MINUTES OF 284th MEETING OF CENTRAL LICENSING BOARD HELD ON 16th DECEMBER, 2021

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284th meeting of the Central Licensing Board (CLB) was held on 16th December, 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. Azhar Jamal Saleemi, Chief Drug Controller, Primary and Secondary Health Department, Government of Punjab, Lahore	Member
2	Mr. Muhammad Salik Zahid, Chief Inspector of Drugs, Government of Balochistan, Quetta	Member
3	Mr. Mohammad YunasKhattak, Chief Inspector of Drugs, Bannu Government of Khyber Pahtunkwa	Member
4	Mr. Abid Ali, Law Expert, Ministry of Law & Justice Division, Islamabad	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 Khalid Muneer, 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) 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 283rdMEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 283rd meeting of the Central Licensing Board (CLB) held on 28th October, 2021.

A. DRUG LICENSING DIVISION

Item-II: **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 Medhouse Pharmaceuticals (Pvt.) Ltd Mouza MangowalGharbi, 1-Km off ChahmughlanRoad, Tehsil & District Gujrat.	05-11-2021 (Formulation)	Good	1) Dr. Zaka –Ur-Rehman COO, PRDTC, Lahore. 2) Dr. Syed Zia Husnain, Federal Inspector of Drugs, DRAP, Lahore, 3) Mr. Shahrukh Ali, AD, DRAP, Lahore.

Recommendations of the panel:

Panel has evaluated documentation in detail revealed by the management of the firm. Panel also physically inspected the unit. Panel has discussed various technical Panel has discussed various technical aspects with the management of the firm at length. On the query of the panel firm management informed that they had established their four sections for production of veterinary drugs only as per their application for grant of Drug Manufacturing License (Original undertaking of the firm is attached herewith for perusal). Based on the documentation revealed by the firm, inspection of the unit and technical discussion with the firm management; panel **recommended** the facility for grant of Drug Manufacturing License to M/s Medhouse Pharmaceuticals (Pvt.) Ltd wouzaMangowalGharbi, 1-Km off Chahmughlan road, Tehsil & District Gujrat only for following sections for veterinary drugs.

1. Oral Powder (General) Section.
2. Oral Liquid (General) Section.
3. Oral Powder (Penicillin) Section.
4. Liquid Injection (Penicillin) Section.

Decision of the Central Licensing Board in 284th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Medhouse Pharmaceuticals (Pvt.) Ltd Mouza MangowalGharbi, 1-Km off Chahmughlan Road, Tehsil & District Gujrat on the recommendations of the panel of experts for the following sections:

1. Oral Powder (General) Section. (Veterinary)
2. Oral Liquid (General) Section. (Veterinary)
3. Oral Powder (Penicillin) Section. (Veterinary)
4. Liquid injection (Penicillin) Section. (Veterinary)

2	M/s Livewell Capsules (Pvt.) Ltd, Plot No. 107-Sunder Industrial Estate, Raiwind Road, Lahore.	**21-09-2021 & 19-11-2021**	**Good**	1) Dr. Munawar Hayat, Director, Drug Testing Lab. Lahore. 2) Ms. Majida Mujahid, Additional Director, DRAP, Lahore. 3) Ms. Maham Misbah, Assistant Director, DRAP, Lahore

Recommendations of the panel:

Keeping in view the facilities like building, HVAC system, machinery and equipment, instruments, personnel, documentation, quality control and testing facilities, the panel of inspectors was of the opinion to recommend the grant of Drug Manufacturing License to M/s Livewell Capsules (Pvt.) Ltd, Plot No. 107, Sunder Industrial Estate, Raiwind Road, Lahore for the following section: -

1) Empty Hard Gelatin Capsule Manufacturing Section.

Decision of the Central Licensing Board in 284th meeting:

The Board considered the facts and approved the grant of Drug Manufacturing License by way of Semi Basic Manufacture in the name of M/s Livewell Capsules (Pvt.) Ltd, Plot No. 107-Sunder Industrial Estate, Raiwind Road, Lahore on the recommendations of the panel of experts for the following section:

1) Empty Hard Gelatin Capsule Manufacturing Section.

3	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 ZakaurRehman, 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 firmM/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 (E& DRAP, Lahore. Mr. Arshad Mehmood, Managing Director of M/s Wallace Pharma Evolutions infor that the inspection of their firm was conducted on 17th September, 2021 wide DRAP Islamabad lette 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 tea 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, 20 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 sin story building and HVAC has been installed on the first floor. But Major changes have been done or

guidance of the previous panel.
We would like to state that we have constructed building as per approved layout plan, the previous p illegally misguided us and advised many changes in the layout plan. Now the other panel having obj on the new changes advised by the previous panel specially Area FID Mr. Ajmal Sohail. He forcefu directed us to follow his directions not the directions of the licensing section. They completely rejec approved layout plan approved by licensing section. So he directed to go for changes according to h mind and unwantedly we have to make changes according to the instruction of Mr Ajmal Sohail FID Now this panel is not agreed with the changes and rejecting the changes we made under advice of M Ajmal Sohail. We are unable to understand which the competent authority is? Mr. Ajmal Sohail FID 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 give 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 pla nothing was wrong about that. So the panel clearly accepted that, so the panel clearly accepted that. But again panel mentioned the misleading sentence that entries are near to the boundary walls. We v like to state sadly that entries were constructed according to approved layout plan, and was purposef constructed near from the boundary wall. The entries are always near to boundary wall as Human re come from the outer boundary gate and it is strange how Panel biasedly added this point in Observat 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. The sections are located at different positions. And it can be verified from the approved layout plan too. 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 separ room has been constructed for Carbapenem. But they have mentioned that firm don't have any rejec 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 thi enough for rejection as this is injectable area and there is no further dispensing in injectable area. Ev material comes in complete packing whether it's 1kg, 2kg or whatever. No dispensing is made in an 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 is pertinent to mention that there's no need of dispensing of carbapenem material. This is injectable are panel must know if they are not biased and aware to the legal requirements, technically there is no n open dispensing of the Dry Injectable Carbapenem material that is in sterile form. As all sterile cont goes directly from Raw Material store to the filling area. So for sampling of the injectable sterile containers, there is a separate pouch that is attached with every container for sampling. So there's no of separate sampling room as well that is again wrong advice from the panel to make a separate sam room. There is a separate small pouch for samples that first material is placed in quarantine, and the sample that already been attached with the container is sent to the QC. When QC passes the sample, 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 of

panel which can be clearly understood.
So we disagree with the observation raised by the panel. Separate Raw Material store is present ther according to approved layout plan.

Moreover we would like to clear the position regarding the concern raised by panel that there's a ver small area towards the raw material store. We would first like to mention that the Carbapenem quan usually 1kg, 5kg or maximum 10kg or 20kg which can be even carried by the human resource himse having said that we would like to mention that there's enough place for any vehicle movement there that can be verified. Again this is biased and very illegal approach from the panel. We legally and 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 material We would like to mention that we have installed AC there, and if any arrangements are required ther are ready to install this but this is again minor and ignorable observation as we have installed AC fo 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 master 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 other 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 and production area is according to approved layout plan. But again panel stated there was open AC inst there that was in corridor along with HVAC, if it's DRAP Requirement we can remove Extra Ac fro 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 prope entries in production area but their observations are differential pressure monitoring devices are not installed between buffers. It is very strange that they have mentioned such a small thing, in my opini material entry room. There is big need of installation of Differential pressure gauges because there's material entry not the human entry. And there is also a hash window installed there so proper buffer there, only monitoring guage is yet to be installed there which can be installed before the production started which will at least take around 18 months onwards as we have to go for 6 month stability and we have our files in que and then issuance of minutes and registration letter will take time so around 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 th was no Polythene wrap there, in this regard panel mentioned that Semi-Automatic machine is not su 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 across t board a clear advisory should be issued with the technical justification that everyone should remove Automatic filling machine. As 90% of companies in Pakistan are using this machine and also this pa has approved a lot of firms inspection who have Semi-Automatic filling machine. And all these mac are qualifying cGMP requirements.

All these Injections are sent in the market after the proper approval of QC department if the vials are 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 ground 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 compar daily basis, but no objection was raised there. So again that's a biased approach and our request is to the panel that why they have written this as in GMP and inspection requirements, there is no given s the Drug Act. The only requirement is that machines should be there which are complying the steril and sterile products. And sterility only can be judged through the quality control tests not by the nak of an individual. So I completely disagree with the recommendation of panel regarding Semi-Autom and if there is any requirement a proper SRO should be issued for all companies mentioning the law 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 the doors. I can provide the pictures and videos right now to the board, that there were excellent SS doo available there. Even the same panel have approved Aluminum doors of other firms and we have SS and the reason known best to them. And again I would mention reason must know better to them, as they are having objection on SS doors and there are no Ridges there as these are not handmade but b machines.
Panel further mentioned that ducts were not properly sealed and sunlight could be seen from the inle diffuser. We disagree with this, maybe panel doesn't know that the Glue for Sealing of the ducts are transparent. Not pure transparent but sometimes light can be seen from it. It doesn't mean that it's o the Sealing Glue is white and little bit light can be seen from it. Again we're unable to understand w minor point is also added as Observation.
Panel mentioned that no transfer trolley was available there. We would like to mention that there's n of transfer trolley there's because our sterilizer is directly opening in the filling and cooling area and are placed in SS Racks there for certain period of cooling time there. So there's no need at all for ca trolley from cooling area to the filling area. These are taken by the human source. Still human are th 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 sterilizer installed, autoclave and washing machine there. But they mentioned that RO Plant has been installe the firm will supply to both Carbapenem and Penicillin section. What is wrong with this point, Sepa 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, tech there is no harm in it. There is no international regulations against it, again that's an illogical observ
The Panel also mentioned that washing area was converted in RO Plant, Not at all. There is a separa room for RO Plant and this Separate RO Plant was constructed as per the instruction of previous par

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 its but still they mentioned that there's a common mixing room for capsule and dry suspension. But it i pertinent to mention that this common mixing room has been approved by licensing section. Again t 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 reas 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 prop

installed for filling and sealing, HVAC are also installed. But monometer was faulty, they didn't me
that Monometer wasn't present there but only one was faulty. They were only having negative appro
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 t
approval of Dry Suspension section Penicillin. Again we disagree with this biased and negative appr

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 re
and very strange that no other member noticed this. The same observations they have mentioned tha
there's space constrain in vial washing area and machines were not placed according to the approve
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 i
layout and that can be verified from the approved layout plan. We are unable to understand the appr
panel that without any observation, there are bundle of observations which are even strong enough t
refuse the grant of DML. They were focusing on use of Semi-Automatic filling machine again, in th
regard we would like to bring this into notice of honorable board that semi-automatic machine is use
majority of companies since 70 years in Pakistan for sterile production of the products and same par
have given approval of several companies in Lahore region. Other details are already mentioned abo
We are disagree with all these recommendation and request the board to approve the section as alrea
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 se
but the panel was unable to verify that whether HVAC system was installed there as there was broke
bamboo there so panel couldn't climb there. We disagree as the proper Ladder was available there a
person could go there for inspection but despite this Panel themselves mention in the whole report a
the sections that they inspected all the differential monitoring guage, and so on they themselves are
accepting that the system was there then on this basis they needed to check it by going up. But we ar
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 of the factory. So again this is
nothing to mention here that they have already accepted that all the sections have HVAC system ins
and differential pressure was there. So again we disagree as we are unable to understand that why no
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 Instrument
chemistry and Microbiology and then further they mentioned that QC was not well equipped. That's
strange as they themselves mentioned HPLC, Uvi spectrometer and other required equipment then w
they were saying it was not well equipped. Further they said there's no Atomic Absorption that is str
that this couldn't be the ground to refuse a firm Grant of DML. The other observation they mentione
FTIR, conductive meter, polarimetry, all three things were shown to Mr Munawar Hayat the membe
panel at his residence after consultation with him.
We requested you can see the FTIR, Dissolution apparatus, conductive meter and polarimeter at the
or we can show you at your office. But he asked our person to come at his home and show the instru
there, the person went there and shown Mr Munawar Hayat all the instruments and he agreed that he
give approval. We don't know what happened next day, reason is unknown why report was sent to D
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 to facilitate the growth of Pharma Industry and to maintain the decorum of justice in the DRAP.

Decision of the Central Licensing Board in 283rd meeting

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.

The decision of the Board was communicated to the firm and the said panel was given mandate for inspection of the firm.

The panel comprising of following members

i. Additional Director (QA/LT) DRAP, Islamabad.
ii. Dr. Zia Husnain, FID, DRAP, Lahore.
iii. AD, DRAP.

has now submitted the panel inspection report the conclusion and recommendations of which is repr as under :

CONCLUSION AND RECOMMENDATION :

Panel has thoroughly inspected the unit and discussed various technical aspects with the managemer the firm at length. In the light of the inspection conducted by the panel and based on the findings det above, panel observed that firm management has made lot of up-gradations as advised in last inspec Further up gradations were also advised by the panel as mentioned in detail in the above report for f verifications by area Federal Inspector of Drugs prior to start of commercial manufacturing.

