**MINUTES OF 269th MEETING OF CENTRAL LICENSING BOARD HELD ON 26th FEBRUARY, 2019**

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269th meeting of the Central Licensing Board (CLB) was held on 26th Febbraury, 2019 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Ghulam Rasool Dutani, Director Drug Licensing, Drug Regulatory Authority of Pakistan, Islamabad.

Following members attended the meeting: -

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| **S. No.** | **Name & Designation** | **Status** |
|  | Dr. Ikram ul Haq, Expert inQC/QA of drugs. | Member |
|  | Prof .Dr. Jamshaid Ali Khan, Department of Pharmacy, University of Peshawar, Peshawar. | Member |
|  | Mr. Muhammad Israr, Law Expert, Mininstry of Law & Justice Division. | Member |
|  | Mr. Muhammad Shoaib Ansari, Chief Inspector of Drug, Department of Health, Government of Sindh, Karachi | Member |
|  | Mr. Munawar Hayat,  Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore | Member |
|  | Dr. Hafsa Karam EllahiRepresentative Director (QA/LT), DRAP, Islamabad | Member |
|  | Zakir Shah, Drug inspector, Department of Health, Govt of Khyber Pakhutonkhuwa. | Member |
|  | Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad. | Secretary/Member |
|  | Mr. Khalid Munir & Mr. Muhammad Nawaz, Representative of Representative of PPMA. | Observer |
|  | Mr.Nadeem Alamgir aand Rashid Mureed Representative of Pharma Bureau. | Observer |
|  | Mr. Kamran Anwar, Representative PCDA | Observer |

The meeting started with the recitation of verses from the Holy Qura’an. The Chairman Central Licensing Board welcomed the honorable members and participants of the meeting. He stated that all the legal and codal formalities would be taken into account for disposal of cases and respective Divisions shall be responsible for the contents, errors and omissions of agenda and minutes. Mr. Abdul Sattar Sohrani, Deputy Director (Quality Control), Mr. Zeeshan Nazir Deputy Director (Quality Assurance) Mr. Ayyaz Ahmad, Deputy Director (Lic), Dr. Muhammad Yaqoob AD (Lic.), Dr. Muhammad Usman, AD (Lic) and Dr. Zunaira Farayad, Assistant Director (Lic), DRAP Islamabad assisted the Secretary Central Licensing Board in presenting the agenda.

**Item-I CONFIRMATION OF THE MINUTES OF 268thMEETING**

 The Central Licensing Board (CLB) formally confirmed the minutes of its 268thmeeting of the Central Licensing Board (CLB) which was held on 10th January, 2019.

**A. DRUG LICENSING DIVISION**

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

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

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| **S #** | **Name of the firm** | **Date of Inspection / Type of License** | Ranking/ Evaluation | **Inspection Panel Members** |
| 1 | **M/s. Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, Western Industrial Zone, Port Qasim, Karachi****APIs**CEPHALOSPORIN (ORAL/STERILE)1. Cefixime (USP) (Oral)
2. Cephradine (USP) (Oral)
3. Cefadroxil (USP) (Oral)
4. Cefaclor (USP) (Oral)
5. Cefepime HCL (USP) (Sterile)
6. Cephalexin (USP) (Oral)
7. Ceftazidime (USP) (Oral)
8. Cefoperazone Sodium (USP) (Sterile)
9. Cefradine ‘L’Arginine (USP) (Sterile)
10. Cefotaxime Sodium (USP) (Sterile)
11. Ceftriaxone Sodium (USP) (Sterile)

GENERAL ITEMS1. Paracetamol (USP)
2. Paracetamol for Suspension (USP)
3. Ibuprofen (USP)
4. Sulfamethoxazole (Ph Eur)
5. Trimethoprim (USP)
6. Azithromycin (USP)
7. Clarithomycin (USP)
8. Ciproloxacin Hydrochloride (USP)
9. Ciprofloxacin Base (USP)
10. Levofloxacin (USP)
11. Doxycycline (Powder) (USP)
12. Montelukast Sodium (USP)
13. Artemether (BP)
14. Moxifloxacin Hydrochloride (USP)
15. Tylosin Taartarate for Suspension (USP)
16. Erthromycin (USP)

STERIODES1. Betamethasone (USP)
2. Dexamethasone (USP)

VITAMINS1. Mecobalamin (JP)
2. Cyanocoblamin (USP)
 | **04-02-2019** | **Good** | 1. Syed Mueid Ahmed, Member CLB, Sindh Karachi.
2. Director, CDL, Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.
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| **Observations, Conclusion and Recommendations of the panel: -***“****A. Observations:***The firm has five sections for manufacturing of APIs, **1) Cephalosporin (Oral)** including APIs Cefixime (USP) oral, Cephedrine (USP) oral, Cefadroxil (USP) oral, Cefaclor (USP) oral Cephlexin (USP) oral, Ceftazidime (USP) oral: **2). Cephalosporin (Sterile)** including APIs Cefoperzone Sodium (USP) sterile, Cefradine ‘L’ Arginine (USP) sterile, Cefotaxime Sodium (USP) sterile, Ceftriaxone Sodim (USP) sterile, Cefepime HCl (USP) sterile. **3). General Section** including Paracetamol (USP), Paracetamol for Suspension (USP), Ibuprofen (USP), Azithromycin (USP), Clarithromycin (USP), Ciprofloxacin Hydrochloride (USP), Ciprofloxacin Base (USP), Levofloxacin (USP), Doxycyline (powder) (USP), Montelukast Sodium (USP), Artemether (USP), Moxifloxacin Hydrochloride (USP), Tylosin tartarate for suspension(USP), Erythromycin (USP) Sulfamethoxazole (USP), Trimethoprim (USP). **4) Steroidal Section / Facility** Including APIs Betamethasone (USP), Dexamethasone (USP). **5) Vitamin section/ Facility** including APIs Mecobalamin (JP), Cyanocobalamin (USP), Necessary facilities for production and quality control are available to manufacturer the above listed APIs. Technical staffs with necessary training skills are competency is also available with the firm. Proper HVAC system and other related utilities are available in qualifies conditions in all sections. Photocopies of Mr. Naseer Ahmed Siddiqui (Production Incharge) and Mr. Ali Akbar (Quality Control Incharge) are annex herewith along with other required lists for consideration please.***B. Conclusions:****Firm has all necessary facilities for manufacturing and quality control of above listed APIs.* ***C. Recommendations:******The panel recommends the grant of Drug Manufacturing License (by way of semi basic)* ”****Decision of the Central Licensing Board in 269th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of Semi Basic manufacture in the name of M/s. Carryfor Pharmaceutical (Pvt) Ltd, Plot No. E-81, Western Industrial Zone, Port Qasim, Karachi with below mentioneed APIs. The Board also authorized the Chairman of the Board to approve necessary corrections in the names of APIs where required as per salt available in official compoedeia.**1) Cephalosporin (Oral)** including APIs Cefixime (USP) oral, Cephedrine (USP) oral, Cefadroxil (USP) oral, Cefaclor (USP) oral Cephlexin (USP) oral, Ceftazidime (USP) oral: **2). Cephalosporin (Sterile)** including APIs Cefoperzone Sodium (USP) sterile, Cefradine ‘L’ Arginine (USP) sterile, Cefotaxime Sodium (USP) sterile, Ceftriaxone Sodim (USP) sterile, Cefepime HCl (USP) sterile. **3). General Section** including Paracetamol (USP), Paracetamol for Suspension (USP), Ibuprofen (USP), Azithromycin (USP), Clarithromycin (USP), Ciprofloxacin Hydrochloride (USP), Ciprofloxacin Base (USP), Levofloxacin (USP), Doxycyline (powder) (USP), Montelukast Sodium (USP), Artemether (BP), Moxifloxacin Hydrochloride (USP), Tylosin tartarate for suspension(USP), Erythromycin (USP) Sulfamethoxazole (PhEur), Trimethoprim (USP). **4) Steroidal Section / Facility** Including APIs Betamethasone (USP), Dexamethasone (USP).  **5) Vitamin section/ Facility** including APIs Mecobalamin (JP), Cyanocobalamin (USP) |

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| 2. | M/s Greater Pharma, Plot No. 35, Street No. SS-3, NIZ, Rawat, Islaamabad |  | **Good** | 1. Prof. Dr. Gul Majeed Khan, Deptt., of Pharmacy, Quaid-e-Azam University, Islamabad.
2. Dr. Hafsa Karam Elahi, Additional Director (QA&LT), DRAP, Islamabad.
3. Mr. Hasan Afzaal, FID-III, DRAP, Islamabad.
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| **Recommendations of the Panel**“Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously agree that the firm fulfills the basic requisite for operating as a Pharmaceutical Manufacturing and Testing Facility, and therefore the panel **recommends** the grant of DML for M/s Greater Pharmaceutical, Rawat, Islamabad for the following section;1. Cream / Ointment Section (General).
2. Topical Lotion Section (General).
3. Capsule Section (General).
4. Cream / Ointment Section (Steroid).
5. Topical Lotion Section (Steroid).

**Decision of the Central Licensing Board in 269th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Greater Pharma, Plot No. 35, Street No. SS-3, NIZ, Rawat, Islamabad with following sections:**Section (05)**1. Cream / Ointment Section (General).
2. Topical Lotion Section (General).
3. Capsule Section (General).
4. Cream / Ointment Section (Steroid).
5. Topical Lotion Section (Steroid).
 |
| 3. | M/s Cure Laboratories (Pvt) Ltd., Plot No. 11 & 12, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi | 19-02-2019&22-02-2019 | **Good** | 1. Prof. Dr. Muhammad Usman, Member, CLB.
2. Additional Director (Lic/Secretary) CLB. Mr. Khalid Mahmood, FID-II, DRAP, Islamabad.
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| **Recommendations of the Panel**“Keeping In view the above facts the panel unanimously **recommended**M/s Cure Laboratories (Pvt) Ltd., Plot No. 11 & 12, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi for the grant of Drug Manufacturing License by way of formulation for sections namely Dry Powder Vial (Sterile) section (Cephalosporin), Dry Powder Suspension section (Cephalosporin) and Capsule section (Cephalosporin) .**Decision of the Central Licensing Board in 269th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Cure Laboratories (Pvt) Ltd., Plot No. 11 & 12, Street No. NS-2, National Industrial Zone, Rawat, Rawalpindi with following sections:**Section (03)**1. Dry Powder Vial (Sterile) (Cephalosporin) section,
2. Dry Powder Suspension (Cephalosporin) section
3. Capsule section (Cephalosporin)
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| 4. | M/s Novex Pharma, Plot No. 54, Street No. S-6, National Industrial Zone, RCCI, Rawat | 12-02-2019 &21-02-2019 | **Good** | 1. Prof. Dr. Muhammad Usman, Member, CLB.
2. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Hasan Afzaal, FID-III, DRAP, Islamabad.
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| **Recommendations of the Panel**“Keeping in view the above facts, detailed visit of facility as of today and review of documents the panel l unanimously **recommends**M/s Novex Pharma, Plot No. 54, Street No. S-6, National Industrial Zone, RCCI, Rawatfor the grant of Drug Manufacturing License (Formulation) for the following sections namely;1. Sterile SVP Liquid Infusion Vial (General).
2. Sterile Liquid Ampoule (General).
3. Sterile Liquid Ampoule (Steroid).
4. Sterile Eye / Ear / Nasal / Preparations (Steroid).

**Decision of the Central Licensing Board in 269th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Novex Pharma, Plot No. 54, Street No. S-6, National Industrial Zone, RCCI, Rawat with following sections:**Section (04)**1. Sterile SVP Liquid Infusion Vial (General).
2. Sterile Liquid Ampoule (General).
3. Sterile Liquid Ampoule (Steroid).
4. Sterile Eye / Ear / Nasal / Preparations (Steroid).
 |
| 5. | M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, RCCI Industrial Estate, Rawat, Rawalpindi | 19-02-2019  | **Good** | 1. Prof. Dr. Muhammad Usman, Member, CLB.
2. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Hasan Afzaal, FID-III, DRAP, Islamabad.
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| **Recommendations of the Panel**“Keeping in view the above facts, detailed visit of facility as of today and review of documents the panel unanimously **Recommends**M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, RCCI Industrial Estate, Rawat, Rawalpindi for the grant of Drug Manufacturing License (Formulation) for the following sections namely;1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment / Gel Section (General).
4. Oral Liquid Syrup / suspension Section (General).
5. Dry Suspension Section (General).
6. Sterile Ampoule (General).
7. Sterile Ampoule (Psychotropic).
8. Tablet Section (Psychotropic).
9. Sterile Ampoule (Steroid).
10. Sterile Infusion/ Small Volume Vial (General).
11. Dry Powder for Injection (Ceph).
12. Capsule (Ceph).
13. Dry Powder for Suspension (Ceph).

**Decision of the Central Licensing Board in 269th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Iqra Pharmaceuticals, Plot No. 2, Street No. S-9, RCCI Industrial Estate, Rawat, Rawalpindi with following sections:**Section (13)**1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment / Gel Section (General).
4. Oral Liquid Syrup / suspension Section (General).
5. Dry Suspension Section (General).
6. Sterile Ampoule (General).
7. Sterile Ampoule (Psychotropic).
8. Tablet Section (Psychotropic).
9. Sterile Ampoule (Steroid).
10. Sterile Infusion/ Small Volume Vial (General).
11. Dry Powder for Injection (Ceph).
12. Capsule (Ceph).
13. Dry Powder for Suspension (Ceph).
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| 6 | M/s Athan Pharmaceuticals, Plot No.84/1, Block-B, Phase-V, Industrial Estate, Hattar.**Sections 08**1. Opthalmic (General) Drop Section.
2. Capsule (General) Section
3. Tablet (General) Section
4. Oral Powder Suspension (General) Section.
5. Cream/Ointment (General) Section
6. Sachet (General) Section
7. Liquid Ampoule (General) Section
8. Dry Powder Vial (General) Section
 | **20-02-2019** | **Good** | 1. Dr. Jamshed, Member, CLB.
2. Additional Director (E&M), DRAP, Peshawar.
3. Area FID, DRAP, Peshawar.
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| **Recommendations of the panel: -**As per facilities of production, quality control and environment control provided, the observations made during inspection, the qualified staff employed abnd evaluation made of the various sections of production and quality control, the panel unanimously recommends the grant of Drug Manufactruing License (DML) by way of formulation to M/s Athan Pharmaceuticals, Plot No.84/1, Block-B, Phase-V, Industrial Estate, Hattar, for the above mentioned sections alongwith QC Lab and Warehouses.**Decision of the Central Licensing Board in 269th meeting**The Board considered and approved the grant of Drug Manufacturing License by way of formulation in the name of M/s Athan Pharmaceuticals, Plot No.84/1, Block-B, Phase-V, Industrial Estate, Hattar with following sections:**Section (08)**1. Opthalmic (General) Drop Section.
2. Capsule (General) Section
3. Tablet (General) Section
4. Oral Powder Suspension (General) Section.
5. Cream/Ointment (General) Section
6. Sachet (General) Section
7. Liquid Ampoule (General) Section
8. Dry Powder Vial (General) Section
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**Item-III**: **GRANT OF ADDITIONAL SECTIONS/EXPANSION/AMENDMENTS ETC.**

Following cases have been forwarded by the respective panel of experts for grant of additional sections. The same are placed before the Board for its consideration and decision.

