/s Bliss Industries (Pvt) Ltd, Karachi on 30th September, 2020 but firm has not submitted CRF since 2013. Accordingly, a personal hearing letter was issued to the firm on 13th April, 2021.

Proceedings and Decision of Central Licensing Board in 280th meeting.

No person on behalf of the firm appeared before the board. The Board after perusal of record and facts decided to defer the case till next meeting of the board for getting update from Budget and Accounts Division.

NDC of CRF is still not received from the firm .

The firm is also called for Personal Hearing vide letter dated 17th August 2021.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

No person appeared on behalf of the company. The Board after considering case background decided to suspend the Drug Manufacturing License 000086(by way of formulation) ofM/s Bliss Industries (Pvt) Ltd, Karachi 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 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

The suspension orders were issued to the firm in compliance to the decision of the CLB. Afterwards, updated NDC of CRF was received from the Budget &Account Division DRAP Islamabad and accordingly orders of revocation of suspension and resumption of production were issued to the firm.

Proceedings and Decision by the Central Licensing Board in 283rd meeting:

The Board considered the facts on the record and ratified the decision of Secretary CLB.

CASE NO. 52. RENEWAL OF DRUG MANUFACTURING LICENCE No. 000025 (FORMULATION) BY M/S PFIZER PAKISTAN LTD, KARACHI.

M/s Pfizer Pakistan Limited, Plot No. B-2, S.I.T.E., Karachi, has applied for renewal of DML No. 000025 by way of formulation for the period of 22-06-2020 to 21-06-2025 on 18th June 2020.

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 7thMay, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Application on Prescribed From-1A.
(ii) Original & Updated certified true copy of Form-29 & From-A issued from SECP along with attested CNIC copies of all directors.
(iii) Prescribed fee for change of management.
(iv) Updated NDC of CRF.
(v) Name and approval letter of Production In charge or if not available then submit complete set of attested documents (as per checklist) for approval.
(vi) Attested section wise machinery for QC Laboratory and of Production.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 18th December, 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Original & Updated certified true copy of Form-29 & From-A issued from SECP along with attested CNIC copies of all directors.

The firm has submitted their reply which is evaluated and application for renewal of DML is still found deficient of following shortcomings / deficiencies: -

i. Updated Certified true of Form-29 & Form-A issued by the SECP as the firm has submitted Form-29 issued by the SECP on which the stamp stated:

"**Certified true copy of the document as filed by the company However this office does not take any responsibility for correctness of the contents of the documents**."

Proceedings and Decision by the Central Licensing Board in 282nd 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 , and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000025 (by way of formulation) of M/s Pfizer Pakistan Limited, Plot No. B-2, S.I.T.E., Karachi may not be suspended or cancelled by Central Licensing Board or application for renewal of DML may not be rejected under Rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

The firm submitted the Original Form-29 & Form-A of SECP before the issuance of show cause notice, therefore, show cause notice was not issued to the firm.

Proceedings and Decision of the Central Licensing Board in 283rd meeting

The Board considering the facts on the record and after thread bare deliberation decided to cease the operation of show cause notice in respect of Drug Manufacturing License No.000025 (Formulation)ofM/s Pfizer Pakistan Limited, Plot No. B-2, S.I.T.E., Karachi.

Case No. 53 REGULARIZATION OF LAYOUT PLAN OF M/S KARACHI CHEMICAL INDUSTREIES (PVT) LIMITED, F-25, S.I.T.E KARACHI UNDER DML NO. 000048 (FORMULATION).

M/s Karachi Chemical Industries (Pvt) Ltd,F/25, S.I.T.E Karachi. under DML No.000048 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. 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) CDI, Govt of Sindh.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mr. Krishan Das, AD DRAP, Karachi

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

Recommendations of the panel:

*"*In compliance to the instructions contained in DRAP Islamabad letter No.F.2-25/84-Lic (Vol-I) dated 06 September, 2021, a detailed panel inspection of Ms. Karachi Chemical Industries

(Private) Limited, F/25, Estate Avenue, SITE, Karachi was carried out on 12/10/2021 under the given TORs. Mr. Saboor Ahmed MD of the firm, Hafiz Ghulam Haider Production Manager and other technical persons from respective departments assisted during the course of inspection. Followings are detailed observations and recommendations of the visit:

1. The firm was found built as per approved design, wherein an appropriate flow of men and materials is given. The premises was found suitably designed to minimize the chances of contamination and cross contamination into the products. Dedicated sections of penicillin, cephalosporin and cream ointment are kept well segregated with separate entries, separate machines and separate HVAC system. A separate dispensing booth has also been provided for steroidal cream/ointment section as required under policy.

2. An appropriate level of sanitation and worker hygiene was noted amid dynamic working conditions, along with respective log books and necessary working SOPs found in place and practiced accordingly. Workers and other technical staff were adequately trained with required qualification and experience.

3. QC lab was satisfactorily equipped and necessary SOPs and other documents were also in place. QA was noted engaged in IP testing, line clearance, validation, calibration, training and other necessary activities for better safety of products well in line to approved SOPs.

4. Well defined and spacious stores are also given and found appropriate level of practices in stores. All utilities are also suitably provided and monitored as per SOPs in place. HVAC was seen in place in all sections and found well operated and monitored. Documents in this regard like air balancing, monitoring devices and relevant documents were well in place.

Based on the above stated observation the panel unanimously recommends the grant of renewal of DML No. 000048 by way of formulation and regularization of existing approved lay out plan for the following sections for the next five years:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	Warehouse (General)	*2.*	Quality Control Laboratory
3.	Tablet (General)	*4.*	Capsule (General)
5.	Liquid External Preparation	*6.*	Ointment (General)
7.	Liquid (General)	*8.*	Sachet Section (General)
9.	Dry Powder Suspension (Penicillin)	*10.*	Capsule (Penicillin)
11.	Warehouse (Penicillin)	*12.*	Dry Powder Suspension (Cephalosporin)
13.	Capsule (Cephalosporin)	*14.*	Warehouse (Cephalosporin)
15.	Repacking Section	*16.*	**********

Proceedings and Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the regularization of layout plan in the name of M/s Karachi Chemical Industries (Pvt) Ltd, F/25, S.I.T.E Karachi under DML No.000048 (Formulation) on the recommendation of panel of experts for the following sections: -

Sr #	Name of Section	Sr. #	Name of Section
1.	Warehouse (General)	2.	Quality Control Laboratory
3.	Tablet (General)	4.	Capsule (General)
5.	Liquid External Preparation	6.	Ointment (General)
7.	Liquid (General)	8.	Sachet Section (General)
9.	Dry Powder Suspension (Penicillin)	10.	Capsule (Penicillin)
11.	Warehouse (Penicillin)	12.	Dry Powder Suspension (Cephalosporin)
13.	Capsule (Cephalosporin)	14.	Warehouse (Cephalosporin)
15.	Repacking Section	16.	**********

Case No. 54 REGULARIZATION OF LAYOUT PLAN OF M/S ZAFA PHARMACEUTICAL LABORAOTIRES(PVT) LIMITED, KARACHI UNDER DML NO. 000040 (FORMULATION).

M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi. under DML No.000040 (Formulation) had applied for regularization of layout plan of running facility for their existing sections. 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) CDI, Govt of Sindh.
2) Federal Inspector of Drugs, DRAP, Karachi.
3) Mst. Sidra Yasmeen, AD DRAP, Karachi

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

Recommendations of the panel:

"In compliance to instructions contained in DRAP Islamabad letter No.F.2-14/2004-Lic (Vol-II) dated 23 June, 2021, the constituted panel under the given TORs inspected in details the entire premises of M/s. Zafa Pharmaceutical Laboratories, L-4/1, A&B, Block-21, Federal B Industrial Area, Karachi on 23/09/2021. The panel found the facility purposefully designed as per approved lay out plan and capable enough to

provide better cleaning, maintaining appropriate sanitization. During the detail inspection the panel further observed good practices in production, QC lab and in stores with respect to GMP documents. An appropriate level of QA System was seen in place. The firm has enough technical persons in each section. HVAC system was seen in good working conditions and validated. Overall an appropriate level of GMP compliance was noted in place. Based on the stated facts and the attitude of the firm towards continuous improvements, the panel unanimously recommends the grant of renewal of DML No.000040 for the following sections along with Regularization of amendments undertaken by them as per approved design :

Sr. No	Name of Sections	Sr. No	Name of Sections
Regularization/Renewal of following sections			
Building - I			
i.	Tablet (General)- I	ii.	e Ophthalmic Drops (General)
iii.	Liquid Syrup (General)	iv.	Capsule (General)
v.	Dry Powder Suspension (General)	vi.	Cream/Ointment (Steroid)
vii.	nal Preparation (Dusting Powder)	viii.	t (General)- II
ix.	Liquid Injection (General)	x.	Nasal Drops (General)
Building II			
i.	Liquid Ampoule SVP (General).	ii.	Aerosol Section.
iii.	Cream/Ointment (General)	iv.	Tablet Section (General) – III.
v.	Liquid Ampoule (General)- I	vi.	Liquid Ampoule (General)- II
vii.	Sachet (General)	viii.	**********

Proceedings and Decision of the Central Licensing Board in 283rd meeting

The Board considered and approved the regularization of layout plan in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, L-4/1, A&B, Block 21, Federal B Industrial Area, Karachi under DML No.000040 (Formulation) on the recommendation of panel of experts for the following sections: -

Sr. No	Name of Sections	Sr. No	Name of Sections
Regularization/Renewal of following sections			
Building - I			
i.	Tablet (General)- I	ii.	e Ophthalmic Drops (General)
iii.	Liquid Syrup (General)	iv.	Capsule (General)
v.	Dry Powder Suspension (General)	vi.	Cream/Ointment (Steroid)
vii.	nal Preparation (Dusting Powder)	viii.	t (General)- II
ix.	Liquid Injection (General)	x.	Nasal Drops (General)
Building II			

i.	Liquid Ampoule SVP (General).	ii.	Aerosol Section.
iii.	Cream/Ointment (General)	iv.	Tablet Section (General) – III.
v.	Liquid Ampoule (General)- I	vi.	Liquid Ampoule (General)- II
vii.	Sachet (General)	viii.	**********

CASE NO. 55 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000033(FORMULATION) OF M/s DELUX CHEMICAL INDUSTRIES KARACHI.

M/s Delux Chemical Industries Karachi, Plot No. LT-26/A-1, Landhi Industrial Area, Karachi, has applied for renewal of DML No. 000033 by way of formulation for the period of 09-01-2021 to 08-01-2026.

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 29th January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Detail/Names of all licensed sections on firm's letter head along with approval letters of all sections issued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.
(ii) Undertaking on stamp paper regarding sole proprietorship along with attested CNIC copy of Sole Proprietor Mr. Nazeef Ch.
(iii) Approval letter of Production in charge Mr. Amir or if not available then submit complete set of attested documents (as per checklist) for approval of production in charge.
(iv) Updated NDC of CRF.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 13th April 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976.

(i) Detail/Names of all licensed sections on firm's letter head along with approval letters of all sections issued from the CLB or if not available then submit layout plan for regularization of manufacturing facility.
(ii) Duly signed Undertaking on stamp of sole proprietorship by Sole Proprietor Mr. Nazeef Ch.
(iii) Clarification regarding name of Production in charge whether (mentioned as production in charge on Form-1A) or Mr. Aftab (which is approved Production in charge) on DML No.00033(Formulation) is currently working as production in charge
(iv) Updated NDC of CRF.

The firm has submitted their reply along with layout plan for regularization which is evaluated and application for renewal of DML is still found deficient of following document:

i. The firm does not possess approval letter of licensed sections and has submitted layout plan for regularization without Prescribed fee and in the layout plan neither the sections are demarcated / specified nor the man & material flow is mentioned with separate colored arrows.

Proceedings and Decision by the Central Licensing Board in 283rd 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000033 by way of formulation of M/s Delux Chemical Industries Karachi, Plot No. LT-26/A-1, Landhi Industrial Area, Karachi may not be suspended or cancelled by the Central Licensing Board.

CASE NO. 55 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000151(FORMULATION) OF M/s EFROZE CHEMICAL INDUSTRIES (PVT) LTD, KARACHI.

1.	M/s Efroze Chemical Industries (Pvt) Ltd. 146/23, Korangi Industrial Area, Karachi. DML No. 000151 (Formulation) Period: Commencing on 08-04-2020 & ending on 07-04-2025.	17-03-2021	Good	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Affan Ali, AD CDL, DRAP, Karachi.

Recommendations of the panel:

"M/s Efroze Chemical Industries (Pvt) Ltd, situated at plot No. 146/23, Korangi Industrial Area, Karachi-Pakistan was inspected in detail on 17-03-2021 in compliance to the directions contained in DRAP, Islamabad letter No. F. 2-11/2000-Lic(Vol-V) dated 20th January, 2021 in connection with renewal of DML by way of formulation.

The panel inspected the firm in detail including all the manufacturing sections, stores and AC Lab and observed that the firm is built as per layout plan approved by the DRAP authorities. The facility has been provided with necessary utilities, machineries and equipment and personnel as per required under the guidelines. Necessary documents relating to QC, QA and installation qualification of machines, HVAC and other utilities were also seen in place. Firm is also exporting the products in various countries of the world.

Based on the people met, documents reviewed, and observations made during the inspection, the panel recommends the regularization of Tablet(Hormone) section and grant of renewal of Drug Manufacturing License No. 000151 by way of formulation for following section: -

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet (General)	2.	Capsule (General)
3.	Oral Liquid Syrup (General)	4.	Dry Powder Suspension

			(General)
5.	Sachet (General)	6.	Tablet (Hormone)
7.	Ware House (General)	8.	Raw Material Store (Hormone)
9.	Quality Control Laboratory	-----	**********

panel of experts was given mandate for inspection regarding regularization of manufacturing facility however in the panel inspection report panel has only recommended the regularization of Tablet (Hormone) section and recommendations of the panel regarding regularization of other sections are not mentioned.

Decision of the Central Licensing Board in 282nd meeting

TheBoard considered and deferred the grant of renewal of DML No. 000151 by way of formulation in the name of M/s Efroze Chemical Industries (Pvt) Ltd. 146/23, Korangi Industrial Area, Karachion the recommendations of the panel of experts for the period Commencing on 08-04-2020 & ending on 07-04-2025 for seeking clarification from panel of experts regarding not reporting other sections mandated for regularization.

In compliance to the decision of the CLB letter was issuedIn response a letter is received back from the FID Karachi Mr. Najam us Saqib and is reproduced as under:

I have the honor to refere to the DRAP Islamabad letter No. F. 211/2000-Lic(Vol-V), dated 1st October, 2021 with reference to the panel inspection report regarding renewal of DML of M/s Efroze Chemical Industries (Pvt) Ltd, 146/23, Korangi Industrial Area, Karachi which was conducted by the panel of exports was forwarded vide this office letter of even number dated 26th April, 2021.

In this connection, it is clarified that panel also recommended regularization of layout plan of all sections as approved by DRAP, Islamabad vide letter No. F.2-11/2000-Lic(Vol-IV) dated 28th February, 2019 along with grant of renewal of DML No. 000151 by way of formulation which are reproduced below:

Sr #	***Name of Section***	***Sr. #***	***Name of Section***
1.	*Tablet Section(General)*	*2.*	*Capsule Section(General)*
3.	Oral Liquid Section (General)	*4.*	*Dry Powder Suspension (General)*
5.	Sachet Section (General)	*6.*	*Tablet Section (Hormone)*
7.	Ware House (General)	*8.*	*Raw Material Store (Hormone)*
9.	Quality Control Laboratory	*10.*	**********

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considered and approved the grant of renewal of DML No. 000151 by way of Formulation in the name of M/s Efroze Chemical Industries (Pvt) Ltd. 146/23, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period Commencing on 08-04-2020 & ending on 07-04-2025 for the following sections: -

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet Section (General)	2.	Capsule Section (General)
3.	Oral Liquid Section (General)	4.	Dry Powder Suspension (General)
5.	Sachet Section (General)	6.	Tablet Section (Hormone)

The Board also considered and approved the regularization of layout plan in the name M/s Efroze Chemical Industries (Pvt) Ltd. 146/23, Korangi Industrial Area, Karachi under DML No.000151 (Formulation) on the recommendation of panel of experts for the following sections: -

Sr #	Name of Section	Sr. #	Name of Section
1.	Tablet Section (General)	2.	Capsule Section (General)
3.	Oral Liquid Section (General)	4.	Dry Powder Suspension (General)
5.	Sachet Section (General)	6.	Tablet Section (Hormone)
7.	Ware House (General)	8.	Raw Material Store (Hormone)
9.	Quality Control Laboratory	10.	**********

Case No. 56 M/s ATCO LABORATORIES LIMITED KARACHI

Mr. Awais Ahmed FID DRAP Karachi conducted GMP inspection of M/s Atco laboratories Limited Karachi on 21.08.2020 and 02.09.2020.

2. FID noticed number of observations. The FID concluded as under: -

Conclusion of FID: -

"Keeping in view above mentioned major and critical observations, violation of Schedule B-II of LRA rules 1976 and approved Layout, non-compliance of the directions issued for suspension of production area for lotion manufacturing in unauthorized area, firm was considered to be operating at

unsatisfactory compliance level of GMP in Old unit, and firm has already been ***directed to suspend their production activities in Sterile Area (Liquid Injectable Ear/Eye/Nasal Drops), Lotion and Enema*** *vide letter No.NO.F.03-03 /2 019 AD / FID-I X (K) dated 09.10.2020 and submit compliance letter and CAPA to QA&L T division for above mentioned observations for onward consideration at earliest."*

3. The Case was placed before the 277th meeting of CLB. Wherein the Board decided as under: -

Decision of 277th meeting of CLB:

After thorough discussion/deliberations, considering all the pros and cons of the case and recommendations of FID in his reports dated 21.08.2020, 02.09.2020 & 01.10.2020 and CAPA submitted by the firm, the Central Licensing Board decided as follows;

i. In order to verify CAPA submitted by the firm following panel has been constituted by the board;

   a. Dr. Abdullah Dayo, Member Central Licensing Board.
   b. Mr. Sajjad Ahmed Abbasi, FID DRAP Karachi.
   c. Area FID, DRAP Karachi

ii. The board authorized Chairman CLB/Additional Director QA&LT to pass orders on the recommendations of the panel of experts, accordingly.

4. The panel conducted inspection of the firm M/s Atco laboratories Limited Karachi on 06.11.2020. The panel concluded as under: -

> ***"firm may be allowed to resume their production activities in Sterile Area (Liquid Injectable, Ear/Eye/Nasal Drops), till shifting to new area or for the period six months, which-ever is the earlier or any other decision, Honorable board may deems fit. However Liquid and Enema section was already in operational condition, which was allowed by area FID on dated 01st Oct 2020, is also hereby endorsed by the panel. Firm unanimously verified the changes as per layout approval, issued vide Letter No. F .2-5/85-Lic (Vol-vi), dated 30th Sep 2020."***

5. It is pertinent to mention here that Dr. Abdullah Dayo, Member CLB gave note as under: -

> *"it was unanimously decided by the panel to allow one year shifting period to firm. Period of six months mentioned was note unanimous decision of panel"*

6. Keeping in view decision of CLB, the report was referred to the Additional Director (QA&LT). The Additional Director (QA&LT) endorsed recommendations of Panel report dated 06.11.2020. Accordingly, resumption of production was allowed vide letter dated 19.11.2020 for a period of Six Months.