Pnael of inspectors **recommendations grant** of drug manufacturing by way of formulation of M/s Wallace Pharma , Kala Wala Stop 20 km Lahore Jaranwala Road **for Capsule (Penicillin) and Oral Dry Powder Suspension (Penicillin) section.**

	Panel also decided that the CLB may also consider Injection (Carbapenem) section and Dry Powder Injection (Penicillin) section for grant of DML (Formulation) subject to the condition of replacement of presently available manual vial filling and sealing machines with upgraded automatic vial filling and sealing machines in both injectable sections prior to start of production. Firm has given undertaking in this regard (Original signed undertaking given by CEO of firm is Attached). **[The original undertaking is not attached]** . As the firm management already submitted to the CLB that they have some information about the use of manual injectable filling and sealing machines by various other firms, therefore, for across the board uniformity and to safe guard the public health at large panel suggests that the list of such firms (if any) may be obtained from management of M/s Wallace Pharma Evolutions and shared with respective FID for on the site GMP audit immediately. Moreover, subsequently advisory to said firms be Issued for replacement of manual injectable filling and sealing machines (if any) with automatic Machines for filling and sealing of injectable. **Decision of the Central Licensing Board in 284th meeting:** The Board considered the facts and approved the grant of Drug Manufacturing License by way of Formulation in the name of M/s Wallace Pharma Evolutions, Kala Wala Stop, 20-km, Lahore Jaranwala Road, Lahore on the recommendations of the panel of experts for the following sections with the advice to install Automatic machines in Injection (Carbapenem) section and Dry Powder Injection (Penicillin) Section under intimation to area Federal Inspector of Drugs before commercial production: 1) Capsule (Penicillin) section. 2) Oral Dry Powder Suspension (Penicillin) section. 3) Injection (Carbapenem) section. 4) Dry Powder Injection (Penicillin) Section.

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 Helix Pharma (Pvt) Ltd, A-56, S.I.T.E, Manghopir Road, Karachi. DML No.000030 (Formulation) Section (01): 1. Tablet Psychotropic – **Regularized.**	**19-11-2021**	**Good**	1) Chief Drug Inspector, Government of Sindh, Karachi 2) Federal Inspector of Drugs, DRAP, Karachi. 3) Mr. Affan Ali, Assistant Director, CDL, 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 **recommends** the grant of Tablet Psychotropic Section under DML No 000030 by way of Formulation. **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following section in the name of M/s Helix Pharma (Pvt) Ltd, A-56, S.I.T.E, Manghopir Road, Karachiunder DML No.000030 (Formulation) on the recommendations of the panel of experts 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: **Section (01):** 1) Tablet Psychotropic – **Regularized.**			
2	M/s Ray Pharma (Pvt) Ltd, S-58, SITE, Karachi. DML No.000642 (Formulation) **Section (01):** 1. Oral Liquid Syrup (General) - **New**	**02-12-2021**	**Good**	1) Dr. Abdullah Dayo, Expert Member. 2) Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Krishan Das, AD, DRAP, Karachi.

Recommendations of the panel:

"The production Liquid Area of Ray Pharma (Private) Limited situated at Plot No.S-58,SITE Karachi was visited and inspected in detail in compliance of the instructions contained in the DARP Islamabad letter No F.24/2007-Lic (Vol-II) dated 2nd November 2021. Mr. Abdul Rasool shaikh (Federal inspector of Drugs, DRAP Karachi), Mr. krishan Das (A.D DRAP Karachi.), Mr. Abdullah Dayo (Expert member Karachi), during the course of inspection. Followings are the detailed observations and recommendations of the visit.

1. The firm has purposefully designed a segregated area for the manufacturing of Liquid syrup/suspension.

2. All the equipment for the said oral Liquid Syrup(General) manufacturing has been installed inside the newly built segregated area along with all utilities and amenities.

3. All the necessary qualification documentation is approved and in place.

4. The segregated area is equipped with HVAC with required filtration to minimize the chances of contamination.

5. Separate personnel flow (PAL) & Material flow (MAL) are also given with secondary change facilities.

6. Separate AHUs are given in this area and entire system has satisfactorily been qualified.

7. Entire production areas have adequately been qualified and would be completed as per SOP in place after formal approval of concerned division of DRAP.

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 **recommends** the grant of oral Liquid Syrup (General) Section under DML No 0000642 by way of formulation.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and approved the grant of following section in the name of M/s Ray Pharma (Pvt) Ltd, S-58, SITE, Karachi under DML No.000642 (Formulation) on the recommendations of the panel of experts:

Section (01):

1. Oral Liquid Syrup (General) – **New.**

3.	M/s Barret Hodson Pakistan (Pvt) Ltd, F-423, SITE, Karachi. DML No.000457(Formulation) **Section (05):** 1. Sterile Liquid Injection LVP (General) – **New** 2. Sterile Liquid Injection SVP (General) - **New** 3. Oral Dry Powder Suspension (General) – **Revised** 4. Tablet (General) – **Revised** 5. Blistering & Packaging Section - **New**	**06-12-2021**	**Good**	1) CDI, Govt of Sindh. 2) Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Sajjad Abbasi, DD CDL, Karachi.

Recommendations of the panel:

"1. As per instructions contained in DRAP Islamabad Letter No. F.2-4/97-LIC (Vol-IV) Dated: 21 September 2021 & 19th November 2021, a detailed and comprehensive targeted panel inspection of newly built and amended/revised sections of Ms. Barrett Hodgson Pakistan (Pvt) Ltd; situated at Plot No: F/423 SITE Karachi was carried out.

2. The firm has designed as per approved lay out plan, two compact lines for SVP and a line for LVP; blistering & secondary packaging areas are also built separately. The sections of Dry Powder Oral Suspension (G) and Tablet (G) are also revised and up graded as per approved design.

3. The panel further observed necessary machines installed in each section required for the manufacturing of their registered products. Two fully compact lines for SVP with sterilization tunnels & filling/sealing machines, granulation suit (Cannan) for tablets, blister and Compression machines were seen installed in respective sections. Necessary Documents, protocols and SOPs for commissioning, installation, operations and maintenance of equipment were seen in place.

4. Each newly built area has been provided with adequately monitored HVAC System with necessary filtration system. The system was seen well in working condition. Buffers, MALs and PALs are purposefully given to avoid the hazards of contamination. Other utilities and required amenities are also well provided in the newly built and revised sections. Overall sections were seen satisfactorily maintained at the time of inspection.

	5. During opening meeting certain key documents like, lay out plan, HVAC Design & its commissioning, installation & qualification of key machineries & procedures, maintenance of areas during and after manufacturing, different working SOPs and relevant QA exercises carried out by their technical persons, were reviewed and discussed at length. 6. Keeping in view the above stated facts, people met and documents reviewed during detail inspection of the facility, the panel unanimously **recommends** the grant of additional sections of Sterile Liquid injection (SVP), Sterile Liquid Injection (LVP) and also **recommends** for necessary approval the amendments/revisions made as per approved design, in their Oral Dry Powder (G), Tablet (G), Blisters & Secondary Packaging Section under DML No. 00457 (Formulation) of M/s; Barrett Hodgson Pakistan (Pvt.) Ltd Karachi." **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s Barret Hodson Pakistan (Pvt) Ltd, F-423, SITE, Karachi under DML No.000457 (Formulation) on the recommendations of the panel of experts: **Section (05):** 1. Sterile Liquid Injection LVP (General) – **New** 2. Sterile Liquid Injection SVP (General) - **New** 3. Oral Dry Powder Suspension (General) – **Revised** 4. Tablet (General) – **Revised.** 5. Blistering & Packaging Section – **New.**			
4	M/s Biorex Pharmaceuticals, Plot No. 251-A, Industrial Triangle, Kahuta Road, Islamabad Drug Manufacturing License No. 000528 (Formulation)	**28-09-2021,** **21-10-2021**	**Good**	1) Additional Director (QA/LT), HQ DRAP, Islamabad. 2) Federal Inspector of Drugs, DRAP, Islamabad. 3) Mr. Muhammad Usman, Assistant Director, DRAP, Islamabad.

	Recommendations: Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** following sections of M/s Biorex Pharmaceuticals, Plot# 251-A, Industrial Triangle Kahuta Road.: **i) grant of additional sections** **1.** Syrup (General) **2.** Dry Suspension (General) **3.** Liquid Injectable (Ampoule) **4.** Liquid Injectable (Vial) **5.** Creams/Ointments (Topical Section) **6.** Lotions/Gels (Topical Section) **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s Biorex Pharmaceuticals, Plot No. 251-A, Industrial Triangle, Kahuta Road, Islamabad under DML No.000528 (Formulation) on the recommendations of the panel of experts: **Section (06):** 1. Syrup (General)– **New** 2. Dry Suspension (General)– **New** 3. Liquid Injectable (Ampoule)– **New** 4. Liquid Injectable (Vial)– **New** 5. Creams/Ointments (Topical Section)– **New** 6. Lotions/Gels (Topical Section).– **New**			
5	M/s The Schazoo Pharmaceutical Laboratories (Pvt) Ltd , Kalawala Stop 20 km, Lahore – Jaranwala Road, District Sheikhupura. Drug Manufacturing License No. 000019 (Formulation) Section (02) : 1. *Tablet Psychotropic* – **New.** 2. *Capsule Psychotropic* – **New.**	**10-12-2021**	**Good**	1. Additional Director DRAP, Lahore. 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Assistant Director, DRAP, Lahore.
	Recommendations: Based on the areas inspected, the technical person met and the documents reviewed and considering the findings of the inspection the panel verified that the firm has developed following sections as per approved layout plan:			

	1. *Tablet Psychotropic* – **New.** 2. *Capsule Psychotropic* – **New.** The panel **recommends** the approval of above-mentioned sections in favour of the TheSchazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalawala Stop 20 km, Lahore – Jaranwala Road, District Sheikhupura. under DML No. 000019 (Formulation). **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s The Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalawala Stop 20 km, Lahore – Jaranwala Road, District Sheikhupura under DML No.000019 (Formulation) on the recommendations of the panel of experts 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: **Section (02):** 1. Tablet Psychotropic – **New.** 2. Capsule Psychotropic – **New.**			
6	M/s British Pharmaceuticals, 23 Km, Sheikhupura Road, Lahore. DML No.000729 (Formulation)	**09-11-2021**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, 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 requirements 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 the registered products and approved sections. Additionally, the panel of inspectors also verified that the firm has developed the following new manufacturing sections as per approved layout plan: 1. Cream/Ointment (General) 2. Oral Dry Powder sachet (General) 3. External/Topical preparations. 4. Liquid Repacking			

	5. Powder Repacking "The panel of inspectors **recommends** the renewal of DML bearing No. 000729 issued in favour of M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore. The panel also recommends the grant of additional manufacturing sections as mentioned above." **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s British Pharmaceuticals, 23 Km, Sheikhupura Road, Lahoreunder DML No.000729 (Formulation) on the recommendations of the panel of experts: **Section (05):** 1. Cream/Ointment (General).– **New** 2. Oral Dry Powder sachet (General).– **New** 3. External/Topical preparations. – **New** 4. Liquid Repacking.– **New** 5. Powder Repacking.– **New**			
7	M/s Fynk Pharmaceuticals, 19-Km GT Road, Kala Shah Kaku, Lahore. DML No.000494 (Formulation)	**23-09-2021**	**Good**	1. Dr. Farzana Chaudhary, Expert Member. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Ufaq Tanvir, Assistant Director, 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 that the firm has developed the following facilities as per amended layout plan: 1. Capsule (Penicillin).– **New** 2. Oral Dry Powder Suspension (Penicillin). – **New** 3. Dry Powder Injectable (Penicillin). – **New** 4. Dry Powder Injectable (Carbapenem). – **New** The panel of inspectors **recommends** the approval/grant of above-mentioned sections/facilities in favour of M/s Fynk Pharmaceuticals (Pvt.) Ltd., under DML bearing No. 000494." **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s Fynk Pharmaceuticals, 19-Km GT Road, Kala Shah Kaku, Lahoreunder DML			

	No.000494(Formulation) on the recommendations of the panel of experts: **Section (04):** 1. Capsule (Penicillin).– **New** 2. Oral Dry Powder Suspension (Penicillin). – **New** 3. Dry Powder Injectable (Penicillin). – **New** 4. Dry Powder Injectable (Carbapenem). – **New**			
8	M/s Horizon Health Care (Pvt) Ltd, Plot No.35-A, Small Industrial Estate, Taxila. DML No.000856 (Formulation)	**14-12-2021**	**Good**	1. Additional Director (QA&LT) HQ, DRAP, Islamabad. 2. Area Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Muhammad Tahir Waqas, Assistant Director (I&E), DRAP, Islamabad.
	Recommendations of the panel: Keeping in view the above facts on record, improvements made by the firm which reference to the previous inspection and the people met during the visit, the panel unanimously **recommended** the grant of following sections; 1. Tablet section (General) Revised. 2. Capsule Section (General) Revised. **However, the Liquid Vial (LVP) section is not recommended as firm has withdrawn their request.** **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s Horizon Health Care (Pvt) Ltd, Plot No.35-A, Small Industrial Estate, Taxila under DML No.000856 (Formulation) on the recommendations of the panel of experts: **Section (02):** 1. Tablet section (General) Revised. 2. Capsule Section (General) Revised. The Board also decided to resume production in above mentioned sections.			
9	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-KM, Adyala Road, Post Office Dahgal, Rawalpindi. DML No.000333 (Formulation).	**04-11-2021**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA/LT-I), HQ, DRAP, Islamabad. 2. Mr. Khalid Mahmood, Federal Inspector of