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| **S #** | **Name of the firm** | **Date of Inspection**  | Ranking/ Evaluation | **Inspection Panel Members** |
| 1. | M/s Zenith Chemical Industries (Pvt) Ltd, Mouza Donday, Jia Baga, Raiwind Road, LahoreDML No. 000733(Semi-Basic Manufacture)**Name of API (01)**1. Sitagliptin Phosphate Monohydrate BP
 | **06-12-2018** | **Good** | 1. Prof. Dr. Mehmood Ahmed, Ex. Dean, University of Bahawalpur.
2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000733 issued in favour of M/s Zenith Chemical Industries (Pvt) Ltd, Mouza Donday, Jia Baga, Raiwind Road, Lahore and grant of additional bulk API as mentioned above.**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of following one additional API in the name ofM/s Zenith Chemical Industries (Pvt) Ltd, Mouza Donday, Jia Baga, Raiwind Road, Lahore.**Name of API (01)**1. Sitagliptin Phosphate Monohydrate BP
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| 2. | M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km, Main Ferozepur Road, Lahore.DML No. 000395(Formulation)**Name of Section (01)**Dry Powder Vial Injection (Cephalosporin) | **31-12-2018** | **Good** | 1. Dr. Zaka-ur-Rehman, Secretary, Pharmacy Council, Punjab.
2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore.
3. Mr. Shoaib Ahmed, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**Keeping in the view the facilities like building, HVAC system, installed production machinery in the respective sections & availability of Quality Control equipment, instruments, Technical & experienced personnel, having adequate documentation regarding production, Quality Control microbiology lab and Technical water production and testing facilities the panel of inspectors is recommends to grant permission for production to M/s Don Valley Pharmaceuticals (Pvt) Ltd, License No. 000395 for the additional section of Injection (Cephalosporin).**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of following one additional section in the name of M/s Don Valley Pharmaceuticals (Pvt) Ltd, 31-Km, Main Ferozepur Road, Lahore.**Section (01)**1. Dry PowderVial Injection (Cephalosporin)
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| 3. | M/s Reckitt Benckiser Pakistan Limited, Plot No. F-18, Sindh Industrial Trading Estate, KarachiDML No. 000022 (Formulation)**Facilities (02)**1.Dispensing booth /Area (Amendments)2. Quality Control Laboratory (Amendments) | **08-11-2018** | **Good** | 1. Mr. Mueid Ahmed Member Central Licensing Board.
2. Additional Director (E&M) DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.
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| **Recommendations of the panel: -***“*Finally, based on the people met, areas visited and commitment of the management for authentication of documentation (of change control) on completion of project and continuous improvements, the panel is of the view to recommend the Grant of Additional Section namely Quality Control Laboratory and Sampling booth as per DRAP, Islamabad letter of even no. dated 1st June, 2017 to the firm M/s. Reckitt Benckiser (Pvt) Ltd,. Plot No. F-18, S.I.T.E, Karachi.**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of following faacilities in the name of M/s Reckitt Benckiser Pakistan Limited, Plot No. F-18, Sindh Industrial Trading Estate, Karachi.**Facilities (02)**1.Dispensing booth /Area (Amendments)2. Quality Control Laboratory (Amendments) |

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| 4. | M/s A&K Pharmaceuticals, 94-A, Small Industrial Estate, Sargodha Road, Faisalabad.DML No. 000534(Formulation) **Section (02)**1. Bolus Section (Gen) (Vet)
2. Oral Dry Powder (Penicillin) (Vet)
 | **9-11-2018** | **Good** | 1. Mr. Muhammad Munnawar Hayat, Chief Drugs Controller, Punjab.
2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**i. The Panel of Inspector Recommends the renewal of DML bearing No. 000534 and grant of Bolus section in favour of M/s A&K Pharmaceutical, 94-A, Small Industrial Estate, Sargodha Road, Faisalabad. ii. The Panel of inspector Does not Recommend the grant of Oral dry Powder (Penicillin) Section at present.**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of following one additional section in the name of M/s A&K Pharmaceuticals, 94-A, Small Industrial Estate, Sargodha Road, Faisalabad.**Section (01)**1. Bolus Section.

The Board did not approved grant of Oral dry Powder (Penicillin) |
| 5. | M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad.DML No. 000628 (Formulation)**Section / Facility:**1. Sachet Section (General) New.
2. Cephalosporin section Extension (First Floor).
3. Changes in ground floor and first floor layout plan.
 | 15-01-2019&17-01-2019 | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
2. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Babar Khan, Area FID, DRAP, Islamabad.
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| **Recommendations of the Panel**“Keeping In view of the above facts on record, the panel unanimously **recommended;**1. Renewal of Drug Manufacturing License by way of formulation (000628) to M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad.
2. Grant of additional section and regularization of facilities as follows;
3. Sachet Section (General) New, and
4. Cephalosporin section Extension (First Floor).
5. Changes in ground floor and first floor layout plan.

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of additional section and regularization of facilities in the name of M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad.**Section and facilities (03)**1. Sachet Section (General) New, and
2. Cephalosporin section Extension (First Floor).
3. Changes in ground floor and first floor layout plan.
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| 6. | M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera.DML No. 000038 (Formulation)**Section (01)**1. Tablet Section (Psychotropic) - **New**
2. Dispensing Area - **Amended**
 | **25-01-2019** | **Very Good** | 1. Dr. Jamshed Ali Khan, Member CLB.
2. Additional Director (E&M), DRAP, Peshawar.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
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| **Recommendations of the Panel:-**The firm has developed a dedicatede tabet psychotropic section and have amended their dispensing area as per approved layout plan. The dispensing area has been provided with the requisite facilities and designed as per GMP requirements. The tablet psychotropic section has been provided with the required machines and equipments in separate rooms. HVAC supply has been provided. Vinyl flooring has been done in the area. As per facilities of manufacturing, quality control and environment control provided, the qualified staff employed and keeping in view the adherence of the firm to cGMP, GSP and GLP, the constituted panel unanimously recommends the grant of following additional/amended sections vide DML No.000038 (Formulation) to M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera.1. Tablet Psychotropic Section (New)
2. Dispensing Area (Amended)

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of additional section and regularization of facilities in the name of M/s. Ferozsons Laboratories Ltd., Amangarh, Nowshera.**Section and facilities (02)**1. Tablet Psychotropic Section (New)
2. Dispensing Area (Amended)
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| 7. | M/s. Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar..DML No. 000565 (Formulation)**Section (01)**1. Dry Powder Vial Injection (Cephalosporin) –**Amended**
 | **21-02-2019** | **Good** | 1. Dr. Jamshed Ali Khan, Member CLB.
2. Chief Drugs Inspector, Khyber Pakhtukhwa.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
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| **Recommendations of the Panel:-**As per facilities checked and technical people met the panel of experts unanimously recommends grant of the following additional sectons to M/s Aries Pharmaceuticals (Pvt) Ltd., 1-W, Hayatabad Industrial Estate, Peshawar (DML No.000565);1. Dry Powder Vial Injectable (Cephalosporin)

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of additional section in the name of M/s. Aries Pharmaceuticals (Pvt) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar.**Section and facilities (01)**1. Dry Powder Vial Injectable (Cephalosporin)
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| 8. | M/s Regal Pharmaceuticals, Plot No. 2-A, Street No. S-5, National Industrial Zone, RCCI, RawatDML No. 000839 (Formulation) | 22-01-2019&12-02-2019 | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
2. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Hasan Afzaal, Area FID-III, DRAP, Islamabad.
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| “Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **Recommended**M/s Regal Pharmaceuticals, Plot No. 2-A, Street No. S-5, National Industrial Zone, RCCI, Rawat DML No. 000839 (Formulation) for the following additional sections as under;1. Capsule Section (Ceph).
2. Dry Suspension Section (Ceph).
3. Dry Powder Vial Injection (Ceph).

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of additional sectionsin the name of M/s Regal Pharmaceuticals, Plot No. 2-A, Street No. S-5, National Industrial Zone, RCCI, Rawat.**Section and facilities (03)**1. Capsule Section (Ceph).
2. Dry Suspension Section (Ceph).
3. Dry Powder Vial Injection (Ceph).
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| 9. | M/s **Geofman Pharmaceuticals, Plot No. 20, Sector 23, Korangi Industrial Area, Karachi**DML No. 000090 (Formulation)**Facility (01)**1. **Ampoule compact Line Section** | 08-11-2018 | Good | 1. Mr. Mueid Ahmed Member Central Licensing Board.
2. Additional Director (E&M) DRAP, Karachi
3. Area Federal Inspector of Drugs, DRAP, Karachi.
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| **Recommendations of the panel: -***“*M/s Geofman Pharmaceuticals is a multiproduct facility and is an old pharmaceutical manufacturing facility that has been inspected on regular basis from time to time. The firm was inspected to verify the existence of the manufacturing sections as per layout plan:Regarding the grant of additional section i-e Ampoule compact Line Section, M/s Geofman Pharmaceuticals has submitted a letter, wherein the management of the firm has requested to postpone the inspection for a period of one month as they are in process of qualification of the equipment.**Decision by the Central Licensing Board in 269th meeting**The Board considered and **did not approve** the grant of additional section / facility in the name of M/s **Geofman Pharmaceuticals, Plot No. 20, Sector 23, Korangi Industrial Area, Karachi****Facility (01)**1. **Ampoule compact Line Section** |

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| 10 | M/s Hiranis Pharmaceuticals (Pvt) Ltd,. Plot No. E-145to E-149, North Western Industrial Zone, Port Qasim, Karachi DML No. 000785 (Formulation)**Section (01)**Tablet (Psychotropic) Section - **New** | 13-02-2019 | Good | 1. Dr. Ghulam Sarwar, Member DRB.
2. Additional Director (E&M) DRAP, Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -*****Following are the Observation:;****The firm was granted drug manufacturing license during the year 2014. The firm is a multi-product manufacturing facility comparing 14 different sections (09sections for General products, 04 sections for steroids and one section for Psychotropic tablet manufacturing), that were observed well maintained.**Firm is observed as per layout plan approved by the DRAP authorities. Relevant equipment and machinery required for the production and quality control of the registered products was observed well maintained and in place. HVAC system was seen installed in all the sections and observed operational.**Technical personnel with adequate qualification and experience was also seen involved in the productions and quality control activates.* *Keeping in view the peoples met, documents reviewed and considering the findings made during the inspections of the facility, panel recommends the grant of renewal of DML (by way of formulation) for the sections mentioned below:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** |  **Name of Sections**  | **Sr. No** |  **Name of Sections**  |
|  | Tablet (General)  |  | Capsule (General) |
|  | Sachet (General) |  | Liquid Syrup (General)  |
|  | Mouth Wash (General) |  | Cream /Ointment/ Gel (General)  |
|  | Liquid Sachet (General)  |  | Dry Powder Suspension (General)  |
|  | Tooth Paste medicated  |  | Liquid (Steroids)  |
|  | Cream Ointment/Gel (Steroid)  |  | Tablet Steroid  |
|  | Capsule (Steroid) | \*\*\*\*\*\*\*\* |

***The panel also recommend for grant of additional section i.e., “Psychotropic table section*****Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of additional section / facility in the name of M/s Hiranis Pharmaceuticals (Pvt) Ltd,. Plot No. E-145to E-149, North Western Industrial Zone, Port Qasim, Karachi **Section (01)**1. **Tablet Section (Psychotropic)**
 |
| 11. | M/s Medimarker’s Laboratories (Pvt) Ltd, Plot No.A-104, S.I.T.E, Hyderabad.DML No. 000615 (Formulation)**Section 02** 1. Capsule (cephalosporin)
2. Liquid Ampoule injection (General)
 | **16-10-2018** | **Good** | 1. Dr. Abdullah Dayo, Member CLB
2. Mr. Najam-us-Saqib Additonal Director (E&M) DRAP, Karachi.
3. Mr. Sajjad Abbasi Area Federal Inspector of Drugs, DRAP, Karachi.
4. Ms. Umme-Laila Assistant Director, DRAP, Karachi.
 |
| **Recommendations of the panel: -**The panel reviewed their overall documentation, inspected manufacturing facilities, Quality control laboratory, stores and utilities and met their technical person and higher management. The panel observed that M/s Medimarker Laboratories is constructed as per DRAP approved layout plan. Good level of sanitation, cleanliness and work hygiene was noted. The firm has adequate number of processing and testing equipment in respective departments. Based on the stated observations. The panel further recommends the regularization of the existing layout plan**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the grant of additional sections in the name of M/s Medimarker’s Laboratories (Pvt) Ltd, Plot No.A-104, S.I.T.E, Hyderabad. However, regularization has already been approved in 266th meeting of Central Licensing Board held on 24th October, 2018**Section 02** 1. Capsule (cephalosporin)
2. Liquid Ampoule injection (General)
 |

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

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

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| --- | --- | --- | --- | --- |
| **S #** | **Name of the firm** | **Date of Inspection** | **Ranking/ Evaluation** | **Inspection Panel Members** |
| 1. | M/s Zenith Chemical Industries (Pvt) Ltd, Mouza Donday, Jia Baga, Raiwind Road, LahoreDML No. 000733 (Semi-Basic Manufacture)**Period**: Commencing on15-06-2016 and ending on 14-06-2021 | **06-12-2018** | **Good** | 1. Prof. Dr. Mehmood Ahmed, Ex. Dean, University of Bahawalpur.
2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**The Panel of Inspectors **Recommends** the renewal of DML bearing No. 000733 issued in favour of M/s Zenith Chemical Industries (Pvt) Ltd, Mouza Donday, Jia Baga, Raiwind Road, Lahore. **Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000733 (Semi-Basic Manufacture) in the name of M/s Zenith Chemical Industries (Pvt) Ltd, Mouza Donday, Jia Baga, Raiwind Road, Lahore ,on the recommendations of the panel of experts for the further period of five years commencing on 15-06-2016 and ending on 14-06-2021. |
| 2. | M/s A&K Pharmaceuticals, 94-A, Small Industrial Estate, Sargodha Road, Faisalabad.DML No. 000534(Formulation)**Period**: Commencing on 12-03-2014and ending on 11-03-2019 | **9-11-2018** | **Good** | 1. Mr. Muhammad Munnawar Hayat, Chief Drugs Controller, Punjab.
2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -** The Panel of Inspector recommends the renewal of DML bearing No. 000534 in favour of M/s A&K Pharmaceutical, 94-A, Small Industrial Estate, Sargodha Road, Faisalabad. **Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000534 (Formulation) in the name of M/s A&K Pharmaceuticals, 94-A, Small Industrial Estate, Sargodha Road, Faisalabad,on the recommendations of the panel of experts for the further period of five years commencing on 12-03-2014 and ending on 11-03-2019. |
| 3. | M/s Aptcure (Pvt) Ltd, 8-Pharma City, 30-Km, Multan Road, LahoreDML No. 000648(Formulation)**Period**: Commencing on 24-10-2018 and ending on 23-10-2023 | **13-12-2018** | **Good** | 1. Dr. Mehmood Ahmed, Ex. Dean Pharmacy, University of Bahawalpur.
2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore.
3. Ms. Uzma Barkat,Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**In the light of the inspection conducted by the panel and based on the findings, the panel of inspectors recommends to grant of renewal of Drug Manufacturing License by way of formation of M/sAptcure (Pvt) Ltd, 30-Km, Multan Road, Lahore for following sections.* 1. Tablet (General) Section.
	2. Capsule (General) Section.