Proceedings of 278thmeeting: -

Quality Assurance Division presented the panel inspection report of the firm M/s Atco laboratories Limited Karachi dated 06.11.2020 in compliance to decision of 277thmeeting of CLB. It was apprised to the Board that resumption of production was allowed vide letter dated 19.11.2020 for a period of six

months. Dr. Abdullah Dayo, Member, CLB added that during inspection it was decided by the panel to allow one-year time to firm for shifting to new premises/building.

Decision of the 278th Meeting of CLB

After thorough discussion/deliberations, the board considered recommendations of Dr. Abdullah Dayo, Member CLB and allow one-year time period for shifting of the firm M/s Atco laboratories Limited Karachi to new premises/building from the date of inspection dated 06.11.2020. In case of failure, Board will proceed as per law.

The decision of the CLB was communicated to the firm by the QA Division DRAP vide letter dated 22nd December 2020.

Now M/s Atco Laboratories Ltd, Karachi wherein the firm has stated as under:

Reference to your letter No. F.8-5/2020-QA (M-278-CLB) dated 22nd December 2020, it is stated for your kind information that Central Licensing Board, DRAP has approved one-year timeline for the shifting of sterile production activities of M/s ATCO Laboratories Limited from existing building to new building. Till then all sterile operations were also permitted to continue in existing approved building. Timeline was started from the date of panel inspection i.e. 6th November, 2020.

Referring to the above-mentioned decision, it is for your kind consideration that sterile production activities are permitted in existing facility till 5th November, 2021. Which is just far 12 months from the date.

In this regard, first of all we are heartily grateful for your earlier consideration and further permission of one-year sterile production activities in existing sterile facility. We would also like to confirm your kind authority that M/s Atco Laboratories Limited, Karachi has great respect with highest possible level of compliance to all the prevailing law regulating Pharmaceutical Industry and has always worked within the legal framework of the DRAP Act 2012, The Drug Act 1976 and Rules framed thereunder in order to ensure delivery of high quality effective and safe drugs to the patients at National as well as Global Level.

In fact, we were very confident that we will meet the permissible timeline of shifting sterile operation from existing building to new building. Therefore, since the decision of CLB dated 22nd December 2020 we have been working by optimum utilization of our human & financial resource. In result, today new sterile area project has been acceded to approx. 75% of the total required work. Detail of major work progress are as follows.

Work	Current Status (As on 24-09-21)	Expected Timeline of Completion
1. Civil work as per DRAP Approved Layout		
Basic Structure	Completed	

Block Masonry work	Completed	
Ceiling work	Completed	
Plaster	Completed	
Flooring	Completed	
Fixing of doors & windows	In-Process	Oct-2021
Paint & Epoxy finishing works	Completed	
2. HVAC Work		
Ordering of equipments	Completed	
Ducting Work	Completed	
Installation of Air handling units	In-Process	Nov-2021
Installation of Air Devices	In-Process	Nov-2021
Air Balancing / Qualification of Equipments	Completed	Dec-2021
3. Electrical Work		
Electrical Conduiting	Completed	
Wiring work	In-Process	Oct-2021
Electrical Devices installation e.g. Switch, Lights etc.	In-Process	Nov-2021
Testing & Commissioning	Completed	Dec-2021
4. Other Utilities Work (e.g. WEI, Compressed Air, Steam etc.)		
Ordering of equipments	Completed	
Utilities Piping works	In-Process	Oct-2021
Utilities installation & Qualification		Dec-2021
5. Production Equipments		
Ordering of equipments	Completed	
Equipment Installation & Commissioning		Dec-2021
6. Equipment & Facility Qualification		Feb-2022

During this course of action, we found pandemic of COVID-19 as a major obstacle for us to meet the target. Due to frequent lockdown by government, smooth supply of required accessories for Civil and Engineering work from local market were adversely disturbed throughout the project. Later on all

commitments related to import of production equipments and utilities were also extensively delaved due to continuous worst international situation during this pandemic.

Even our best effort to complete this project within permitted timeline, now it seems that overwhelming impact of this pandemic will not allow us to meet the advised timeline by CLB.

As we mentioned earlier that basic jobs related to this project e.g. Civil work, Utilities arrangements, Production equipment's arrangement etc. have been completed. However, Paint of building, commissioning / installation of utilities distribution lines and HVAC devices are under process and hopefully will be completed within permissible timeline.

But the major challenge is commissioning / installation of already arranged Utilities and equipments at their dedicated places and then qualification of the same. You may realizea equipments utilities cannot be plan for installation until civil finishing work and commiss utilities distribution lines have been completed. Whereas, Area Qualification will be followedjes the installation & qualification of Production Equipment's / Utilities and HVAC System.

Reference to the above-mentioned work progress sheet, we understand on the basis of state la that new sterile area project will be completed till 5th March 2022. Which is four (04) months later then the permissible timeline to shift Sterile production activity from existing building to new building.

According to the stated fact, you may endorse that we have strived our level best to complete the project within permissible timeline but unfortunately current circumstances of pandemic not allow us for the same.

Therefore, your kind authority is humbly requested to revisit your decision of letter No. F.8-5/2020QA (M-278-CLB) dated 22nd December 2020 and provide us the nominal extension of four (04) months from the earlier approved timeline i.e. 6th November, 2020. Hence, this extension will allow us to continue the sterile production activity in the existing sterile building till 5th March 2022.

We would also like to share an integral information with your kind authority that ATCO is manufacturing several Orphan Sterile products. Even in a short span, non-production of these products may reproduce worst shortage of the products in market. We understand, this point is very pertinent to the subject and should also be consider for approval of our request for extension of timeline.

Further, you are also humbly informed that ATCO Laboratories is exporting high volume of Eve Drone in several countries. We have multiple big orders of different countries in our hand which are planned to dispatch from November-2021 to Feb-2022. In fact, extension in timeline is essential to produce and dispatch these export orders on time. Otherwise, we have no choice other than that toegret respective exporting countries for the supply of these orders.

We believe that you may consider the stated fact and will approve our request for the extension in earlier approved timeline till 5th March 2022.

Your favorable response will be highly appreciated and provide us an opportunity to obliged your kind authority once again.

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considered the case and decided the seek progress report from the Federal Inspector of Drugs in the light of request of the firm. The Board also decided to afford personal hearing to the company in the next meeting of the Board before reaching on considerate decision.

Case No. 57 CORRECTION IN THE ADDRESS OF DRUG MANUFACTURING LICENSE OF M/s SAMI PHARMACEUTICALS (PVT) LTD, KARACHI

1.	M/s Sami Pharmaceuticals (Pvt) Ltd., Plot No. 140/A, S.I.T.E Karachi. Sections: 1. Spansules (General) 2. Ware House (General) 3. Quality Control Laboratory	07-04-2021	**Good**	1. Dr. Abdullah Dayo, Expert Member. 2. FID, Karachi. 3. Ms. SanamKausar, Assistant Director, DRAP, Karachi.

Recommendation of panel:

Keeping in view the good facilities of storage, production, quality control, sanitation and hygiene, HVAC operations, calibration, validation of all equipment and process and other utilities, the panel recommends the grant of Drug Manufacturing License, by way of formulation facility for following section:

1. Spansules (General)
2. Ware House
3. Quality Control Lab

Decision of the Central Licensing Board in 282nd meeting

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Sami Pharmaceuticals (Pvt) Ltd., Plot No. 140/A, S.I.T.E Karachi on the recommendations of the panel of experts for the following section:

Sections (01)

1. Spansules (General)

The Drug Manufacturing License No. 000938(Formulation) was issued to the firm in compliance to the decision of the CLB.
In the agenda and subsequently in the minutes of 282nd meeting of the CLB, the address of the firm was mentioned was Plot No. 140/A, S.I.T.E Karachi **instead of Plot No. F-140/A, S.I.T.E Karachi**.

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation allowed the correction in address of the firm as M/s Sami Pharmaceuticals (Pvt) Ltd., Plot No. F-140/A, S.I.T.E Karachi.

Case No. 58. RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000131 (FORMULATION) OF M/s AL-KEMY PHARMACEUTICAL LABOROATRIES (PVT) LTD, HYDERABAD.

M/s Al-kemy Pharmaceutical Laboratories (Pvt) Ltd, Plot No. P/9, S.I.T.E Hyderabad has applied for renewal of DML No. 000131 by way of formulationfor the period of 02-11-2020 to 01-11-2025.

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 18th January, 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Original Certified true copy of Form-29 & Form-A (Updated) issued by S.E.C.P along with attested CNIC copies of all directors.

(ii) Detail of all sections of firm on firm's letter head along with approval letters of all sections issued from CLB & if not available then submit layout plan for Regularization of facility.

(iii) Updated NDC of CRF.

(iv)

No reply was received from the and a Reminder dated 16th August 2021 was issued to the firm to submit the said documents. The firm submitted documents / reply in response to Reminder which were evaluated and the application is still deficient of following documents:

(i) Proof of with approval letters of all sections issued from CLB & if not available then submit layout plan for Regularization of facility.

Proceedings and Decision by the Central Licensing Board in 283rd 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 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why Drug Manufacturing License No 000131 by way of formulation of M/s Al-kemy Pharmaceutical Laboratories (Pvt) Ltd, Plot No. P/9, S.I.T.E Hyderabad may not be suspended or cancelled by the Central Licensing Board.

Case No. 59 NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976 BY M/S PHARMEDIC PHARMACEUTICAL INDUSTIES, LAHORE.

Budget & Accounts Division, DRAP, Islamabad. They have forwarded audit observation by the Directorate General Audit (Federal Audit). They have referred to Rule 19(14) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 which is reproduced below;

> "(14) The Licensee shall by the 30th June and the 31st December each year, whichever is immediately after the annual financial closing of the company, contribute one per cent of his gross profit before deduction of income-tax towards the Central Research Fund to be maintained by the Federal Government and utilized by it in accordance with the Drugs (Research) Rules, 1978."

The Audit has observed that there were 639 active Drug Manufacturing Licensed (DML) companies and the management did not collect receipts on account of CRF from 125 companies in 2015-16, 75 companies in 2016-17 and 136 companies in 2017-18. The management did not reflect these recoverable receipts as receivables in the balance sheet of the fund. Audit is of the view that non-recovery of receipts deprived the public exchequer from its due receipts. Audit is also of the view that non-disclosure of Receivables in the balance sheet is misstatement of facts. Matter may be justified to the audit.

It is submitted that M/s Pharmedic Pharmaceuticals Industries (Pvt) Ltd., 17KM, Multan Road, Lahore under DML No. 000853 (by way of Formulation) has not submitted CRF till to date. However, firm has failed to submit nothing due certificate for the further period which is mandatory under Rule 12 of the Drugs (Licensing, Registering & Advertising) Rules, 1976. The case was placed before the Central Licensing Board in its 269th meeting held on 26-02-2019 and decided as under:-

> "The Board considered the case and decided to serve show cause notice to the above-mentioned firms 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 Drug manufacturing Licensee may not be suspended till settlement of Central Research Fund".

In the light of Central Licensing Board's decision, a Show Cause Notice was issued to M/s Pharmedic Pharmaceuticals Industries (Pvt) Ltd., 17-Km, Multan Road, Lahore under DML No. 000853 (by way of Formulation) on 30th September, 2020 but firm has not submitted CRF since the grant of DML.

The case may be placed in agenda of next meeting of Central Licensing Board for its consideration, please.

Proceedings and Decision of the Central Licensing Board in 282nd meeting

Mr Muhammad Saeed Kamran, Production Manager appeared before the Board. He argued that they had taken up the matter with Division of Budget and Accounts and as soon as nothing due certificate is received it would be submitted with the Secretariat of CLB.

The Board after hearing the representative of the firm and considering case background to suspend the Drug Manufacturing License 000853(by way of formulation) of M/s PharmedicPharmaceuticals Industries (Pvt) Ltd., 17KM, Multan Road, Lahore 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 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till settlement of Central Research Fund. Afterwards, Secretary CLB may take decision and case may be placed before the Board for ratification.

Incompliance of above decision of the CLB, suspension order was issued on29/09/2021.

Now firm has submitted No Objection Certificate in response to this Division's Show Cause Notice issued on 28th September, 2021 for renewal of Drug Manufacturing License. The application for renewal of Drug Manufacturing License for the period from 19-12-2020 to 18-12-2025 is now complete.

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to cease the suspension order for further period in respect of Drug Manufacturing License No.000853 (Formulation)of M/s Pharmedic Pharmaceuticals Industries (Pvt) Ltd., 17-Km, Multan Road, Lahore.

CASE NO. 60 GRANT OF ADDITIONAL/AMENDED SECTIONS OF M/S HORIZON HEALTHCARE (PVT) LTD, PLOT NO.35-A, SMALL INDUSTRIAL ESTATE, TAXILA.

M/s Horizon Healthcare (Pvt) Ltd, Plot No.35-A, Small Industrial Estate, Taxila. DML No. 00000856 (Formulation). **Section/Facility (06):** **i.** Capsule (General) Section (Revised). **ii.** Tablet (General) Section (Revised). **iii.** Injectable lyophilized Section (New). **iv.** Liquid Injectable (LVP) Section (New). **v.** Warehouse (Revised). **vi.** Change room (Revised).	**26-05-2021** **&** **01-06-2021**	**Unsatisf actory**	1) Mr. Muhammad Akhtar Abbas Khan Additional Director (Quality Assurance & Lab Testing), DRAP, Islamabad. 2) Mrs. Tehreem Sara, Federal Inspector of drugs, DRAP, Islamabad. 3) Mr. Tahir Waqas, Assistant Director (I & E), DRAP Islamabad.
Recommendations of the panel: "Keeping in view the above facts on record and the people met during the visit, the panel unanimously **rejectthe grant** of additional section Liquid vial Section (LVP). The firm informed that they have withdrawn application for grant of lyophilized section. However, they are advised to remove the			

shortcomings pointed out in Revised Tablet and Capsule sections. It is further recommended that the firm may not be granted any further registration s till the enhancement of their storage facilities."

Decision of the Central Licensing Board in 282nd meeting

The Board considered the case and did not approve the following additional Sections on the recommendation of panel of experts. The firm may follow the procedure as provided under Rule 10 of the Drugs (Licensing, Advertising and Registering) Rules, 1976: -

1. Injectable lyophilized Section (New).
2. Liquid Injectable (LVP) Section (New).

The Board also advised the firm to submit CAPA for the improvements in the light of the recommendation of the panel of experts in the following Sections. No production shall be carried till rectification and verification of improvements by the panel to be constituted by the Board.

1. Capsule (General) Section (Revised).
2. Tablet (General) Section (Revised).
3. Warehouse (Revised).
4. Change room (Revised).

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

Decision of Central Licensing Board was conveyed to the firm vide letter 30th September, 2021.

Now, the firm has submitted Corrective Action plan which is reproduced as under:

CAR No.	DETAIL OF NON-CONFORMANCE/OBSERVATION	CORRECTIVE / PREVENTIVE ACTION	EVIDENCE (Documentary and Pictorial Evidences are enclosed as Annexure #)
	PRODUCTION (TABLET)		
01	**01-Mixing&Granulation:** **a-** The safety measure needto be observed in the mixing area to avoid any mishap. **b-** The sewage in this area is not provided after the utensil washing residues will flow through the corridor that needs to be checked out.	**TABLET:** **a-**Safety grill has been Installed for avoid any mishap Operational Sop also has been revised **b-**we made a washing trolley to collect residual water to drain in washing area to avoid cross contamination we also revised our	a)Revised Operational Cone Mixer Sop &Pictorial evidence has been attached (Annexure 1) b) Pictorial evidence of washing trolley has been attached.

		Operational &cleaning SOP of ribbon blade mixer	Operational &Cleaning sop of ribbon blade mixer also has been attached (Annexure 2)
02	**02-SizingRoom:** The equipment is present but log book of equipment is not maintained The logbook is not signed not reviewed neither production In charge nor by QA Officer.	**02-SizingRoom:** The remaining signature has been entertained as per Data integrity sop Log book has been maintained and dully signed by Production pharmacist and QA officer.	Copy of Operational oscillating granulator logbook has been attached. (Annexure 3)
03	**03-Drying** No Safety measure are provided for worker	**03-Drying** Smoke detector has been installed , Clear safety instructions has been pasted in tray Dryer room .	Pictorial evidence of smoke detector & safety Instructions of tray Dryer has been attached (Annexure 4)
04	**04-Blending/Final Mixing** Need to provide safety grill with equipment.	**04-Blending/Final Mixing** Safety grill has been installed with cone mixer and operational Sop has been revised.	Revised Operational Sop of Double cone Mixer &Pictorial evidence of safety grill has been attached (Annexure 5)
05	**05-CompressionRoom** **i.** The logbooks of the equipments are not maintained. **ii.** The punches need to be kept in proper box to avoid rust and are advised to keep them lubricate for proper working. **iii.** The spare punches in this tablet area is advised to use in rotation. **iv.** Washing SOPs of the equipment/utensils need to be observed properly. **v.** Advise to provide necessary equipment for IPQC.	**05**-CompressionRoom **i-** The remaining signature has been entertained as per Data integrity sop Log book has been maintained and dully signed by Production pharmacist and QA officer. **ii**-Separate SS box has been made for the placement of Punches and dies. Sop for handling of punches and dies has been revised. **iii**-Spare punches has been made to use in rotation. **iv**- Revised Cleaning Sop of Equipments and Utensils has been reviewed according to CGMP	i-Copy of compression Machine Operational logbook & Sop of Data Integrity has been attached. (Annexure 6) ii- Sop for handling of dies and punches &Pictorial evidence of SS box has been attached. (Annexure 7) iii-Quotation &Purchase order for spare punches has been attached. (Annexure 8) iv-Revised

		v-All necessary equipment in IPQC has been provided	CleaningSop of Equipments and Utensils has been attached. .(Annexure 9) v-List of IPQC equipment has been attached (Annexure 10)
06	**06-CoatingSection** I-The section is provided with automatic coating machine at the time of inspection question related to aqueous and non aqueous coating was asked but firm's management is unable to answer the same .they are advised to make a proper SOP for the formulation in tablet section that required Aqueous and Non Aqueous coating and of(sugar coating) II- Sop for handling of equipment need to be revised and prominently displayed.	**06-**CoatingSection I- Firm has been performed Hydro Alcoholic Coating performed On all tablet dosage form. Copies of Tablet SMP has been attached . II- Sop for handling of equipment has been revised and prominently displayed.	I-Copies of Tablet SMP has been attached II- Operational Sop of Thio Coata has been attached (Annexure 11)
07	**07-Overprinting** This section is inter connected with In-process quarantine, some batches of previously manufactured batches are placed there and they have not conducted hold time testing	**07-**Overprinting Over printing section has been separated from in process Quarantine. In process Quarantine has been separated, Hold time study Sop has been revised.	Approved Re-Revised Map has been attached (Annexure12) Hold time study Sop has been attached (Annexure 13)
		CAPSULE	
08	**1-**Safety grill needs to be provided.	**1-**The safety grill has been installed on the double cone Mixer & operational Sop has been revised.	Revised Operational Sop of Double cone Mixer &Pictorial evidence of safety grill has been attached (Annexure 14)
09	**2-**Temperatureand humidity should be kept in mind according to the requirement of formulations	**2-**Temp and humidity control Sop is designed according to requirement of formulation.	Revised Sop of Temp and Humidity has been attached (Annexure 15)
10	**3-**Washing and cleaning sops of Equipments and utensils are required to be revised.	**3-** Cleaning Sop of Equipments and utensils has been revised	Revised cleaning sops of Equipments and utensils has been attached (Annexure