	Period: Commencing on 07-01-2021 ending on 06-01-2026.			Drugs-II, DRAP, Islamabmad. 3. Mst. Haleema Sharif, Assistant Director, DRAP, Islamabad.
	"Keeping in view the above facts, detailed visit of facility and supporting documents (attached with report) provided by the company, the panel unanimously **Recommends** M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-KM, Adyala Road, Post Office Dahgal, Rawalpindi for the renewal of DML No. 000333 (Formulation) seventeen section (17 sections) and grant of two (o2) additional section namely Sachet Section (General) and Oral Dry Powder Suspension (General) (mentioned below):- 1. Sachet Section (General) – New. 2. Oral Dry Powder Suspension (General) – New. **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-KM, Adyala Road, Post Office Dahgal, Rawalpindi under DML No.000333 (Formulation) on the recommendations of the panel of experts: **Section (02):** 1. Sachet Section (General) – New. 2. Oral Dry Powder Suspension (General) – New.			
10	M/s Shrooq Pharmaceuticals (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore DML No.000577 (Formulation).	**26-10-2021** **&** **29-10-2021**	**Good**	1. Dr. Zaka-ur-Rehman, Chief Operating Officer, PDTRC, Lahore. 2. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. 3. Ufaq Tanveer, Assistant Director, DRAP, Lahore.
	"In view of above inspection proceedings and facilitates 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 for the following section to M/s Shrooq Pharmaceuticals (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore by way of formulation only: 1. Eye / Ear / Nose Drop Section (New Section). **2.** Capsule (Steroid) Section (New) **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s Shrooq Pharmaceuticals (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore under DML No. 000577			

	(Formulation) on the recommendations of the panel of experts: **Section (02):** 1. Eye / Ear / Nose Drop Section (New Section). 2. Capsule (Steroid) Section (New)			
11	M/s Welmark Pharmaceuticals, Plot No.122, Block-B, Phase-V, Industrial Estate, Hattar. DML No.000614 (Formulation) **Section (01):** 1. Tablet (Psychotropic) Section- **New**	**15-12-2021** (Formulation)	**Good**	1. Mr. Zahid Khan, CDI, Peshawar. 2. Federal Inspector of Drugs, DRAP, Peshawar. 3. Syed Adnan Ali Shah, AD, DRAP, Peshawar.
	Recommendations of the panel: Based on detailed physical inspection of the firm, technical persons met, documents reviewed and availability of security features adopted by the firm for handling of controlled substances, the panel unanimously recommends grant of license of **Tablet (Psychotropic)** Section, subject to fulfillment of other codal formalities specified for such case as per policy. **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of following sections in the name of M/s Welmark Pharmaceuticals, Plot No.122, Block-B, Phase-V, Industrial Estate, Hattarunder DML No.000614 (Formulation) on the recommendations of the panel of experts 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: **Section (01):** 1. Tablet Psychotropic Section.**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 License. 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 Novartis Pharma Pakistan Limited, Plot No. C-21, S.I.T.E, Karachi DML No. 000003 (Formulation) Period: Commencing on 18-09-2020 & Ending 17-09-2025.	**08-09-2021**	**Good**	1. Chief Drug Inspector, Govt of Sindh. 2. Deputy Director, CDL, Karachi 3. FID, DRAP, Islamabad
	Recommendation of panel : During the inspection, the Panel thoroughly inspected their production areas, QC Lab, Warehouse, Utilities and reviewed related document/records. The Panel met their technical personnel in respective areas as well to know their expertise and relevant job knowledge. The panel reviewed documents during inspection and found in compliance. Keeping in view the overall GMP compliance Panel unanimously recommend regularization of manufacturing facility as per approved layout plan and renewal of their DML No. 000003 by way of formulation and to M/s Novartis Pharma (Pakistan) Limited for following section. 1. Tablet (General) 2. Cream/Ointment (General) 3. Quality Control Lab 4. Ware House (General) **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000003 by way of Formulation in the name of M/s Novartis Pharma Pakistan Limited, Plot No. C-21, S.I.T.E, Karachi on the recommendations of the panel of experts for the period commencing on 18-09-2020 & ending 17-09-2025for the following section: - 1. Tablet (General) 2. Cream/Ointment (General) 3. Quality Control Lab 4. Ware House (General)			

<table>
<tr><td>2</td><td>M/s. Mediate Pharmaceutical (Pvt) Ltd, Plot No. 150-151, Sector-24, Korangi Industrial Area, Karachi.

DML No. 000167 (Formulation)

Period: Commencing on 17-05-2015 & Ending 18-05-2020</td><td>27-10-2021</td><td>Good</td><td>1. Dr. Abdullah Dayo, Member CLB, Karachi.

2. Chief Drugs Inspector, Govt. of Sindh, Karachi.

3. Area Federal Inspector of Drugs /Additional Director (E&M), Karachi.</td></tr>
<tr><td></td><td colspan="4">Recommendation of panel :

Based on the people met, documents reviewed, and observations made during the inspection the panel recommends the grant of renewal of Drug Manufacturing License No. 000167 by way for Formulation for following section:

<table><tr><td>Sr #</td><td>Name of Section</td></tr><tr><td>1.</td><td>Capsule (Psychotropic</td></tr></table>
<u>Decision of the Central Licensing Board in 284th meeting:</u>

The Board considered and approved the grant of renewal of DML No. 000167 by way of Formulation in the name of M/s Mediate Pharmaceutical (Pvt) Ltd, Plot No. 150-151, Sector-24, Korangi Industrial Area, Karachi on the recommendations of the panel of experts for the period commencing on 17-05-2015 & ending 18-05-2020for 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:

1. Capsule (Psychotropic)</td></tr>
<tr><td>3</td><td>M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, B-10, SITE, Super Highway, Karachi

DML No. 000558(Formulation)

Period: Commencing on 09-12-2019 & Ending 08-12-2024</td><td>03-11-2021</td><td>Good</td><td>1. Dr. Abdullah Day, Expert Member.

2. Federal Inspector of Drugs, DRAP, Karachi.

3. Mr. Krishan Das, Assistant Director, DRAP, Karachi.</td></tr>
</table>

Recommendation of panel :

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.000558 for the following sections along with Regularization of layout plan for the next five years from

09-12-2019 ti;; 08-12-2024.

Name of Sections	Name of Sections
Tablet (Penicillin)	Dry Powder Suspension (Penicillin)
Capsule (Penicillin)	Dry Powder Injection (Penicillin)

Decision of the Central Licensing Board in 284th meeting:

The Board considered and approved the grant of renewal of DML No. 000558 by way of Formulation in the name of M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, B-10, SITE, Super Highway, Karachion the recommendations of the panel of experts for the period commencing on 09-12-2019 & Ending 08-12-2024 for the following section:

Name of Sections	Name of Sections
Tablet (Penicillin)	Dry Powder Suspension (Penicillin)
Capsule (Penicillin)	Dry Powder Injection (Penicillin)

4.	M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-KM, Adyala Road, Post Office Dahgal, Rawalpindi. DML No.000333 (Formulation). Period: Commencing on 07-01-2021 ending on 06-01-2026.	**04-11-2021**	**Good**	1. Dr. Hafsa Karam Elahi, Additional Director (QA/LT-I), HQ,DRAP, Islamabad. 2. Mr. Khalid Mahmood, Federal Inspector of Drugs-II, DRAP, Islamabad. 3. Mst. Haleema Sharif, Assistant Director, DRAP, Islamabad.

"Keeping in view the above facts, detailed visit of facility and supporting documents (attached with report) provided by the company, the panel unanimously **Recommends** M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-KM, Adyala Road, Post Office Dahgal, Rawalpindi for the renewal of DML No. 000333 (Formulation) seventeen section (17 sections) and grant of two (o2) additional section namely Sachet Section (General) and Oral Dry Powder Suspension (General) (mentioned below):-

1. Tablet Section (General).
2. Capsule Section (General).
3. Oral Liquid Section (General).
4. Topical Section (Cream / Ointment / Gel / Lotion (General).

	5. Sterile Eye Drops Section (General). 6. Pelletization Section (for in House use only). 7. Liquid Injection (Ampoule and Vials Section. 8. Dry Powder Injection Section (Cephalosporin). 9. Dry Powder for Suspension Section (Cephalosporin). 10. Capsule Section (Cephalosporin). 11. Lyophilized Powder for Injection Section. 12. Sterile Eye Drops (Steroid) Section. 13. Cream / Ointment / Gel (Steroid). 14. Tablet (Hormone). 15. Cream / Ointment / Gel (Steroid). 16. Liquid Injection Ampoule (Hormone). 17. Lyophilized Injection Vials (Steroidal Hormone). **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000333 by way of Formulation in the name of M/s Shaigan Pharmaceuticals (Pvt) Ltd, 14-KM, Adyala Road, Post Office Dahgal, Rawalpindion the recommendations of the panel of experts for the period commencing on 07-01-2021 ending on 06-01-2026 for the following section: 1. Tablet Section (General). 2. Capsule Section (General). 3. Oral Liquid Section (General). 4. Topical Section (Cream / Ointment / Gel / Lotion (General). 5. Sterile Eye Drops Section (General). 6. Pelletization Section (for in House use only). 7. Liquid Injection (Ampoule and Vials Section. 8. Dry Powder Injection Section (Cephalosporin). 9. Dry Powder for Suspension Section (Cephalosporin). 10. Capsule Section (Cephalosporin). 11. Lyophilized Powder for Injection Section. 12. Sterile Eye Drops (Steroid) Section. 13. Cream / Ointment / Gel (Steroid). 14. Tablet (Hormone). 15. Cream / Ointment / Gel (Steroid). 16. Liquid Injection Ampoule (Hormone). 17. Lyophilized Injection Vials (Steroidal Hormone).			
5.	M/s Shrooq Pharmaceuticals (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore DML No.000577 (Formulation). Period: Commencing on 12-05-2020 ending on 11-05-2025.	**26-10-2021** **&** **29-10-2021**	**Good**	4. Dr. Zaka-ur-Rehman, Chief Operating Officer, PDTRC, Lahore. 5. Aisha Irfan, Federal Inspector of Drugs, DRAP, Lahore. 6. Ufaq Tanveer, Assistant Director, DRAP, Lahore.
	"In view of above inspection proceedings and facilitates 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 for the following section to M/s Shrooq Pharmaceuticals (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore by way of formulation only: 1. Tablet General Section. 2. Tablet (Quinolone) Section. 3. Oral Liquid Section. 4. Capsule (General) Section. 5. Sachet Section. 6. Capsule (Cephalosporin) Section. 7. Dry Powder Suspension (Cephalosporin) Section. 8. Topical (Cream, Ointment, Lotion and Gel) Section. 9. Dry Powder Injection (Cephalosporin). 10. Injection Ampoule (General) Section. 11. Vial Infusion Section. **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000577 by way of Formulation in the name of M/s Shrooq Pharmaceuticals (Pvt) Ltd, 21-KM, Ferozepur Road, Lahore on the recommendations of the panel of experts for the period commencing on 12-05-2020 ending on 11-05-2025 for the following section: 1. Tablet General Section. 2. Tablet (Quinolone) Section. 3. Oral Liquid Section. 4. Capsule (General) Section. 5. Sachet Section. 6. Capsule (Cephalosporin) Section. 7. Dry Powder Suspension (Cephalosporin) Section. 8. Topical (Cream, Ointment, Lotion and Gel) Section. 9. Dry Powder Injection (Cephalosporin). 10. Injection Ampoule (General) Section. 11. Vial Infusion Section.			
6.	M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District, Sheikhupura. DML No.000484 (Formulation). Period: Commencing on 19-12-2020 ending 18-12-2025. Sections; i. Liquid Injectable (Including Blow Seal Area)	**05-10-2021**	**Good**	1. Mrs. Majida Mujahid, Additional Director (E&M), DRAP, Lahore. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.