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000648 (Formulation) in the name of M/s Aptcure (Pvt) Ltd, 8-Pharma City, 30-Km, Multan Road, Lahore, on the recommendations of the panel of experts for the further period of five years commencing on 24-10-2018 and ending on 23-10-2023 for following two sections:1. Tablet (General) Section.
2. Capsule (General) Section.
 |
| 4. | M/s Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205, Industrial Triangle, Kahta Road, IslamabadDML No. 000417 (Formulation).**Period**: Commencing on 26-02-2018 and ending on 25-02-2023. | 26-12-2018. | **-** | 1. Dr. Hafsa Karam Elahi, Additional Director (QA&Lt-I), DRAP, Islamabad.
2. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
3. Mr. Babar Khan, Area FID, DRAP, Islamabad.
 |
| **Recommendations of the Panel**“Keeping In view of the above facts on record, the panel unanimously **recommended** the renewal of Drug Manufacturing License by way of Formulation to M/s Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205, Industrial Triangle, Kahta Road, Islamabad”. **Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000417 (Formulation) in the name of M/s Global Pharmaceuticals (Pvt) Ltd., Plot No. 204-205, Industrial Triangle, Kahta Road, Islamabad, on the recommendations of the panel of experts for the further period of five years commencing on 26-02-2018 and ending on 25-02-2023. |
| 5. | M/s Medizan Laboratories (Pvt) Limited, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad.DML No. 000572 (Formulation)**Period**: Commencing on 13-05-2015 and ending on 12-05-2020 | 11-01-2019. | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
2. Dr. Hafsa Karam Elahi, Additional Director (QA&Lt-I), DRAP, Islamabad.
3. Dr. Muhammad Umair. AD (I&E). DRAP, Islamabad.
4. Mr. Babar Khan, Area FID, DRAP, Islamabad.
 |
| “Keeping In view of the above facts on record, the panel unanimously **recommended** the renewal of Drug Manufacturing License 000572 by way of Formulation to M/s Medizan Laboratories Private Limited, Plot 313, Industrial Area, Islamabad”.**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000572 (Formulation) in the name of M/s Medizan Laboratories (Pvt) Limited, Plot No. 313, Industrial Triangle, Kahuta Road, Islamabad, on the recommendations of the panel of experts for the further period of five years commencing on 13-05-2015 and ending on 12-05-2020 |
| 6. | M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, IslamabadDML No. 000628 (Formulation)**Period**: Commencing on 19-06-2018 and ending on 18-06-2023.  | 15-01-2019&17-01-2019 | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
2. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Babar Khan, Area FID, DRAP, Islamabad.
 |
| “Keeping In view of the above facts on record, the panel unanimously **recommended** Renewal of Drug Manufacturing License by way of formulation (000628) to M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad.**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000628 (Formulation) in the name of M/s Focus & Rulz Pharmaceuticals (Pvt) Ltd, 44-Industrial Triangle, Kahuta Road, Islamabad, on the recommendations of the panel of experts for the further period of five years commencing on 19-06-2018 and ending on 18-06-2023 |
| 7. | M/s Frontier Dextrose Limited, Plot No.18/3, Phase-I, Hattar Industrial Estate, Haripur.DML No. 000633 (Formulation)**Period**: Commencing on 19-06-2018 and ending on 18-06-2023 | **04-02-2019** | **Good** | 1. Prof. Dr. Jamshed Ali Khan, Member Central Licensing Board.
2. Chief Drug Inspector, KPK.
3. Area Federal Inspector of Drugs, DRAP, Peshawar.
 |
| “In compliance to Licensing Division, DRAP, Islamabad letter No.F.3-9/2007- Lic (Vol-I) dated 27-12-2018, the constituted panel ibnsepcted the premises of M/s Frontier Dextrose Ltd., Industrial Estate, Hattar and observed that the firm has provided all the required facilities for the manufacturing and quality control testing of the registered parenteral pridcuts (LVP & SVP). They have provided enviroemental control facilities and classified the areas as A, B, C & D as per requirements. Proper storage facilities and aqrrangements for control of humidity and temperature in these areas provided. Processes are carried out as per written protocols and documentation maintained. Competent qualified staff employed in production, quality control and quality assurance. Based upon the panel observations, evaluation of the manufacturing, quality control and environmental facilities provided, qualified personnelemployed and keeping in view the overall GMP compliance status, the constituted panel unanimously recommends the grant of renewal of Drug Manufacturing License No. 000633 of M/s Frontier Dextrose Limited, Plot No.18/3, Phase-I, Hattar Industrial Estate, Haripur.”.**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000633 (Formulation) in the name of M/s Frontier Dextrose Limited, Plot No.18/3, Phase-I, Hattar Industrial Estate, Haripur, on the recommendations of the panel of experts for the further period of five years commencing on 19-06-2018 and ending on 18-06-2023 |
| 8. | M/s Elegance Pharmaceuticals, Chak Belli, Pindori Road, District RawalpindiDML No. 000739 (Formulation)**Period**: Commencing on 27-08-2017 and ending on 26-08-2022.  | 04-09-2018&14-12-2018 | **Good** | 1. Mr. Manzoor Ali Bozdar, Secretary Additional Director (Lic), DRAP, Islamabad.
2. Mr. Babar Khan, Area FID, DRAP, Islamabad.
3. Mr. Khalid Mahmood, Area FID.
 |
| **Recommendations of the Panel**“Keeping In view the above facts,detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended**M/s Elegance Pharmaceuticals, Chak Belli, Pindori Road, District Rawalpindi for the renewal of Drug Manufacturing License No. 000739 (by way of formulations). **Since the firm does not possess atomic Absorption therefore, panel is of view that the Drugs containing minerals may be de-registered / cancelled and recommendation of the panel may be sent to Directorate of PE&R.****Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000739 (Formulation) in the name of M/s Elegance Pharmaceuticals, Chak Belli, Pindori Road, District Rawalpindi, on the recommendations of the panel of experts for the further period of five years commencing on 27-08-2017 and ending on 26-08-2022. The Board also decided to forward recommendations of panel of inspectors for consideration of Drug Registraation Board regarding availability of Atomic Absorption. |
| 9. | M/s EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, IslamabadDML No. 000752 (Formulation)**Period**: Commencing on 29-08-2017 and ending on 28-08-2022.  | 13-02-2019 | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
2. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
3. Mr. Babar Khan, Area FID, DRAP, Islamabad.
 |
| **Recommendations of the Panel**“Keeping In view the above facts on record, the panel unanimously **recommended the renewal of Drug Manufacturing License No. 000752 (by way of Formulation)** to M/s EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad. **Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000752 (Formulation) in the name of M/s EG Pharmaceuticals, 13-A, Industrial Triangle, Kahuta Road, Islamabad, on the recommendations of the panel of experts for the further period of five years commencing on 29-08-2017 and ending on 28-08-2022. |

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| 10. | M/s Hiranis Pharmaceuticals (Pvt) Ltd,. Plot No. E-145to E-149, North Western Industrial Zone, Port Qasim, Karachi DML No. 000785 (Formulation)**Period**: Commencing on 03-02-2019and ending on 02-02-2024.  | 13-02-2019 | Good | 1. Dr. Ghulam Sarwar, Member DRB.
2. Additional Director (E&M) DRAP, Karachi.
3. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -*****Following are the Observation:;****The firm was granted drug manufacturing license during the year 2014. The firm is a multi-product manufacturing facility comparing 14 different sections (09sections for General products, 04 sections for steroids and one section for Psychotropic tablet manufacturing), that were observed well maintained.**Firm is observed as per layout plan approved by the DRAP authorities. Relevant equipment and machinery required for the production and quality control of the registered products was observed well maintained and in place. HVAC system was seen installed in all the sections and observed operational.**Technical personnel with adequate qualification and experience was also seen involved in the productions and quality control activates.* *Keeping in view the peoples met, documents reviewed and considering the findings made during the inspections of the facility, panel recommends the grant of renewal of DML (by way of formulation) for the sections mentioned below:*

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr. No** |  **Name of Sections**  | **Sr. No** |  **Name of Sections**  |
|  | Tablet (General)  |  | Capsule (General) |
|  | Sachet (General) |  | Liquid Syrup (General)  |
|  | Mouth Wash (General) |  | Cream /Ointment/ Gel (General)  |
|  | Liquid Sachet (General)  |  | Dry Powder Suspension (General)  |
|  | Tooth Paste medicated  |  | Liquid (Steroids)  |
|  | Cream Ointment/Gel (Steroid)  |  | Tablet Steroid  |
|  | Capsule (Steroid) | \*\*\*\*\*\*\*\* |

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000785 (Formulation) in the name of M/s Hiranis Pharmaceuticals (Pvt) Ltd,. Plot No. E-145to E-149, North Western Industrial Zone, Port Qasim, Karachi, on the recommendations of the panel of experts for the further period of five years commencing on 03-02-2019 and ending on 02-02-2024. |

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| 11. | M/s Crystolite Pharmaceuticals, Plot No. 1&2, S-2, National Industrial Zone, Rawat, IslamabadDML No. 000778 (Formulation).**Period**: Commencing on 30-08-2018 and ending on 29-08-2023. | **12-11-2018****&****02-01-2019** | **Good** | 1. Dr. Muhammad Usman, Member, Central Licensing Board, Islamabad.
2. Dr. Hafsa Karam Elahi, Additional Director (QA&Lt-I), DRAP, Islamabad.
3. Mr. Hasan Afzaal, Area FID-III, DRAP, Islamabad.
 |
| “Keeping In view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Crystolite Pharmaceuticals, Plot No. 1&2, S-2, National Industrial Zone, Rawat for the renewal of Drug Manufacturing License No. 000778 (Formulation) for the following sections namely;1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment Section (General).
4. Topical Lotion Section (General).
5. Cream / Ointment Section (Steroid).
6. Topical Lotion Section (Steroid).
7. Oral Sachet (General).
8. Soft Gelatin Capsule (General).
9. Syrup Section (General).

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000778 (Formulation) in the name of M/s Crystolite Pharmaceuticals, Plot No. 1&2, S-2, National Industrial Zone, Rawat, on the recommendations of the panel of experts for the further period of five years commencing on 30-08-2018 and ending on 29-08-2023 for the following sections1. Tablet Section (General).
2. Capsule Section (General).
3. Cream / Ointment Section (General).
4. Topical Lotion Section (General).
5. Cream / Ointment Section (Steroid).
6. Topical Lotion Section (Steroid).
7. Oral Sachet (General).
8. Soft Gelatin Capsule (General).
9. Syrup Section (General).
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| 12. | M/s Medifine Laboratories (Pvt) Ltd., Plot No. A-11, New Industrial Area, Mirpur, Azad Kashmir DML No. 000672 (Formulation)**Period**: Commencing on 05-10-2014 and ending on 04-10-2019 | **09-11-2018** | **Good** | 1. Mr. Manzoor Ali Bozdar, Additional Director (Lic), DRAP, Islamabad.
2. Dr. Raja Muhammad Hanif, Chief Drug Inspector, AJK.
3. Mr. Hasan Afzaal, Area FID-III, DRAP, Islamabad.
 |
| “Keeping in view the above facts, detailed visit of facility and supporting documents provided by the company, the panel unanimously **recommended** M/s Medifine Laboratories (Pvt) Ltd., Plot No. A-11, New Industrial Area, Mirpur, Azad Kashmir for the renewal of Drug Manufacturing License (Formulation) for the following sections;1. Tablet Section (General).
2. Capsule Section (General).
3. Tablet Section (Psychotropic).

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000672 (Formulation) in the name of M/s Medifine Laboratories (Pvt) Ltd., Plot No. A-11, New Industrial Area, Mirpur, Azad Kashmir, on the recommendations of the panel of experts for the further period of five years commencing on 05-10-2014 and ending on 04-10-2019 for the following sections:1. Tablet Section (General).
2. Capsule Section (General).
3. Tablet Section (Psychotropic).
 |
| 13. | M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate, Lahore Road, Sargodha.DML No. 000609 (Formulation)**Period**: Commencing on 21-03-2017 and ending on 20-03-2022 | **9-11-2018** | **Good** | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore.
2. Mr. Asim Rauf, Additional Director (E&M), DRAP, Lahore.
3. Ms. Majida Mujahid, Federal Inspector of Drugs, DRAP, Lahore.
 |
| **Recommendations of the panel: -**Keeping in view the above improvements made by the firm, the members of the panel **recommends** the renewal of Drug Manufacturing License (000609) for the following section by way of formulation only:-1. Tablet (General) Section.