			16)
11	**4-** pharmacist need to be assign the duty as currently Anique Ejaz is supervising the manufacturing processes of tablet and capsule section as per detailed provided by firm	**4-**Separate pharmacist has been appointed.	Appointment letter has been attached (Annexure 17)
12	**5-**Log books are not maintained	**5-**Log books hasbeen maintained as per Data integrity Sop	Copies of Logbook has been attached (Annexure 18)
13	**6-**In most of the area, Equipment ID is different on the log book with the number mentioned on the sticker pasted on the machine.	**6-**Equipment ID has been corrected according to logbook	List of Equipment ID and Log book has been attached (Annexure 19)
Quality Control			
14	**1-** Installationqualificationofallthemachineryandequipmentsisrequiredtobedone.	**1-**Installation qualification has been performed at the time of installation of equipments record has been overlook during inspection.	List of quality Control equipment has been attached and copies of qualification Documents has been attached (Annexure 20)
15	**2-**Labequipments log books need to be updated with reference to the model present (as dissolution apparatus of Sigma Company is present and logbook indicate it as of CURIO.	**2-**Dissolution log book has been corrected according to Equipment ID.	Corrected ID log book page has been attached(Annexure 21)
16	**3-** ReferenceStandardandworkingStandardsto require condition are not maintained.	**3-**Reference standard and working standard has been maintained according to required storage conditions that is mentioned	List Of working standard has been attached(Annexure 22)
17	**4-**21CFRcompliant system is claimed to exist but its authorization protocols and testing of material and their audit trail &track needs to be in accordance with the requirements	**4-**21 CFR complaint system audit trail and authorization has been controlled according to regularity requirements.	Sop for system policy and access control of Laboratory Instruments has been attached (Annexure 23)
18	**5-**Firm intended to manufacture Quinolone (Moxifloxacin &Levofloxacin) along with other molecule. they are advised to conduct growth promotion test both for media and for positive control for products.	**5-**Growth promotion test has been already performed on media now we started growth promotion to conduct on quinolones product.	Growth Promotion test Sop has been attached (Annexure 24)
STORE			

19	**1**-The firm has revised the layout for the storage of Raw materials but the stores do not have sufficient space and accessories to fulfill the requirement of existing registered products.	**1-2**Store space has been increased in which separate liquid store, inflammable store has been added receiving bay and de dusting area has been separated. quarantine area has also been separated in re-revised layout	Approved Re-revised layout has been attached here (See Annexure 12)
20	**2**-The released materials are dumped in quarantine Area which is also very congested.		Approved Re-revised layout has been attached here (See Annexure 12)
21	**3**-The packing Materials stores are with other end of the building adjacent to the liquid vial washing area which has not appropriate place.	**3**-we convert the approved packaging material store to Active raw material store to enhance the space of Raw material store so we converted approved Hormonal Raw Material store& packaging material store to single General packaging Material store on the other side of the building	Approved Re-revised layout has been attached here (See Annexure 12)
22	**4**-TheFinishGoods/Product Store is also very Congested.	**4**-Sop for transfer to Finish Goods to centralized warehouse has been revised	Revised Sop has been attached (Annexure 25)
23	**5**-The material are not labeled properly	**5**-Sop for labeling has been revised	Revised Sop has been attached (Annexure 26)
24	**6**-The temp and humidity requirement for API are not observed	**6**-The temp and humidity requirement in store has been maintained according to API storage condition.	List of API with storage condition has been attached (Annexure 27)
25	**7**-The color of the label of quarantine and that of release is different on different container/cartons.	**7**-The color variation in Quarantine and released label has been rectified	See
26	**8**-The dispensing booth for general and steroidal is provided but lacking accessories	The accessories have been provided in dispensing booth.eg spoons, scoops, poly bags	Pictorial Evidence of Dispensing booth with accessories has been attached (Annexure 28)
27	**9**-The Aluminum foil (printed /unprinted) is not provided with AHU	**9**-AHU has been provided in Aluminum foil room.	Pictorial Evidence has been attached (Annexure 29)
WORKER ENTRY			
28	**1**-Two female worker entries are provided but these are not connected with AHU	**1**-Ac has been installed in female worker.	Pictorial Evidence has been attached (Annexure 30)
29	**2**-The air curtain in these areas is operating manually.	**2**-The Door closer of door has not been working properly air curtain in this area has been shifted to	Pictorial Evidence has been attached (Annexure 31)

		automatic mode.	

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to re-inspect the firm by the following panel.

i. Addl Director (QA/LT), DRAP, Islamabad
ii. Federal Inspector of Drugs, Islamabad
iii. Mr Tahir Waqas, AD, Islamabad

Case No. 61 CORRECTION IN NAME OF SECTION OF M/S ROTEX PHARMA (PVT) LTD, PLOT NO. 206 & 207, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD (DRUG MANUFACTURING LICENSE NO. 000651-FORMULATION).

M/s Rotex Pharma (Pvt) Ltd, Plot No. 206 & 207, Industrial Triangle, Kahuta Road, Islamabad has requested for correction in the following licensed Sections;

S.No	Name of Licensed Section	Corrigendum Required
1.	Biotech rDNA Vial Section. (filling and sealing)	Biotech rDNA Vial Section.
2.	Biological – Non-rDNA Vial Section. (filling and sealing)	Biological – Non-rDNA Vial Section.
3.	Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form).	Biological – Vaccines Ampoule Filling & Sealing (Ready to Fill Form).
4.	Restructuring/Extension of QC as per approved layout.	Restructuring/Extension of QC as per approved layout.

It is pertinent to mentioned thatthe Central Licensing Board in its 274th meeting held on 07th April, 2020 has considered and approved the grant of following four additional section to the firm M/s Rotex Pharma (Pvt) Ltd, Plot No.206 & 207, Industrial Triangle, Kahuta Road, Islamabad (Drug Manufacturing License No. 000651 (Formulation), accordingly;

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.

Proceedings and Decision of the Central Licensing Board in 283rd meeting:

The Board considering the facts on the record and after thread bare deliberation decided to give personal hearing to the firm in next meeting of Central Licensing Board.

QUALITY ASSUARNCE CASES

Item No. I. GMP non-compliance cases

Case No. I:- M/s Pak Risen Pharmaceuticals, Hattar (DML No. 000573).

An inspection report of the firm M/s. Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar, was received. The inspection was conducted on 05th& 06th August, 2021 by Mr. Faisal Shahzad, FID-I, DRAP, Peshawar.

2. The FID mentioned in his report that prior to this inspection, FID visited the premises of the firm on 05.03.2021 wherein the firm informed that their facility is under maintenance and inspection was postponed on the request of the firm. Later on the firm informed vide their letters dated 06.04.2021 and 28.05.2021 that they have done all maintenance work, resumed production and are ready for inspection. This surprise inspection of the firm was done in order to evaluate adherence of the firm towards cGMP compliance under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.

3. As per report dated 5th and 6th August, 2021, the FID noticed following observations: -

Change Rooms: -

i. Air curtains installed at the entrance of change rooms are poorly maintained and found rusty / dusty, having number of open cracks in wall at installation points.
ii. Change room for male staff was found maintained with proper step over bench. However, minor maintenance w.r.t. paint job was advised.
iii. Female change room was found not maintained. No insect killer was installed. Change room was found dirty.
iv. SOPs for changeover were not found observed in the female change room.
v. Change room provided for female staff needs improvement w.r.t. hygienic conditions, placement of street shoes/ clothes/ bags etc., in proper cabinets.
vi. Training for change over to avoid any risk of contamination to production areas may be arranged periodically for workers.

Storage Areas: -

i. The firm has provided receiving bay for the incoming raw/ packing materials. However, receiving bay was found poorly maintained. No cleaning equipment was found for dusting / cleaning of incoming materials.
ii. No quarantine area was found / marked in ware house.
iii. No sampling booth facility is available.
iv. Rejection / Recall area is being used as quarantine area.
v. In the raw material approved area temperature / humidity needs to be properly maintained with supporting data / record.

vi. In the dispensing area, dispensing booth is not provided with proper air supply. The same dispensing booth is used for sampling of raw materials. Tools for raw material dispensing also need to be properly labelled after cleaning.

vii. The firm has small finished goods store. No product was found available in the finished goods store. The QCM of the firm informed that all the batches are dispatched as soon as released from their department and no stocks are usually available in the finished goods store.

viii. Empty Ampoules and vials storage area;

1. This area is located at the other end of the building in front of ancillary area i.e., WCs (not properly maintained) provided by the firm for the workers. In front of these WCs, an opening through a narrow, dark gallery leads directly to vials / ampoules storage area without any door.

2. All the vials / ampoules were found without any QC release labels.
3. Storage conditions were found un-hygienic with placement of stocks on dirty floor. Walls, ceiling were also found dirty.
4. Drainage and un-plugged sewerage holes were observed at several places.
5. The firm has provided pass through window from this un-maintained / unhygienic, ampoules / vials store which opens in the De-Cartoning / washing area of injectable section of the firm.

Production areas:-

Liquid Ampoules / Infusion Section:-

i. Vial washing area as reported above is connected with the vials / ampoules store by a pass through SS window. The taps and water sink provided for vial / ampoules washing was observed rusty and not properly maintained.

ii. Similarly, ampoules / small / large vial washing area is provided by a SS overhead hood without any filters while background air quality, though provided through a small HEPA filter, do not seems qualified for class C nor any evidence is produced by the firm for area qualification for injectable vial/ ampoule washing.

iii. Drainage / sewerage system in the area was observed un-hygienic status, filled with mud / broken glass / contaminants and un-fixed slabs over drainage line.

iv. HVAC system of the area is without any proper qualification as the firm did not provided any documentary evidence.

v. Distill water loop system was not satisfactory as the water loop system required for injectable section.

vi. Vials / Ampoules sterilizers were also not properly maintained with tilted, rusty panels/ brackets inside.

vii. No qualification of blowers is done for hot air or their cleaning/ maintenance or air quality inside the heat chambers of sterilizers.

viii. Liquid ampoules/ large vials manufacturing area as well as filling/ sealing area needs maintenance w.r.t. walls, flooring, ceiling, air inlet and outlet grills, epoxy paint, cleaning of machines/ equipment etc.,

ix. Optical checking area as well as packing area also need proper maintenance of walls, floor, and ceiling.

x. In process storage area was not clearly marked. It was informed that all the finished products are stored in finished goods area and as soon as released from QC, it is shifted to sale points.

xi. A spare ampoule filling machine (rusted) is also placed in area which was advised to be removed immediately.
xii. Overall HVAC system of the area is not as per GMP requirements w.r.t. air quality, area segregations w.r.t. air quality, lacking proper doors as required in injectable area, air locks, pressure differentials monitoring and need overall improvement in accordance with GMP guidelines.

Dry Powder Vial Injection:-

i. The vial washing area and sterilization area have same observations as mentioned for liquid injectable since common areas are being used for said purpose. Further, Ceph area requires dedicated facilities and the firm has informed that they are in process of revising their lay out plan. However, the observations of vial washing as well as vial sterilization are same for Ceph vials, as reported above.
ii. Vials after sterilization are opened in vial filling area. The firm was unable to explain how the sterile vials are transported to vial filling station under controlled environment to keep them sterile, since the products are not terminally sterilized manufactured in this section. Area background was informed as Class C (though no validation data available with the firm) while filling operations is under laminar Class A. Laminar curtains (flexible plastic) also not properly mounted not properly cleaned.
iii. The panels of the manual filling machine were observed rusty and sticky powder was observed due to scotch tapings done around the machine panels.
iv. Backside of filling machine was also found not properly maintained and not cleaned.
v. Area not maintained w.r.t. walls, flooring and ceiling. Crack/ peel of plaster was observed at the laminar hood mounting.
vi. Vial sealing machine is also an old rusty equipment not maintained properly.
vii. Overall HVAC system of the area is not as per GMP requirements w.r.t. air quality, area segregations w.r.t. air quality, lacking proper doors as required in injectable area, air locks, pressure differentials monitoring and need overall improvement in accordance with GMP guidelines.

Quality Control:-

i. The firm management has procured Liquid Particle Counter in the year 2020 but it was never functional.
ii. Similarly, Total Organic Carbon analyzer was also procured by the firm Management in 2020 but it was never functional.
iii. Testing methods are still on UV based as provided HPLC by the management is not with required columns and columns oven. HPLC is also not 21CFR compliant.
iv. FTIR is planned to be procured by the firm Management for License Renewal preparation.
v. Latest Pharmacopeias are also not provided.
vi. Reference standards were never procured; it was advised to procure RSs stepwise from independent source.
vii. Stability studies are being performed but without following a proper stability protocol, the studies are not acceptable. Further, no power backup exists for QC equipment or stability chambers.
viii. No records exist for testing of primary packing materials like glass vials or rubber stoppers.
ix. Microbiology Lab also needs to be upgraded w.r.t. infrastructure, design, facilities, equipment and air system. Testing of all HVAC air systems w.r.t. particulate matter/ microbiological testing must be in line with GMP guidelines.

Quality Assurance:-

i. The department nor any personnel exists for Quality Assurance. The firm has informed that they are in process of hiring of well qualified QA manager.

Personnel:-

i. Hired staff for production but the production Manager was found absent on both occasions of inspection. Further, no leave record of qualified production Manager was available or provided by the firm. One production pharmacist with 2-years' experience is hired by the firm who assisted during the inspection of production areas.
ii. Mr. Jehangir Alam is performing duties as QCM. One microbiologist is hired for microbiology lab.
iii. No technical person hired for QA department.
iv. One non-technical female staff is hired as store incharge.
v. No training record was available for the technical staff/ workers.

Allied facilities:-

i. The firm has not provided satisfactory loop distill water system along with proper monitoring as required for injectable areas as well as liquid injection manufacturing.
ii. Ancillary areas are also not up to the mark.

Conclusion

"Based on the areas inspected in detail, the people met and the documents reviewed and considering the findings of the inspection as well as type of production facilities, ***the firm is not complying GMP requirements as defined under Schedule B-II of the Drugs (Licensing, Registering & Advertising) Rules, 1976.****"*

3. Keeping in view the observations noticed and conclusion of report by the FID, **Show Cause Notice / Order of Suspension of Production Activities in all Sections** was issued to the firm M/s. Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar vide No. F.4-2/2006-QA (vol-I) dated 23.08.2021.

4. In response to this office show cause notice, the firm replied vide letter No. PAK/HTTR/021-1 dated 09.09.2021. The response of firm reproduced below;

"Itis humbly stated that we have received show cause notice No. f 4-2/2006-QA (vol-I) on 30th of August 2021. We have deeply gone through the notice and would like to explain our position to the honorable DRAP infollowings: -

During FID visit the firm was already out of production from 2nd August, 2021. FID has visited and witnessed by himself and checked allareas and records there was noproduction at all.

Lots of thingscaughtroughandunfinishedproperlybecause our layoutPlan has been submittedfor regularization and already discussed in Licensing department and approval is about to be issued within few days as told by the concern department from DRAP.

So, a lot of civil works need to be done that's why we had left our routine (03 months interval) scheduled maintenance/refurnish work and because of unsatisfactory conditions we opted the stoppage of production.

At the time of inspection only Q.C Staff was present in entire unit because of installation and calibration team of Q.C Equipment had to visit at that very day and Rest of that staff was on leave just because there was a stoppage period of the production.

Moreover, Raw Material store Finished Goods store areas are as per DRAP recommendations as previous DML inspection panel approved and suggestedthis.

Still we aregoing to do a huge civil work for Layout Plan regularization we need a lot ofamendments and rearrangements of our unitflow.

We have noticed and accepted the honorable FID's suggestion and recommendation with open heartand we will follow them and will amend. And we would like to inform you that we have already done most of the work in connection to FID's recommendations before writing this show cause replyi.e.

1	*In Change Rooms New Roof Sealing has been done in both Male and Female & SOPs affixed.*	
2	*HVAC system has been qualified through DOP test and as recommended air supply has been increased by addition supply duct as to comply with standards.*	
3	*In QC HPLChas been updated (21CFR compliances) latest Pharmacopeias and Working Standards have been purchased. TOC and Liquid particle counterrepaired.*	
4	*In R.M store Dispensing both has been supplied with filtered Air.*	
5	*S. Steel items have been republished & repaired.*	

Rest of the points / works will automatically be rectified when we will do civil works/constructions for Layout plan regularization.

Dear Sir,

We request the honorable DRAP not to take any strict action give us a chance and time as we are in process for regularization of our unit's layout and forthat we will have to refurnish, reconstruct andwill reinstall most of the sections path ways and their entrance and associated related areasagain.

So, ultimately the firm will come with new and improved look as per GMP andDrug Rule (ScheduleB-11)"

5. The firm was asked vide this office letter No. 4-2/2006-QA(Vol-I) dated 21.09.2021 to submit all supporting documents as evidence for the Corrective and Preventive Action (CAPA) plan to this office. The reply of the firm is still awaited.

6. The firm has submitted a detailed reply vide letter No. PRP/DRAP/2021 dated 01.10.2021 wherein they have stated that they are working on rectifying deficiencies pointed out by the FID. Furthermore, they have stated that rectification of most of the observations is associated with civil work. The civil work is associated with regularization of LOP, for which, they have applied.

Proceedings of 283rd meeting of Central Licensing Board;

7. Mr. Shoaib Khan, Admin Manager of M/s Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar appeared before the board and stated that management could not appear before the board due to death of their son.

8. Mr. Shoaib Khan stated that they will construct their facility as per regularized lay out plan within time period of 1 month.

Decision of 283rd meeting of Central Licensing Board;

9. The board after considering the statement of firm's representative and deliberating on the matter and decided as under;

i. The production of the firm M/s Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate, Hattar shall remain suspended.

ii. Following panel of experts shall inspect the firm M/s Pak Risen Pharmaceutical, Plot No. 3, Block B, Phase I-II, Industrial Estate Hattar;

   a. Prof. Dr. Jamshaid Ali Khan, Expert Member.

   b. Area FID DRAP Peshawar.

   c. Area Assistant Director DRAP Karachi.

iii. The Additional Director QA&LT shall pass orders on the recommendations of panel inspection report and present case in subsequent meeting of CLB for ratification.

Item No. II. GMP non-compliance case

Case I: - **M/s Healer Laboratories (Pvt.) Ltd. Peshawar (DML No. 000303).**

Background:-

Mr. Atiq-Ul-Bari, FID-II, DRAP, Peshawar, on 04.09.2018 conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar.