	(General), ii. Dry Powder for injection (General) iii. Dry Powder for injection (Cephalosporin),			
	"The panel of inspector Recommends the renewal of DML bearing No. 000484 (Formulation) issued in favor of M/s Surge Laboratories (Pvt) Ltd, in respect of all approved section". **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000484 by way of Formulation in the name of M/s Surge Laboratories (Pvt) Ltd, 10-KM, Faisalabad Road, Bikhi, District, Sheikhupura on the recommendations of the panel of experts for the period commencing on 19-12-2020 ending 18-12-2025 for the following section: 1. Liquid Injectable (Including Blow Seal Area) (General), 2. Dry Powder for injection (General). 3. Dry Powder for injection (Cephalosporin),			
7	M/s GT Pharma (Pvt) Ltd, 713-Sunder Industrial Estate, Lahore. DML No.000829 (Formulation) Period: Commencing on 03-12-2020 ending on 02-12-2025.	**13-10-2021**	**Good**	1. Dr. Zaka –Ur-Rehman COO, PRDTC, Lahore. 2. Majida Mujahid, Additional Director, DRAP, Lahore. 3. Mehwish Jamil Butt, Assistant 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 personnel, having adequate documentation, regarding production, QA, quality control, microbiology lab and purified water production and testing facilities, the panel of inspectors recommend the grant of Renewal of Drug Manufacturing License to GT PHARMA PVT.(Ltd) bearing Lic No. 000829 for the following four section: 1. Liquid Injectable (General) for ampoules and vials (SVP) 2. Oral Dry Suspension (General) 3. Sachet (General) 4. Capsule (General) **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000829 by way of			

	Formulation in the name of M/s GT Pharma (Pvt) Ltd, 713-Sunder Industrial Estate, Lahore on the recommendations of the panel of experts for the period commencing on 03-12-2020 ending on 02-12-2025 for the following section: 1. Liquid Injectable (General) for ampoules and vials (SVP) 2. Oral Dry Suspension (General) 3. Sachet (General) 4. Capsule (General).			
8	M/s GlaxoSmithKline Consumer Health Care Pakistan Ltd, Petaro Road, Jamshoro. DML No.000010 (Formulation) Period: Commencing on 30-03-2020 ending on 29-03-2025.	**13-10-2021**	**Good**	1) Dr. Abdullah Dayo, Expert Member. **2)** Federal Inspector of Drugs, DRAP, Islamabad. **3)** DD, CDL, Karachi.

Recommendations of the panel:

GSK Consumer Healthcare Pakistan was inspected by the panel members in connection with grant of renewal of Drugs Manufacturing License and regularization of sections. Keeping in view, peoples met, documents reviewed, and observations noted during the course of inspection, and commitment of management towards continual improvement, the panel recommends as follows:

(i) Recommend renewal of Drug Manufacturing License (ML # 000010) by way of formulation to the firm GSK Consumer Healthcare Pakistan, Petaro Road Jamshoro Sindh. (ii)Recommend regularization of sections namely, Tablet section (General) - 1. Tablet section (General) - II. Tablet section (General) - III. Tablet section (General) - IV. Capsule (General) section, Dry Powder Suspension (General) section, Cream/Ointment/ Gel (General) section, Liquid Syrup (General) section. Quality Control Lab and Warehouse (General)

Decision of the Central Licensing Board in 284th meeting:

Name of Sections	Name of Sections
1. Tablet (General)- I	2. Tablet (General)- II
3. Tablet (General)- III	4. Tablet (General)- IV
5. Capsule (General)	6. Cream/Ointment/Gel (General)
7. Dry Powder Suspension (General)	8. Liquid Syrup (General)
9. QC Laboratory	10. Ware House (General)

The Board considered and approved the grant of renewal of DML No. 000010 by way of Formulation in the name of M/s GlaxoSmithKline Consumer Health Care Pakistan Ltd, Petaro Road, Jamshoro on the recommendations of the panel of experts for the period commencing on 30-03-2020 ending on 29-03-2025 for the following section:

Name of Sections	Name of Sections
1. Tablet (General)- I	2. Tablet (General)- II
3. Tablet (General)- III	4. Tablet (General)- IV
5. Capsule (General)	6. Cream/Ointment/Gel (General)
7. Dry Powder Suspension (General)	8. Liquid Syrup (General)
9. QC Laboratory	10. Ware House (General)

9	M/s Biorex Pharmaceuticals, Plot No. 251-A, Industrial Triangle, Kahuta Road, Islamabad Drug Manufacturing License No. 000528 (Formulation) Period: Commencing on 28-03-2019 ending on 27-03-2024.	**28-09-2021,** **21-10-2021**	**Good**	Additional Director (QA/LT), HQ DRAP, Islamabad. Federal Inspector of Drugs, DRAP, Islamabad. Mr. Muhammad Usman, Assistant Director, DRAP, Islamabad.

Recommendations:

Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommended** following sections ofM/s Biorex Pharmaceuticals, Plot# 251-A, Industrial Triangle Kahuta Road.:

ii) the renewal of Drug Manufacturing License by way of Formulation

1. Tablet (General)
2. Capsule (General)
3. Capsule (Cephalosporin)
4. Dry Suspension (Cephalosporin))
5. Dry Powder Injection (Cephalosporin).

Decision of the Central Licensing Board in 284th meeting:

The Board considered and approved the grant of renewal of DML No. 000528 by way of Formulation in the name of M/s Biorex Pharmaceuticals, Plot No. 251-A, Industrial Triangle, Kahuta Road, Islamabad on the recommendations of the panel of experts for the period commencing on 28-03-2019 ending on 27-03-2024 for the following section:

1. Tablet (General)
2. Capsule (General)
3. Capsule (Cephalosporin)
4. Dry Suspension (Cephalosporin))
5. Dry Powder Injection (Cephalosporin).

10.	M/s Well & Well Pharma (Pvt) Ltd, Plot No. 07, Street S-8, National Industrial Zone RCCI, Rawat. Drug Manufacturing License No. 000687 (Formulation) **Period: Commencing on** 20-06-2020 ending on 19-06-2025**.**	**7th& 8th December 2021.**	**Good**	1. Dr. Hafza Karam Elahi, Additional Director QA/LT, DRAP, Islamabad, 2. Federal Inspector of Drugs, DRAP, Islamabad. 3. Mr. Malik Muhammad Asad. DD Lic, DRAP, Islamabad.
	Recommendations: Keeping in view the above facts on record and the people met during the visit, the panel unanimously **recommendedthe approval of DML (By way of Formulation) to** Well & Well Pharmaceuticals, Plot No. 07, Street S-8, National Industrial Zone RCCI, Rawat. With following sections : **1.** Tablet (General) **2.** Capsule (General) **3.** Sachet (General) **4.** Dry Suspension (General) **5.** Capsule (Cephalosporin) **6.** Dry Suspension (Cephalosporin)) **7.** Dry Powder Injection (Cephalosporin) **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000687 by way of Formulation in the name of M/s Well & Well Pharma (Pvt) Ltd, Plot No. 07, Street S-8, National Industrial Zone RCCI, Rawat on the recommendations of the panel of experts for the period commencing on 20-06-2020 ending on 19-06-2025 for the following section: **1.** Tablet (General) **2.** Capsule (General) **3.** Sachet (General) **4.** Dry Suspension (General) **5.** Capsule (Cephalosporin) **6.** Dry Suspension (Cephalosporin)) **7.** Dry Powder Injection (Cephalosporin)			
11	M/s Highnoon Laboratories Limited, 17.5-Km Multan Road, Lahore. DML No. 000155 (Formulation) Period: Commencing on 21-08-	**11-11-2021**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.

	2020 ending on 20-08-2025. **Sections (12)** 1. Semi Solid (Cream, Ointment)(Renewal) 2. Dry Powder Inhaler Capsule (Steroid) (Renewal) 3. Sachet (General) (Renewal & Regularization) 4. Tablet (Renewal & Regularization) 5. Capsule (General) (Renewal & Regularization) 6. Capsule (Hormone) (Renewal & Regularization) 7. Syrup (General) Renewal) & Regularization) 8. Oral Drops (General) (Renewal & Regularization) 9. Tablet (Hormone) (Renewal & Regularization) 10. Dry Powder Suspension (General) (Renewal & Regularization) 11. Quality Control Laboratory (Regularization) 12. Warehouse (Regularization)			3. Ms. Mehwish Jamil Butt, Assistant Director, DRAP, Lahore.
	Recommendations of the panel: "The panel of inspectors recommends the renewal of DML bearing No. 000155 and regularization of all approved sections in respect of M/s Highnoon Laboratories Limited, 17.5-Km Multan Road, Lahore. **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000155 by way of Formulation in the name of M/s Highnoon Laboratories Ltd, 17.5-Km Multan Road, Lahore on the recommendations of the panel of experts for the period commencing on 21-08-2020 ending on 20-08-2025 for the following section:			

	i. Semi Solid (Cream, Ointment) (Renewal) ii. Dry Powder Inhaler Capsule (Steroid) (Renewal) iii. Sachet (General) (Renewal & Regularization) iv. Tablet (General) (Renewal & Regularization) v. Capsule (General) (Renewal & Regularization) vi. Capsule (Hormone) (Renewal & Regularization) vii. Syrup (General) Renewal) & Regularization) viii. Oral Drops (General) (Renewal & Regularization) ix. Tablet (Hormone) (Renewal & Regularization) x. Dry Powder Suspension (General) (Renewal & Regularization) xi. Quality Control Laboratory (Regularization) xii. Warehouse (Regularization).			
12	M/s Daneen Pharma (Pvt) Ltd, Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, Lahore. DML No.000688 (Formulation) Period: Commencing on 21-06-2020 ending on 20-06-2025. **Section(04):** 1. Capsule (Cephalosporin) Section. 2. Dry Powder Injectable (Cephalosporin) Section. 3. Dry Powder Suspension (Cephalosporin) Section. 4. Tablet (General) Section (Expansion & Renewal).	**08-02-2021 & 27-10-2021**	**Good**	1) Dr. Farzana Chaudhry, Member, Lahore. 2) Mrs. Majida Mujahid, Additional Director, DRAP, Lahore. 3) Ms. Ufaq Tanveer Butt, Assistant Director, DRAP, Lahore
	Recommendations of the panel: In the light of the inspection conducted by the panel of inspection and based on the findings related to documentation, personnel, HVAC system, environment, machinery. Quality Control and testing facilities, the Panel of inspectors recommends grant of renewal of the Drug Manufacturing License by the way of Formulation of M/s Daneen Pharma (Pvt) Ltd, 27, Sundar Industrial Estate, Sundar Raiwind Road, Lahore. **Decision of the Central Licensing Board in 284th meeting:** The Board considered and approved the grant of renewal of DML No. 000688 by way of Formulation in the name of M/s Daneen Pharma (Pvt) Ltd, Plot No. 27, Sundar Industrial Estate, Sundar Raiwind Road, Lahore on the recommendations of the panel of experts for the period commencing on 21-06-2020 ending on 20-06-2025 for the following section: i. Capsule (Cephalosporin) Section.			

	ii. Dry Powder Injectable (Cephalosporin) Section. iii. Dry Powder Suspension (Cephalosporin) Section. iv. Tablet (General) Section (Expansion & Renewal).			
13	M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore. DML No. 000729 (Formulation) Period: Commencing on 22-06-2021 ending on 21-06-2026.	**09-11-2021**	**Good**	1. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 2. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore. 3. Ms. Maham Misbah, Assistant Director, 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 requirements 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 the registered products and approved sections. Additionally, the panel of inspectors also verified that the firm has developed the following new manufacturing sections as per approved layout plan:

1. Cream/Ointment (General)
2. Oral dry powder sachet (General)
3. External/Topical preparations
4. Liquid repacking
5. Powder repacking

"The panel of inspectors recommends the renewal of DML bearing No. 000729 issued in favour of M/s British Pharmaceuticals, 23 Km Sheikhupura Road, Lahore. The panel also recommends the grant of additional manufacturing sections as mentioned above."

Decision of the Central Licensing Board in 284th meeting:

The Board considered and approved the grant of renewal of DML No. 000729 by way of Formulation in the name of M/s British Pharmaceuticals, 23-Km, Sheikhupura Road, Lahore the recommendations of the panel of experts for the period Commencing on 22-06-2021 & ending on 21-06-2026 for the following section: -

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

ITEM-V MISCELLANEOUS CASES

Case No. 1 **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.

Accordingly, a personal hearing letter was issued to the firm on 06-12-2021.

Decision of the Central Licensing Board in 284th meeting:

Ms. Samina Javed owner and Mr. Zeeshan appeared before the Board on behalf of the firm. The Board decided to cancel the Drug Manufacturing License No. 000727 (Formulation) of M/s Jasons Pharmaceuticals, Plot No. 26, Street No. SS-2, National Industrial Zone, Rawat. as the Drug Manufacturing License No. 000727 is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976. However, firm may file an application afresh under Rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No. 2 **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.

Accordingly, a personal hearing letter was issued to the firm on 06-12-2021.

Decision of the Central Licensing Board in 284th meeting

No one appeared before the Board on behalf of the firm. The Board decided to cancel the Drug Manufacturing License No. 000384 (Formulation) of M/s Ceicil Laboratories (Pvt) Ltd, 21-Km, Ferozepur Road, Doolu Khurd, Lahore as the Drug Manufacturing License No. 000384 is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976. However, firm may file an application a fresh under Rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No. 3 **RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000277 (FORMULATION) OF M/s KAILGON AGRO INDUSTRIES (PVT) LTD, HITE BALOCHISTAN.**

M/s KailgonAgro Industries (Pvt) Ltd, 849 PAthra Road, Hub Chowky Road, Lasbella Baluchistan had applied for renewal of DML No. 000277 by way of formulation for the period of commencing on 13-10-2021 & ending on 12-10-2026.