**Decision by the Central Licensing Board in 269th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000609 (Formulation) in the name of M/s Quaper (Pvt) Ltd, 26-A, Small Industrial Estate, Lahore Road, Sargodha, on the recommendations of the panel of experts for the further period of five years commencing on 21-03-2017 and ending on 20-03-2022 for the following sections:1. Tablet Section (General).
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**ITEM – V: MISC CASES**

**Case No. 1. GRANT OF RENEWAL OF DML NO. 000493 OF M/S. NAWABSONS LABORATORIES, LAHORE**

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|  | M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.DML No. 000493 (Formulation)**Period**: Commencing on 27-02-2017 ending on 26-02-2022 | **26-11-2018** | Unsatisfactory | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Mr. Abid Saeed Baig, Secretary PQCB, Govt. of Punjab, Lahore.
3. Mr. Ajmal Sohail Asif, Federal Inspector of Drugs, Lahore.
 |
|  | **Recommendations of the panel: -**The Panel of inspectors **Does Not Recommend** the renewal of DML bearing No. 000493 issued in favour of M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The Show Cause notice dated 29th January, 2019 was issued to M/s Nawabsons Laboratories (Pvt) Ltd, Jia Bagga, Off Raiwind Road, Lahore.The firm has replied to show cause notice and the firm has requested to provide sufficient time to explain their position in writing.**A letter of Personal hearing has been issued on 19-02-2019****Decision by the Central Licensing Board in 269th meeting**Mr . Arjumand Bhutta, Director of the company appeared before the Board and contended that almost most of the shortcomings have been rectified as advised during the panel inspection and report recived with Showcause Notice. He further contended that period of one month is required to rectify rest of the shortcomings as reported in the report. The Board after hearing the representative of the firm decided to give one month period to the firm. The company shall submit request for re-inspection of the unit once rectification are made and accordingly a panel would be constituted to conduct inspection for consideration of the Board. Meanwhile Licence of the company shall remain suspended. |

**Case No. 2. GRANT OF RENEWAL OF DML NO. 000449 OF M/S. HIRRA PHARMACEUTICAL LABORATORIES (PVT) LTD, LAHORE**

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| --- | --- | --- | --- | --- |
|  | M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd., 1.3-Km (Asli Raiwind Road, Ladhaky Bhular) Lahore.DML No. 000449 (Formulation)**Period**: Commencing on 01-08-2015 ending on 31-07-2020 | 23-10-2018 |  | 1. Dr. Farzana Chaudhary, Director, UVAS, Lahore
2. Dr. Qurban, Member, Drug Registration Board.
3. Mr. Asim Rauf, Additional Director, DRAP, Lahore.
4. Mr. Shoaib Ahmed, Federal Inspector of Drugs, Lahore.
 |
| The panel inspected following sections of the firm.1. Powder (General Veterinary) Section.
2. Oral Liquid (Veterinary) Section.
3. Vaccine (Veterinary) Section.

**Recommendations of the panel: -**The Panel of inspectors, therefore, **does not recommend** the renewal of Drug Manufacturing License bearing No. 000449 of M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd, 1.3-Km (Asil Raiwind Road, Lodhaky Bhular) Lahore in respect to all approved sections.**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The Show Cause notice dated 29th January, 2019 was issued to M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd, 1.3-Km (Asil Raiwind Road, Lodhaky Bhular) Lahore.No reply of the show cause notice is received from the firm.**A letter of Personal hearing has been issued on 19-02-2019.****The Show Cause Notice issued has returned back with the remarks. “ لاہورفیروز پورروڈ سے ڈ لیور ہو گا”.****Decision by the Central Licensing Board in 269th meeting**No person appeared on behalf of the company. The Board decided to ensure delivery of the Showcause Notice through Federal Inspection of Drugs of the jurisdiction and subsequent personal hearing would be afforded to take the decision as required under the law. |

**Case No. 3. GRANT OF RENEWAL OF DML NO. 000581 OF M/S. HANSEL PHARMACEUTICAL (PVT) LTD, LAHORE**

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| --- | --- | --- | --- | --- |
|  | M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore.DML No. 000581 (Formulation)**Period**: Commencing on 24-06-2015 ending on 23-06-2020 | **27-11-2018 &****11-12-2018 & 24-12-2018** | **-** | 1. Dr. Farzana Chowdhary, Director IPS, UVAS, Lahore.
2. Mr. Asim Rauf, Additional Director (E&M), Lahore.
3. Ms. Uzma Barkat, Federal Inspector of Drugs, Lahore.
 |
| **OBSERVATIONS** **Raw Material Store (Main)**1. Firm was storing raw material and Alu-PVC rolls in the same store. To overcome this shortcoming, firm converted the room for released inactive material storage in to room for storage of Aluminum foil and PVC rolls.
2. **Firm had shifted the bulk inactive material and some packing material which was previously placed in main RM store, to the basement. Firm had not taken approval from DRAP for use of this storage area in the basement. It was also seen that there was no temp/humidity maintenance and monitoring system in that area. Separate dispensing room HVAC yet to be provided.**
3. Civil work of new dispensing area was in process. Area was yet to be painted and HVAC system was yet to be installed

**General Capsule Section**1. Manometer of mixing room was not functional.

**General Tablet Section**1. Differential pressure in drying room was positive.
2. Differential pressure in compression cubicles was positive.
3. Air conditioners were installed in all three blistering rooms. Firm was advised to remove AC and provide HVAC system. **26.2˚C/47% RH** seen in Blistering 3 at the time of inspection. **24.1˚C/58% RH** seen in Blistering 1 at the time of inspection.

**General Tablet Section (Amended)**1. Differential pressure was found to be positive in granulation room.
2. Manometer of coating room 2 was not functional.
3. Humidity of granulation area was not maintained.

 **Temp/ humidity observed on 27/11/2018 = 21.2˚C/73% RH** **Temp/ humidity observed on 11/12/2018 = 17.8˚C/70% RH** **Temp/humidity observed on 24-12-2018= 15.8˚C/72% RH** 1. Firm had provided an emergency exit in the granulation area which was not present in the approved layout. This emergency exit was not safe and appropriate in the given location.
2. **Eye Drop Section**
3. RM store was very congested. Firm was using some analytical grade raw materials. The firm was advised to use pharmaceutical grade raw materials in manufacturing.
4. A window had been provided in the Solution preparation area for transfer of material to autoclave room which was opening in main corridor. Advised to provide proper pass through hatch.
5. The filling machine was installed directly under the HVAC diffuser blocking the HVAC supply. Moreover filling nozzles were directly under dead patch of LFC.

**Cream/Ointment Section** 1. Section was not operational
2. HVAC system of the area was under maintenance as informed by the firm’s management.

**Liquid Injectable Section (General)**1. Firm had provided two solution preparation rooms and two filling areas.
2. The firm was advised to provide HVAC system in the buffer of ampoule washing area.
3. Firm was advised to provide flushed lights and windows in solution preparation and filling areas.
4. In material transfer room I, there was no HVAC return duct. Manometer was not installed.
5. In material transfer room II, there was neither HVAC supply nor return. Manometer was not installed.
6. The firm was advised to remove AC from Autoclave room and provide HVAC system.
7. The firm was advised to provide HVAC system in the whole corridor providing access to sterile areas.
8. De-cartoning area was just a closed room. There was no air treatment mechanism in de-cartoning area. The firm was advised to provide HVAC system in this area.

**Dry Powder Injection Section (Cephalosporin)**1. Firm was advised to replace rusted hooks in vial washing area, provide GMP compliant drains throughout the unit and provide flushed lights and windows. Open tube lights and dead spaces were present in LFC.
2. Firm was advised to provide continuous LFC on filling machine without any dead patch.

**Dry Powder Suspension and Capsule Section (Cephalosporin)**1. Firm was advised to provide physical partitioning between bottle filling and sealing operations.
2. Differential pressure was positive inside mixing and filling room.
3. Firm was advised to provide pressure gauges and suction in bottle blowing machine.
4. Dispensing hood room opens in to main corridor. There is a risk of cross contamination.

**Hormone Tablet Section**1. No ventilation or temp/humidity maintenance and monitoring system was provided in quarantine area.
2. In the dispensing room and raw material released area, HVAC system was not functional.
3. Firm was advised to provide proper transfer hatch in dispensing area.
4. Humidity in granulation area : **23.3˚C/ 60% RH (area at rest)**
5. Humidity in mixing room area : **17.5˚C/ 66% RH (area at rest)**
6. Humidity in drying room area : **17.7˚C/ 64% RH (area at rest)**
7. Humidity in blistering area: **19.9˚C/ 69% RH (area at rest)**
8. **Packing hall had been provided an access to the basement where the finished goods will be stored as informed by the firm’s management. Firm had not obtained approval for this FG store from DRAP. It was also seen that there was no temp/humidity maintenance and monitoring system in that area.**

**Hormone Injection Section**1. Dispensing hood was provided. However, firm was advised to provide proper enclosed dispensing room.
2. Sampling booth/area was not provided.
3. Calibration of gauges/equipment/machine parts in this section was yet to be completed.
4. Open tube lights had been installed in LFCs of both solution preparation areas and filling machines. The firm was advised to provide flushed lights.
5. The firm was advised to provide magnehelic gauge for pressure monitoring in buffers for material transfer.
6. Physical partitioning required between vial filling and sealing operation.
7. Water, compressed air, nitrogen gas filters were yet to be installed.
8. No LFC trolley for ampoule cooling/transfer was not provided.

**Quality Control Laboratory:**1. Firm was advised to provide TOC analyzer.

The firm has submitted plan vide letter No. 271218/HP/DRAP/18 dated 27-12-2018 wherein they have given a timeline for rectification/compliance of the observations made during the inspections.**Decision by the Central Licensing Board in 268th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License (No. 000581(Formulation) ) may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The Show Cause notice dated 29th January, 2019was issued to M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore.The firm has replied to show cause notice and submitted compliance report with the request to verify the rectification before taking any action against the firm.**A letter of Personal hearing has been issued on 19-02-2019****Decision by the Central Licensing Board in 269th meeting**Mr. Muhammad Hanif, Managing Director of M/s. Hansel Pharmaceutical (Pvt.) Ltd., Plot No. 02, Pharma City, 30-K.M. Multan Road, Lahore appeared before the Board. He contended that most of the rectifications have been made as pointed out by the panel and they are ready for re-inspection.The Board after hearing the representative of the company decided to inspect the premises by the same panel. Meanwhile production of the company shall remain suspended for the said period. The Chairman shall pass orders on the report of the panel if panel recommends respumtion of production and case would be placed in the next meeting of the Board for ratitication. |

**Case No. 4. RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S FLOW PHARMACEUTICALS (PVT) LTD, LAHORE.**

M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km,Sheikhupura Road,, Lahore had applied for renewal of DML No. 000428 by way of formulation for the period of 26-03-2016 to 25-03-2021 on 28-03-2016.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 3rd October, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Change (s) in name of proprietor / director partner (if an change)
2. Detail of premises including layout plan and proof of section from CLB.
3. Latest Form 29 attested by S.E.C.P.
4. Approval letter of Production Incharge an QC Incharge.
5. Nothing due certificate regarding CRF from STO.

The firm did not submit their reply and again a letter dated 1st February, 2018 was issued to the firm with following shortcomings:

1. Due date of renewal application is 25-03-2016 and renewal application was received on 28-03-2016 which is 03 days late. According to Rule 6 of Drugs (L, R&A) rule 1976 the additional surcharge 5,000/- each day and total Rs. 15,000/- = (03X5000) should be deposited.
2. Form-29 at the time of previous renewal and latest Form-29 duly attested by S.E.C.P
3. Nothing due certificate regarding CRF from STO (R&D) DRAP, (Updated).
4. Approval letters of Production Incharge, and Quality Control Incharge if change, complete set of duly attested documents (As per checklist) alongwith prescribe fee of Rs-10,000/-
5. Detail of premises including copy of approved master layout plan.
6. Proof of sections approved by Central Licensing Board.
7. **All documents should be duly attested.**

The firm did not reply and final reminder dated 31st May, 2018 was issued to the firm with following shortcomings: -

1. Due date of renewal application is 25-03-2016 and renewal application was received on 28-03-2016 which is 03 days late. According to Rule 6 of Drugs (L, R&A) rule 1976 the additional surcharge 5,000/- each day and total Rs. 15,000/- = (03X5000) should be deposited.
2. Form-29 at the time of previous renewal and latest Form-29 duly attested by S.E.C.P
3. Nothing due certificate regarding CRF from STO (R&D) DRAP, (Updated).
4. Approval letters of Production Incharge, and Quality Control Incharge if change, complete set of duly attested documents (As per checklist) alongwith prescribe fee of Rs-10,000/-
5. Detail of premises including copy of approved master layout plan.
6. Proof of sections approved by Central Licensing Board.
7. **All documents should be duly attested.**

Reply of the firm is still awaited and application for renewal of DML is incomplete as of today.

Meanwhile, A copy of letter is received from Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab wherein he has informed that Provincial Quality Control Board has suspended the Drug Manufacturing License of M/s Flow Pharmaceuticals (Pvt) Ltd, Lahore, for 15 days w.e.f 17-9-2018 vide ordered dated 17th September, 2018 based on the inspection report (i.e. Inspection conducted on dated 5th July,2018)submitted by Drug inspector Industries, Lahore. The Board further decided to direct Drug Inspector industries to re-inspect the factory premises after 15 days to evaluate CAPA and remedial measures taken by the firm for further necessary action.

Orders of the Provincial Quality Control Board, Punjab marked as **Annex-I**.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

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 5(6), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of DML No. 000428 by way of formulation of M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km,Sheikhupura Road, Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.The Central Licensing Board also decided to seek updated report from PQCB on the matter pending before them.

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

The Show Cause notice dated 29th January, 2019 was issued to M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km,Sheikhupura Road, Lahore

The firm has replied to the show cause notice and stated that they will provide the short documents in 2 weeks. Furthermore, the firm has stated that they are in the process of renovation / upgradation of their manufacturing facility as per latest GMP requirements and for that propose they have already voluntarily stopped their production since November, 2018 with intimation to DRAP, Lahore.

**A letter of Personal hearing has been issued on 19-02-2019.**

Meanwhile, Secretary, PQCB, has conveyed the decision of the PQCB in its 194th meeting held on 18-10-2018 of M/s Flow Pharmaceuticals (Pvt) Ltd, District Sheikhupura in which the Board decided to recommend the DRAP for **cancellation** of Drug Manufacturing License of M/s Flow Pharmaceuticals (Pvt) Ltd, District Sheikhupura as the firm failed to comply with the orders / directions of PQCB and also failed to submit CAPA report. The firm continued manufacturing of Drugs despite suspension of its DML by PQCB and no improvement was made in GMP.