2. The FID during inspection noted number of critical observations.

Action taken by DRAP:

3. The firm M/s Healer Laboratories, Peshawar was served Show Cause Notice on 23.10.2018.

4. The case was placed in 267th meeting of CLB. Wherein the Board decided as under: -

Decision of the 267thMeeting of CLB

5. Dr. Zakir Hussain, Quality Control Manager of the firm M/s Healer Laboratories appeared before the board. After thorough discussion/deliberations, the Central Licensing Board decided to: -

I. Constitution of following panel of experts for detailed GMP inspection of the firm:-
   a. Prof. Dr. Jamshaid Ali Khan, Member, CLB
   b. The Area Federal Inspector of Drugs, Peshawar

II. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 25.10.2018, with clear and candid recommendations.

6. The panel conducted inspection of the firm M/s. Healer Laboratories (Pvt) Ltd, Peshawar on 26.03.2019 and concluded as under: -

"The firm has rectified majority of observations noted in the previous inspection and the management is committed to further improve their cGMP compliance. The firm may be considered operating in satisfactory level of cGMP compliance."

7. The panel further recommended the firm to:-

i. Provide an Air conditioner in Raw Material Quarantine area.
ii. Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
iii. Provide room for retention samples.

Proceedings of 271st meeting: -

8. Quality Assurance Division presented the case before the Board, keeping in view the recommendations of panel in its report dated 26.03.2019. The Board raised query regarding the further recommendations made by the firm.

Decision of the 271st Meeting of CLB

9. After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to:-

i. Re-Inspect the firm by same panel of experts, constituted in 267th meeting of CLB, to verify the following improvements suggested by the panel in its report dated 26.03.2019:-

   a) Provide an Air conditioner in Raw Material Quarantine area.
   b) Calibrate balances from external sources and provide digital balances in process QC and Capsule filling Section.
   c) Provide room for retention samples.

ii. The panel shall submit detailed inspection report including rectification status of the observations with clear and candid recommendations.

iii. Production of the firm M/s Healer Laboratories, Peshawar shall remain suspended till recommendation by panel and subsequent approval by the CLB.

10. The decision of 271st meeting of CLB was communicated on 01.10.2019. A reminder was issued for panel inspection on 16.09.2020. The panel inspected the firm on 16.12.2020. The compliance status of previous observations is reproduced below as reported by the panel;

S. No.	Observations	Compliance
1.	Provide an air conditioner in the raw material quarantine area.	Air condition is installed in raw material quarantine and is in working condition.
2.	Calibrate balances from external sources and provide digital balances in process QC and capsule filling section.	Balances calibration record check and found maintained. Furthermore, firm has arranged digital balances for capsule filling (encapsulation) area and in-process QC.
3.	Provide room for the retention of samples.	Firm has provided a segregated area within the QC lab for retention samples which is provided with shelves.

11. The panel gave following new suggestions in their report dated 16.12.2020;

Production Area:-

i. Validate the HVAC from external source.

Quality Control:-

i. Purchase one more stability chamber with back up facility.

ii. Improve the documentation of their tests performed in accordance with designed testing methods and for proper traceability.

12. The conclusion of panel inspection report dated 16.12.2020 is reproduced below;

"Based on the area inspected, the people met and documentations reviewed and considering the findings of inspection, the panel unanimously decided to recommend the resumption of production of M/s. Healer Laboratories (Pvt) Ltd. Peshawar.

It is pertinent to bring on record that, at present, the total size of the plot of the firm is less than 2000sq. yard, as described in Drug (Licensing, Registration and Advertising) Rules, 1976. The management of the firm informed that due to this reason they are in process of shifting the manufacturing facility and had already submitted lay-out of their new site to Licensing Division."

Proceeding and Decision of 283rd meeting of CLB;

13. After thorough deliberation and considering the panel report dated 16.12.2020, the board decided as under;

i. Allow the firm M/s. Healer Laboratories (Pvt) Ltd, Plot No. 96-102-C, Small Industrial Estate, Kohat Road, Peshawar to resume their production activities.

ii. Cease the effect of show cause notice vide No. No.F.4-22/92-QA dated 23.10.2018.

CASE No. II M/s Well Care pharmaceuticals Sargodha

Background:

Mrs. Majida Mujahid, FID, DRAP, Lahore conducted inspection of the firm M/s. Well Care Pharmaceuticals, Sargodha, conducted on 13.03.2019.

2. The FID during inspection noted the following observations which need attention and rectifications:-

Entrance of General Production Area:-

i. Provide executive / workers entries which were not met as per GMP requirements.
ii. Remove all stay places.
iii. Give air supply in entries.
iv. Improve hygiene condition of area and implement all SOPs regarding to hygiene and sanitations.
v. Remove small holes / gutters in above said areas.
vi. Covered all necked electric wires in production corridors.

Ware House (Raw Material Store, Packing Material Store, Finished Goods Store):-

vii. No de-dusting area and Quarantine area were provided.
viii. No temperature / humidity record was maintained.
ix. Identification labels regarding to Quarantine, Release was not properly pasted on Raw Material.
x. No GSP was seen in their ware house.
xi. No proper dispensing / sampling booth was installed. They were directed to develop proper sampling / dispensing area with sampling / dispensing booths.

Production Area:-

xii. Validate HVAC system.
xiii. Unilateral flow of manufacturing was not seen.
xiv. They were directed to remove bottle blowing machine in filling area.
xv. Production area needed civil work regarding to paint on walls / corridor.
xvi. All their machineries / equipment installed in production area needed polish / buffing.
xvii. No In-processes Quality Control Laboratory was provided by firm.

Quality Control Laboratory:-

xviii. To installed FTIR, Automatic Polarimeter.

Quality Assurance Department:-

xix. No Quality Assurance Department or personal was hired as Quality Assurance Manager.

Reference Standard:-

xx. No reference standards were available.
xxi. It was observed that firm had not doing their test / analysis on their Raw Material and on finished products. They were releasing products without doing any test / analysis which was alarming / serious.
xxii. No proper format was developed for BMR which seemed poor traceability of product.

Documentations:-

xxiii. Poor documentation related to production / Quality control was seen.

Stability:-

xxiv. No Stability chamber or SOPs were available regarding to stability.

Vendor Validation:-

xxv. Firm did not do any vendor validation of their Raw Material.

Process Vendor:-

xxvi. Firm did not do processes validation of their critical steps of manufacturing of their any products.

Complaint / Recall System:-

xxvii. No SOPS was developed for complaint / recall system.

Medical Record:-

xxviii. No Medical record was maintained.

Water Treatment Plant:-

xxix. No validation of water treatment was carried by the firm.
xxx. No flow diagram was available.
xxxi. No identification of their Colum was mentioned.

Conclusions:-

"Condition of firm was unsatisfactory regarding to premises, Production area, Quality Control laboratory, documentation and SOPs related to Production / Quality Control and Quality Assurance Laboratory."

Action taken by DRAP:

3. The firm M/s Well Care Pharmaceutical, Sargodha was served Show Cause Notice and suspension of production activities order No.F.4-11/2001-QA on 10.05.2019.

Reply of the firm:

4. The firm M/s Well Care Pharmaceutical, Sargodha vide letter dated 13.05.2019 submitted reply of Show Cause Notice and submitted compliance report. The firm stated that they have improved in all aspects and they want to be presented in person.

Proceedings of 271st meeting:-

5. Quality Assurance Division presented the case before the Board. Mr. Malik Saeed Akhtar, MD of the firm M/s Well Care Pharmaceutical, Sargodha appeared before the Board. He informed that

improvements have been done, as mentioned by the FID. He further stated that the firm is ready for inspection.

Decision of the 271st Meeting of CLB

6. After thorough discussion/deliberations, considering all the pros and cons of the case, the Central Licensing Board decided to:-

i. Constitute following panel of experts for verification of the observations noted by the FID in its report dated 13.03.2019 before resumption of production:-

   a) Dr. Mehmood Ahmad, Ex-Dean, Faculty of Pharmacy, Islamia University Bahawalpur
   b) Dr. Hafsa Karam Elahi, Addl. Director (QA&LT), DRAP, Islamabad
   c) Area Federal Inspector of Drugs, Lahore

ii. The panel shall submit detailed inspection report including rectification status of the observations noted by the FID in its report dated 13.03.2019, with clear and candid recommendations.

iii. Production of the firm M/s Well Care Pharmaceutical, Sargodha shall remain suspended till recommendation by panel and subsequent approval by the CLB.

7. Dr. Hafsa Karam Elahi, Additional Director, DRAP, Islamabad requested as under: -
"In this regard, it is stated that the undersigned was nominated as the panel member for verification of the observations noted by the FID in its report dated 13.03.2019 before resumption of production. The undersigned couldn't conduct that inspection along with other panel members due to some inevitable reasons. Therefore, it is requested to replace the undersigned and the panel may be re-constituted for the said inspection, please."

8. The competent Authority i.e. Additional Director (QA & LT), DRAP, Islamabad replaced Dr. Hafsa Karam Elahi with Mrs. Majida Mujahid, FID, DRAP, Lahore.

9. Now the following panel was constituted vide letter No. F. 4-11/2001-QA dated 26.07.2021. The following panel conducted the inspection on 10.09.2021 in order to verify the rectification of observations made during the last routine GMP inspection dated 13.03.2019 and to evaluate the overall GMP compliance of the firm.

i. Prof. Dr. Mehmood Ahmad, Ex-Dean, Faculty of Pharmacy, Islamia University Bahawalpur.
ii. Mrs. Majida Mujahid, Additional Director, DRAP, Lahore.
iii. Area Federal Inspector of Drugs, DRAP, Lahore.

10. **The panel has concluded that:-**

"Reference to previous inspection it was found that the firm has made improvements to meet the minimum level of cGMP compliance. Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection regarding the improvements made by the firm M/s. Well Care Pharmaceuticals, A-7 Punjab Small Industrial Estate, Lahore Road,

Sargodha was considered to be operating at satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under."

11. **The panel has Recommended that:-**

"The observations of this inspection were discussed with the management at length. The management expressed very firm commitment for earlier compliance to the suggestions and for further improvements as planned and committed.

Keeping in view the improvements made by the firm, positive attitude of the management towards betterment, the panel recommends the resumption of production in all approved sections."

The proceedings and decision of 283rd meeting of Central Licensing Board;

12. After thorough deliberation and considering the panel report dated 10.09.2021, the board decided as under;

i. Allow the firm M/s Well Care Pharmaceutical, A-7 Punjab Small Industrial Estate, Lahore Road, Sargodha to resume their production activities.

ii. Cease the effect of show cause notice vide No. No.F.4-11/2001-QA dated 10.05.2019.

Item No. III Cases for Ratification and Information of the Board

Case No. I:- M/s Mediceena Pharma(Pvt.) Ltd. Lahore

An inspection of M/s Mediceena Pharma (Pvt) Ltd., 27-Km, Raiwind Road, Lahore was conducted by Ms. Aisha Irfan on 03.08.2021, to check the GMP compliance of the firm.

2. The observations and suggestions of FID are reproduced below;

Building and Facility:-

i. To install proper emergency fire doors linked with alarm system.
ii. Smoke detector, fire alarms, and hydrant system also required.
iii. Provide approved layout plan.

Changing Areas:-

i. The step-over benches were too wide to cross; practically were not feasible.
ii. Workers changing areas required improvement with respect to cleanliness and implementation of SOPs.

Material management:-

i. It was observed that the flow of de-dusting area and quarantine area was not proper as it opened in finished goods store.
ii. The quarantine area was also very small.
iii. Expired raw material was seen in the ware house.
iv. It was advised to install proper software for data handling.
v. Sampling and dispensing hoods were not proper.
vi. The firm has registration of steroids and penicillin containing products, however separate dispensing hoods for both were not provided. General dispensing area was being used.
vii. Light in the stores was not sufficient.
viii. Packing material store required improvements with respect to primary and secondary packaging materials. Proper bottle, ampoules, vial store was not developed. Cartons containing new vials and bottles were stored outside in the open area and were full of dust.

Production (General / Antibiotic Tablet Section):-

i. No production was in in-process at the time of inspection.
ii. Fluidized bed dryer was rusted from where the air comes in contact with the powder.
iii. Advised to remove dust collector from above the mixer as it interferes with HVAC system.
iv. HVAC system was not validated and function properly.
v. Manometers were not installed. Positive pressures were observed as the flow of air was
vi. outside, hence increasing chances of contaminations.
vii. No separate area for paste mixing and solution preparation for coating material provided.
viii. Safety grill around cone mixers required. In-process quarantine area was not available.
ix. Meditlam-SR coated tablets, without blistering was placed in the corridor of general
x. Tablet Section area since April 2021, without any temperature / humidity control. The firm did not have SOPS for hold time testing as well.
xi. No IPQC laboratory developed for in process testing.
xii. Section Incharge was not present.

Oral Liquid Section:-

i. Bottle blowing machine was not functioning properly.
ii. Bottle washing machine was installed, however the plant manager informed that they do not use this machine, it was advised to immediately remove machine, so that chance so fused bottles being washed should be eliminated. Oven was also installed for bottle drying.
iii. De-cortoning area was not available.
iv. Proper filter in filtration assembly was not provided.
v. No. production was in process. Section in charge was not available.
vi. HVAC system was not functional.
vii. Cleaning / validation SOPS were not provided.

General Injectable Section:-

i. Hot air ovens for sterilization of ampoules were installed, however the validation of ovens were not performed.
ii. Semi-automatic ampoule washing machine was rusted hence was advised to replace it with automatic ultrasonic machine.
iii. Interlocking of buffer doors, not provided to ensure air lock systems.
iv. HVAC system was not functioning properly neither validated.
v. No. production was under process at the time of inspection.
vi. It was advised to replace air curtains with closed system around filling machine.
vii. Tube lights should be replaced with concealed lights in order to avoid contamination of dust and particles.
viii. Bubble point test of filters was not being performed.
ix. Filter integrity DOP test of HEPA filters of filling machines was not performed.
x. Autoclave installed for terminal sterilization was not validated.
xi. HEPA filter trolleys, required for transfer of ampoules from ovens to filling machines were not available.
xii. SS cabinet for uniform gowning / de-growing area required to be installed.
xiii. In the general injectable-II, seepage on the walls of filling room was seen. Tube lights were installed instead of concealed flush lights.
xiv. Other observations of the general injectable (II) of the solution preparation room, buffers, were same as mentioned in general injectable (I).
xv. Optical checking required improvement, Magnifying glasses need to be installed. Eye sight checkup of workers required.
xvi. No production was in-process. Section incharge not present.

Eye Drops Section:-

The section was not functional, manufacturing and mixing area machinery was dismantled. Under maintenance label was pasted, however no maintenance work was under process at the time of inspection.

Dry Powder Injectable:-

i. In the washing area, hot air oven for sterilization of vials not validated.
ii. Semi-automatic vials washing machine was installed, which was rusted.
iii. Shippers were seen inside the washing area. Decartoning outside the area was not performed,
iv. DOP tests of filters of filling machine were not performed.
v. HVAC system was not functional.
vi. Interlocking of buffers not provided.
vii. No production was seen.

IV Infusion:-

The washing and solution preparation areas were same as of liquid injectable section. However, in the filling area DOP test of HEPA filters of filling machine were not performed. No partition between filling and sealing machine was provided. SS cabinet for uniforms at gowning /de-growing were required. Interlocking of buffers was not provided. HVAC system was not functional. Epoxy paint required improvement.

In Process Quarantine:-

Separate in process quarantine area was provided which required improvement with respect to proper storage, lights and temperature / humidity controls.

Cephalosporin:-

Segregated area was provided for the cephalosporins. Separate raw material store with dispensing, quarantine and release areas were available. It was advised to provide air conditioner in quarantine area, Dispensing log book required amendment with respect to raw materials entries. Section pharmacist was not hired.

Cephalosporin Dry Powder Injectable:-

i. In the washing area, two ovens were installed for sterilization of vials, but were not validated.
ii. DOP test of HEPA filters of filling machine were not performed.
iii. **HV**AC system was not validated and functioning properly hence required classes A & B, in the area were not maintained.
iv. Buffers were not interlocked.
v. Optical checking not developed properly.
vi. Media fill trials not performed.

Cephalosporin Dry Powder Suspension:-

i. Bottle blowing machine was not provided.
ii. Safety grill required around mixer.
iii. HVAC system not functional.

Cephalosporin Tablet:-

In this section granulation, drying, mixing compression, coating and packaging processes were involved. Coating and solution preparation room was empty. No equipment was installed.

HVAC system was not functional

Cephalosporin Capsule:-

Semiautomatic capsule filling machine was installed. HVAC system was not functional

Dry Powder Suspension (General):-

In this section two manual filling machines were installed. HVAC system was no. functional. No production was seen

Penicillin Section:-

The section was segregated and was developed in the same building with separate entries. A door of penicillin section was also linked with the general corridors.

Stores:-

Separate dispensing of Penicillin was not provided.

Penicillin Tablet / Capsule:-

In this section thermal mapping of dryer required, safety grill around mixer was not provided, Compression machines required closed coverings. HVAC system was not functional, No solution preparations coating area developed. No production activity was seen. Section Incharge not hired.

Cream/Ointment:-

Two rooms were provided for mixing and filling. The section was not in operation.Decartoning area and tube cleaning machine was not available.

Laboratory Controls:-

The quality control laboratory was independent of other departments. Mr. Shahid Afzal the approved of quality control incharge was not present at the time of inspection. The quality control equipment was not sufficient. It was observed that two HPLCs were installed, one was not functional the other HPLC's calibration was expired and the quality control analyst was unable to explain its working as he could not perform test on HPLC. The firm had more than 300 registered products and only one HPLC was installed, which was also not operative at the time of inspection, TOC apparatus was also out of order. Liquid particle counter was installed, without laminar flow hood. The equipment such as UV Spectrophotometer, dissolution apparatus etc were calibrated from Galvanic Scientific however, no entries to log book, were available. Some working standards were available, reference standards were not available. The microbiology laboratory also required improvement with respect to buffers. HVAC system, sterility room and media preparation areas. Microbiologist was not present. Bacterial cultures were not available. Particle Counter was not calibrated. Necessary tests required for antibiotic / penicillin's were not being performed. Testing SOPs were not provided. It was advised to perform tests as per pharmacopoeia methods.

Water Purification System:-

The system involved double R.O water treatment, softener, ion exchanges double distillation, storage tank with loop system. The cleaning / validation of system required improvement.

Documentation:-

The BMRs were available, however several deficiencies were noted. SOPs required improvement. APQR of products was not performed. The organogram approved layout plan, list of approved sections were not provided.

Quality Management & Self-Inspection: -

The quality management system was not properly established. Self-audits and trainings were not being perfumed.

Personnel: -

The technical staff was not sufficient for production, quality control and quality assurance department. The firm had more than 15 sections and only two pharmacists in sections were hired, who were also absent at the team of inspection. The medical record of the staff was not available. The management was directed to appoint more technical staff for each section.

Air Handling: -

HVAC system was not functional. Validation of HVAC system was not performed. The differential pressures were not checked properly as manometers were not installed in some areas and were not proper. The temperature / humidity, number of air changes were not controlled through HVAC system.

Conclusion

"in view of above inspection proceedings and facilities verified, such as building production, in process controls, quality control testing, material management, machinery / equipment, personnel and documentation etc, it was noticed that the GMP practices were not being followed properly in line with GMP guidelines, and the overall conditions of the firm required improvements. The management was advised to submit CAPA.

Hence the firm was not operating at a satisfactory level of GMP compliance."