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 21st April 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Dully retained fee challan by AD (Revenue) DRAP, Islamabad.
(ii) Updated Form-29 and Form-A issued by SECP.
(iii) Attested CNIC copies of all directors.
(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) Complete set of documents of new proposed production In charge Mr. Mushtaq Ahmed Khan.
(iv) Updated NDC of CRF.
(v) Attested section wise detail of machinery for manufacture.
(vi) Attested section wise detail of machinery for QC Laboratory.

(vii) Detail of all licensed sections along with approval letter.

No response was received from the firm and a Reminder dated 25th June 2021 was issued to the firm to provide the said documents.

No response / documents are received from the firm regarding completion of application for renewal of DML .

In the meanwhile a letter is received from the firm , in which the firm has intimated that the firm intends to stop the production operations.

The firm is also called for personal hearing vide letter dated 07th December 2021.

Decision of the Central Licensing Board in 284th meeting

No one appeared before the Board on behalf of the firm and the board decided to give Final Opportunity of Personal Hearing to the firm in next meeting of the Board.

Case No. 4 **RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MYRTLE PHARMA, KARACHI**

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

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

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

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

1. Undertaking on stamp paper of Proposed Quality Incharge & Production Incharge
2. Attested copy of CNIC and academic degree along with Registration Certificate issued from Pharmacy Council of proposed Production Incharge Mr. Rana Akram (dully attested).
3. Experience certificates of proposed Production Incharge.

4. Relevant experience certificates in testing of drugs of 10 years of Proposed Quality Incharge.
5. **All documents should be duly attested.**

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

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

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

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

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

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

Decision by the Central Licensing Board in 273rd meeting

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

Firm is also called for personal hearing vide letter Dated : 27-08-2020 .

Proceedings and Decision by the Central Licensing Board in 276th meeting:

No Person appeared before the Board on behalf of the firm. The Board decided to suspend the Drug Manufacturing license No. 000722 by way of formulation of M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone,BinQasim Karachi, for the period of six (06) months. Production shall be resumed after approval by the Central Licensing Board.

The decision of the Board/Suspension Orders were issued to the firm vide letter dated 25th September 2021.

The firm was required to submit application for renewal of DML No. 000722 (Formulation) for the tenure commencing on 22-06-2021 & ending on 21-06-2026 but the said application is not received in the division of Dug Licensing DRAP, Islamabad as of today.

The firm is also called for personal hearing vide letter dated 07th December 2021.

Decision of the Central Licensing Board in 284th meeting

Ms. Arhama appeared before the Board on behalf of the firm and contended that she has obtained the succession certificate after the death of the owner of the firm. The Board decided to cancel the Drug Manufacturing License No. 000722 (Formulation) of M/s Myrtle Pharma Karachi Plot No. E-100, North Western industrial Zone, Bin Qasim Karachi as the Drug Manufacturing License No 000722 is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976. However, firm may file an application a fresh under Rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No. 5 **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. 7,500/- 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.

The firm is also called for Personal Hearing

Decision of the Central Licensing Board in 284th meeting

Mr. Naeem Mansoor Production In charge appeared before the Board on behalf of the firm and contended that the production of the firm is stopped for one and half months. The Board decided to cancel the Drug Manufacturing License No. 000734 (Formulation) of M/s Saturn Pharmaceuticals (Pvt) Ltd, Lahore as the Drug Manufacturing License No. 000734 (Formulation) is no more valid as under Rule 5 (6) of Drug (L, R & A) Rule, 1976. However, firm may file an application a fresh under Rule 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976

Case No. 6 **SURRENDER OF LICENSE NO. 000225 BY WAY OF (FORMULATION) OF M/S SOMA LABORATORIES, LAHORE.**

M/s Soma Laboratories, Plot No. 43-D, Sundar Industrial Estate, Raiwind Road, Lahore, where they have informed that they intend to surrender Drug Manufacturing License No. 000225 by way of (Formulation).

A letter of personal hearing is served to the said firm to appear personally before the Board.

Decision of the Central Licensing Board in 284th meeting

No person appeared before the Board on behalf of the firm . The Board decided to accede the request of the firm.

Case No. 7 **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 that the 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.

A letter of personal hearing is served to the firm to appear personally before the Board.

Decision of the Central Licensing Board in 284th meeting:

Mr. Umer Farooq Director of the firm appeared before the Board along with Mr. Shoaib Manager Biological on behalf of the firm. The Board decided to verify the facility by the following panel of experts for the said purpose :

1. Additional Director (QA/LT), DRAP, Islamabad.
2. Additional Director (Biological), DRAP, Islamabad.
3. Area FID, DRAP, Islamabad.

Case No. 8 **ESTABLISHMENT OF A PHARMACEUTICAL UNIT OF M/S SNAM LABORATORIES AT MOUZA GHAWINDI, TEHSIL LAHORE CANTT, DISTT, LAHORE.**

Site verification report of M/s SNAM Laboratories, Mouza Ghawindi, Tehsil Lahore Cantt, Distt, Lahore. The inspection was conducted by Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore on 20-04-2021, in response to this office letter dated 9th February, 2021. The recommendations of the inspection report are as under:-

Location:	The proposed site was located at Mouza Ghawindi, Tehsil Lahore Cantt, Distt. Lahore and was approached through 30 feet wide, metaled BadianBarki Road, at 7 KM away from Haddira.
Surrounding:	On the front side of the site there was 30 feet wide metaled road. On the across of the 30 feet wide road there was 1st Defense line of security agencies. On the right, left and back side of the said site there was agricultural land.
Size:	The total area of the site was 04 kanals as per documents provided by the applicant. The dimension of the plot is annexed along with the report.
Recommendations	The firm was located in the jurisdiction of Security Agencies so, the firm was directed to provide NOC from Security Agencies for construction, as no contraction is allowed in the Jurisdiction of Security Agencies. However, the firm was failed to provide the above said documents. In view of the above the site was **not suitable** for the establishment of a pharmaceutical unit as of today as per requirement, laid down under paragraph 1 of section-1 of the Schedule "B" (SRO, 470 (1)/98, dated 15-05-1998, under rule 16 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

A letter of personal hearing was also issued to the firm.

Decision of the Central Licensing Board in 284th meeting

Mr. Shafiq Ahmed Fayyaz appeared before the Board on behalf of the firm and inform the Board that the firm was willfully withdrawing the request for site verification and stated that the firm will file new application for site verification. The Board decided to accede the request of the firm regarding withdrawal of application for site verification.

Case No. 9**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.

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.

Decision of the Central Licensing Board in 284th meeting

The Board considered the case and decided to cease the show cause notice issued to the firm.

Case No. 10 **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 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 Pharmedic Pharmaceuticals Industries (Pvt) Ltd., 17KM, 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 decided to suspend the Drug Manufacturing License 000853(by way of formulation) of M/s Pharmedic Pharmaceuticals 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.

In the light of Central Licensing Board's decision firm has submitted No Objection Certificate regarding CRF.

Decision of the Central Licensing Board in 284th meeting:

The Board considered the case and decided to cease the show cause notice issued to the firm.

Case No. 11 **CHANGE OF MANAGEMENT OF M/S M/S SIMZ PHARMACEUTICALS (PVT) LTD, PLOT NO. 574-575, PUNJAB INDUSTRIAL ESTATE, SUNDAR, LAHORE, UNDER DRUG MANUFACTURING LICENSE NO. 000762 BY WAY OF (FORMULATION).**

M/s Simz Pharmaceuticals (Pvt) Ltd, Plot No. 574-575, Punjab Industrial Estate, Sundar, Lahore, DML No.000762 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. Dr. Muhammad Hassan S/o Mumtaz Hussain, CNIC No.35202-1601696-7. 2. Mrs. Samina Hassan W/o Dr. Muhammad Hassan, CNIC No.35201-5335499-2.	1.Dr. Salman Hassan S/o Dr. Muhammad Hassan, CNIC No.91509-0173536-9. 2.Mr. Imran Hassan S/o Dr. Muhammad Hassan, CNIC No. 91509-0189411-3.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/ Simz Pharmaceuticals (Pvt) Ltd, Plot No. 574-575, Punjab Industrial Estate, Sundar, Lahore, DML No.000762 (By way of Formulation) as under:-

Previous management as per Form-29.	New management as per Form-29.
1. Dr. Muhammad Hassan S/o Mumtaz Hussain, CNIC No.35202-1601696-7. 2. Mrs. Samina Hassan W/o Dr. Muhammad Hassan, CNIC No.35201-5335499-2.	1. Dr. Salman Hassan S/o Dr. Muhammad Hassan, CNIC No.91509-0173536-9. 2.Mr. Imran Hassan S/o Dr. Muhammad Hassan, CNIC No. 91509-0189411-3.

Case No. 12 **CHANGE OF MANAGEMENT OF M/S CROWN PHARMACEUTICALS, PLOT NO. 286, INDUSTRIAL TRIANGLE, KAHUTA ROAD, ISLAMABAD, UNDER DRUG MANUFACTURING LICENSE NO. 000456 BY WAY OF (FORMULATION).**

M/s Crown Pharmaceuticals, Plot No. 286, Industrial Triangle, Kahuta Road, Islamabad, DML No.000456 by way of formulation has submitted request for change in management of the firm with prescribed fee. The detail of management of the firm is as under;

Previous management	New management
1. Dr. Khalid Mehmood S/o Asmatullah, CNIC No.37405-0280439-5.	1. Dr. Ali Khalid S/o Khalid Mehmood, CNIC No.37405-3303685-7.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/s Crown Pharmaceuticals, Plot No. 286, Industrial Triangle, Kahuta Road, Islamabad, DML No.000456 (By way of Formulation) as under:-

Previous management	New management
1. Dr. Khalid Mehmood S/o Asmatullah, CNIC No.37405-0280439-5.	1. Dr. Ali Khalid S/o Khalid Mehmood, CNIC No.37405-3303685-7.

Case No. 13 **CHANGE OF MANAGEMENT OF M/S MEDLEY PHARMACEUTICAL, PLOT NO. 41/A, PUNJAB SMALL INDUSTRIAL ESTATE, JHANG BAHTAR ROAD, WAH CANTT, UNDER DRUG MANUFACTURING LICENSE NO. 000237 BY WAY OF (FORMULATION).**

M/s Medley Pharmaceutical, Plot No. 41/A, Punjab Small Industrial Estate, JhangBahtar Road, Wah Cantt DML No.000237 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	Current Management as per Partnership Deed
1. Mr. Shabbir Ahmad S/o ShahmasUd Din CNIC No.38403-7945363-1 2. Mr. Haroon Rashid S/o Ch. Rashid Ahmad CNIC No.35202-3954123-5. 3. Mr. Javed Iqbal Chishti S/o Abdul Hameed CNIC No.37406-6558480-7.	1. Mr. Muhammad Zia Ul Haq S/o Javied Iqbal Chishti CNIC No. 37406-3835477-1. 2. Mr. Shabbir Ahmad S/o ShahmasUd Din CNIC No.38403-7945363-1. 3. Mr. Muhammad Munir S/o ShahmasUd Din CNIC No.38403-4474939-7. 4. Mr. Haroon Rashid S/o Ch. Rashid Ahmad CNIC No.35202-3954123-5.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/s Medley Pharmaceutical, Plot No. 41/A, Punjab Small Industrial Estate, JhangBahtar Road, Wah Cantt DML No.000237 (By way of Formulation) as under:-

Previous Management	Current Management as per Partnership Deed
1. Mr. Shabbir Ahmad S/o ShahmasUd Din CNIC No.38403-7945363-1 2. Mr. Haroon Rashid S/o Ch. Rashid Ahmad CNIC No.35202-3954123-5. 3. Mr. Javed Iqbal Chishti S/o Abdul	1. Mr. Muhammad Zia Ul Haq S/o Javied Iqbal Chishti CNIC No. 37406-3835477-1. 2. Mr. Shabbir Ahmad S/o ShahmasUd Din CNIC No.38403-7945363-1.

Hameed CNIC No.37406-6558480-7.	3. Mr. Muhammad Munir S/o ShahmasUd Din CNIC No.38403-4474939-7. 4. Mr. Haroon Rashid S/o Ch. Rashid Ahmad CNIC No.35202-3954123-5.

Case No. 14 **CHANGE OF MANAGEMENT OF M/S PANACEA PHARMACEUTICALS (PVT) LTD, PLOT NO. 4, STREET NO. S-6, NATIONAL INDUSTRIAL ZONE, RAWAT, UNDER DRUG MANUFACTURING LICENSE NO. 000600 BY WAY OF (FORMULATION).**

M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, DML No.000600 by way of formulation has submitted request for change in management of the firm as partnership deed with prescribed fee. The detail of management of the firm is as under;

Previous Management as per partnership deed.	New Management as per partnership deed.
1. Mr. Irfan Afzal S/o Mohammad Afzal CNIC No. 61101-7315339-5. 2. Mr. Adnan Afzal S/o Mohammad Afzal CNIC No. 61101-9816203-1.	1. Mr. Irfan Afzal S/o Mohammad Afzal CNIC No. 61101-7315339-5. 2. Mr. Abdul Haseeb Irfan S/o Irfan Afzal CNIC No. 61101-2171318-7.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/s Panacea Pharmaceuticals, Plot No. 4, Street No. S-6, National Industrial Zone, Rawat, DML No.000600 (By way of Formulation) as 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:-

Previous Management as per partnership deed.	New Management as per partnership deed.
1. Mr. Irfan Afzal S/o Mohammad Afzal CNIC No. 61101-7315339-5. 2. Mr. Adnan Afzal S/o Mohammad Afzal CNIC No. 61101-9816203-1.	1. Mr. Irfan Afzal S/o Mohammad Afzal CNIC No. 61101-7315339-5. 2. Mr. Abdul Haseeb Irfan S/o Irfan Afzal CNIC No. 61101-2171318-7.