**Decision by the Central Licensing Board in 269th meeting**

No person appeared on behalf of the firm. The Board considering the facts on record and updated report for PQCB Punjab decided to suspend the Drug Manufacturing Licence No. 000428 of M/s Flow Pharmaceuticals (Pvt) Ltd, 17-Km,Sheikhupura Road, Lahore for the period of six months 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 5(6), Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976. Production shall be resumed after approval of Central Licensing Board.

**Case No. 5. APPROVAL OF PRODUCTION INCHARGE OF M/S ORTA LABORATORIES (PVT) LTD, LAHORE.**

 M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohlanwal, Lahore had applied for approval of Production Incharge on 10th November, 2017. The application for the was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on
27th December, 2107.

1. CNIC Copy of appointee (Valid CNIC)
2. Registration certificate from Pharmacy Council (Valid Copy).
3. Resignation of earlier Production Incharge.
4. **All documents should be duly attested**

 The firm submitted their reply on 17thJanuary, 2018. After evaluation of the submitted documents, final reminder was issued on 5thMarch, 2018 to the firm with following shortcomings: -

1. Resignation / retirement of earlier Production Incharge.
2. Registration certificate from pharmacy council which is valid as of today.
3. All documents should be duly attested.

The firm has not replied to Final reminder and application for approval of Production Incharge is incomplete.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No.000075 by way of Formulation in the name of M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohlanwal, Lahore may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 29th January, 2019 was issued to M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohlanwal, Lahore

The firm has replied the show cause notice and application of proposed Production Incharge has been completed by the firm.

**A letter of Personal hearing has been issued on 19-02-2019**

**Decision by the Central Licensing Board in 269th meeting**

Mr. Farooq Tanveer, Plant Manager of M/s Orta Laboratories (Pvt) Ltd, 24-Km, Multan Road, Off Defence Road, Mohlanwal, Lahore appeared before the Board. He submitted that since legal and codal formalities has been complied therefore showcause may be withdrawn. The Board after hearing the representative of the firm decided to cease the operation of the showcause Notice . The Board also decided to issue warning to the firm to be careful in future for compliance of the law.

**CASE NO.6. RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S OBSONS PHARMACEUTICALS , LAHORE.**

**Case Background:**

The case was placed in 243rd meeting of CLB held on 9th September, 2015 as under: -

|  |  |  |  |
| --- | --- | --- | --- |
| **S No.** | **Name of the firm** | **Date of Inspection / Type of License** | **Decision of CLB** |
|  | M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore.DML No. 000416 (Formulation) | **04-06-2015**(Formulation) | **The Board was apprised of the back ground of the case and reply of the panel as under:****Background:** The case was previously considered in 242nd meeting of CLB held on 8th July, 2015.Previous recommendations of panel.As per current policy and the SRO No.470(1)/98, dated 15-05-1998 and schedule B to the Drug Act 1976, the firm does not full fill the requirement of area land i.e. of 2000 sq. yards so the panel of experts is not in a position to recommend the renewal of Drug Manufacturing License No. 000416 (by way of formulation) to M/s. Obsons Pharmaceuticals, 209-S, Industrial Estate, Kot Lakhpat, Lahore and suggests that the case may be referred to the Honorable Drug Licensing board for further decision in this regard the management may be directed to full fill the requirement of area as per SRO No.470(1)/98, dated 15-05-1998 within a shortest period of time. In the meantime, they may be allowed to carry on production at the present premises by maintaining the cGMP conditions. DML was granted to them before promulgation of SRO No.470(1)/98, dated 15-05-1998Decision of CLB of 242nd meeting held on Wednesday, 08th July, 2015Deferred the renewal of DML for want of following information from panel: 1. Rating of the firm with regard to inspection as same is not mentioned. 2- Deficient area/plot of the firm as same is not mentioned. 3- Compliance of GMP with regard to renewal of DML.The panel was conveyed above decision of CLB on 4th August, 2015. In reply the panel has furnished as under: -1. I have the honour to refer to DRAP, Islamabad letter No.F.1-84 (Vol-III), dated 04-08-2015 on the subject cited.
2. The panel inspection report of M/s Obsons Pharmaceutical (Pvt) Ltd, Lahore has already been sent to your good office vide this office letter No. 9319/2015-DRAP (Lic), dated 07-07-2015.
3. The detailed section wise evaluation proforma is attached herewith for ready reference, duly signed by the members of the panel.
4. So far as the plot size is concerned the firm has total land / area, 1295 sq. yards. However, as per SRO.470 (1)/98, dated 15-05-1998 Schedule B to the Drugs (Licensing, Registering & Advertising) Rules, 1976, the minimum area of 2,000 sq. yard is required. In this way, the firm is deficient of 705 sq. yards as per the requirement.
5. The firm fulfills the basic requirements for manufacturing of their registered products. As per GMP requirements, however, some points for further improvements were discussed with the management.

**Keeping in view the above situation, the Board decided and deferred the case for personal hearing of the firm. Board further directed that the firm shall be informed about the observations of inspection panel.** |

Accordingly, firm was called for personnel hearing before the Board, please.

Proceedings:

Mr. S.M. Naeemullah CEO M/s Obsons Pharmaceuticals appeared before the Board. He submitted that they were granted license in 1996 and subsequent renewals have been made from time to time. At present, firm have four sections having the prescribed area however the overall size of the plot is less than 2000 sq. yards as the license was granted before the promulgation of SRO 470(I)/98. Mr. Khurram Shahad Mughal representative of M/o Law, Justice and Human Rights, Islamabad informed the Board that it is mandatory to fulfill the conditions of SRO 470(I)/98 i.e. plot size should not be less than 2000 sq. yards. Mr. S.M. Naeemullah admitted the condition of 2000 sq. yards of plot size and submitted an undertaking to Board stating that they will arrange the required area as per SRO 470(I)/98 dated 15-05-1998 within the period of three years i.e. 30-12-2018.

Decision of CLB:

* In the light of undertaking by the firm that they will arrange the required area as per SRO 470(I) /98 dated 15-05-1998 with in the period of three years i.e. 13-12-2018, the Board approved the renewal of DML of the firm

Board further decided and directed the firm to develop new premises with plot size of not less than 2000 sq. yards as per given undertaking within 03 years.

M/s Obsons Pharmaceuticals209-S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore had applied for renewal of DML No. 000416 by way of formulation for the period of 17-08-2015 to 16-08-2020 on 05-08-2015.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 8th June, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Nothing due certificate regarding CRF
2. Detail of management / Partner / director and if any change
3. Copies of all directors CNIC (Attested)
4. Proof Sections From CLB
5. Approved layout plan of firm.

The firm did not reply to this letter.Meanwhile, the firm applied on 23rd May, 2016 for approval of Ms. Nadia Saeed Khan as Quality Control Incharge. Application was incomplete and a letter was issued on 30th November, 2016 for completion of application with following shortcomings.

1. Fee of 5000/- for proposed QC Incharge.
2. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm.
3. Undertaking as whole time employee.
4. All documents should be duly attested.

 The firm did not response to letter of shortcomings and filed a new application of Quality Control Incharge. Application of Mr. Muhammad Asim is received for approval as Production Incharge but application was incomplete and the firm was asked vide letter dated 28th December, 2017 for completion of application:

1. Prescribed fee of Rs. 5000/- retained from STO, DRAP, Islamabad.
2. Appointment letter and job acceptance letter.
3. Undertaking as whole time employee on stamp paper.
4. Resignation of appointee from previous firm.
5. All documents should be duly attested.

The firm, then, submitted documents of Proposed Production Incharge i.e. Mr. Muhammad Nadeem. Final Reminder dated 13th April, 2018 was issued with following shortcomings:

1. Updated Nothing due certificate regarding CRF from STO, DRAP, Islamabad.
2. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs. 50,000/- for change of management.
3. Legal status of the applicant, if sole proprietor, Undertaking as sole proprietor on Stamp Paper. If Partnership firm, Copy of partnership deed and Form-C from Registrar of firms alongwith CNIC copies of owner/partners/Directors.
4. Copy of approved master layout plan.
5. Proof of CLB approved sections, if not available, apply for regularization of layout plan.
6. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of proposed Production Incharge (Not less than 10 years).
7. Resignation/retirement of earlier Production Incharge.
8. Prescribed fee of Rs.5000/- original challan retained from STO, DRAP, Islamabad (Quality Control Incharge).
9. Complete set of duly attested documents (as per checklist) for approval of proposed Quality Control Incharge.
10. All documents should be duly attested.

The firm submitted documents on 06-07-2018 in reply to reminder along with new application for approval of Production Incharge but following documents are still deficient in the application:

1. Prescribed fee of Rs. 50,000/- for change of management.
2. NOC from previous management.
3. Dissolution certificate of firm from registrar of firms.
4. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of proposed Quality Control Incharge (Not less than 10 years in relevant field).
5. Valid/ renewed Registration Certificate from Pharmacy Council (Quality Control Incharge& Production Incharge).
6. All documents should be duly attested.

Meanwhile, request for extension of time frame given to the firm for shifting of their existing unit in the light of SRO-470(1) /98.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

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 16, Rule 19 and Schedule B (Paragraph 1.3) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of DML No. 000416 by way of formulation of M/s Obsons Pharmaceuticals209-S, Quaid e Azam Industrial Estate, Kot Lakhpat, Lahore may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 21st January, 2019 was issued to M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.

The firm has replied the show cause notice but application is still deficient of the following documents.

1. Experience Certificate as under Drugs (Licensing, Registering and Advertising) Rules, 1976 of proposed Quality Control Incharge (Not less than 10 years in relevant field).
2. Valid/ renewed Registration Certificate from Pharmacy Council (Quality Control Incharge& Production Incharge).
3. All documents should be duly attested.

Furthermore, the firm has filed W.P. No. 4907/2018 Misc. other M/s Obsons Pharmaceuticals-VS-FOP etc in the Islamabad High Court, Islamabad which has been disposed off byHon’ble Chief Justice, Islamabad High Court, Islamabad by directing the competent authority to afford an opportunity of hearing to an authorized representative of the petitioner company and thereafter pass a speaking order.

**A letter of Personal hearing has been issued on 19-02-2019**

**Decision by the Central Licensing Board in 269th meeting**

Mr Noor Hussain Gondal, Partner of the firm appeared before the Board and contended that he has recently taken over management of the firm and submitted an undertaking on Affidavit that he would shift to new premises for which he has already submitted an application for site verification. The Secretariat of the Licensing Division also confirmed that application for site verification is recived and being processed. The Board after hearing the representative of the firm and perusal of orders of the Honourable High Court observed that SRO. 470 (I)/98 which specify the minimum area rerquirement for a pharmaceutical firm is applicable as renewal of a Drug Manufacturing Licence is always subject to upadated law and rules. The Board considering the commitment of new management decided to give period till August, 2020 to the firm to shift to new premises and for that purpose the applicant shall get its site verified and Lay ou plan appaoved by 30th April, 2019 and shall file application for grant of Licence before 31st August, 2020.

**CASE NO.7.** **M/S ASTLE MEDICAL DEVICES PAKISTAN (PVT) LTD, PLOT NO. 545-B, SUNDER INDUSTRIAL ESTATE, LAHORE.**

 Drug Manufacturing License No. 000743 (Formulation) was issued to M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *“if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application”.* But, in this case the application for renewal of DML for the period 11-10-2017 to 10-10-2022 has not been received till date. Therefore, DML No. 000743 (Formulation) M/s Astle Medical Devices Pakistan (Pvt) Ltd, Lahore is no more valid.

**Proceedings and Decision of Central Licensing Board in 268th meeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000353 by way of formulation M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore may not be declared cancelled.

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

The Show Cause notice dated 23rd January, 2019 was issued to M/s Astle Medical Devices Pakistan (Pvt) Ltd, Plot No. 545-B, Sunder Industrial Estate, Lahore.

No reply of the show cause notice is received from the firm.

**A letter of Personal hearing has been issued on 19-02-2019.**

**Decision by the Central Licensing Board in 269th meeting**

No person appeared on behalf of the firm. However, Secretariat of the Licensing Division informed that a call is recived form Mr. Kashif ( Cell. 03008450930). He introduced himself as MD of the company and informed that he had recived letter of personal hearing on the date of meeting therefore time may be give to appear in the next meeting of the Board. The Board after considering the facts decided to defer the case to give final opportunity to the firm to plead his case.

**CASE NO.8.** **M/S KAKASIAN PHARMACEUTICALS (PVT) LTD,29th KM FEROZEPUR ROAD, LAHORE.**

 Drug Manufacturing License No. 000353 (Formulation) was issued to M/s Kakasian Pharmaceuticals (Pvt) Ltd,29th Km Ferozepur Road, Lahore. It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *“if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application”.* But, in this case the application for renewal of DML for the period 02-03-2015 to 01-03-2020 has not been received till date. Therefore, DML No. 000353 (Formulation) M/s Kakasian Pharmaceuticals (Pvt) Ltd, Lahore is no more valid.

**Proceedings and Decision of Central Licensing Board in 268th meeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No. 000353 by way of formulation M/s Kakasian Pharmaceuticals (Pvt) Ltd,29th Km Ferozepur Road, Lahore may not be declared cancelled.

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

The Show Cause notice dated 23rd January, 2019 was issued to M/s Kakasian Pharmaceuticals (Pvt) Ltd,29-Km Ferozepur Road, Lahore.

No reply of the show cause notice is received from the firm.

**A letter of Personal hearing has been issued on 19-02-2019.**

**Decision by the Central Licensing Board in 269th meeting**

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

**CASE NO. 9. M/S MEDIWAYS INTERNATIONAL, LAHORE**

**Background:-**

M/s Mediways International, Multan Road, Lahore was inspected on 09.02.2015 by Mr. Ajmal Sohail Asif, FID Lahore to see/verify the GMP compliance. During inspection the FID pointed out a number of serious shortcomings and gross violations including the following:-

**Change Rooms:**

1. Air curtains were installed but were not functional at the time of inspection.
2. No Separate change room was provided for visitors or executives.
3. Change rooms were very small and need to be reorganized in respect of outside doors.
4. The firm was also advised to provide cabinets in the change rooms for keeping the workers belongings etc.
5. It was also noticed that at the time of inspection the change rooms were not maintained and were not neat and clean.