3. Keeping in view the observations noticed and conclusion made by the FID, **Show Cause Notice / Suspension of Production Activities in all Sections** was issued vide letter No. F.4-45/2004-QA (Vol-I) dated 30.08.2021 to the

4. The firm M/s. Mediceena Pharma (Pvt) Ltd., 27-Km, Raiwind Road, Lahore submitted CAPA report vide letter dated 31.08.2021. Following panel of experts was constituted for verification of CAPA;

i. Mr. Muhammad Shamoon, Member
ii. Ms. Majida Mujahid, FID, DRAP, Lahore.
iii. Ms. Mehwish Jamil, Assistant Director, DRAP, Lahore

5. The above panel inspected M/s. Mediceena Pharma (Pvt) Ltd., 27-Km, Raiwind Road, Lahore on 10.09.2021. The Verification of rectification of shortcomings pointed out during last inspection dated 03.08.2021 as reported by the panel is reproduced below;

Inspection Dated 03-08-2021	**Current Inspection Dated 10-09-2021**
Building and Facility	**Building and Facility**
To install Proper Emergency fire door linked with alarm system.	The firm has increased signs of Emergency Exit and shifted Fire Extinguisher from end of the corridor to the middle of corridor.
Smoke detectors, Fire alarms and hydrant system required	The firm has installed Smoke detectors in all sections. Firm alarm system is also available.
Provide approved layout plan.	Approved layout plan is provided.

Changing Area	**Changing Area**
The Step-over benches were too wide to cross, practically not feasible.	The firm has provided new step over bench.
Workers changing areas required improvement with respect to cleanliness and implementation of SOP's	Cleanliness of worker change room is improved. SOP provided and implemented.
Material Management	**Material Management**
It was observed that the flow of de-dusting area and quarantine area was not proper as it opened in F.G. Store.	Area is approved in the map but the Firm was advised to develop new de-dusting area in six weeks as per new cGMP.
The quarantine area was also very small.	The firm was advised to develop new quarantine area adjacent to de-dusting area in six weeks.
Expired methacrylic acid was seen in the warehouse.	Inactive raw material was destroyed and destruction note attached as evidence.
Sampling and dispensing hood was not proper.	Sampling and dispensing hood are available with inbuilt return duckets.
The firm has registration of steroid and penicillin containing products; however no separate dispensing and sampling hoods are provided. General dispensing area was being used.	The firm was advised to provide separate dispensing hood in six weeks.
Light in the store was not sufficient	The firm has installed new lights.
Packing material store required improvement with respect to primary and secondary packaging material. Proper bottles ampoule vial store were not developed. Cartons containing new vials and bottles were store outside in the open area and were full of dust.	Cleaning and segregation of materials done in packing Material store.
General / Antibiotic Tablet Section	**General / Antibiotic Tablet Section**
No production was in process at the time of inspection.	The firm informed that required production has already been done.
Fluidized bed dryer was rusted from where the air comes in contact with the powder.	The firm was advised to provide new mesh for FBD in three weeks.

Advised to remove dust collector from above the mixer as it interferes with HVAC system	The firm informed that previously it was advised by competent authority to installs the dust collectors.
HVAC system was not validated and function properly	The firm HVAC was functional and validated at the time of inspection. .
Manometers were not installed. Positive pressure was observed as the flow of air was outside hence increasing chances of contaminations.	The Firm has now installed new Manometers for monitoring of Positive pressure.
No separate area for paste mixing and solution preparation for coating material provided.	The firm was advised to purchase new paste kettle in three weeks. The firm informed that readymade coating material is used for coating.
Safety grill around cone mixer required.	The firm has provided safety switch in cone mixer door.
In process quarantine area is not present.	The firm has now Quarantine area.
Mediflam-SR coated tablets, without blistering was placed in the corridor of general tablet section area since April 2021, without any temperature / humidity control.	The firm is now monitoring temperature and humidity in the area. Record was seen by panel.
The firm did not have SOPS for hold time testing as well.	The firm has SOP for whole time study.
No IPQC lab develop for in-process testing	The Firm has developed IPQC in Production area.
The section in charge was not present	The incharge Pharmacist was on leave at the day of inspection but today was available.
Oral Liquid Section	**Oral Liquid Section**
Bottle blowing machine was not functioning properly	Bottle blowing machine was working at the time of inspection.
Bottle washing machine was installed, however plant manager informed that they don't use this machine it was advised to immediately remove the machine so that chances of used bottles being washed should be eliminated. The Oven	The firm has removed the machine from the area.

was also installed for bottle drying.	
Decartoning area was not available	The firm was advised to develop decartoning area in six weeks they agreed.
Proper filter in filtration assembly was not provided	The firm was advised to purchase new filtration assembly in six weeks.
No production was in process. The section in charge was not present	Section Pharmacist was available at the time of inspection.
HVAC system was not functional	HVAC is operational and validated at the day of visit **(copy is attached)**
Cleaning / validation Sops were not provided	The firm has provided SOP and Protocol for cleaning.
General Injectable Section	**General Injectable Section**
Hot air ovens for sterilization of ampoules were installed, however the validation of ovens were not performed.	The firm has validated the hot air oven. Document provided.
Semi-automatic ampoule washing machine was rusted hence it was advised to replace it with automatic ultra-sonic washing machine	The firm has cleaned and polishes the Machine. However they were agreed to purchase ultrasonic machine within shortest period of time.
Interlocking of buffer doors not provided to ensure air lock systems	The firm ensure the interlocking of buffer doors through HVAC System.
HVAC system was not functioning properly neither validated	The firm has informed that HVAC system is functional and validated.
It was advised to replace plastic curtains with closed system around filling machine.	Machine curtains are available.
Tube lights should be replaced with concealed lights in order to avoid contamination of dust and particles.	The firm has replaced the lights with concealed lights. They agreed.
Bubble point test for filters was not being performed.	The firm was advised to provide bubble point test apparatus in four weeks.
Filter integrity DOP test of HEPA filters of filling machine was not performed	The firm has Performed DOP tests. Document provided.
Autoclave installed for terminal sterilization was	The firm has validated the Autoclave.

not validated	Document provided.
HEPA Filter Trolley are required for transfer of ampoule from oven to filling machines were not available	The firm has provided trolley for transfer of Ampoules.
SS cabinet for uniform gowning and de-gowning area required to be installed.	The firm was advised to provide cabinet for gowning in four weeks.
In general injectable 2 seepage on the wall of filling room was seen. Tube lights are installed instead of concealed flush lights.	The firm has replaced the lights with concealed lights. Seepage is also removed.
Optical checking required improvement. Magnifying glasses need to be installed. eye sight checkup of workers required,	Optical checking area improved. Eye checkup of workers done. Medical reports provided.
No production was in process .The section in charge was not present.	Pharmacist was present at the time of inspection.
Eye Drop Section	**Eye Drop Section**
The area was not functional manufacturing and mixing area machinery was dismantled, under maintenance label was pasted however no maintenance work was under process at the time of inspection.	Maintenance work under process.
Dry powder injectable	**Dry powder injectable**
In the Washing area hot air oven for sterilization of vials was not validated.	The firm has validated the Hot Air Oven. Document provided.
Semi-automatic vials washing machine was installed which was rusted.	Condition of machine was good/clean.
Shippers were seen inside the washing area means De-cortoning outside the area not performed	Shippers removed from the area. De-cortoning was being done outside the area.
DOP test of filters of filling machine was not performed	The firm has performed DOP tests. Document provided.
HVAC system was not functional	HVAC system is functional and validated. Document provided.
Interlocking of buffers not provided	The firm ensures the interlocking of buffer

	doors through HVAC System.
No production was seen.	The firm informed that required production has already been done
IV infusion	**IV infusion**
The washing and solution preparation areas were same as of liquid injectable section. However, in the filling area DOP test of HEPA filters of filling machine were not performed. No partition between filling and sealing machine was provided. SS cabinet for uniforms at gowning / de gowning was required. Interlocking of buffers was not provided. HVAC system was not functional. Epoxy paint required improvement.	The firm has performed DOP Test. The firm explained that Rubber stopper was placed on vials and then moved for sealing. Machine was covered with curtains. The firm is advised to provide cabinet for Gowning in three weeks The Firm ensures the Interlocking through HVAC System. HVAC system is functional now. New Epoxy was under process at the time of inspection.
In Process quarantine	**In Process quarantine**
Separate in process quarantine area was provided which required improvement with respect to proper storage, lights and temperature/humidity controls.	The firm has provided new Lights in area and racks were painted. Temperature/humidity was monitored and record was maintained.
Cephalosporin Area	**Cephalosporin Area**
Segregated area was provided for the cephalosporin's. Separate raw material store with dispensing, quarantine and release areas were available. It was advised to provide air conditioner in quarantine area, Dispensing log book required amendment with respect to raw materials entries. Section pharmacist was not hired.	HVAC was working. Dispensing log book has been improved. It was advised to hire Pharmacist.
Cephalosporin Dry powder Injectable	**Cephalosporin Dry powder Injectable**
In the washing area ,two ovens were installed for sterilization of vials but were not validated	The firm informed that both ovens were calibrated. Document provided.
DOP test of filters of filling machine was not performed	The firm has performed DOP Test. Document provided.

HVAC system was not validated and functional properly hence required classes A& B in the area were not maintained.	HVAC was functioning properly and validated. Document provided.
Buffers were not interlocked	The firm ensures the Interlocking through HVAC System.
Optical checking not developed properly	The firm has improved Optical checking area and provides Eye checkup certificates of workers.
Media fill trail not performed	The firm informed that Protocol will be developed and will be incorporated in master validation plan.
Cephalosporin Dry Powder Suspension	**Cephalosporin Dry powder suspension**
Bottle blowing machine was not present.	The firm was advised to provide new machine in eight weeks. They agreed.
Safety grill required around mixer	The firm has provided safety switch in the door of mixer.
HVAC system was not functional	The firm informed that HVAC was functional and validated. Document provided.
Cephalosporin Tablet	**Cephalosporin Tablet**
In this section granulation, drying, mixing compression, coating and packaging processes were involved. Coating and solution preparation room was empty. No equipment was installed. HVAC system was not functional	The firm has placed necessary equipment's in the area and HVAC was functional and validated.
Cephalosporin Capsule	**Cephalosporin capsule**
HVAC system was not functional	The firm informed that HVAC is functional and validated. Document provided.
Dry Powder Suspension (General)	**Dry Powder Suspension (General)**
In this section two manual filling machines were installed. HVAC system was not functional. No production was seen	The firm has validated HVAC at the time of visit. Document provided.
Penicillin Section	**Penicillin Section**

The section was segregated and was developed in the same building with separate entries. A door of penicillin section was also linked with the general corridors.	Layout plan has been approved by DRAP
Stores	**Stores**
Separate dispensing hood of penicillin was not provided	The firm was advised to provide separate dispensing both within six weeks.
Penicillin Tablet / Capsule	**Penicillin Tablet / Capsule**
In this section thermal mapping of dryer required, safety grill around mixer was not provided, Compression machines required closed coverings. HVAC system was not functional, No solution preparations coating area developed. No production activity was seen. Section Incharge not hired.	The firm has provided Calibration of Thermal gauges in the dryer. The firm has provided Safety grill around the mixer. The firm has validated HVAC. The firm was using readymade coating materials for coating. Section pharmacist is hired
Cream / Ointment	**Cream / Ointment**
The section was not in operation	The firm explains that the section was in operation but have no orders.
Laboratory Controls	**Laboratory Controls**
The quality control laboratory was independent of other departments. Mr. Shahid Afzal the approved of quality control incharge was not present at the time of inspection. The quality control equipment was not sufficient. It was observed that two HPLCs were installed, one was not functional the other HPLC's calibration was expired and the quality control analyst was unable to explain its working as he could not perform test on HPLC. The firm had more than 300 registered products and only one HPLC was installed, which was also not operative at the time of inspection, TOC apparatus was also out of order. Liquid particle counter was installed, without laminar flow hood. The equipment such as UV Spectrophotometer, dissolution apparatus etc were calibrated from Galvanic Scientific	The approved quality control incharge Mr. Shahzad Afzal was present at the time of inspection. The firm provides List of essential equipment's. The firm has provided calibration certificate for HPLC. The firm was advised to make arrangements for operative of second HPLC in eight weeks TOC was available but required maintenance. The Firm informed that LPC has inbuilt cover for sample materials The firm has reference standards and provided Reference standard Certificates

however, no entries to log book, were available. Some working standards were available, reference standards were not available. The microbiology laboratory also required improvement with respect to buffers. HVAC system, sterility room and media preparation areas. Microbiologist was not present. Bacterial cultures were not available. Particle Counter was not calibrated. Necessary tests required for antibiotic / penicillin's were not being performed. Testing SOPs were not provided. It was advised to perform tests as per pharmacopoeial methods.	The firm has improved the Microbiology Laboratory with respect of buffers and media preparation. Microbiologist was present at the time of inspection. The firm was performing all necessary tests. The firm is performing tests according to Pharmacopeia. (Standard Testing Method Provided)
Water purification system	**Water purification system**
The system involved double R.O water treatment, softener, ion exchanges double distillation, and storage tank with loop system. The cleaning / validation of system required improvement.	The firm has provided protocol for validation of water System and improve the system.
Documentation	**Documentation**
The BMRs were available, however several deficiencies were noted. SOPs required improvement. APQR of products was not performed. The organogram, approved layout plan, list of approved sections were not provided.	The firm has improved SOPs. Provide all the required documents(APQR, Organogram and list of approved section.)
Quality Management & Self inspection	**Quality Management & Self inspection**
The quality management system was not properly established. Self-audits and trainings were not being perfumed.	The firm has established quality management system. Protocols for self-audit and training record provided.
Personnel	**Personnel**
The technical staff was not sufficient for production, quality control and quality assurance department. The firm had more than 15 sections and only two pharmacist in sections were hired, who were also absent at the team of	The hiring of technical staff was under process. The firm has provided the medical record of workers. The firm was advised to hire

inspection. The medical record of the staff was not available. The management was directed to appoint more technical staff for each section.	minimum two pharmacists.
Air Handling	**Air Handling**
HVAC system was not functional. Validation of HVAC system was not performed. The differential pressures were not checked properly as manometers were not installed in some areas and were not proper. The temperature / humidity, number of air changes were not controlled through HVAC system.	The differential pressures were checked properly as manometers was installed. HVAC was in working condition at the time of inspection.

6. The conclusion of report is reproduced below;

"*In view of above findings of inspection, areas checked, documents reviewed, the panel is of the opinion that the firm had rectified most of the previous observations. Hence the firm may be allowed to resume the production activities. The management assured that they would strictly follow the Drugs Act 1976 as per GMP compliance".*

7. Keeping in view the conclusion of panel reproduced herein above. The matter was placed before the Additional Director QA&LT for consideration. The resumption of production activities was allowed to the firm in all production areas vide this office letter No. 4-45/2004-QA (Vol-I) dated 17.09.2021

Proceedings and Decision of 283rd meeting of CLB:

8. The board deliberated on the matter and decided as under;

i. Ratify the decision of Additional Director QA & LT issued vide letter No. 4-45/2004-QA (Vol-I) dated 17.09.2021.
ii. Cease the enforcement of show cause notice vide No. 4-45/2004-QA (Vol-I) dated 30.08.2021.

Case No. II. M/s Medlay Pharmaceuticals, Wah Cantt. (DML No. 000237).

A letter vide No. F.2-8/2010-FID-II (ISD) dated 25.05.2021 was received from Tehreem Sara, FID DRAP Islamabad wherein she submitted inspection report of M/s Medlay Pharmaceuticals, Plot No. 41-A, P.S.I.E. Jhang Bahtar Road, Wah Cantt. The inspection was conducted on 07.05.2021.

2. As per report, the FID reported following observations;

i. **Technical Staff:**
   a. Miss Nabeela Noor working as Plant Manager and also working as Assistant Quality Control Manager.
   b. Technical persons are not approved from DRAP.

ii. **Raw Material Stores:**
   a. The dedusting area is not provided for the equipment required for the dedusting.
   b. The temperature and humidity requirement for the thermolabile products (cold room) is not maintained. The temperature monitoring shall be observed according to the requirement of cold room.
   c. The cartons in the dispensing booth provided to keep the utilities/tools need to be replaced with proper boxes.
   d. The pharmacist needs to be appointed for supervision of proper storage condition of materials.

iii. **Change Rooms:**
   a. The step over facility and the change room SOPs needs to be displayed and properly maintained from time to time. The facility of change needs to be upgraded in order to meet the requirement of cGMP.
   b. The washing facility with open sewage needs immediate attention.
   c. Hand sanitizer needs to be provided in the change room.

iv. **Capsule Area:**
   a. It was strictly advised to maintain temperature and humidity prior to the production in this facility and validate their HVAC accordingly to meet the requirement of production of various molecules in capsule section.
   b. IPQ testing equipment require to be placed at the work station.

v. **Tablet Area:**
   a. In process quarantine area is neither provided with HVAC nor with AC facility.
   b. Proper SOPs need to be observed and to be displayed in each area.
   c. Shelves/station for the storage of log books and in process testing equipment needs to be provided.
   d. Separate Pharmacist to look after the working in this section is needed to be appointed.

vi. **Liquid Section:**
   a. Separate Pharmacist to look after the working in this section is needed to be appointed.

vii. **Injectable area; Terminally Sterilized Products:**
   a. The utilities and record register are needed to be removed from air locks/ buffers.
   b. Mr. Attiq ur Rehman (Matric) is looking after the ampoule preparation and filling operation as provided in the details by the firm that is immediately required to be supervised by a pharmacist to carry out the production in the sterile area.
   c. The HVAC system SOP need to be strictly observed with reference to the efficiency of filters and its integrity as observed during the inspection when one of HVAC unit is opened.
   d. The proper safety measures should be considered while using the Autoclave and this equipment need to be provided with proper alarm system and safety valve to avoid any unpleasant incident/emergency.

viii. **Quality Control:**

a. An independent quality assurance manager is required.

ix. **Sanitation and Hygiene:**

a. The SOPs related to sanitation and hygiene needs to be displayed and revised / changed from time to time.
b. The record of medical checkup of their workers every year should be maintained.
c. They are advised to clean the floor and drainage line with antiseptic detergent.

x. **Qualification and Validation:**

a. Validate and calibrate the equipment in QC and production on 6 months basis.

3. The conclusion of report is reproduced below;

"Overall the working condition in non-sterile/oral sections is satisfactory. They have improved many short comings pointed put during last inspection and the GMP guidelines at a satisfactory level is followed by the firm. They are further advised to rectify the shortcomings/observations mentioned above.

However, in the sterile area improvement is required with reference to the area monitoring. The appointment of technical/qualified person. They are further advised to conduct media fill trial to ensure that the sterility of the product throughout the manufacturing process is maintained."

4. Keeping in view the observations and conclusion of report, firm was directed vide letter No. F.4-14/2011-QA dated 10.08.2021 to stop production activities in Sterile Area, rectify observations reported by the FID and submitted detailed CAPA report.

5. The firm M/s Medley Pharmaceuticals, Plot No. 41-A, P.S.I.E. Jhang Bahtar Road, Wah Cantt vide letter No. DRAP/QA-II/ISL/01/21 dated 12.08.2021 submitted that they have corrected all the observations and have successfully conducted media fill trials. The firm has also requested for re-inspection of their firm for verification of CAPA.