Case No. 15 **CHANGE OF MANAGEMENT OF M/S FILIX PHARMACEUTICALS (PVT) LTD, PLOT NO.4-A, MAIN ROAD, RCCI, RAWAT UNDER DRUG MANUFACTURING LICENSE NO. 000779 BY WAY OF (FORMULATION).**

M/s Filix Pharmaceuticals (Pvt) Ltd, Plot No.4-A, Main Road, RCCI, Rawat under DML No. 000779 by way of formulation has submitted request for change in management of the firm as per Form-29. The detail of management of the firm is as under;

Previous Management as per Form-1	Current Management as per Form-29
1. Mr. Zeeshan Shahzad S/o Nazir Hussain Shahzad CNIC No.61101-5711044-3.	1. Mr. Zeeshan Shahzad S/o Nazir Hussain Shahzad CNIC No.61101-5711044-3. 2. Mrs. Amna Zeeshan W/o Zeeshan Shahzad CNIC No.42301-3910494-8.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/ Filix Pharmaceuticals (Pvt) Ltd, Plot No.4-A, Main Road, RCCI, Rawat under DML No. 000779 (By way of Formulation) as under:-

Previous Management as per Form-1	Current Management as per Form-29
1. Mr. Zeeshan Shahzad S/o Nazir Hussain Shahzad CNIC No.61101-5711044-3.	1. Mr. Zeeshan Shahzad S/o Nazir Hussain Shahzad CNIC No.61101-5711044-3. 2. Mrs. Amna Zeeshan W/o Zeeshan Shahzad CNIC No.42301-3910494-8.

Case No. 16 **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.

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.

Decision of the Central Licensing Board in 284th meeting

The Board considered the case and decided to cease the show cause notice issued to the firm.

Case No. 17 **CORRECTION IN NAME OF SECTION OF M/S BRYON PHARMACEUTICALS (PVT) LTD., 48-HAYATABAD INDUSTRIAL ESTATE, PESHAWAR (DRUG MANUFACTURING LICENSE NO. 000388-FORMULATION).**

M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Hayatabad Industrial Estate, Peshawar wherein they have requested for correction in the name of Sections.

It is submitted that a panel of expert for renewal of DML/regularization for following section was constituted, accordingly;

i. Dry Suspension (Cephalosporin)
ii. Capsule (Cephalosporin)
iii. Dry Powder (General) -Regularization
iv. Tablet-I (General) -Regularization
v. Tablet (Psychotropic) -Regularization
vi. Liquid Syrup (General) -Regularization
vii. Ointment/Cream (General) -Regularization
viii. Capsule (General) -Regularization

The Area FID submitted panel inspection report and recommended renewal/Regularization for above mentioned sections. The Central Licensing Board in its 283rd meeting held on 28th October, 2021 considered and approved the grant of renewal of Drug Manufacturing License No. 000388 by way of Formulation of M/s Bryon Pharmaceuticals (Pvt) Ltd., 48-Hayatabad Industrial Estate, Peshawar. However, *Injectable Vial (Cephalosporin) and Sachet (General)* sections were inadvertently mentioned instead of *Dry Powder (General)and Tablet (Psychotropic)*in the agenda and same was reflected in the minutes of the said meeting.

Decision of the Central Licensing Board in 284th meeting

The Board considered the case and decided to approved the correction in the title/name of the sections of the firm **OralDry Powder (General) and Tablet (Psychotropic)** instead of **Injectable Vial (Cephalosporin) and Sachet (General) sections .**

Case No. 18 **GRANT OF ADDITIONAL SECTIONS/ REVISION/AMENDMENTS ETC RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDERA PHARMACEUTICALS (PVT) LTD, RAWAT UNDER DML NO.000714**

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**

Dry Powder Suspension (Cephalosporin)- **New**

M/s Medera Pharmaceuticals, Plot No. 2, St No. N-4, National Industrial Zone, Rawat. DML No. 000714 (Formulation).	21-10-2021 & 26-10-2021	Good	1. Additional Director (QA & LT), DRAP, Islamabad. 2. Federal Inspector of Drugs, DRAP, Islamabad.

Period: Commencing on 15-06-2021 & ending on 14-06-2026.			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)

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

Decision of the Central Licensing Board in 284th meeting

The Board considered the case and decided to approved the correction in the tilte/name of the firm "M/s Medera Pharmaceuticals (Pvt) Ltd" instead of "M/s Medera Pharmaceuticals".

Case No. 19 **APPROVAL OF QUALITY CONTROL INCHARGE & RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000818(FORMULATION) OF M/s ZETA PHARMACEUTICALS, LAHORE.**

M/s Zeta Pharmaceuticals, Plot No. 494-A, Sunder Industrial Estate Lahore has applied for renewal of DML No. 000818 by way of formulation for the period of 23-06-2020 to 22-06-2025.

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 24th September 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Form-1A along with enclosure/annexure.
(ii) Detail of Management at the time of previous renewal and at present, if nay change, apply for change of management.
(iii) Attested CNIC's of all directors.
(iv) Latest Certified True copy of From-29.
(v) Detail/of premises including layout plan.
(vi) Proof of sections from the CLB.
(vii) Updated NDC of CRF from STO DRAP.

No reply was received from the firm and a Reminder dated 13th July 2021 was issued to the firm to submit documents mentioned above for completion of the application for renewal of DML.

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

i. NDC of CRF issued from STO DRAP.
ii. There is change in management and the firm has not applied for change of management from the time of last renewal

The firm also applied for approval of QC In charge Mr. Muhammad Abid Rasool which were evaluated and a letter dated 13th July 2021 was issued to the firm to submit following documents :

i. Registration certificate from Pharmacy Council.
ii. Experience certificates as under the Prescribed Rules.
iii. Resignation of earlier QC In charge.
iv. Resignation letter of appointee from previous firm.

The reply/documents submitted by the firm were evaluated and later on a Reminder dated 17th September 2021 was issued to the firm to submit the documents following documents :

i. Registration certificate from Pharmacy Council.
ii. Experience certificates as under the Prescribed Rules, it should be not less than six years and if not available then submit documents of another person.

The reply/documents submitted by the firm was evaluated and it is evaluated that the proposed QC In charge has done degree (Pharm-D) on 23-11-2016 and does not fulfill the requirement of Rule 16 in terms of required experience .

Decision of the Central Licensing Board in 284th 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 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000818 by way of formulation of M/s Zeta Pharmaceuticals , Plot No. 494-A, Sunder Industrial Estate Lahore may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 20 **APPROVAL OF PRODUCTION INCHARGE& RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000342 (FORMULATION) OF M/s TRIGON PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Trigon Pharmaceuticals (Pvt) Ltd , 8-km, Thokar Raiwind Road, Lahore had applied for renewal of DML No. 000342 by way of formulation for the period of commencing on 16-10-2019 & ending on 15-10-2024.

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 6th October 2020 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Form-1A along with enclosure/annexure.
(ii) Classes of Drugs attested.
(iii) Dosage Form of Drugs attested.
(iv) Name (s) of drugs registered / approved.
(v) Detail of Management at the time of previous renewal and at present, if any change, apply for change of management.
(vi) Attested CNIC's of all directors.
(vii) Latest Certified True copy of From-29 issued by SECP.
(viii) Detail/of premises including layout plan.
(ix) Proof of sections from the CLB.
(x) Section wise detail of machinery for manufacture.
(xi) Section wise detail of machinery for Quality Control Laboratory.
(xii) Approval letters of Production/QC In charge or if not available then submit complete documents as per check list.
(xiii) Updated NDC of CRF from STO DRAP.

No reply was received from the firm and a Reminder dated 8th January 2021 was issued to the firm to submit documents mentioned above for completion of the application for renewal of DML.

No reply is received from the firm and the application for renewal of DML No. 000342 (Formulation) is still incomplete .

The firm also applied for approval of Production In charge Mr. Imran Mehmood which were evaluated and a letter dated 8th May 2020 was issued to the firm to submit following documents :

i. Experience certificates as under the Prescribed Rules.
ii. Resignation of earlier Production In charge.
iii. Resignation letter of appointee from previous firm.
iv. Documents should be dully attested.

The reply/documents submitted by the firm were evaluated and later on a Reminder dated 7th January 2021 was issued to the firm to submit the documents following documents :

i. Experience certificates as under the Prescribed Rules, it should be not less than six years and if not available then submit documents of another person.

In reply, the firm has submitted **un attested** and **incomplete (Undertaking on stamp paper, resignation of previous production in charge & Resignation of appointee from previous firm)** documents for approval of **new Proposed Production in charge Mr. Hafiz Muhammad Naseem** Sarwar and the complete attested documents as per checklist are still to be provided by the firm.

Decision of the Central Licensing Board in 284th 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 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000342 by way of formulation of M/s Trigon Pharmaceuticals (Pvt) Ltd , 8-km, Thokar Raiwind Road, Lahore may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No.21 **WITHDRAW/VOLUNTARY SURRENDER OF LICENSED SECTIONS BY M/S THE SCHAZOO PHARMACEUTICAL LABORATORIES (PVT) LTD , PLOT NO.**

KALAWALA STOP, 20-KM, LAHORE-JARANWALA ROAD,DISTRICT SHEIKHUPURADML NO. 000019 BY WAY OF FORMULATION.

M/s The Schazoo Pharmaceutical Laboratories (Pvt) Ltd , Kalawala Stop, 20-km, Lahore-Jaranwala Road, District Sheikhupura under DML No. 000019 by way of Formulation has submitted request for withdrawal of following licensed section namely:

i. Tablet (Cephalosporin).
ii. Capsule (Cephalosporin).
iii. Dry Powder Suspension (Cephalosporin).

The firm had got approval of Layout Plan of new Psychotropic sections in place of above mentioned sections.

Decision of the Central Licensing Board in 284th meeting

The Board considered and acceded the request of the firm regarding surrender/ withdrawal of following licensed sections of the firm :

i. Tablet (Cephalosporin).
ii. Capsule (Cephalosporin).
iii. Dry Powder Suspension (Cephalosporin).

Case No. 22 RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S SCHAZOO PHARMACEUTICAL LABORATORIES (PVT) LTD, DISTRICT, SHEIKHUPURA.

	M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupura. DML No. 000019 (Formulation) Tenure. Commencing on11-06-2019 and ending on 10-06-2024.	**26-02-2021**	**Good**	1. Dr. Ikram Ul Haq, Member CLB. 2. Mr. Azhar Jamal Saleemi, Chief Drug Controller, Punjab. 3. Mrs. Majida Mujahid, Area Federal Inspector of Drugs.
	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 personnel and documentation etc., the panel recommends the Renewal of Drug Manufacturing License No. 000019 by way of (Formulation) to M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala			

Road, District, Sheikhupura for following sections:-

1. General Solid Oral Dosage form for Tablet, Capsule & Sachet.
2. Oral Liquid Section for suspension and Syrup.
3. (Ampoule) General & Psychotropic Injectable Section.
4. Ophthalmic & Nasal Drops Section.
5. Tablet, Capsule and Oral Dry Powder Suspension (Cephalosporin).

Note: It is submitted that following sections in the inspection report are approved with following nomenclature as per record of Licensing Division at page 89/Corr.

In Inspection Report.	*As per Licensing Division.*
1. Oral Liquid Section for Suspension & Syrup. ***2. Ampoule (General & Psychotropic) Injectable Section.***	***1. Oral Liquid Syrup.*** ***2. Liquid Ampoule.***

It is further submitted that Sachet Section in inspection report is not approved as per record of Licensing Division as it been checked from last renewal letter, from layout plan submitted by firm with renewal application and from panel inspection letter for renewal of DML.

Decision of the Central Licensing Board in 280th meeting

The Board considered and approved the grant of renewal of (DML No. 000019) by way of Formulation in the name of M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupuraon the recommendations of the panel of experts for the period commencing on 11-06-2019 and ending on 10-06-2024..for following sections :

1. Tablet (General)
2. Capsule (General)
3. Sachet (General)
4. Oral Liquid Section for suspension and Syrup.
5. (Ampoule) General & Psychotropic Injectable Section.
6. Ophthalmic & Nasal Drops Section.
7. Tablet, Capsule and Oral Dry Powder Suspension (Cephalosporin).

The Board deferred following sections for clarification

1. Oral Liquid Section for Suspension & Syrup.
2. Ampoule (General & Psychotropic) Injectable Section.
3. Sachet Section.