**Storage Areas:**

1. Quarantine area not properly demarcated and separated from the de-dusting area.
2. The firm has provided a dispensing hood which was placed in the raw material store for recipients. But it seemed not to be in use, since there were no accessories like balance, scoops etc inside the dispensing booth.
3. Balances and other accessories for dispensing were available on one of the racks of raw materials.
4. No separate facility for sampling of the materials was available; the firm was advised to provide proper sampling facility.
5. The firm was also advised to rearrange the placement of dispensing hood providing separate cabin and proper flow of pre and post dispensed materials
6. However packing material store was congested the firm was advised to expand the storage area for packing materials.

**Production Areas:**

1. HVAC was not functional at the time of inspection due to load shedding as informed by management of the firm.
2. The firm was advised to partition this room for separation of de-cartooning and bottle blowing functions.
3. It was also noticed that all the doors in production area were wooden and the firm was advised to replace all the wooden doors.

**Quality Control Laboratory:**

1. It was noticed that QC lab was accessed through the de-dusting/ quarantine area of raw material store; the firm was advised to provide some other entrance to QC laboratory in order to avoid unnecessary movements QC of staff in stores.

**Quality Assurance:**

1. During the last inspection the firm has presented a QA officer but at the time of this inspection no QA personnel was present.
2. From ware houses to production and quality control no prevalence/involvement of quality assurance was observed.
3. The management of the firm was also advised during previous inspection to strengthen the QA department but no improvement was seen in this department.
4. Due to lack of QA system, deviations from SOPs, GMP, GSP etc, were observed in stores, manufacturing areas and quality control.
5. Non existence of an independent check and balance system may result in compromises, by manufacturing and QC personnel, for routine deviations from practices and procedures. Such a situation may pose a great potential of compromises on overall quality of the products being manufactured.

**Sanitation and Hygiene:**

1. The equipments in QA laboratory and different gauges, matters and equipment in manufacturing areas were not calibrated.
2. There was no system for qualification and validation of machines, procedures and practices.
3. The firm has no procedures for cleaning validation and was advised to develop.

**Products Recalls:**

1. The firm was advised to assign a separate area for recall products and demark it well

**Self Inspection and Quality Audit:**

1. No record was available for any audit.

**Personnel:**

1. However, there was no technical person to look after the QA.
2. The firm was advised to establish proper QA department and to hire appropriate personnel to strengthen the QA

**Training:**

1. However, It was not being implemented as no record was available

**Equipment & Machinery:**

1. However, the firm was advised to upgrade the syrup filling machine.
2. The machines/equipments were not properly labeled regarding the status.
3. However, the firm was advised to purchase the FTIR on priority basis.

**Materials:**

1. The firm was advised to purchase the materials from manufacturers or authorized suppliers.
2. The firm was also advised to conduct vendor qualification.
3. The firm has not developed a proper material management system.
4. The materials were not properly labeled.
5. The firm was advised to affix the label on each and every container / bag of a lot of material.
6. The firm was also advised to develop and implement the procedures for safety and security of the workers/personnel handling the materials in stores and also to mark the racks and allocate locations of the materials.
7. In packing materials store the firm was advised for safe storage of printed materials and unit cartons under lock and key.

**Documentation:**

1. It was found that some of the SOPs and BMRs needed review, improvement and updating regarding the actual practices.
2. The log books for QC equipment were not maintained.
3. The firm was advised to prepare procedure for OOS, cleaning validation etc.

**Good Practices in Production:**

1. In general the practices were observed not to be in accordance with the prescribed procedures.
2. The firm was asked to present the BMR for the last batch of a product namely “Antizile Syrup” but the management failed to produce any documentation.

**Good Practices in Quality Control:**

1. There were procedures for QC analysis but they needed to be updated.
2. The log books for instruments and equipments were not maintained.
3. In general the practices were observed not to be in accordance with the prescribed procedures.

**Utilities**

**Water Purification System:**

1. The firm was advised to install transfer pipes for supply of purified water to manufacturing area to minimize the exposure to external environment during manual transfer.

**HVAC System:**

1. The firm was advised to repair the manometer so that the pressure gradients in buffer and manufacturing areas may be checked.

**The FID further concluded that:** The non compliant behavior of the firm towards advises made during previous panel inspection; the firm was considered to be operating at unsatisfactory level of the compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under.

**Action Taken by DRAP**: - Accordingly, a show cause notice and suspension of production order in all section was issued to the firm on 20.03.2015 with immediate effect.

**Reply of the firm**: - In response to show cause notice the firm vide letter No. Nil dated 15.06.2015 submitted their reply and requested to verify the shortcomings through area FID.

**Proceedings of 245th meeting of CLB held on 30.12.2015**

 Mr. Jamil Ahmad, CEO of the firm appears before the Board. He informed that the observations given by the FID were given attention and most of the observations have been rectified and compliance report was also submitted. The firm is ready for inspection.

**Decision of 245th meeting of CLB held on 30.12.2015**

The case was placed before the Central Licensing Board for consideration. The Board after thorough discussion, keeping in view the available record, compliance report and request from CEO of the firm, decided to conduct panel cGMP inspection of the firm, on approved Schedule B-II cGMP format and panel will also submit report in tabulated form identifying the previous observations and the current status, by the following members:-

1. Dr. Ikram ul Haq, Member, CLB
2. Dr. Zaka ur Rehman, Member, CLB
3. Mr. Ajmal Sohail Asif, Area FID.

Accordingly decision of 245th meeting of CLB was conveyed to the firm on 10.02.2016

**Letter of Secretary PQCB, Lahore:-**

 Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Deputy Drug Controller Allama Iqbal Town Lahore alongwith other members inspected the premises on 16.06.2016. The team observed that:-

1. Manufacturing of Drugs was being carried out under unhygienic conditions.
2. Improper storage of drugs (at 40 degree Centigrade).
3. Illegal or unauthorized import of raw materials without label (misbranded).

 The case was placed in 249th meeting of CLB held on 29.08.2016.

**Proceedings of the 249th meeting of CLB**

The Board was informed that Mr. Ajmal Sohail Asif, FID conducted inspection of the firm on 09.02.2015. The firm was issued order for suspension of production activities and issued showcause notice / Suspension of production order No.F.4-4/2001-QA on 20.03.2015. Accordingly, the case was discussed in 245th Meeting of CLB, wherein the CLB had constituted following panel of experts to verify the improvements:-

1. Dr. Ikram ul Haq
2. Dr. Zaka ur Rehman
3. Mr. Ajmal Sohail Asif

Inspection report of the firm is still awaited. The Board also discussed and evaluated the reports / cases forwarded by the Secretary, PQCB, Punjab, Lahore and Chief Drug Controller, Punjab for cancellation / suspension of DML of the firm M/s Mediways, Lahore. The Board also consider sub Rule 3 of Rule 5 of Punjab Drugs Rules, 2007 which categorically stated that *“The provincial and district Board shall examine a case referred to it by an inspector and shall , if an action is proposed to be taken against a person under the Act or the rule, issue a showcause notice to the personal and provide him an opportunity for hearing before taking the action about the prosecution of the person or recommending suspension or cancellation of his license to the licensing authority.”*

**Decision of the 249th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, the Board considered the recommendations of the Secretary, PQCB, Punjab and took a serious notice on illegal / unauthorized manufacturing and violation of the orders of the DRAP’s letter No. No.F.4-4/2001-QA dated 20.03.2015. The Board decided to issue a showcause notice to the firm M/s Mediways, Lahore on illegal / unauthorized production activities and disobeying the orders of DRAP.

Accordingly showcause notice was issued to the firm on 03.10.2016.

**Proceedings of the 250th Meeting of CLB**

Mr. Jamil Ahmed, Chief Executive of the firm M/s Mediways International, Lahore appeared before the Board for personal hearing. He informed that the production is suspended since March, 2015, as per direction of the Division of QA&LT. The provincial government during the raid sealed the premises, which was later on de-sealed on the order of the Drug Court, Lahore. He also informed that inspection book is also in the custody of provincial drug inspector, which has not been handed over to him till date, despite number of requests. Dr. Ikram ul Haq, Member CLB informed the Board that he along-with other members of the panel visited the firm, in compliance to decision of 245th Meeting of CLB, but the firm was found closed and the inspection could not be carried out.

**Decision of the 250th Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the available record, non serious and non-professional attitude of the firm, , the Board decided to:-

1. Suspend the Drug Manufacturing License of the firm M/s Mediways International, Lahore for a period of six months under Section 41 of the Drugs Act, 1976 read with Rule 12 (1) of the Drugs (LR&A) Rules, 1976.
2. Direct the area FID to visit the firm on alternate months to verify the suspension of production and submit report.
3. Resumption of production shall only be allowed after completion of suspension of DML period, verification by the panel of experts and subsequent approval from the Competent Authority.

**Updated status:-**

The panel constituted by the Director QA&LT conducted inspection of the firm on 26.12.2017 (received on 17.04.2018). The panel submitted detailed inspection report including previous observations and updated status on Schedule B-II format and recommended as under:-

 *“Based on the areas inspected, the people met and the documents reviewed, and considering the finding of the inspection in comparison with the observations of the previous inspection, the panel of inspectors does not consider the firm to be at a satisfactory level of compliance with GMP guidelines as per Drugs Act, 1976 and rules framed there under. The plot size is smaller than the prescribed requirement. However, CLB in its 241st meeting held on 15.5.2015 decide “to allow two years time for shifting of unit / enhancement of plot size according to rules”; and that two years period. Therefore, the panel of inspectors does not recommend M/s Mediways International, 16KM Multan Road, Lahore, for resumption of production. The report is forwarded herewith for further consideration and necessary action”.*

**Proceedings of the 261st meeting of the CLB**

The case was placed before the board for appraisal in the light of recommendations of the panel of experts in its report dated 26.12.2017.

**Decision of the 261st Meeting of CLB**

After thorough discussion/deliberations, considering all the pros and cons of the case, recommendation of the panel of experts in its report dated 26.12.2017, the Central Licensing Board decided to:-

1. Further extend Suspension of DML period for next six months from the date of issuance of decision of 261st meeting of CLB.
2. The Licensing Division Shall place the case in forthcoming meeting of CLB in the light of decision of 241st meeting of CLB.

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

 The Central Licensing Board in its 241st meeting held on 15th May, 2015 has considered the case of M/S Mediways International, Lahore and decided as under:

* *“To allow two years time for shifting of unit / enhancement of plot size according to the rules.*
* *To scrutinize the application of the renewal of DML of the firm for the period 09-02-2015 to 09-02-2020 and inform the applicant the status of the application according to Rule 5[2A] of the Drugs (Licensing, Registering & Advertising) Rules 1976 and conduct inspection of the firm after completion of application of renewal of DML.”*

 The same decision was conveyed to the firm vide letter issued on 24th August, 2015 but till date no application is received from the firm for shifting of their existing facility and application for renewal of DML No. 000468 (Formulation) for period of 09-02-2015 to 08-02-2020 is incomplete with following documents being deficient:

1. Nothing due certificate regarding CRF (Updated).
2. Approval letters of Production Incharge and Quality Control Incharge, if not approved, complete set of duly attested documents (as per checklist) of qualified staff alongwith prescribed fee of Rs.10,000/-
3. Detail of management at the time of previous renewal and at present renewal, if any change, prescribed fee of Rs.50, 000/- for change in management.
4. CNIC copies of owner/partners.
5. Proof of CLB approved sections.
6. Legal status of the firm.

**Proceedings and Decision of Central Licensing Board in 265thmeeting**

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 16 and Rule 19,Schedule B-II and Rule 20 (a) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/sMediways International, Multan Road, Lahore, under Drug Manufacturing Licence No. 000468 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 27thSeptember, 2018 was issued to the M/sMediways International, Multan Road, Lahore which was returned back. Then The Additional Director (E&M),DRAP, Lahore requested to ensure delivery and receiving of show cause notice to the firm.

 The firm replied to the show cause notice and the application for renewal of DML is incomplete till date with following short comings.

1. Nothing due certificate regarding CRF (Updated).
2. Proof of CLB approved sections.
3. Undertaking as sole proprietor on stamp paper.

Furthermore, the firm requested to allow three year for shifting unit after earning some revenue as the production has remained suspended for two years.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to call the firm M/s Mediways International, Multan Road, Lahore for personal hearing in forthcoming meeting of the Central Licensing Board.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to call the firm M/s Mediways International, Multan Road, Lahore for personal hearing in forthcoming meeting of the Central Licensing Board.

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

**A letter of Personal hearing has been issued on 19-02-2019**

**Submitted for consideration and orders of the Board, please.**

**Decision by the Central Licensing Board in 269th meeting**

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

**Case No. 10. CONVERSION OF UNIVERSITY OF SARGODHA PHARMACEUTICAL LABORATORIES INTO RESEARCH / TRAINING ENTITY ONLY.**

A Pharmaceutical industrial Unit (University of Sargodha Pharmaceutical Laboratories) was established by the University of Sargodha for commercial and research purpose and requisite license was attained from Drug Regulatory Authority of Pakistan, vide license No.000859, dated 21-06-2017 for the said purpose.

It is to inform you that the syndicate of the university of Sargodha in its 1/2018 meeting held on 12-05-2018 has declared Pharmaceutical Industrial Unit as Research entity only, in order to provide research opportunities to the student of university of Sargodha and to strengthen the research activities at UOS. Photocopy of notification is attached for reference.

Now, as per decision of the syndicate, the above Industrial Unit will be used only as “Research and Training Unit” for Pharmacy students and researchers, as well as other integrated disciplines. This Pharmaceutical Industrial Unit will not be run for commercial purpose.

1. This is for your kind information and subsequent necessary action in this regard please,
2. It is requested that kindly facilities in this regards according to the law and Licensing terms to run above unit as research and training only.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to call the firm for personal hearing in forthcoming meeting of the Central Licensing Board.

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

**A letter of Personal hearing has been issued on 19-02-2019.**

**Decision by the Central Licensing Board in 269th meeting**

Dr. Muhammad Tahir Haseeb, Lecturer, faculty of Pharmacy, University of Sargodha, appeared before the Board and contended that due to change in management at the University decision has been taken to shut the facilty and therefore request has been submitted for voluntarily cancellation of Drug Manufacturing Licence by way of formulation. He further contended that University may be allowed to avail the facility for research purpose. The Board after hearing the representative of the University decided to cancel the Drug Manufacturing Licence No. 000859 by way of Formulation in the name of M/s University of Sargodha Pharmaceutical Laboratories, Sargodha under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Regsitering and Advertising) Rules, 1976. The Board also decided to seek detailed proposal from the University for future utility of the facilty.