6. Following panel of experts was constituted by the Additional Director QA&LT for reinspection of the firm with request to give recommendations whether production activities in sterile area shall be resumed or otherwise;

i. Mrs. Tehreem Sara, Area FID-IV, DRAP Islamabad.
ii. Mr. Hasan Afzaal, Assistant Director (QA-I) DRAP, Islamabad.
iii. Mr. Ayub Naveed Assistant Director (NCL-BIO), Islamabad.

7. The panel inspected M/s Medlay Pharmaceuticals, Punjab Small Industrial Estate, Jhang Bahtar Road, Wah Cantt (DML No. 000237) on 26.08.2021. The rectification status of observations reported by panel is reproduced below;

Sr. No.	Observations of the report conducted on 07-05-2021	Verification of corrective action by the panel
1.	**TECHNICAL STAFF:** Technical persons are not approved from DRAP	Quality Control Manager has been approved from DRAP where now as the firm informed that the documents of Production Manager having 14-year experience has been submitted to DRAP since June 2018
2.	**RAW MATERIAL STORES:** The dedusting area is not provided	The firm has provided the area with the equipment required

	for the equipment required for dedusting	
3.	The Temperature and humidity requirement for the thermolabile products (cold room) is not maintained need to be maintained according to cold room requirement	The temperature and humidity have been maintained and controlled by replacement of old Air conditioner with new Air conditioner. the temperature monitoring is done regularly in according to standard guidelines for cold room and record in maintained properly.
4.	The cartons in the dispensing area provide to keep utensils should be replaced with proper boxes	The firm has now refurbished the whole area and is provided with SS shelves and proper storage containers (Non-Shredding) for utilities and tools. They were further advised to provide proper dispensing booth.
5.	Pharmacist need to be appointed for supervision of proper storage condition of materials.	The firm has informed the panel that they have hired a new pharmacist.
6.	**CHANGE ROOMS:** Step over facility and SOPs need to be displayed and maintained. Executive change room need to be upgraded in order to meet requirements of cGMP	All the relevant SOPs have been upgraded and new SOPs have been displayed properly. New Aluminum cabins have been provided in executive change room. The step over facility have also been upgraded to meet requirement of cGMP
7.	The washing facility in change room with open sewage needs immediate attention	The washing facility with open sewage has been closed and sealed by the firm.
8.	Hand sanitizer needs to be provided in the change room	The firm has replaced the Old hand sanitizer dispenser with new one.
9.	**CAPSULE AREA:** IPQ testing equipment requires to be placed at the work station.	The firm has now placed IPQ testing equipment on the designated areas of all sections (Tablet/capsule/Liquid syrups) with proper documentation.
10.	**TABLET AREA:** IPQ area to be provided with HVAC point.	The firm has provided HVAC system (duct)with all necessary requirements in IPQ area of Tablet section.
11.	Proper SOPs need to be observed	All the SOPs have been updated and displayed at

	and displayed in each area	conspicuous places of each section.
12	Shelves/Station for log books should be provided	The firm has now provided new SS File holders and Shelves for log books and various IPQ records
12.	Separate Pharmacist for Tablet and Capsule section need to be appointed	The firm has appointed new production Pharmacist.
13.	**LIQUID SECTION:** Separate Pharmacist to look after working in liquid section is needed to be appointed	The firm has hired a new pharmacist.
14	**INJECTABLE AREA: TERMINALLY STERLIZED PRODUCTS:** The utilities and record register are need to be removed from air lock/buffer of injection area	The cabinets for utilities and record register have been removed and SS file holder have been hanged.
15.	Experience pharmacist to look after working in Sterile area.	The firm has designated Miss Nosheen Assist. Production Pharmacist having 3 years' experience in Medley Pharmaceuticals to look after production in sterile area which is further closely supervised by **Production Manager** also. Whereas Mr. Attique is working as **ampoule machine operator** and assisting the pharmacist having cumulative of 08 years' experience for sterile area.
16	HVAC system SOPs need to be strictly observed in terms of filters integrity and efficiency.	All the SOPs have been updated and all the filters have been changed as per schedule. The filters are also regularly washed as per SOPs.
17.	Safety valve on the autoclave of injection area need to be provided	The safety valve has been provided. The efficiency of safety valve is also been checked with proper display of SOP in the designated area.
18.	Conduct Media fill trial	**The firm has conducted Media fill trail and results are submitted in this office which indicate that the test is conducted according to the official compendia and the results of the test are also satisfactory.**
19.	**QUALITY CONTROL:**	The management inform that miss Nabeela Noor has now work as independent QA manager having 7.5 years

	Independent QA manager required	of industrial experience closely working with miss shazam Shaukat having 3-year experience, already looking our QA department as QA inspector. so, a separate QA department exists with proper delivery of its responsibilities.
20.	**SANITATION AND HYGIENE:** SOPs related to sanitation and hygiene need to be displayed and revised/changed from time to time	All the relevant SOPs have been revised and 6 monthly training of the cleaning staff is also been conducted.
21.	The record of medical Checkup to be maintained	All of the permanent staff is enrolled with social security and undergo basic medical checkup on regular basis with record keeping. In addition, temperature of each staff is monitored on start of every day before entrance in to the production area.
22.	Clean Floor and drainage with antiseptic detergent	The floors and drainage are regularly cleaned with antiseptic agent
23.	**QUALIFICATION AND VALIDATION:** Validate and Calibrate the equipment on 6 monthly basis	All the equipment is calibrated on 6 monthly bases with having a definite contract with an authentic calibration vendor. In addition, daily in-house calibration is also been done

8. The conclusion of report is reproduced below;

"Since the GMP is an ongoing process that need continuous monitoring. So, QA department of the firm is advised to conduct its regular self-audit to maintain the sustained GMP level. Few suggestions related to the dispensing area. buffing and polishing of equipment in oral dosage from, area monitoring of sterile area, validations of certain processes and manufacturing of sterile products under Aseptic condition are given by the panel, which the firm agreed to follow prior to resumption of production. In view of the above rectification made by the firm the panel is of the view to recommend the resumption of production in the sterile area."

9. The matter was placed before the Additional Director QA&LT. Keeping in view the recommendations of panel given in their inspection report dated 26.08.2021, resumption of production activities in sterile area of M/s Medley Pharmaceuticals, Plot No. 41-A, P.S.I.E. Jhang Bahtar Road, Wah Cantt (DML No. 00237) were granted on 09.09.2021.

Proceeding and Decision of 283rd meeting of CLB:

8. The board ratified the decision of Additional Director QA&LT.

Case No.III:- **M/s Perfect Pharma (Pvt.) Ltd. Lahore.**

Background

An inspection of M/s. Perfect Pharma (Pvt.) Ltd., Located at 5-KM, Manga Raiwind Road, Lahore (DML No.00469) was conducted with reference to DRAP Islamabad's Letter No. F. 13-196/2019-QC (Vol-I) dated 27-04-2021 on the subject titled, ***"MANUFACTURING / SALE OF UNREGISTERED DRUGS BY M/S. PERFECT PHARMA (PVT) LTD., 5-KM, MANGA RAIWIND ROAD, LAHORE."***by Mrs. Majida Mujahid, Area Federal Inspector of Drugs, DRAP, Lahore and Ms. Maham Misbah, Assistant Director, DRAP, Lahore on 08-06-2021. The panel has reported the case background, which has been reproduced hereunder: -

"The firm was asked about the production of its purported product Nrufen Suspension. The firm's management responded that they had recently taken over the firm from the previous management. The Central Licensing Board in its 273rd meeting held on 15-01-2020 had endorsed the change of management and the decision had been communicated vide DRAP, Islamabad letter No. F.1-15/98-Lic (Vol-III) dated 10-06-2020. ***(Letter of change of management attached, Annex 2)****. The CEO of the firm informed the panel that his firm had not manufactured Nrufen Suspension (Ibuprofen Suspension) since the change of management neither had they received any record of production (BMR) of Nrufen Suspension from the previous management, at the time of change of management. He further stated that his team did not receive any registration letter of Nrufen Suspension from the previous management, therefore, the same could not be reproduced before the panel. Nrufen Suspension was not included in the Section-wise registered product list of the firm, as shown to the panel. No Ibuprofen API, unit carton or label of Nrufen suspension was found in the premises at the time of inspection. Further, no production record of Nrufen Suspension, testing record of Ibuprofen API, testing record of finished Nrufen suspension or any retained samples of Nrufen Suspension were found in the premises at the time of inspection".*

2. The panel conducted inspection to check cGMP compliance of the firm. The observations of the panel are as follows:

Change Rooms:

i. The entry into male and female change rooms was through the toilets.
ii. Toilet doors were open. Toilets needed repair.
iii. There was no exhaust, AC or HVAC supply in the workers' change rooms.
iv. Change-over instructions, hand sanitizer, etc were not displayed / available.
v. In the executive change area, air conditioner was not operational.
vi. Disposable overalls were not available for visitors.
vii. Hand sanitizer was not installed.
viii. SOPs for change-over were not available.
ix. Firm was directed to develop and implement SOPs for change over as per cGMP requirement without fail.

Material Entry / Material Receiving:

i. There were recesses in the doors of the material receiving.

ii. No vacuum cleaner or cloth was available for de-dusting of the incoming material.
iii. There were long cracks in the walls of material receiving area.
iv. Paint was chipping off.
v. Printed labels were stored without lock and key in the material receiving area.
vi. PET bottles were also stored in the area.
vii. Even rejected unit cartons were found in this area.

Raw Material Quarantine Area:

i. Material was stored in haphazard manner.
ii. HVAC supply or return was not given.
iii. There was no thermo-hygrometer installed in the area.
iv. Released material was also present in the quarantine area.
v. Temperature and humidity was not maintained and firm failed to produce any temperature and humidity record before the panel.

Sampling:

i. Entrance to the sampling area was partially obscured with packing material.
ii. Entry to the sampling area was from de-dusting area without any door in between.
iii. Fungal growth was seen on the walls of sampling area.
iv. A thick layer of dust was observed in the area.
v. Paint was chipping off from the walls.
vi. Moreover, shippers were stored on the floor in this area.
vii. The shippers were also stacked inside the sampling hood.
viii. Temperature and humidity was not maintained; HVAC and thermo-hygrometer were not installed. Sampling tools were not present.
ix. It seemed that the area had not been used for sampling since long.

Raw Material Store:

i. The raw material store was congested.
ii. Lighting and working space was inadequate.
iii. Materials were stored haphazardly.
iv. Multiple materials were stored on same rack without physical partition.
v. There was no segregation between API's and excipients.
vi. Thermo-hygrometer was not installed.
vii. There was no log of temperature and humidity only AC was installed.
viii. Empty gelatin capsules were also stored in the same area / conditions without fulfilling the storage requirements.
ix. Walls, floor and roof of this room needed repair.
x. A thick layer of dust had accumulated on the containers and pellets in the store.
xi. Firm was directed improve the conditions and maintain log of environmental conditions and materials present in the store

Rejected Material Store:

i. The rejected material area was a small cabin
ii. Materials were stored haphazardly inside.
iii. There was no log/ record of the materials stored inside.
iv. The rejected goods area was not locked.

Dispensing:

i. Dispensing hood was installed.
ii. A few scoops were placed inside the hood for dispensing.
iii. Civic work was required in the area.

Packing Materials Store:

i. It was advised to rearrange the packing material store and maintain temperature and humidity conditions.

Production Areas:

i. Cartons containing finished goods were stacked on the floor in the production corridors.
ii. There was no supply of HVAC in the production corridors.

Oral Liquid Section:

Bottle Blowing / De-Cartoning Area:

i. HVAC was not operational.
ii. The conditions in the area were unsanitary and unhygienic.

Oral liquid manufacturing:

i. In the oral liquid manufacturing area, HVAC was not operational at the time of inspection.
ii. There seemed to be fungal growth on the roof of the manufacturing area.
iii. Firm was directed to ensure platform for workers, improve epoxy flooring and civic work ensure buffing of all machines / equipment and replace all rusted equipment with new one.
iv. Further directed to make HVAC functional and install GMP compliant drains.
v. Also directed to label water supply and remove all plastic containers from the area.

Oral Liquid Filling:

i. There was open drain in filling area.
ii. Civic work needed a lot of improvement. HVAC was not functional.
iii. Firm was directed to immediately replace all material transfer pipes with SS line for material transfer.

Oral Liquid Packing and Labeling:

i. It was directed to ensure partitioning between filling and packing area.
ii. Further directed to provide SS stools for personnel in packing area.

Tablet Section (General):

Mixing:

i. HVAC was not operational at the time of inspection.
ii. Temperature and humidity was 27.1C and 54% respectively.
iii. Firm was directed to ensure functional HVAC and maintain log of temperature and humidity.
iv. Further advised to get all manometers calibrated and repaired immediately and to maintain pressure differential.
v. Also directed to ensure buffing of all equipment regularly.

Drying:

i. One FBD was installed in the drying area.
ii. It was directed to calibrate the gauge of FBD.
iii. Management was further directed to ensure proper partitioning between mixing and drying area.

Final Mixing:

i. A single cone mixer was installed in the final mixing area.
ii. The area was small and not suitable for operation of the cone mixer.

iii. It was advised to place the cone mixer in a suitable area.

In-Process Quarantine:

i. The in-process quarantine area was not maintained.
ii. In-process materials was stored haphazardly inside the area.
iii. The management was directed to ensure proper storage of materials in the area and maintain log of all materials in the area.

IPQC Lab:

i. There was no proper IPQC Lab.
ii. Only a balance and friability tester were placed openly in the corridor outside the compression rooms.
iii. It was directed to develop proper IPQC lab.

Compression Area:

i. There were three compression rooms.
ii. The HVAC was not operational in the area at time of inspection.
iii. The management was directed to immediately replace the installed machines with GMP compliant compression machines.

Capsule Section:

i. Manometers were not installed.
ii. Mixing and filling equipment needed buffing and repair.
iii. Capsule polisher was not installed.
iv. At the time of inspection, the temperature and humidity in the filling area was 27 C and 57% respectively, which was not suitable for hard gel capsules.

External Preparations (Repacking) Section:

i. HVAC was not installed in the section.
ii. The management was directed to improve civic work immediately and ensure seamless floor, roof and walls.
iii. It was also directed to immediately repair and maintain the filling machine and storage vessels.

Psychotropic Tablet Section:

i. This section was located on the first floor.
ii. The firm informed that they had not manufactured any psychotropic tablets till date due to the unavailability of quota.
iii. The overall conditions of the section were unhygienic.
iv. HVAC was not operational. Equipment needed immediate repair / maintenance and / or replacement.
v. Packing of General Tablet, Femozine (Famotidine) 20mg (Batch no. 537, Mfg date 05/21, Expiry 05/23) was being done in the packing hall of psychotropic section.

Semi-Solid Section:

i. The area not maintained. HVAC was not operational.
ii. The equipments were unclean and needed immediate repair.
iii. Firm's management was directed to immediately undertake civic work in the area.
iv. The air return grills in the manufacturing area was not fitted properly.

v. There was a big gap in the wall though which air from outside environment could directly enter into the area.

Quality Control Lab:

i. In the Quality control lab, the management was directed to install proper fume hood and emergency shower.
ii. Further directed to install chemical resistant worktops in the wet chemistry lab.
iii. The FTIR was out of order.
iv. The QC analyst informed the panel that the FTIR had been out order for the last one year.
v. No work order could be shown to the panel in this regard.
vi. Therefore, it seemed that the firm had not done identification test of incoming raw materials since last one year.
vii. Only one HPLC was installed.
viii. Column oven was not available even though firm required 35C column temperature for testing of one of its products (Diclofenac Potassium Tablets).
ix. Firm was directed to conduct complete testing of all raw and packing materials and finished goods as per pharmacopoeia.
x. Two stability chambers were installed.
xi. There was no electricity backup / UPS for the chambers, as informed by the QC team.

Retained Sample Area:

i. The management was directed to develop log of all product samples which were stored in the area.

Training and Personnel:

i. The technical personnel required training and refresher course on GMP.
ii. It was advised to ensure atleast one pharmacist in each section.
iii. ***Further advised to immediately appoint Quality Assurance Manager with relevant experience,*** as required and to develop a Quality Assurance team.

Documentation:

i. Poor documentation was seen with regards to production and Quality Control.
ii. Firm was directed to immediately develop organogram and update all job descriptions of key personnel.
iii. It was also directed to the management to submit report / record of all equipment calibrations, process validations, cleaning validations, analytical method validations, internal audit, self-inspection and Annual Product Quality Review.
iv. The panel further directed the management to submit record of complaint handling, product recalls, OOS results and medical fitness of employees to this office within three working days, without fail.

Conclusion:

*"Overall, the sanitary and hygienic conditions of the firm were **poor** at the time of inspection. The civic work, working of HVAC and condition of equipment was found **unsatisfactory** at the time of inspection. Firm **did not comply** with the current GMP requirements as per Schedule B-II of the Drugs (Licensing, Registration and Advertisement) Rules, 1976."*

3. A letter vide REF. No: PPL/212/2021 dated 15.06.2021 from M/s. Perfect Pharma (Pvt) Ltd, 5-KM, Manga Road, Raiwind, Lahore received, wherein the firm has informed that they had stopped their production on 15.06.2021 due to periodic upgradation in their factory with reference to FID's inspection on 08.06.2021. They further informed that the information regarding voluntary stoppage of production had been submitted to FID on 15.06.2021.

4. Keeping in view the observations, the firm was issued a show cause notice vide No. 4-43/98-QA (pt) dated 08.07.2021 along with directions to not to resume production prior to the approval of this Directorate, subject to relevant proceeding as deemed necessary by the Competent Authority.

5. The firm submitted reply to this office show cause notice vide letter REF. NO. PPL/238/2021 dated 15.07.2021 wherein they have stated that they have already voluntarily stopped all kind of Production in their factory since 15.06.2021 in order to make improvements and to remove all the deficiencies with reference to FID's guidance on her visit on 08.06.2021 and communicated to FID, Lahore through their Letter No: PPL/192/2021 dated 15.06.2021. Letter to stop production voluntarily also submitted in DRAP through their Letter No: PPL/212/2021 dated 28.06.2021. The firm has informed that they have removed all the deficiencies in their factory as pointed out by FID in her visit and always ready to make further improvements. The management of the firm has requested to ask FID to visit their factory and check the improvements they have made and allow them to resume Production in their factory.

Proceedings of the 282nd meeting of the Central Licensing Board.

6. Mr. Ashfaq General Manager and Mr. Salman Shafique CEO of the firm M/s. Perfect Pharma (Pvt) Ltd, 5-KM, Manga Road, Raiwind, Lahore appeared before the board and informed that they have rectified all the observations noted by the FID during her inspection dated 08.06.2021 and are ready for re-inspection.

Decision of 282nd meeting of the Central Licensing Board.