	*It is submitted that the following sections have been written inadvertently both in the list of approved and deferred sections while drafting of minutes: - 1. Oral Liquid Section for Suspension & Syrup. 2. Ampoule (General & Psychotropic) Injectable Section. 3. Sachet Section.

Decision of the Central Licensing Board in 282nd meeting

The Board considered and ratified the correction.

The firm later on had submitted request for issuance of renewal letter of pending sections.

The record of the Licensing Division, is checked and the firm is asked to submit layout plan for regularization of Injectable (Psychotropic) section and of Sachet (General) Section.

The case of the firm for **renewal of following pending sections** is placed before the CLB for consideration.

1. Liquid Ampoule (General) Section.
2. Oral Liquid Syrup/Suspension (General).

Decision of the Central Licensing Board in 284th meeting

The Board considered and approved the grant of renewal of (DML No. 000019) by way of Formulation in the name of M/s Schazoo Pharmaceutical Laboratories (Pvt) Ltd, Kalalwala Stop, 20-KM, Lahore-Jaranwala Road, District, Sheikhupura on the recommendations of the panel of experts for the period commencing on 11-06-2019 and ending on 10-06-2024..for following pending sections :

1. Liquid Ampoule (General) Section.
2. Oral Liquid Syrup/Suspension (General).

Case No. 23 CHANGE OF MANAGEMENT OF M/S NEXTAR PHARMACEUTICALS (PVT) LTD, KARACHI

M/s. Nextar Pharmaceuticals (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone, Port Qasim Authority, KarachiDML No. 000777 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Sr. No	Existing Management	Sr. No	New Management as per Form- 29 & Form-A (SECP)
1.	Ms. Abdul Jabbar Saya S/o Haji Abdul Razzak Palwala CNIC No. 42000-8684288-1.	**1**	Mr. Rashid Abdulla S/o Mr. Abdulla A.Razzaq CNIC No. 42201-1132967-1.

2.	Mr. Sarfaraz Niazi S/o Niaz Fatehpuri	**2**	Mr. Muhammad Sajid Hafeez S/o Eijaz Ahmed Siddiqui CNIC No. 42101-3124729-3.
	**********	**3**	Mr.Tahir Ahmed S/o S. Maqbool Ahmed CNIC No. 42201-0163711-5.
4.	**********	**4**	Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.
5.	**********	**5**	Ms. Abdul Jabbar Saya S/o Haji Abdul Razzak Palwala CNIC No. 42000-8684288-1.

The case is hereby submitted for consideration and orders of the Board, please.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/ Nextar Pharmaceuticals (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone, Port Qasim Authority, KarachiDML No. 000777 (By way of Formulation) as under:-

Sr. No	Existing Management	Sr. No	New Management as per Form- 29 & Form-A (SECP)
1.	Ms. Abdul Jabbar Saya S/o Haji Abdul Razzak Palwala CNIC No. 42000-8684288-1.	**1**	Mr. Rashid Abdulla S/o Mr. Abdulla A.Razzaq CNIC No. 42201-1132967-1.
2.	Mr. Sarfaraz Niazi S/o Niaz Fatehpuri	**2**	Mr. Muhammad Sajid Hafeez S/o Eijaz Ahmed Siddiqui CNIC No. 42101-3124729-3.
	**********	**3**	Mr.Tahir Ahmed S/o S. Maqbool Ahmed CNIC No. 42201-0163711-5.
4.	**********	**4**	Mr. Asad Abdulla S/o Shahid Abdulla CNIC No. 42201-8964822-9.
5.	**********	**5**	Ms. Abdul Jabbar Saya S/o Haji Abdul Razzak Palwala CNIC No. 42000-8684288-1.

Case No. 24 **CHANGE OF MANAGEMENT OF M/S WINILTON PHARMACEUTICALS (PVT) LTD, RAWAT**

M/s. Winilton Pharmaceuticals (Pvt) Ltd, Plot No. 45, Street S-5, National Industrial Zone, Rawat DML No. 000721 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee as under: -

Current Management Form-1A	New Management as per Form-29 & Form-A of SECP (Year 2021)
i. Mr. Hammad Ahmad Chaudry S/o Shafiq Ahmad Chaudry CNIC No. 37405-2289282-1. ii. Mrs. Amna Asif S/o AsimWaheed CNIC No. 61101-1827531-2. iii. Mr. Ali Akbar Halai S/o Anwar Ali Halai CNIC No 36302-4541510-7. iv. Mr. Tariq Mehmood S/o Muhammad Tufail CNIC No. 36302-4383449-5.	i. Mr. Amir Fazal S/o Noor Muhammad CNIC No. 37102-1265579-1. ii. Mr. Hammad Ahmad Chaudry S/o Shafiq Ahmad Chaudry CNIC No. 37405-2289282-1. iii. Mr. Muhammad Younus S/o Muhammad Ramzan CNIC No 37405-6756351-9. iv. Mr. Samar Akhtar S/o Asif Mehmood CNIC No. 37405-0236577-8.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/s **Winilton Pharmaceuticals (Pvt) Ltd, Plot No. 45, Street S-5, National Industrial Zone, Rawat** DML No. 000721 (By way of Formulation) as under:-

Current Management Form-1A	New Management as per Form-29 & Form-A of SECP (Year 2021)
i. Mr. Hammad Ahmad Chaudry S/o Shafiq Ahmad Chaudry CNIC No. 37405-2289282-1. ii. Mrs. Amna Asif S/o AsimWaheed CNIC No. 61101-1827531-2. iii. Mr. Ali Akbar Halai S/o Anwar Ali Halai CNIC No 36302-4541510-7. iv. Mr. Tariq Mehmood S/o Muhammad Tufail CNIC No. 36302-4383449-5.	i. Mr. Amir Fazal S/o Noor Muhammad CNIC No. 37102-1265579-1. ii. Mr. Hammad Ahmad Chaudry S/o Shafiq Ahmad Chaudry CNIC No. 37405-2289282-1. iii. Mr. Muhammad Younus S/o Muhammad Ramzan CNIC No 37405-6756351-9. iv. Mr. Samar Akhtar S/o Asif Mehmood CNIC No. 37405-0236577-8.

Case No. 25 CHANGE OF MANAGEMENT OF M/S AHSONS DRUG COMPANY SINDH

M/s. Ahsons Drug Company, T/1, SITE, Tando Adam Sindh DML No. 000138 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 Management Form-1A	**New Management as per Form-29 & Form-A of SECP (Year 2021)**
i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1. iv. Mr. Abdul Saleem S/o Abdul Hakeem CNIC No. 44206-0143901-1. v. Mst. Shakooran Begum Wd/o Late Abdul Hakeem	i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.

The case is hereby submitted for consideration and orders of the Board, please.

Decision of the Central Licensing Board in 284th meeting:

The Board considered and accepted for record the change of management of M/s **Ahsons Drug Company, T/1, SITE, Tando Adam Sindh** DML No. 000138 (By way of Formulation) as under:-

Current Management Form-1A	**New Management as per Form-29 & Form-A of SECP (Year 2021)**
i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1. iv. Mr. Abdul Saleem S/o Abdul Hakeem CNIC No. 44206-0143901-1.	i. Mr. Abdul Wahab S/o Abdul Hakeem CNIC No. 44206-4077486-1. ii. Mr. Abdul Qadir S/o Abdul Hakeem CNIC No. 42101-1951842-5. iii. Mr. Abdul Sattar S/o Abdul Razzaq CNIC No. 44206-0143901-1.

v. Mst. Shakooran Begum Wd/o Late Abdul Hakeem	

Case No. 26 **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.

The orders for suspension were about to issue and in the meanwhile the firm did submit complete documents as per Form-1A and the application for renewal of DML No. 000147(Formulation) was complete, therefore, the decision of the CLB/orders for suspension were not issued to the firm.

Decision of the Central Licensing Board in 284th meeting:

The Board considered the case and decided to revoke the decision of suspension of DML No. 000147 (Formulation) of M/s Eros Pharmaceuticals (Pvt) Ltd, Plot No. 93-95, Sector 23, Korangi Industrial Area, Karachi.

Case No. 27**RENEWAL OF DRUG MANUFACTURING LICENCE No. 000425(FORMULATION) & APPROVAL OF QC INCHARGE BY M/S EPOCH PHARMACEUTICALS, KARACHI.**

M/s Epoch Pharmaceutical, Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi, has applied for renewal of DML No. 000425 by way of formulation for the period of 25-3-2021 to 24-03-2026 on 1st March 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 7th May , 2021 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

(i) Name / detail of directors/partners on letter head along with attested CNIC copies of all partners.
(ii) Dully attested annexure/enclosure of Form-1A.
(iii) Dully attested updated partnership deed.
(iv) 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.
(v) Updated NDC of CRF.

Later on firm submitted reply / documents which were evaluated and a reminder letter was issued on 2nd July 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) Attested documents regarding management including attested CNIC copies of partners.

The firm has submitted their reply received on 15th July 2021 which is evaluated and application for renewal of DML is still found following shortcomings / deficiencies:-

i. Approval letters of all licensed sections issued from the CLB or submit layout plan for regularization of manufacturing facility in the light of approved layout plan as the firm only **possess approval letters of only four (04) sections** namely Human Liquid Injection amp & vial (General) , Ophthalmic Drop (General) , Liquid Injection Vet (Gen antibiotic), Oral Veterinary.

The firm also submitted layout plan for regularization of existing manufacturing facility which was not legible and the firm is advised to submit legible copy of layout plan and also depute technical person to discuss the layout plan.

The firm also applied for approval of QC In charge Mr. Ahmed Saeed which were evaluated and a letter dated 23rd August 2021 was issued to the firm to submit following documents :

i. Copy of Detail Marks sheet (M.Sc Chemistry).
ii. Relevant Experience certificates as under the Prescribed Rules.
iii. Dully notarized Undertaking on stamp paper regarding whole time employment.

iv. Resignation letter of appointee from previous firm.

The reply/documents submitted by the firm were evaluated and later on a Reminder dated 18th October 2021 was issued to the firm to submit the documents following documents :

i. Dully attested copy of Detail Marks sheet (M.Sc Chemistry).
ii. Dully attested Relevant Experience certificates as under the Prescribed Rules.
iii. Dully notarized Undertaking on stamp paper regarding whole time employment.
iv. Attested Resignation letter of appointee from previous firm.

No reply/documents are submitted by the firm in response to Final Reminder.

Decision of Central Licensing Board in 284th 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 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000425 by way of formulation of M/s Epoch Pharmaceutical, Plot No. 83-85, Sector 15, Korangi Industrial Area, Karachi may not be rejected by Central Licensing Board or their Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

Case No. 28 **CORRECTION IN SECTION NAME ON RENEWAL OF DRUG MANUFACTURING LICENCE NO. 000513 (FORMULATION) TO M/S ZAFA PHARMACEUTICAL LABORAOTIRES (PVT) LTD KARACHI.**

1	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**	1. Dr. AbullahDayo, Expert Member. 2. FID, DRAP, Karachi. 3. Mr. Krishan Das, AD, DRAP, Karachi.

Recommendation of panel :

Based on the above stated observations the panel unanimously recommends the grant 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)

Accordingly, the decision/DML was issued/renewed.

However, it is observed that the panel of experts was given mandate for inspection of following sections for renewal and regularization :

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 vial/ampoule SVP (Biotech)*
7.	Cream Ointment (General)	*8.*	*Ware House (General)*
9.	Sterile Dry Powder Injection (General)	*10.*	*Q C Laboratory*

However in the panel inspection report the panel recommended the grant of renewal of 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)***

And same was granted by the CLB and the DML was issued accordingly.

Decision of the Central Licensing Board in 284th meeting

The Board considered the case and decided to approved the correction in the licensed sections and sections title/name of the firm M/s Zafa Pharmaceutical Laboratories (Pvt) Ltd, Plot No. L-1B, Block 22, Federal B Industrial Area, Karachi under DML No. 000513 (Formulation) may be read as under:

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)*

QUALITY ASSURANCE (QA) CASES

Item No. I.: M/s PCP Laboratories, 98-KM, Multan Road Akhtarabad, Okara (DML No. 000814) [Personal Hearing].

The firm M/s. PCP Laboratories, 98-KM, Multan Road, Akhtarabad, Okara was inspected by Dr. Syed Zia Husnain FID DRAP Lahore on 03.11.2020 to check the cGMP compliance.

2. The observations reported by the FID conclusion of report are given below;

Workers & Executive Entrance:-

i. The hand sanitizer needs to be provided overall cleanliness required improvements.

Raw Material Store & Packing Material Store:-

i. Lightening was not proper and needs improvement.
ii. Storage conditions need to be improved and in this regard qualified pharmacist exclusively for store needs to be appointed to consistently monitor the storage conditions properly.
iii. Temperature and humidity control measures needs to be taken.
iv. Temperature control is not in operation which is required to maintain the product up to the mark.

Finished Goods Store:-

i. Lighting is insufficient.
ii. Safety helmets needs to be provided.