**Case No. 11. NON DEPOSITION OF CRF SINCE 2010 BY M/S ZUMARS PHARMA, FTY. (PVT) LTD., KARACHI UNDER DML NO.000116 (FORMULATION)**

A letter was received from Director (B&A), DRAP, Islamabad wherein he had informed the Licensing Division that the CRF status of M/s Zumars Pharma, FTY, (Pvt) Ltd., Karachi is outstanding since
01-07-2010 till date in response, a letter dated 15-05-2018 was issued to the firm to submit no objection certificate (updated CRF) issued from Statistical Officer DRAP within fifteen days positively.

The firm has not submitted the no objection certificate (updated CRF) till date.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

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 Rule12 and Rule 19(14) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why theDML No. 000116 by way of formulation of M/s Zumars Pharma, FTY, (Pvt) Ltd., Karachi may not be suspended by Central Licensing Board.

The show cause notice dated 31st January, 2019 was issued to the firm. The reply of the show cause notice is not received. The firm is called for personal hearing vide letter dated 19th February, 2019.

**Decision by the Central Licensing Board in 269th meeting**

Mr. Yasin Ilyas, Managing Director of the Company appeared before the Board and submitted Nothing Due Certificaate issued by Division of Budget and Accounts to the company and contended that since Nothing due Certicate has been issued therefore ShowCause Notice may be withdrawn. The Board after hearing the represtative of the firm decided to cease the operation of Show Cause Notice issued the company.

**Case No. 12. GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. APEX PHARMACEUTICALS (PVT) LTD, KARACHI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachi.DML No. 000746 (Formulation)**Period**: 27-08-2017 to 26-08-2022 | **08-08-2018** | **N/A** | 1. Dr. Abdullah Dayo, Member CLB.
2. Dr. Saif-ur-Rehman, Director CDL, Karachi.
3. Mr. Abdul Rasool Sheikh, FID, DRAP, Karachi.
 |
| **Recommendations of the panel: -**The panel conducted inspection on 08-08-2018 and noted following observations;Observations: 1. During inspection the panel came to know that the firm had been granted DML No. 000746 (Formulation) in the year 2012 and in the subsequent years the firm got almost 16 registrations in all four approved sections that are Tablet (General), Capsule (General), Capsule (Cephalosporin) and Dry Powder Suspension (Cephalosporin).
2. The panel observed that firm had not manufactured a single batch of any of their registered products. The in complete documents were shown purporting the only trial batch of Cefixime manufacturing during past six years.
3. The panel observed the unit under inoperable conditions and management was of the view that due to high operational cost and limited number of registrations they were unable to start it for commercial purpose.
4. The panel observed that the firm had relocated some of their storage areas and provided HVAC aimlessly in those sections. The additional section of Cream/Ointment was noted incomplete during inspection.
5. It was very difficult for the panel to asses their current GMP compliance lever amid such inactive conditions although firm possesses sufficient number of registrations and could have started production to meet the national regulatory requirements.

**Conclusion.** Based on the above observations the panel decided to defer the grant of renewal of their DML, grant of additional section of Cream/Ointment and regularization of their existing LOP. Panel further requests the board concerned to see the current inactive status of their DML under DRAP Act, 2012/Drug Act, 1976.**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue showcause notice under secion 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The show cause notice dated 29th January, 2019 was issued to the firm. The reply of the show cause notice is not received. The firm is called for personal hearing vide letter dated 19thFebruary, 2019.**Decision by the Central Licensing Board in 269th meeting**Syed Azhar ul Hassan, General Manager of M/s Apex Pharmaceuticals (Pvt) Ltd., Plot No.D-21-A/1, S.I.T.E., Super highway, Karachiappeared before the Board. He contended that most of the rectifications have been made as pointed out by the panel and Lay out plan as per advice of the panel has been revised and submitted with Division of Licensing for approval. As soon as Lay out plan is approved they would make improvements and accordingly one month time may be given. The Board after hearing the representative of the firm decided to give one month period to the firm to make improvements as per revised Lay out plan. The company shall submit request for re-inspection of the unit once improvements and rectification are made and accordingly a panel would be constituted to conduct inspection for consideration of the Board. Meanwhile Licence of the company shall remain suspended for the said period. Production shall be resumed after approval by the Central Licensing Board. |

**Case No. 13. GRANT OF RENEWAL OF DRUG MANUFACTURING LICENSE OF M/S. SPENCER & COMPANY (PVT) LTD, KARACHI**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | M/s Spencer & Company (Pvt) Ltd, D-105, S.I.T.E, Karachi.DML No. 000272 (Formulation)**Period**: 19-07-2015 to 18-07-2020 | **13-09-2018 &18-10-2018** | **Un-satisfactory** | 1. Mr. Syed Muied Ahmed, Member Central Licensing Borad.
2. Director DTL, Sindh Karachi. (**Not available**)
3. Director CDL, DRAP, Karachi
4. Area Federal Inspector of Drugs, DRAP, Karachi.
 |
| **Recommendations of the panel: -****Conclusion:-**1. Firm has some penicillin, veterinary and Topical products which needs to be de-registered forthwith as no dedicated sections exist for them.
2. The available arrangements with the firm for production and quality control of their registered products needs massive up gradation / improvements especially in areas mentioned under pint no. 4 of Observations, for compliance with cGMP regulations.

**Recommendations:-**1. Penicillin, Topical products and veterinary products registered in the name of the firm should be de-Registered forthwith as no dedicated sections exist for them.
2. Renewal of drugs manufacturing license (No. 000272 By way of Formulation) may be deferred till rectification of observations/ Improvements as identified by the panel. **Renewal not recommended**.

**Decision by the Central Licensing Board in 267th meeting**The Board considered the case and decided to issue show cause notice under section 41 of the Drugs Act 1976 read with under Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the Drug Manufacturing License may not be suspended for the period as provided in the Rule, 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**Proceedings of Licensing Division in compliance to the decision of Central Licensing Board.**The show cause notice dated 29th January, 2019 was issued to the firm. The reply of the show cause notice is not received. The firm is called for personal hearing vide letter dated 19th February, 2019.**Decision by the Central Licensing Board in 269th meeting**No person appeared on behalf of the company. Moreover, a letter was recived on the date meeting from the Company wherein it was requested that they may be called in next meeting to resond the Showcause. The Board after perusal of letter decided to give final opportunity to the firm in the next meeting of the Central Licensing Board. |

**Case No. 14. CHANGE OF TITLE OF M/S GLAXOSMITHKLINE OTC CONSUMER HEALTH CARE PAKISTAN LTD, [FORMERLY M/S. GLAXOSMITHKLINE OTC PRIVATE LIMITED] JAMSHORO**

M/S GlaxoSmithKline Consumer Health Care Pakistan Ltd, [Formerly M/s. GlaxoSmithKline OTC Private Limited] Jamshoro, under DML No. 000010 by way of formulation has submitted request for change of title of the firm as per Certificate of incorporation Form S.E.C.P with prescribed Fee Challan of Rs.50,000/-. The detail is as under:

|  |  |
| --- | --- |
| **Existing Name**  | **New Name** |
| M/s. GlaxoSmithKline OTC Private Limited | M/s. GlaxoSmithKline Consumer Health Care Pakistan Limited |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and endorsed the change of title / name of M/S GlaxoSmithKline Consumer Health Care Pakistan Ltd, [Formerly M/s. GlaxoSmithKline OTC Private Limited] Jamshoro, under DML No. 000010 by way of formulation as under ;

|  |  |
| --- | --- |
| **Existing Name**  | **New Name** |
| M/s. GlaxoSmithKline OTC Private Limited | M/s. GlaxoSmithKline Consumer Health Care Pakistan Limited |

**Case No.15. CHANGE OF MANAGEMENT OF M/S GLAXOSMITHKLINE CONSUMER HEALTH CARE PAKISTAN LTD, [FORMERLY M/S. GLAXOSMITHKLINE OTC PRIVATE LIMITED] JAMSHORO.**

M/S GlaxoSmithKline Consumer Health Care Pakistan Ltd, [formerly M/s. Glaxosmithkline OTC Private Limited]Jamshoro, under DML No. 000010 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Incoming Management** | **New management**  |
| 1. Mr. Syed Azeem Abbas Naqvi S/o Syed Takreem Hussain Naqvi

CNIC: 35202-2835969-1.1. Mr. Sohail Ahmed S/o Mohammad Matin

CNIC: 42000-9133745-7. | 1. Mr. Husain Lawai S/o Haji Moosa

CNIC: 914000-140464-5.1. Ms. Emine Tasci Kaya D/o Yildiz Tasci

Passport No: U00287385.1. Ms. Annelize Roberts D/o David William Roberts

Passport No: 510602988.1. Mr. Syed Anwar Mahmood S/o Syed Mahmood

CNIC: 61101-7697428-9.1. Mr. Talal Javed Ahmed S/o Javed Ahmed

CNIC: 42201-8932528-1.1. Mr. Muhmmad Zindah Moin Mohajir S/o Muhmmad Abdullah Mohajir

CNIC: 42301-8664878-1. | 1. Mr. Syed Azeem Abbas Naqvi S/o Syed Takreem Hussain Naqvi

CNIC: 35202-2835969-1.1. Mr. Sohail Ahmed S/o Mohammad Matin

CNIC: 42000-9133745-7.1. Mr. Husain Lawai S/o Haji Moosa

CNIC: 914000-140464-5.1. Ms. Emine Tasci Kaya D/o Yildiz Tasci

Passport No: U00287385.1. Ms. Annelize Roberts D/o David William Roberts

Passport No: 510602988.1. Mr. Syed Anwar Mahmood S/o Syed Mahmood

CNIC: 61101-7697428-9.1. Mr. Talal Javed Ahmed S/o Javed Ahmed

CNIC: 42201-8932528-1.1. Mr. Muhmmad Zindah Moin Mohajir S/o Muhmmad Abdullah Mohajir

CNIC: 42301-8664878-1. |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and endorsed the change of management of M/S GlaxoSmithKline Consumer Health Care Pakistan Ltd,, [formerly M/s. Glaxosmithkline OTC Private Limited] Jamshoro, under DML No. 000010 by way of formulationas under ;

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Syed Azeem Abbas Naqvi S/o Syed Takreem Hussain Naqvi CNIC: 35202-2835969-1.
2. Mr. Sohail Ahmed S/o Mohammad Matin CNIC: 42000-9133745-7.
 | 1. Mr. Husain Lawai S/o Haji Moosa

CNIC: 914000-140464-5.1. Ms. Emine Tasci Kaya D/o Yildiz Tasci

Passport No: U00287385.1. Ms. Annelize Roberts D/o David William Roberts

Passport No: 510602988.1. Mr. Syed Anwar Mahmood S/o Syed Mahmood

CNIC: 61101-7697428-9.1. Mr. Talal Javed Ahmed S/o Javed Ahmed

CNIC: 42201-8932528-1.1. Mr. Muhmmad Zindah Moin Mohajir S/o Muhmmad Abdullah Mohajir

CNIC: 42301-8664878-1. | 1. Mr. Syed Azeem Abbas Naqvi S/o Syed Takreem Hussain Naqvi

CNIC: 35202-2835969-1.1. Mr. Sohail Ahmed S/o Mohammad Matin

CNIC: 42000-9133745-7.1. Mr. Husain Lawai S/o Haji Moosa

CNIC: 914000-140464-5.1. Ms. Emine Tasci Kaya D/o Yildiz Tasci

Passport No: U00287385.1. Ms. Annelize Roberts D/o David William Roberts

Passport No: 510602988.1. Mr. Syed Anwar Mahmood S/o Syed Mahmood

CNIC: 61101-7697428-9.1. Mr. Talal Javed Ahmed S/o Javed Ahmed

CNIC: 42201-8932528-1.1. Mr. Muhmmad Zindah Moin Mohajir S/o Muhmmad Abdullah Mohajir

CNIC: 42301-8664878-1. |

**Case No.16. CHANGE OF MANAGEMENT OF M/S HARRISON PHARMACEUTICALS,SARGODHA.**

M/s Harrison Pharmaceuticals, 10-Km Lahore Road,Sargodha under DML No. 000634by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Abdul Ghafir S/O Abdul QayyumCNIC: 35202-5304270-12. Mr. Irfan Gulzar Anjum S/O Gulzar MuhammadCNIC: 38403-2956767-53. Mr. Muhammad Irshad Uppal S/O Muhammad Nawab ud Din UppalCNIC: 35200-7366578-34. Mr. Usman Ali S/O Muhammad Gulazr KhanCNIC: 35202-2193693-35. Mr. Sajjad Hussain S/O Muhammad Gulzar KhanCNIC : 35202-7516210-16. Dr. Muhammad Saleem S/O Muhammad SiddiquiCNIC : 37405-0355334-1.7. Dr. Muhammad Zubair Faisal S/O Muhammad HafeezCNIC : 35202-6439427-38. Mr. Rashid Iqbal S/O Muhammad IqbalCNIC : 35202-3203509-1 | 1. Mr. Abdul Ghafir S/O Abdul QayyumCNIC: 35202-5304270-12. Rashid Iqbal S/O Muhammad IqbalCNIC: 35202-3203509-1 | 1. Mr. Irfan Gulzar Anjum S/O Gulzar MuhammadCNIC: 38403-2956767-5.2. Mr. Muhammad Irshad Uppal S/O Muhammad Nawab ud Din UppalCNIC: 35200-7366578-3.3. Mr. Usman Ali S/O Muhammad Gulzar KhanCNIC: 35202-2193693-3.4. Mr. Sajjad Hussain S/O Muhammad Gulzar KhanCNIC : 35202-7516210-1.5. Dr. Muhammad Saleem S/O Muhammad SiddiquiCNIC : 37405-0355334-1.6. Dr. Muhammad Zubair Faisal S/O Muhammad HafeezCNIC : 35202-6439427-3.7. Mr. Amir Saeed Kazi S/o Kazi Muhammad Saeed CNIC No. 35202-4171375-7.8. Mr. Adil Saeed Kazi S/o Kazi Muhammad Saeed CNIC No. 35202-4066970-7. |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and endorsed the change of management of M/s Harrison Pharmaceuticals, 10-Km Lahore Road,Sargodha under DML No. 000634by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Existing management**  | **Retiring Management** | **New management**  |
| 1. Mr. Abdul Ghafir S/O Abdul QayyumCNIC: 35202-5304270-12. Mr. Irfan Gulzar Anjum S/O Gulzar MuhammadCNIC: 38403-2956767-53. Mr. Muhammad Irshad Uppal S/O Muhammad Nawab ud Din UppalCNIC: 35200-7366578-34. Mr. Usman Ali S/O Muhammad Gulazr KhanCNIC: 35202-2193693-35. Mr. Sajjad Hussain S/O Muhammad Gulzar KhanCNIC : 35202-7516210-16. Dr. Muhammad Saleem S/O Muhammad SiddiquiCNIC : 37405-0355334-1.7. Dr. Muhammad Zubair Faisal S/O Muhammad HafeezCNIC : 35202-6439427-38. Mr. Rashid Iqbal S/O Muhammad IqbalCNIC : 35202-3203509-1 | 1. Mr. Abdul Ghafir S/O Abdul QayyumCNIC: 35202-5304270-12. Rashid Iqbal S/O Muhammad IqbalCNIC: 35202-3203509-1 | 1. Mr. Irfan Gulzar Anjum S/O Gulzar MuhammadCNIC: 38403-2956767-5.2. Mr. Muhammad Irshad Uppal S/O Muhammad Nawab ud Din UppalCNIC: 35200-7366578-3.3. Mr. Usman Ali S/O Muhammad Gulzar KhanCNIC: 35202-2193693-3.4. Mr. Sajjad Hussain S/O Muhammad Gulzar KhanCNIC : 35202-7516210-1.5. Dr. Muhammad Saleem S/O Muhammad SiddiquiCNIC : 37405-0355334-1.6. Dr. Muhammad Zubair Faisal S/O Muhammad HafeezCNIC : 35202-6439427-3.7. Mr. Amir Saeed Kazi S/o Kazi Muhammad Saeed CNIC No. 35202-4171375-7.8. Mr. Adil Saeed Kazi S/o Kazi Muhammad Saeed CNIC No. 35202-4066970-7. |