7. After thorough deliberation, considering compliance report of the firm and personal hearing of the firm's representatives, the board decided as under;

i. Following panel of experts is constituted for inspection of the firm M/s. Perfect Pharma (Pvt) Ltd, 5-KM, Manga Road, Raiwind, Lahore to verify of rectification of observations reported by the FID in her report dated 08.06.2021;
    a. Mr. Azhar Jamal Saleemi, Chief Drug Controller Punjab.
    b. Area FID DRAP Lahore.
    c. Ms. Maham Misbah, Assistant Director, DRAP Lahore.
ii. The Additional Director QA&LT shall pass orders based on recommendations of the panel of experts regarding production activities and present case in subsequent meeting of Central Licensing Board for ratification and information.

8. The panel conducted inspection of the firm on 22.09.2021 & 08.10.2021. The panel reported the updated status of observations as under;

Observations during Inspection dated 08.06.2021	Observations during inspection dated 22.09.2021 & 08.10.2021
Change Room: i. The entry into male and female change rooms was through thetoilets. ii. Toilet doors were open. Toiletsneeded repair. iii. There was no exhaust, AC orHVAC supply in the workers' change rooms. iv. Change-over instructions, hand sanitizer, etc were notdisplayed/available. v. In the executive change area, air conditioner was notoperational. vi. Disposable overalls were not available for visitors. vii. Hand sanitizer was not installed. viii. SOPs for change-over were not available. ix. Firm was directed to develop and implement SOPs for change over as per cGMP requirement without fail.	**Change Room:** Change rooms were improved with reference to civic work. Advised to remove cleaning supplies from change room.
rial Entry / Material Receiving: i. There were recesses in the doors of the material receiving. ii. No vacuum cleaner or cloth was available for de-dusting of the incoming material. iii. There were long cracks in the walls of material receiving area. iv. Paint was chipping off. v. Printed labels were stored without lock and key in the material receiving area. vi. PET bottles were also stored in the area. vii. Even rejected unit cartons were found in this area.	**rial Entry / Material Receiving:** Recesses were not closed. Advised to close recesses & install shed outside material receiving. Civil work was done. Area was clean and maintained. Vacuum cleaner for de-dusting was available. No material was stored in the area, at the time of inspection.
Material Quarantine Area: i. Material was stored in haphazard	**Material Quarantine Area:** as installed. Thermo-hygrometer was installed.

manner. ii. HVAC supply or return was not given. iii. There was no thermo-hygrometer installed in the area. iv. Released material was also present in the quarantine area. v. Temperature and humidity was not maintained and firm failed to produce any temperature and humidity record before the panel.	Firm had started keeping record of temperature & humidity. Area was maintained.
ling: i. Entrance to the sampling area was partially obscured with packing material. ii. Entry to the sampling area was from de-dusting area without any door in between. iii. Fungal growth was seen on the walls of sampling area. iv. A thick layer of dust was observed in the area. v. Paint was chipping off from the walls. vi. Moreover, shippers were stored on the floor in this area. vii. The shippers were also stacked inside the sampling hood. viii. Temperature and humidity was not maintained; HVAC and thermo-hygrometer were not installed. Sampling tools were not present. ix. It seemed that the area had not been used for sampling since long.	**Sampling:** Obstruction was removed. Door was installed between de-dusting and sampling area. Walls were smooth and clean. Area was clean and maintained. HVAC was installed. It was advised to the management to get change in layout plan regularized from DRAP.
Material Store: i. The raw material store was congested. ii. Lighting and working space was inadequate. iii. Materials were stored haphazardly. iv. Multiple materials were stored on same rack without physical partition. v. There was no segregation between API's and excipients. vi. Thermo-hygrometer was not installed. vii. There was no log of temperature and humidity only AC was installed. viii. Empty gelatin capsules were also stored in the same area / conditions without fulfilling the storage requirements.	**Material Store:** ing and civic work was improved. s were installed for storage of raw materials. ate racks were designated for APIs and excipients. had started to maintain record of temperature & humidity. onment conditions and overall cleanliness was improved. However, the store was still congested. Therefore, firm was advised to expand the store without fail and get prior regulatory approval.

ix. Walls, floor and roof of this room needed repair. x. A thick layer of dust had accumulated on the containers and pellets in the store. xi. Firm was directed improve the conditions and maintain log of environmental conditions and materials present in the store.	
ted Material Store: i. The rejected material area was a small cabin ii. Materials were stored haphazardly inside. iii. There was no log/ record of the materials stored inside. iv. The rejected goods area was not locked.	**ted Material Store:** parate room was designated for storage of rejected materials. It was advised to keep the area locked and maintain log of all materials to be stored therein.
nsing: i. Dispensing hood was installed. ii. A few scoops were placed inside the hood for dispensing. iii. Civic work was required in the area.	**nsing:** work was done. Area was neat and clean. It was advised to wrap the clean dispensing scoops in polythene bags, separately. Further advised to hire store pharmacist. ed to provide seamless SS scoops and SS trolley.
ng Materials Store: i. It was advised to rearrange the packing material store and maintain temperature and humidity conditions.	**ng Materials Store:** as installed. Firm had started to maintain log of temperature & humidity. However, it was advised to change labelling and packing of few products which were resembling labeling and packing of marketed products of other companies.
uction Areas: i. Cartons containing finished goods were stacked on the floor in the production corridors. ii. There was no supply of HVAC in the production corridors.	**Production Areas:** HVAC was not installed in production corridor. Finished goods were removed from the corridor.
Oral Liquid Section: **Bottle Blowing / De-Cartoning Area:** i. HVAC was not operational. conditions in the area were unsanitary and	**Oral Liquid Section:** **Bottle Blowing / De-Cartoning Area:** Sanitation & hygiene conditions were improved.

unhygienic.	Advised to install & calibrate pressure gauge/ manometer in bottle blowing areas.
Oral liquid manufacturing: i. In the oral liquid manufacturing area, HVAC was not operational at the time of inspection. ii. There seemed to be fungal growth on the roof of the manufacturing area. iii. Firm was directed to ensure platform for workers, improve epoxy flooring and civic work ensure buffing of all machines / equipment and replace all rusted equipment with new one. iv. Further directed to make HVAC functional and install GMP compliant drains. v. Also directed to label water supply and remove all plastic containers from the area.	**Oral liquid manufacturing:** HVAC was operational at the time of inspection. Area was neat & clean. It was again advised to ensure platform for workers, ensure calibration of gauges of equipment & install GMP complaint drains across the oral liquid section. Further advised to ensure proper working space for all equipment and ensure loop system in the section without fail.
Oral Liquid Filling: i. There was open drain in filling area. ii. Civic work needed a lot of improvement. HVAC was not functional. iii. Firm was directed to immediately replace all material transfer pipes with SS line for material transfer.	**Oral Liquid Filling:** Civic work was improved. HVAC was functional at the time of inspection. SS material transfer line was installed. However, firm was advised to improve it further, fix it properly & prepare SOP for cleaning of material transfer line. Further advised to ensure disinfection in drain and maintain record, accordingly.
Oral Liquid Packing and Labeling: i. It was directed to ensure partitioning between filling and packing area. ii. Further directed to provide SS stools for personnel in packing area.	**Oral Liquid Packing and Labeling:** It was advised to ensure proper partitioning between filling and packing area. SS stools were provided.
Tablet Section (General): **Mixing:** i. HVAC was not operational at the time of inspection. ii. Temperature and humidity was 27.1C and 54% respectively. iii. Firm was directed to ensure functional HVAC and maintain log of temperature and humidity.	**Tablet Section (General)** **Mixing:** HVAC was operational. It was advised to get regular validation of HVAC from third party. Manometers were calibrated. Equipment was improved. However, firm was advised to get regular buffing of machine in the future as

iv. Further advised to get all manometers calibrated and repaired immediately and to maintain pressure differential. v. Also directed to ensure buffing of all equipment regularly.	well.
Drying: i. One FBD was installed in the drying area. ii. It was directed to calibrate the gauge of FBD. iii. Management was further directed to ensure proper partitioning between mixing and drying area.	**Drying:** FBD gauge was calibrated. Partitioning between mixing and drying was not done due to space constraint.
Final Mixing: i. A single cone mixer was installed in the final mixing area. ii. The area was small and not suitable for operation of the cone mixer. iii. It was advised to place the cone mixer in a suitable area.	**Final Mixing:** Cone mixer was placed in suitable area. Safety belt was installed. Firm was advised to get any changes in approved LOP, regularized from DRAP.
In-Process Quarantine: i. The in-process quarantine area was not maintained. ii. In-process materials was stored haphazardly inside the area. iii. The management was directed to ensure proper storage of materials in the area and maintain log of all materials in the area.	**In-Process Quarantine:** Maintained. Advised to provide pallets and maintain temperature & humidity.
IPQC Lab: i. There was no proper IPQC Lab. ii. Only a balance and friability tester were placed openly in the corridor outside the compression rooms. iii. It was directed to develop proper IPQC lab.	**IPQC Lab:** A small IPQC lab was developed. However, firm was advised to further improve the lab and maintain proper record of equipment utilization.
Compression Area: i. There were three compression rooms. ii. The HVAC was not operational in the area at time of inspection. iii. The management was directed to immediately replace the installed machines with GMP compliant compression machines.	**Compression Area:** HVAC was operational. Firm was advised to ensure air balancing and ensure covering of all compression machines. Firm's management informed that they were in the process of procuring a new compression machine.

Capsule Section: i. Manometers were not installed. ii. Mixing and filling equipment needed buffing and repair. iii. Capsule polisher was not installed. iv. At the time of inspection, the temperature and humidity in the filling area was 27 C and 57% respectively, which was not suitable for hard gel capsules.	**Capsule Section:** Manometers were installed. Temperature and humidity was maintained within the defined limits. Capsule polisher was installed in mixing area. It was advised to move it to filling area. Further advised hatch between capsule mixing and filling area. **Also advised inbuilt dehumidifier in AHU**. Advised to ensure buffing and repair of equipment as and when needed in the future.
External Preparations (Repacking) Section: i. HVAC was not installed in the section. ii. The management was directed to improve civic work immediately and ensure seamless floor, roof and walls. iii. It was also directed to immediately repair and maintain the filling machine and storage vessels.	**External Preparations (Repacking) Section:** HVAC was installed but the management informed **that the HVAC was not operational and was under repair**. It was advised to ensure partition between filling and packing area and make HVAC operational without fail.
Psychotropic Tablet Section: i. This section was located on the first floor. ii. The firm informed that they had not manufactured any psychotropic tablets till date due to the unavailability of quota. iii. The overall conditions of the section were unhygienic. iv. HVAC was not operational. Equipment needed immediate repair / maintenance and / or replacement. v. Packing of General Tablet, Femozine (Famotidine) 20mg (Batch no. 537, Mfg. date 05/21, Expiry 05/23) was being done in the packing hall of psychotropic section.	**Psychotropic Tablet Section:** **The area was not ready for inspection.** The firm's management informed that they have not been allocated quota for psychotropic materials. Therefore, the area was not operational and not inspected.
Semi-Solid Section: i. The area not maintained. HVAC was not operational. ii. The equipments were unclean and needed immediate repair. iii. Firm's management was directed to immediately undertake civic work in	**Semi-Solid Section:** Epoxy was done. Machine buffing was done. HVAC was operational.

the area. iv. The air return grills in the manufacturing area was not fitted properly. v. There was a big gap in the wall though which air from outside environment could directly enter into the area.	Civic work was done.
ity Control Lab: i. In the Quality control lab, the management was directed to install proper fume hood and emergency shower. ii. Further directed to install chemical resistant worktops in the wet chemistry lab. iii. The FTIR was out of order. iv. The QC analyst informed the panel that the FTIR had been out order for the last one year. v. No work order could be shown to the panel in this regard. vi. Therefore, it seemed that the firm had not done identification test of incoming raw materials since last one year. vii. Only one HPLC was installed. viii. Column oven was not available even though firm required 35C column temperature for testing of one of its products (Diclofenac Potassium Tablets). ix. Firm was directed to conduct complete testing of all raw and packing materials and finished goods as per pharmacopoeia. x. Two stability chambers were installed. xi. There was no electricity backup / UPS for the chambers, as informed by the QC team.	**Quality Control Lab:** Fume hood and emergency shower were installed. Glass and granite work tops were installed. FTIR was under installation. Only one HPLC was installed. Firm was advised to procure another HPLC. Column oven was installed and calibrated.

	Analytical method validation SOP was developed. Firm was advised to develop protocol and conduct validations. UPS was installed. It was advised to install alarm system in stability chambers.
ned Sample Area: i. The management was directed to develop log of all product samples which were stored in the area.	**Retained Sample Area:** Log was developed.
ing and Personnel: i. The technical personnel required training and refresher course on GMP. ii. It was advised to ensure at least one pharmacist in each section. iii. ***Further advised to immediately appoint Quality Assurance Manager with relevant experience,*** as required and to develop a Quality Assurance team.	**Training and Personnel:** QA Manager was appointed namely Waqas bin Aftab. Firm was advised to send his documents to DRAP, Islamabad for approval. Only one pharmacist i.e. Production Incharge was available in production. The management stated that they shall appoint one pharmacist per section immediately after resumption of production.
mentation: i. Poor documentation was seen with regards to production and Quality Control. ii. Firm was directed to immediately develop organogram and update all job descriptions of key personnel. iii. It was also directed to the management to submit report / record of all equipment calibrations, process validations, cleaning validations, analytical method validations, internal audit, self-inspection and Annual Product Quality Review. iv. The panel further directed the	**Documentation:** Firm was in the process of improving its documentation. SOPS were developed. Firm's management committed to maintaining the necessary records meticulously in future.

	management to submit record of complaint handling, product recalls, OOS results and medical fitness of employees to this office within three working days, without fail.	**Further Advises:** Firm was advised upgrade its RO plant, install loop system, upgrade and expand its Finished Goods Store, upgrade the tablet coating area and give necessary training to all technical personnel.

9. The panel has concluded the report as under;

"The previous inspection of the firm was conducted by the panel of inspectors on 08.06.2021. Serious non-compliance to cGMP were observed. The panel had forwarded its report to DRAP, Islamabad.

The CLB, in its 282nd meeting had constituted the panel comprising Mr. Azhar Jamal Saleemi, Chief Drug Controller, Mrs. Majida Mujahid, Federal Inspector of Drugs and Ms. Maham Misbah, Assistant Director, for verification of improvements made by the firm. The panel visited the premises of M/s. Perfect Pharma on 22.09.2021 to verify the cGMP compliance and again on 08.10.2021. Details of the inspection are tabulated above. Overall, the firm showed satisfactory improvements as per cGMP requirements."

10. The panel of experts have not given any recommendations regarding production activities of the firm.

Proceeding and Decision of the 283rd meeting of CLB:

11. The board considered and deliberated on the rectification status of previous observations reported in panel inspection report dated 22nd September, 2021 and 08th October, 2021. Keeping in view all the facts and panel inspection report, the board decided as under;

i. Allow the firm M/s Perfect Pharma (Pvt) Ltd. 5 KM Raiwind Manga Road Lahore to resume production activities in all sections except External Preparations Section & Psychotropic Tablet Section.

ii. Following panel shall inspect the firm after rectification of observations and submit report to the Additional Director QA<

   a. Area FID, DRAP Lahore.

   b. Area Assistant Director I &E, DRAP Lahore.

iii. The Additional Director QA&LT shall pass orders on the recommendations of panel inspection report and present case in subsequent meeting of CLB for ratification.

QUALITY CONTROL CASES

[F. No. 04-53/2018-QC]

Case No. 01: MANUFACTURE AND SALE OF UNREGISTERED DRUG PRODUCTS BY M/S. ROYAL HERBAL ENTERPRISES CO., KARACHI.

01. Mr. Syed Hakim Masood, FID-III & IV, Karachi vide No. F. SHM-NTF-35-40/2018-DRAP(K) dated 18.05.2018 has informed with reference to his visit alognwith officers and officials of DRaP, Karachi on 10.04.2018, where in FID-III&IV, Karachi took following samples for the purpose of test/analysis on prescribed Form-3 also seized on prescribed Form-2 and order "Made not to dispose off" on prescribed Form-I under the Drugs Act 1976/DRAP Act 2012.

Sr. No.	Name of product	Reg. No.	Batch No.	Mfg. date	Exp. Date	Mfg. by
01	Knight Rider Extra Powder Tester Delay Capsule	Nil	Nil	12-16	12-20	M/s. Royal Herbal Ent., Co., Plot No. 1730, Near Office Baldia town No. 3, Karachi.
02	Knight Rider Tester Delay Tester	Nil	Nil	02-12-16	01-12-20	-do-
03	Tiger Balm	Nil	Nil	01-11-16	01-11-21	-do-
04	Knight Rider Herbal Delay Cream	Nil	Nil	09-14	10-17	-do-
05	Unlabelled Filled capsule	Nil	Nil	Nil	Nil	-do-
06	Unlabelled Off white powder	Nil	Nil	Nil	Nil	-do-

02. FID submitted that the above samples were sent to the Federal Government Analyst, Central Drugs Laboratory, Karachi, for the purpose of test/analysis on prescribed Fomr-4. The sealed portion of the products was also send to the Chairman CLB vide this office letter of even no. dated 10th April, 2018

03. The Federal Government Analyst, CDL, Karachi, has declared the following 06 samples as "Un-registered". Details are as under

Serial	Name of Drug	Name of Allopathic	Batch	Manfg.	Expiry	Manufactured	Result

No.		ingredient identified	No.	Date	Date	By	
1	Knight Rider Extra Powder Tester Delay Capsule	Sildenafil citrate	Nil	12-2016	12-2020	M/s Royal Herbal Ent.. Co., Plot No. 1730, Near Office, Baldia Town No. 3, Karachi-Pakistan	**Un-Registered Drug Product** vide test report No. KQ.SC. 242/2018 Dated 30.04.2018
2	Knight Rider Tester Delay Tester	Lidocaine	Nil	02-12-2016	01-12-2020	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 243/2018 Dated 30.04.2018
3	Tiger Balm	Methyl Salicylate	Nil	01-11-2016	01-11-2021	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC. 244/2018 Dated 30.04.2018
4	Knight Rider Herbal Delay Cream	Lidocaine	Nil	Nov. 2014	Oct. 2017	-do-	**Un-Registered Drug Product** vide test report No. KQ.SC.

							245/2018 Dated 30.04.2018
5	Unlabelled Filled Capsule	Sildenafil citrate	Nil	Nil	Nil	Nil	**Un-Registered Drug Product** vide test report No. KQ.SC. 246/2018 Dated 30.04.2018
6	Unlabelled Off White Powder	Sildenafil citrate	Nil	Nil	Nil	Nil	**Un-Registered Drug Product** vide test report No. KQ.SC. 247/2018 Dated 30.04.2018

04. FID-III&IV, Karachi informed that he has directed the firm to explain their position that why action may not be taken against them under the Drugs Act 1976 & DRAP Act 2012

05. The reply of the firm was un-satisfactory as reported by the FID-III&IV, Karachi which he has received vide Dy. No. 1432 dated 14.05.2018 alongwith enclosures

06. Findings of FID-III & IV, Karachi:

"as per above said Federal Government Analyst, CDL, Karachi test reports M/s Royal Herbal Ent. Co. situated at Plot No. 1730/121, Near Office, Baldia Town No. 3, Karachi is involved in manufacturing and selling of Un-registered Drugs which is in violation of Section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b) and 23(1)(e) of the Drug Act 1976 enacted with DRAP Act 2012.