Production Area:-

(A) Oral Dry Powder Suspension Section (Cephalosporin):-

i. Area was not well maintained.
ii. HVAC installed but was not operational.
iii. Cleanliness required to be improved.
iv. Lightening is also not up to the mark therefore immediate steps required to be taken for improvements in lightening.
v. Section needs revamping regarding paints.
vi. Measures required to be taken to avoid mix-ups.

(B) Capsule Section (Cephalosporin):-

i. Tool boxes and old manufactured finished goods and different cartons were placed in blister packing area.
ii. HVAC installed but was not operational.
iii. Cleanliness level needs improvements.
iv. Area was not properly maintained.
v. SOPs needs to be developed and implemented accordingly.
vi. Establish the IPQC with necessary equipment.

vii. HVAC system needs to be validated time to time.

(C) Dry Powder Injection (Cephalosporin):-

i. Area was not well maintained.
ii. Cartons and wastes were placed in buffer areas as well as production areas.
iii. GMP compliance was very poor.
iv. Partly production was going on and one batch was under optical checking however there was no concept of batch identification and proper technical supervision.
v. Cleanliness level was very poor.

Validation and Calibration:-

i. No equipment was calibrated.
ii. Process validations were also not being done.
iii. Timely calibrate the equipment / machinery as per scheduled time.

Quality Control Department:-

i. SOPs were not in place.
ii. Number of technical staff required to be increased.
iii. Stability chamber was not operational.
iv. Microbiology laboratory was also non-operational completely.
v. All equipment needed calibrations.
vi. Lighting needs improvements.

Quality Assurance:-

i. Lot of improvements required regarding Quality Assurance.
ii. More technical staff required to be appointed immediately.
iii. Quality Assurance is continuous process therefore; keep on upgrading the working environment.
iv. The cleanliness levels needs up-gradation.
v. Overall renovation and up-gradations required particularly in QC and Microbiology Laboratories.

Documentation:-

i. Documentation needs improvements.
ii. Missing SOPs needs to be developed.
iii. Renewal of the firm is due w.e.f. 23.06.2020 and firm informed that they had applied for the renewal which needs verification from record of DRAP.
iv. Immediately update DRAP, Islamabad about the change of management.
v. BMRs were not being managed properly.

Personnel Safety:-

i. Continuously focus on the equipments of fire-fighting.
ii. Take necessary certifications from various government departments regarding safety.

Internal Audit System:-

i. Develop the internal audit system and keep records.

Trainings:-

i. Conduct the time to time training programs and keep records.

Sanitation and Hygiene:-

i. Currently condition was not satisfactory.
ii. Needs to be focus the sanitation and hygiene.

Conclusion:-

*"**Overall GMP compliance was not satisfactory presently and in current circumstances production cannot be continued till the complete up-gradation and operational status of Quality Control and Microbiology Laboratory.** Firm informed that they are going to renovate and up-grade the premises and shall stop production for 15 days. Following advises were given to firm for the improvements in addition to advises given above in the report and already given in various inspections time to time.*

1) *It was advised to the firm to completely up-grade the production areas and QC as well as microbiology laboratory before resumption of production.*
2) *Up-date the DRAP, Islamabad about change of management and ownership of the firm.*
3) *Improve lightening in the factory and also arrange alternate power source.*
4) *Missing SOPs needs to be developed.*
5) *Quality Control equipment needs to be calibrated to make the laboratory operational prior to resumption of production.*
6) *Process validations needs to be done and keep the records.*
7) *Appoint additional technical staff in QA department.*
8) *Stability chamber needs to be used for product reviews and keep records.*
9) ***Microbiology laboratory required to be made functional prior to resumption of production.***
10) *Improve raw material store by providing different zone samplers, safety helmets.*
11) *Overall material management and storage required to be improved under the supervision of qualified pharmacist exclusively for stores.*
12) *Follow the import and export rules for purchase of raw materials.*
13) *Raw material required to be purchased from qualified vendor only as permitted by law.*
14) *Alternate power source required for maintenance of temperature.*
15) *Cleanliness level needs to be improved.*
16) *Safety measures required as mentioned in report above and in this regard necessary certifications from various government departments should be obtained.*
17) *Reference standards required to be arranged instead of only working standards.*
18) *IPQC needs to be developed in various sections.*

Management of the firm has shown positive response towards compliance of above advises within period of two weeks to further up-grade the plant. Firm was directed to submit CAPA document immediately. Re-inspection shall be conducted to verify the up-gradations done by the firm."

3. The post of the Director QA&LT was vacant so the matter was pended and FID was asked to perform Risk based sampling of the batches which have been manufactured since the microbiology lab was non-operational and also order not to dispose of suspected stock till the report of CDL, Karachi is received.

4. Dr. Syed Zia Husnain, FID, DRAP, Lahore re-inspected the firm M/s. PCP Laboratories, 98-KM, Multan Road, Akhtarabad, Okara on 29.09.2021 and reported that none of the previously

identified deficiencies from inspection dated 03.11.2020 have been rectified. The FID has concluded as under;

> *"Unit was not operational at the time of inspection. Management present at the time of inspection informed that ownership of the unit is being changed, hence unit was not operational since long. Firm has not complied the advises and observations given during last inspection. Presently the unit was not fit for any kind of production, therefore to safe guard the public health; firm was advised to keep the production stopped till the complete up-gradation, re-vamping and compliance of DRAP, Islamabad and area FID. Firm was also advised to complete their application for renewal of Drug Manufacturing License No. 000814 as directed by Licensing Directorate of DRAP, Islamabad time to time."*

5. Keeping in view the observations noticed and conclusion by the FID in two reports dated 3.11.2020 & 29.09.2021, **Show Cause Notice and order of Suspension of Production activities in all sections** was issued to the firm M/s. PCP Laboratories, 98-KM, Multan Road, Akhtarabad, Okara vide letter No. 4-133/2015-QA dated 01.11.2021.

6. The firm vide letter Ref. No. PCP/DML.R/QA dated 09.11.2021 has informed that they will rectify all observations by December 2021. The firm has requested to merge the CAPA verification inspection with DML renewal inspection.

The matter is placed before the board and representatives of the board are called upon to appear before the board for personal hearing.

Decision of the Central Licensing Board in 284th meeting

Mr. Naseem Khan and Mujahid Munir appeared before the Board. They contended that thy would be ready for inspection by the end of January, 2022.

It was apprised that Drug Manufacturing Licence of the firm is suspended from Licensing Division therefore after ceasing of suspension apanel would be constituted keeping view request of the firm.

Item No. II.: M/s Alen Pharmaceutical (Pvt.) Ltd. Plot No. 138-A, Nowshera Industrial Estate Risalpur, KP. (DML No. 000435) [Illegal manufacturing].

Mr. Zia Ullah FID-III DRAP Peshawar inspected the firm M/s. Alen Pharmaceuticals (Pvt) Ltd., 138, Nowshera Industrial Estate, Risalpur (DML No. 000435) on 23.12.2019 to check the GMP compliance.

2. The FID reported following observations;

Change Rooms:-

i. Replace air curtains at entrances of the change rooms as the existing air curtains are inefficient.
ii. Make arrangement for placements of overhauls, shoes etc in the executive change rooms.
iii. Provide almirahs / cupboards for placement of uniforms / clothes and stainless steel racks for shoes. Cleaning of the change rooms should be monitored and its record should be maintained properly.

iv. Blind the glass partitions and to properly seal the gaps towards the upper part of these partitions to ensure complete segregation.
v. Apart from this the other small gaps present in these partitions also need to be sealed completely.
vi. Provide a separate liquid materials store for such materials.
vii. Arrange and install a suitable dispensing booth at the earliest and to provide HVAC system with HEPA filters in the dispensing room as required for the dispensing operations.
viii. Facilities for keeping the relevant record of the raw materials store such as stocks ledgers, bin cards, sampling request slips, manufacturing orders forms etc. should also be provided.

Tablet Section (General):-

i. Arrange a separate double cone mixer for the tablet section and install in the designated room as per approved layout plan.
ii. For the drying purpose, there is an old tray dryer provided, which lacks appropriate facilities of uniform drying. It is recommended to replace tray dryer with a more efficient and GMP compliant dryer.
iii. Installed HVAC system in the section; however the wet mixing and drying room lack the HVAC system. The firm directed to install HVAC system in these rooms.

Blistering / Packing Hall:-

i. Segregate the blistering area and the blister machine by installing a partition, so that the blistering and packing operations can be performed in separate areas.

Cephalosporin Sections:-

i. Provide a laminar flow dispensing booth as well.

Quality Control:-

i. Arrange another stability chamber for the real time and accelerated stability studies with data loggers and backup power supply.
ii. Stability studies protocols need to be developed and followed.
iii. Purchase recent editions of official books and official testing methods should be adopted for the products manufactured by the firm.

HVAC System:-

i. HVAC system for tablet section needs to be properly validated for its various parameters.
ii. The HVAC system in this section lacks the bag filters.
iii. Pressure monitoring gauges were also not functioning, which need to be refilled.

Premises / Building:-

i. Seepage was observed in multiple areas, which need urgent treatment.
ii. The walls in certain areas also need to be painted afresh as it appeared that the building has not been given due attention over the course of time.

Personnel:-

i. Appoint quality assurance personnel.

Conclusion:-

"As per preceding observations made during inspection including but not limited to absence of HVAC system in tablet wet mixing and drying areas, a suitable GMP compliant dryer in tablet section, lack of dry mixing facility in tablet section, a properly and completely functioning validated HVAC system in the tablet section, the firm is directed to immediately stop the production activities in tablet section and rectify all the shortcomings at the earliest."

3. Keeping in view the observations and conclusion by the FID, the firm was directed to **Suspend Production Activities in Tablet Section** vide this office letter No. 4-22/2002-QA dated 15.01.2020.

4. M/s. Alen Pharmaceutical (Pvt) Ltd, Plot No. 138-A, Nowshera Industrial Estate, Risalpur, KPK-Pakistan vide letter Ref. No: - DRAP/QA-001 dated 15.03.2021 submitted plan for rectification of the observations which were observed in GMP inspection of their firm conducted on 23.12.2019 by Mr. Zia Ullah, FID, DRAP, Peshawar.

5. While response of the firm was being processed, an inspection, report of the same firm was received from Mr. Faisal Shahzad, FID-I, DRAP, Peshawar dated 19.04.2021. The report is reproduced below;

"The firm M/s Alen Pharmaceuticals (Pvt.) Ltd. 138, Nowshera Industrial Estate, Risalpur was visited to observe compliance DRAP letter No. F. 4-22/2002-QA dated 15.01.2020 wherein production activities in Tablet Section were suspended. During the visit, no production activities of tablet section were observed, however, the following product was recovered from the tablet section;

1- Dolint 7.5mg tablet, Mfg. date 01/2021, Exp. Date 12/2023, 62 packs Reg. No. (031016) claimed to be manufactured by the firm M/s. Alen Pharmaceuticals (Pvt) Ltd., Risalpur.

Accordingly, the product was seized on Form-2. Case will be processed as per the DRAP Act, 2012 / Drug Act, 1976."

5. The firm was issued show cause notice vide No. 4-22/2002-QA dated 07.05.2021 on illegal/unauthorized manufacturing, to which the firm submitted following reply vide letter No. No. 02/QAI/QC/02 dated 28.05.2021;

"Referring to your letter (Show Cause Notice-Copy Attached) No. F.4-22/2002-QA dated 07th May, 2021 and received on 24th May 2021, it is to inform you that our tablet section has been closed by area FID on 23rd December 2019 on behalf of some shortcomings.
Sir, it took reasonably long time to complete these shortcomings and the reasons of this delay was nothing but Covid 19. Meanwhile due to non-production activity because of tablet section closing and Covid 19, the firm becomes unable to pay the pending salaries of the staff. Remember that during this critical time, we have not fired even a single worker of the firm.
It was the beginning of the Holy Ramadan and Eid ul Fitr was ahead. Keeping all these factors in mind, we decided to manufacture a batch of tablet (it should be noted that our 92% production belongs to tablet section only) and to relieve the workers on this special occasion of Holy Ramadan and Eid ul Fitr.
We decide it purely on the intension and humanity basis and the aim was clear…..to facilitate the worker financially ahead of Eid ul Fitr.
Sir, we know that we have contravened the law but we have done it with good intensions and that it is to relieve the staff. We hope that you will spare our mistake and will consider our THIS application sympathetically."

6. The Additional Director/FID DRAP Peshawar was requested vide letter No. 4-22/2002-QA dated 28.09.2021 to investigate the matter of unauthorized manufacturing of Dolint 7.5mg Tablet and provide names of the responsible persons. Till date no response has been received from the field office in this regard.

7. The firm M/s Alen Pharmaceutical Pvt. Ltd Risalpur has submitted another letter dated 15.12.2021 wherein they have stated that their 92% percent production is mainly concerned to tablet section and they are facing loses. The firm has requested to constitute a panel to visit the firm and resume the tablet section.

The matter is placed before the board for deliberation, please..

Decision of the Central Licensing Board in 284th meeting

The Board considered the case and decided to advise the Federal Inspector of Drugs to complete the case within 15 days and submit for the consideration of the Board.

The meeting ended with the vote of thanks to and by the Chair.