07. That the accused persons given below have violated the provisions of Schedule-II, of DRAP Act 2012 and hence, committed offences as under:-

a) A (1)(a)(vii) i.e. export, import are manufacture for sale or sell any therapeutic goods which is not registered or is not in accordance with conditions of registration as disclosed in the registration dossier and that has undergone pharmaceuticals evaluation;

b) A (1)(a)(x) i.e. export, import are manufacture for sale or sell any therapeutic good in contravention of any of the provision of this Act are rules made thereunder;

c) A (1)(b), manufacture for sale any therapeutic goods except under and in accordance with the condition of a license issued under this Act and;

d) A (1)(e), Import or export any therapeutic goods drugs for the import or export of which a license is required except under , and in accordance with the conditions of such license.

e) A (1)(i) sell any therapeutic good without having warranty in the prescribed form bearing the name and batch number of the therapeutic good issued

08. The Prohibitions mentioned above are offences and punishable under schedule III of DRAP Act 2012:

a) (1)(a), exports, imports, manufacturers for sale or sells any spurious therapeutic goods or any therapeutic good which is not registered.

b) (1)(b) Manufactures for sale any therapeutic good without a license.

c) (1)(c), Imports without license any therapeutic goods for the import of which a license is required.

d) (4) i.e. contravention of rules:- subject to the provisions of clause (1) (2) and (3) whoever himself or by any other person on his behalf contravenes any of the provisions of this Act or any rule shall be punishable with imprisonment for a term which may extend to five years or with fine which may extend to one lakh rupees or with both.

e) (6), Penalty for violating the prohibitions: whoever himself or by any other person on his behalf violates any prohibitions specified in schedule-II shall be punished with imprisonment for a term upto five years and with fine up to five hundred thousand rupees.

09. FID III&IV, Karachi has requested that permission of lodging of FIR may be grant against the following accused persons:

"in the light of above, permission for FIR against the following accused persons may kindly granted at the earliest:

1. *M/s Royal Herbal Enterprises company (Pvt) (Ltd), 1730/121 Gujrat Colony Baldia Town Karachi.*

2. *Muhammad Rafiq s/o Muhammad Mustafa CNIC No. 42401-1720339-1*

3. *Muhammad Siddiq s/o Muhammad Mustafa CNIC No. 424013-961859-1"*

10. Decision of the Board:

The Central Licensing Board in its 263rd meeting considered the report of Federal Inspector of Drugs Karachi, test reports and relevant record of the case and decided to allow FID, Karachi to lodge FIR against the following accused persons for violations mentioned above:

i. M/s Royal Herbal Enterprises company (Pvt) (Ltd), 1730/121 Gujrat Colony Baldia Town Karachi.

ii. Muhammad Rafiq s/o Muhammad Mustafa CNIC No. 42401-1720339-1

iii. Muhammad Siddiq s/o Muhammad Mustafa CNIC No. 424013-961859-1

11. Syed Hakim Masood, the then Area FID Karachi vide letter No. F. SHM-NTF-35-40/2018-DRAP(K-III) dated 08-03-2021 forwarded the copy of Final Investigation Report in case FIR No. 10/2018 of FIA. Conclusion of the said report is given as under:

> *"[…] From the investigation conducted and evidences collected so far on record, it has been established that M/s Royal Herbal Enterprises Company (Pvt) Ltd and its Director / shareholder, as per record of CRO, SECP, Karachi, namely Muhammad Siddiq S/o Muhammad Mustafa, as well as his brother namely Muhammad Raiq S/o Muhammad Mustafa have committed the offences U/s 23 Drugs Act 1976 punishable U/s 27 ibid and rules framed thereunder, for which they are liable to be prosecuted before the Hon'ble Drug Court Sindh at Karachi by way of filling a complaint by the Federal Inspector of Drugs.[…]"*

12. Moreover, Syed Hakim Masood informed that the matter is now in area of jurisdiction of Mrs. Hira Bhutto (FID-III Karachi) and final recommendations on the matter will be submmited by Mrs. Hira Bhutto accordingly.

13. Mrs. Hira Bhutto (FID-III Karachi) was requested vide letter No. F. 04-53/2018-QC 22-04-2021 to complete the investigation and and provide clear and candid recommendations regarding the case matter for submission to the Board.

14. FID-III Karachi, vide letter No. SHM-NTF-35-40/2018-DRAP(K-IV) dated 04-08-2021 has submitted the complete case as under:

> *"I have the honour to refer to DRAP Islamabad letter No. 04-53/2018-QC dated 22nd April 2021 on the subject captioned above and to submit that Syed Hakim Masood the than Federal Inspector of Drugs Karachi along with the team of Officers & Officials and Muhammad Aslam. S HO Police Station Baldia Town, Karachi inspected the Premises of M/s Royal Herbal Enterprises Company Pvt Limited. 1730/121. Gujrat Colony, Baldia Town. Karachi on 10-04-2018.*
>
> - *That complete inspection detail was sent to Director (H&OTC), DRAP Islamabad vide this office letter of even number dated 11th July 2018 (Annexure-A)*

- *That DRAP Islamabad vide their letter No.4-53/2018-QC(263-CLB) dated 14th June 2018 communicated the decision of Central Licensing Board. DRAP Islamabad that file complaint for registration of FIR against the following accused persons.(Anncxure-B)*

- ***Name of Accused persons:-***

    1. *M/s Royal Herbal Enterprises Company (pvt) Ltd: 1730 121 Gujrat Colony Baldia Town. Karachi.*

    2. *Muhammad Rafiq S/O Muhammad Mustafa CNIC No.42401-1720339-1*

    3. *Muhammad Siddiq S/O Muhammad Mustafa CNIC No.424013*

- *That Syed Hakim Masood the than FID DRAP Karachi vide their letter of even number dated 24th July 2018. requested Director FIA. Karachi for registration of HR against the accused persons. (Annexure-C)*

- *That the Additional Director. FIA. ACC. Karachi vide their letter No. FIA/ACCK/FIR-10-2018/2021/330-31 dated 22nd February 2021 provided the Final Investigation report to this office (Annexure-D)*

- *That Syed Hakim Masood the than FID DRAP Karachi vide their letter of even number dated 08th March 2021 forwarded the Final Investigation report of FIA. ACC, Karach. to DRAP Islamabad for further necessary action.(Annexurc-E)*

In view of above it is clariy that following accused persons are found involved in manufacturing & selling of unregistered Drugs and violated the Section 23(1)(a)(vii), 23(1)(a)(x), 23(1)(b), 23(1)(e), 23(1)(i) under the provision of Drugs Act 1976 and rules framed thereunder, which is punishable under section 27(1)(a), 27(1)(b), 27(1)(c) & 27(4), under the Drugs Act, 1976. It is therefore requested that permission for prosecution in the Drug Court Sindh Karachi against the following accused persons may kindly be accorded.

NAME OF ACCUSED PERSONS:-

1. ***M/s Royal Herbal Enterprises Company (pvt) Ltd: 1730/121 Gujrat Colony Baldia Town, Karachi***
2. ***Muhammad Rafiq S/O Muhammad Mustafa CNIC No. 42401-1720339-1 1730/121 Gujrat Colony Baldia Town, Karachi***
3. ***Muhammad Siddiq S/O Muhammad Mustafa CNIC No. 424013-961859-1 1730/121 Gujrat Colony Baldia Town, Karachi."***

PROCEDINGS AND DECISION OF THE 282ND MEETING OF THE CLB:

15. The Board considered the facts of the case and the Final Investigation report submitted by I/O FIA, decided to issue Show cause notice for prosecution against the following:

i. M/s Royal Herbal Enterprises Company (pvt) Ltd: 1730/121 Gujrat Colony Baldia Town, Karachi

ii. Muhammad Rafiq S/O Muhammad Mustafa CNIC No. 42401-1720339-1 1730/121 Gujrat Colony Baldia Town, Karachi

iii. Muhammad Siddiq S/O Muhammad Mustafa CNIC No. 424013-961859-1 1730/121 Gujrat Colony Baldia Town, Karachi.

16. The accused will be called before the Board for a chance of personal heaing in the forthcomming meeting.

17. In the light of decision of the 282nd meeting of the Board, the accused were issued show-cause notice vide letter F.No.03-29/2021-QC (282-CLB) dated 23-09-2021. Till date no reply has been received from the accused.

18. The accused are called before the Board for personal hearing.

PROCEDINGS AND DECISION OF THE 283rd MEETING OF THE CLB:

19. The accused neither by themselves, nor through any counsel appeared before the Board therefore the Board after considering the facts of the case and Final Investigation report submitted by I/O FIA, granted permission to the area Federal Inspector of Drugs, Karachi for prosecution of case in the court of competent jurisdiction against the following:

i. M/s Royal Herbal Enterprises Company (pvt) Ltd: 1730/121 Gujrat Colony Baldia Town, Karachi

ii. Muhammad Rafiq S/O Muhammad Mustafa CNIC No. 42401-1720339-1 1730/121 Gujrat Colony Baldia Town, Karachi

iii. Muhammad Siddiq S/O Muhammad Mustafa CNIC No. 424013-961859-1 1730/121 Gujrat Colony Baldia Town, Karachi.

Case No. 02: <u>SEIZURE OF UN REGISTERED DRUGS UNDER SECTION 18(1) OF THE DRUG ACT 1976. RAID ON M/S MAHMOOD PHARMACY S-77-R/85/C, JAIL ROAD, OPPOSITE SERVICES HOSPITAL LAHORE.</u>

01. The FID Lahore Mr. Syed Zia Husnain visited the premises of M/s Mahmood Pharmacy S-77-R/85/C, Jail Road, opposite Services Hospital Lahore on 26th August, 2016. The FID forwarded the case to the Director, QA&LT, DRAP, Islamabad vide letter No.12406/2016-DRAP (L-V) dated 29th August, 2016.

02. At the time of raid Mr. Sana ullah S/o Muhammad Suleman R/o H. No.05 St. No.05, mohallah Amin park Ravi road Lahore who is manger was present. Mr. Atif Ejaz S/o Ejaz pervaz R/o 67/C Punjab Co-operative housing Society, defense Lahore (Qualified person as per drug sale license) was gone for jumma prayer as informed by the manager Mr. Daud Tareen s/o Muhammad Aslam Tareen R/o B-42, GOR-III Shadman, Lahore (Proprietor) was absent.

03. The FID Lahore seized the following drugs on form-2 under section 18 (1) (f) of Drug Act, 1976:

S. No.	Name Of Product(s)	Batch/Lot No.	Mfg Data	Exp. Date	Manufactured by	Quantity
01.	Marevan 5mg Tablets	A520518	11-15	05-18	Mfd By. GSK (Detail address not mentioned in English)	(13) Thirteen jars
02.	Marevan 5mg Tablets	A521058	03-16	09-16	-do-	(11) Eleven jars
03.	Marevan 5mg Tablets	A520917	02-16	08-18	-do-	(04) Four jars
04.	Marevan 5mg Tablets	A520916	02-16	08-18	-do-	(15) Fifteen jars
05.	Marevan 5mg Tablets	A520917	02-16	08-18	-do-	(03) Three jars
06.	Centrum	M25939	-	Sep-17	Marked by. Pfizer	(03) Three

	Silver				Madison, NJ07940 USA 2015 Pfizer Inc Made in Canada	Packs
07.	Centrum Silver	M87735	-	Dec-17	2014 Pfizer Inc Made in Canada	(02) Two Packs
08.	Centrum Silver	N43989	-	01-18	2014 Pfizer Inc marked by M/s Pfizer Madison, NJ07940	(02) Two Jars
09.	Colomycin Injection	11393	10-2014	10-2017	M/s Forest Laboratories UK, Ltd, Whiddon Valley, Branstaple, North Devon Ex 32 8NS, United Kingdom.	02 Packs×10 Vials
10.	Viagra 100mg Tablets	MALL 19990544G	Dec-2013	01-Apr-2018	Mfd by. Brooklyn, Ne Packed by: Pfizer Ply Ltd, Australia	(03) Three Packs× 06 Tablets
11.	Cialis 20mg Tablets	Control No. 0674654099	-	April-04/2018	Made in USA	(02) Two Packs× 03 Tablets
12.	Centrum Tablets	M877733	-	Dec-17	Mfd. Pfizer Inc. Canada	(02) Packs
13.	Neurobion Injection	213371	12-2015	112017	Mfd. Merck kGaA, Darmstadt, Germany	(03) Three Packs

14.	Pirfenex 200mg Tablets	BA60218	Dec-15	Nov-17	Mfd. Cipla Malpur, Solan 173205 India	(01) One Pack

04. The FID seized these unregistered drugs in contravention to section 23 of Drugs Act, 1976 and also contravention to DRAP Act, 2012 and the room was locked and sealed under section 18 (i) (h) of Drugs Act, 1976.

05. Samples of drugs which were available in sufficient quantities were also sent to Federal Government Analyst for test/ analysis.

06. The details of test/analysis results of said drugs by Federal Government Analyst, Central Drug Laboratory are as under:-

S.No.	**Test Report No.& date**	**Name of Drug with batch No.**	**Mfg by**	**Remarks of CDL**
1.	Test Report No. R.LHR.403/2016 dated 01-11-2016	Marevan 5mg Tablets Batch No.A521058	M/s GSK	Declared **Unregistered** report no.R.LHR.403/2016 dated 01-11-2016
2.	Test Report No. R.LHR.404/2016 dated 01-11-2016	Centrum Sliver Batch No.M30477	M/s Pfizer Inch, Canada	Declared **Unregistered** report no.R.LHR.404/2016 dated 01-11-2016
3.	Test Report No. R.LHR.405/2016 dated 02-11-2016	Cialis 20mg Batch No.0674654099	M/s GSK	Declared **Unregistered** test report no. R.LHR.405/2016 dated 02-11-2016
4.	Test Report No. R.LHR.406/2016 dated 02-11-2016	Pirfenex Tablets Batch No.BA60218	M/s Cipla Ltd India	Drug is not included in any Pharmacopoeia, test report no.

				R.LHR.406/2016, dated 02-11-2016

07. The FID requested to allow to keep the safe custody of the seized drugs mentioned on Form-2 under Section 19(5) of the Drug Act 1976 as the firm is involved in illegal and unregistered manufacturing of drugs.

08. Permission of safe custody of the stock was granted to the FID on 16th September 2016. Meanwhile M/s Mehmood Pharmacy S-77-R/85/C, Jail Road Opposite Services Hospital Lahore filed application in the **Drug Court**, Lahore in connection with case under reference. On the order of Drug Court Lahore, premises (room) under reference was de-sealed on 17-11-2016.

Findings:-

Since the sale and stock of un registered drugs in prohibited under section 23 (1) and section A(1) (a)(vii) of schedule II of Drugs Regulatory Authority of Pakistan Act 2012 which is punishable under section 27(1) (A) of the Drug Act 1976 and schedule III of DRAP Act 2012. Sale of un-registered drug is cognizable offence under section 30(2) of the Drug Act 1976 and schedule IV(1) (a) of Drug regulatory authority of Pakistan Act 2012. As pharmacy is not explaining its position in response to the letters of FID. The FID further informed that all four reports of Federal Government Analyst have also been received, therefore under the explained circumstances mentioned above case is being forwarded under section 19(7) of Drugs Act, 1976 and section 7 of schedule V of Drugs Regulatory Authority of Pakistan Act 2012 to seek further orders of central licensing Board as to action to be taken against the following accused persons in respect of contravention of Drug Act 1976 and Drug Regulatory Authority of Pakistan Act 2012.

09. The Show cause notice was issued to the following accused persons on 25th January 2017.

M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Mr. Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore	**Mr. Sana Ullah** S/O M Suleman House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore
Mr. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.	**Mr. Daud Tareen** S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).

10. *Permission For FIR against the following accused persons may be granted to the FID Lahore For selling un registered drugs in violation to the Drug Act 1976 and DRAP Act 2012*:-

i. Mr. Sana Ullah S/O M Suleman
House No. 05, Street No.05

Mohellah Amin Park Ravi Road, Lahore.

ii. Mr. Atif Ejaz S/O Ejaz Perves R/O67/C
Punjab Co-Operative Housing Society Defense,
Lahore.

iii. Mr. Daud Tareen S/O M Aslam Tareen R/O
B-42, GOR-III, Shadman, Lahore (Proprietor).

11. **Decision of 259th meeting of the Board:-**

A. The Central Licensing Board examined/evaluated the facts of the case in the light of investigations conducted by the FIDs and Quality Assurance Division and decided to grant permission for registration of FIR against the following accused persons:-

M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Mr. Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore	Mr. Sana Ullah S/O M Suleman House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore
Mr. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.	Mr. Daud Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).

B. The accused persons are involved in contraventions of the provision of schedule-II and schedule-III of the DRAP Act 2012 as under:-

i. Sale of un registered drugs
ii. Sale of drugs without warranty.
iii. Manufacturing/import without authorization from the DRAP.

The offence is punishable under section 1 (a) and para (4) (contraventions of rules) of schedule-III of DRAP Act 2012.

12. In compliance to the decision of 259th meeting of Central Licensing Board, Permision for registration of FIR was issued to area FID vide letter F. No. 3-21/2018-QC/pt/(259-CLB) dated 20-04-2018.

13. Federal Inspector of Drugs-IV Lahore vide letter No. 4080/2021-DRAP(L-IV) dated 17-03-2021 has submitted complete challan of M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital Lahore with reference to FIR No. C163/2018 wherein Assistant Director FIA/CCC

Lahore has submitted that following accused were found guilty of violating the provisions of the Drugs Act 1976 and rules made thereunder;

i. M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore.
ii. Daud Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).
iii. Sana Ullah S/O M Suleman, House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore.
iv. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.

PROCEDINGS AND DECISION OF THE 282ND MEETING OF THE CLB:

14. The Board considered the facts of the case and the Final Investigation report submitted by I/O FIA, decided to issue Show cause notice for prosecution against the following:

i. M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore.
ii. Daud Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).
iii. Sana Ullah S/O M Suleman, House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore.
iv. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore

15. The accused will be called before the Board for a chance of personal hearing in the forthcmming meeting of the Board.

16. In the light of decision of the 282nd meeting of the Board, the accused were issued show-cause notice vide letter F.No.03-29/2021-QC (282-CLB) dated 23-09-2021. Till date no reply has been received from the accused.

17. The accused are called before the Board for personal hearing.

PROCEDINGS AND DECISION OF THE 283rd MEETING OF THE CLB:

18. The accused neither by themselves, nor through any counsel appeared before the Board therefore the Board after considering the facts of the case and Final Investigation report submitted by I/O FIA, granted permission to the area Federal Inspector of Drugs, Lahore for prosecution of case in the court of competent jurisdiction against the following:

i. M/s. Mehmood Pharmacy S-77-R/85/C, Jail road, Opposite Services Hospital, Lahore through its proprietor Daud Khan Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore.
ii. Daud Tareen S/O M Aslam Tareen R/O B-42, GOR-III, Shadman, Lahore (Proprietor).
iii. Sana Ullah S/O M Suleman, House No. 05, Street No.05 Mohellah Amin Park Ravi Road, Lahore.
iv. Atif Ejaz S/O Ejaz Perves R/O67/C Punjab Co-Operative Housing Society Defense Lahore.

Meeting ended with the vote of thanks to and by the Chair