**Case No.17. CHANGE OF MANAGEMENT OF M/S OBSONS PHARMACEUTICALS, LAHORE.**

 M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, under DML No. 000416 by way of formulation has submitted request for change in management of the firm as per Partnership deed along with prescribed Fee Challan of 50,000/-. The detail of management is as under:-

|  |  |  |
| --- | --- | --- |
| **Previous management**  | **Interim management**  | **New Management**  |
| 1. Mr. S.M Naeem Ullah S/o Shaikh Ubaid Ullah CNIC No. 35201-7048684-3.
2. Mr. S.M Inam Ullah.
3. Ms. Mumtaz Begum.
 | 1. Mr. S.M Naeem Ullah S/o Shaikh Ubaid Ullah CNIC No. 35201-7048684-3.
 | 1. Mr. Salah-ud-din Gondal S/o Haji Muhammad Ishaq Gondal CNIC No. 35202-7730120-5.
2. Mr. Muhammad Abu Bakar Gondal S/o Salah-ud-din Gondal CNIC No. 35202-7529670-5.
3. Ms. Asma Salah-ud-din D/o Salah-ud-din Gondal CNIC No. 35202-4330935-8.
4. Mr. Noor Hussain Gondal S/o Muhammad Ibrahim Gondal CNIC No. 35202-3033622-3.
 |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and endorsed the change of management of M/s Obsons Pharmaceuticals, 209-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore, under DML No. 000416 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous management**  | **Interim management**  | **New Management**  |
| 1. Mr. S.M Naeem Ullah S/o Shaikh Ubaid Ullah CNIC No. 35201-7048684-3.
2. Mr. S.M Inam Ullah.
3. Ms. Mumtaz Begum.
 | 1. Mr. S.M Naeem Ullah S/o Shaikh Ubaid Ullah CNIC No. 35201-7048684-3.
 | 1. Mr. Salah-ud-din Gondal S/o Haji Muhammad Ishaq Gondal CNIC No. 35202-7730120-5.
2. Mr. Muhammad Abu Bakar Gondal S/o Salah-ud-din Gondal CNIC No. 35202-7529670-5.
3. Ms. Asma Salah-ud-din D/o Salah-ud-din Gondal CNIC No. 35202-4330935-8.
4. Mr. Noor Hussain Gondal S/o Muhammad Ibrahim Gondal CNIC No. 35202-3033622-3.
 |

**CASE NO.18. REGULARIZATION / AMENDMENT OF REVISED LAYOUT PLAN OF M/S GEOFMAN PHARMACEUTICAL, PLOT NO. 20, SECTOR 23, KORANGI INDUSTRIAL AREA, KARACHI.**

M/S Geofman Pharmaceutical, Plot NO. 20, Sector 23, Korangi Industrial Area, Karachi., DML No. 000090 (Formulation), has applied for regularization of layout plan of running facility for their existing sections which were licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory:

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

1. Mr. Syed Muied Ahmed, Member Central Licensing Board.
2. Dr. Najam-us-saqib, FID/Additional Director, Karachi

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

**Following are the observations:**

*“*M/s Geofman Pharmaceuticals is a multiproduct facility and is an old pharmaceutical manufacturing facility that has been inspected on regular basis from time to time. The firm was inspected to verify the existence of the manufacturing sections as per layout plan:

|  |
| --- |
| **GROUND FLOOR** |
| **Sr. No** | **Name** | **Sr. No** | **Name** |
|  |  Tablet (General) Section. |  | Capsule (General Antibiotic) Section. |
|  |  Capsule (General) Section. |  | Dry Syrup (Cephalosporin) Section. |
|  | Liquid Syrup (General) Section |  | Capsule (Cephalosporin) Section.  |
|  | Liquid Injectbale (General) Section. |  | Sachet (Cephalosporin) Section. |
|  | Large Volume Parentrals (General) Section. |  | Dry Powder Injectable (Cephalosporin) Section. |
|  | Nasal Drop Section. |  | Packing Material Store. |
|  | Tablet Section (General Antibiotic) Section. |  | Raw Material Store & Finished Goods Store. |
| **FIRST FLOOR** |
|  | Small Volume Parentrals (General)Section |  | Dry Suspension (Pencillin) Section |
|  | Capsule Pallet Filling (General)Section |  | Cream/Ointment section |
|  | Injectable (Hormone) Section |  | Ampoule Compact Line Section **(additional)** |
|  | Tablet (Pencillin) Section |  | Quality Control Laboratory |
|  | Capsule (Pencillin) Section |  | **\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*** |

During the detailed inspection and verification, it revealed that all the above sections are as per layout plan approved by the DRAP authorities except the following:

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Name** | **Remarks** |
|  | Capsule (General Antibiotic) Section | In the map the capsule antibiotic section does not exist on the ground floor, but as per physical verification it was observed that the capsule antibiotic area is located in the general antibiotic section at the ground floor. Management explained that due to typographical error encapsulation cubicle did not mentioned in the general antibiotic section. A corrected copy of layout plan is also attached alongwith this report. |
|  | Packaging Material Store | Packaging material store is located at the second floor physically as shown on the layout plan (However it is mentioned in the afore mentioned DRAP letter on the first floor). |

**Conclusion:**

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, regularization of the Layout plan for all the above-mentioned section is recommended with the following corrections:

|  |  |  |
| --- | --- | --- |
| **Sr. No** | **Name** | **Remarks** |
|  | Capsule (General Antibiotic) Section | This section exists on the ground floor in the general antibiotic section. |
|  | Packaging Material Store | Packaging material store is located at the second floor physically as shown on the layout plan (However it is mentioned in the afore mentioned DRAP letter on the first floor). |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved regularization of the lay out plan as per recommendations of the panel of experts.

**Case No.19. GRANT OF DRUGS FOR RE-PACKING:**

M/s Medicure Laboratories, F/109, S.I.T.E, Hub River Road, Karachi, under DML No. 000034 by way of formulation has submitted request for Grant of following Re-packing drugs as per Schedule-D. Firm has submitted challan Fee of 5,000/ per product.

|  |  |  |
| --- | --- | --- |
| **Sr. No.** | **Drug** | **Schedule-D** |
|  | Methyl salicylate | Yes |
|  | Zinc Oxide | Yes |
|  | Sodium Bicarbonate | Yes |
|  | Sodium Citrate | Yes |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved repacking items in the name of M/s Medicure Laboratories, F/109, S.I.T.E, Hub River Road, Karachi as under:

|  |  |
| --- | --- |
| **Sr. No.** | **Drug** |
|  | Methyl salicylate |
|  | Zinc Oxide |
|  | Sodium Bicarbonate |
|  | Sodium Citrate |

**Case No. 20. REQUEST/APPLICATION FOR RETAINNG A SUBSTANTIAL PORTION OF CRF FOR THE YEAR 2017 BY M/S. GETZ PHARMA (PVT) LIMITED, KARACHI UNDER DRUG MANUFACTURING LICENSE NO. 000284 (FORMULATION)**

M/s Getz Pharma (Pvt) Limited Karachi has submitted request for retaining substantial portion of CRF and has stated as under ;

1. At the outset, we would like to state that Sub-Rule 14 of Rule 19 of the Licensing, Registering and Advertising Rules, 1976 (LR&A Rule), requires a pharmaceutical company to contribute one percent of its gross profit before deduction of income tax towards the Central Research Fund to be maintained by the Federal Government.
2. However; under the proviso to this Sub-Rule 14 of Rule 19, the Central Licensing Board may allow a portion of such contribution to be spent by the Firm/Pharmaceutical Company itself for research and development of new drugs or for establishing research laboratories, when it is satisfied that such expenditure is being utilized for the said purpose effectively and properly.
3. To keep the record straight, we would like to submit that Getz Pharma has been paying CRF to DRAP since 1995. The total amount of CRF paid as of today in the last 21 years is Rs. 295.73 million [from 1995-2016].
4. We note with great regret that billions of rupees are lying unutilized in the Central Research Fund for which the pharma companies including Getz Pharma has contributed one percent profit to the CRF under the Rule LR&A Rules.
5. It is submitted that the total one percent CRF contribution of Getz Pharma for the year, 2017, comes to Rs. 86.49 million. However, the sums of investments made towards research and development of new drugs and/or for establishing research laboratories in the year, 2017, are Rs. 232 million. As it is obvious, the amount of investments and expenditure incurred by Getz Pharma in the year, 2017, it almost three times more than the annual CRF contribution of Getz Pharma for the year, 2017.
6. Therefore, in view of the forgoing provisions and submissions, we would like to make our requests as follows:
7. **In accordance with Sub-Rule (14) of Rule 19 of the LR & A Rules, Getz Pharma may kindly be allowed to retain a substantial portion out of one percent CRF annual contribution on the grounds that it has already made substantial investment towards development of new drugs and establishing research laboratories/facilities, in the year, 2016, which investments exceed the prescribed limit of one percent. A summary of investments and audit reports are enclosed herewith (which can be substantiated with documentary proof as and when so required). We would also like to note that Getz Pharma is continuously making, and will be making, investments towards the development of new drugs and establishing research laboratories/facilities and we are willing to provide details of such continuous and future investments, as and when required (subject to requirements of business and trade confidentiality).**
8. **We should be informed as to the quantum of the CRF contribution which can be retained by Getz Pharma.**
9. As you are already aware, and as is our legal right, the contribution to CRF is subject to intimation by DRAP regarding the quantum of the contribution which can retained by the company. Therefore, once you have informed us as to how much of the contribution can be retained by Gets Pharma and what the balance reminder amount is, the balance remainder amount will be deposited by Getz Pharma.
10. In the meantime, no adverse or coercive action, including but not limited to suspension of Getz Pharma’s routine work concerning pending or new registration applications, should be taken by DRAP. Please note that in relation to CR amount, we have filed a Constitution Petition No. 3896 of 2016, which is pending before the Honorable High Court of Sindh, and through Order dated 01-07-2016, the Honorable High Court has been pleased to restrain DRAP from taking my adverse or coercive action against us. Therefore, if any adverse or coercive action, including but not limited to suspension of Getz Pharma’s routine work concerning the pending new registration applications is taken against Getz Pharma by DRAP, We reserve the right to institute contempt proceedings against you and other relevant officials. Similarly, another Const. Petition No. D-5820 of 2017 is also pending before the Honorable Sindh High Court in relation to CRF amounts for the year, 2016, and the Honorable Sindh High Court was pleased; vide Order dated 11-4-2018, to restrain, inter-alia, DRAP from taking any adverse/coercive action against Getz Pharma.

 Budget & Accounts Division, DRAP, Islamabad has also 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. Getz Pharma (pvt) Ltd, Karachi having DML no. 000284 has submitted CRF till year 2014. 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.

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and deferred the case till decision by the Court on the matter since the matter is *sub judice*.

**CaseNo.21. CHANGE OF MANAGEMENT OF M/S HIRANIS PHARMACEUTICALS (PVT) LIMITED, PLOT NO. E-145 TO 149 NORTH WESTERN INDUSTRIAL ZONE, KARACHI.**

M/s Hiranis Pharmaceuticals (Pvt) Limited, Plot No. E-145 to 149 North Western Industrial Zone, Karachi, under DML No. 000785by way of formulation has submitted request for change in management of the firm as per Form-1A along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Existing Management**  | **Incoming Management** | **New Management**  |
| 1. Mr. Amin Muhammad S/O Mr. Badar ud Din CNIC NO. 42301-0816444-3
2. Mr. Adnan Hirani S/O Mr. Amin Muhammad CNIC NO. 42301-8515591-3
 | 1. Mr. Ali Shah S/O Mr. Amin Muhammad CNIC No. 42301-4073978-7
 | 1. Mr. Amin Muhammad S/O Mr. Badar ud Din CNIC NO. 42301-0816444-3
2. Mr. Adnan Hirani S/O Mr. Amin Muhammad CNIC NO. 42301-8515591-3
3. Mr. Ali Shah S/O Mr. Amin Muhammad CNIC No. 42301-4073978-7
 |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and endorsed the change of management M/s Hiranis Pharmaceuticals (Pvt) Limited, Plot No. E-145 to 149 North Western Industrial Zone, Karachi, under DML No. 000785by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous management**  | **Interim management**  | **New Management**  |
| 1. Mr. Amin Muhammad S/O Mr. Badar ud Din CNIC NO. 42301-0816444-3
2. Mr. Adnan Hirani S/O Mr. Amin Muhammad CNIC NO. 42301-8515591-3
 | 1. Mr. Ali Shah S/O Mr. Amin Muhammad CNIC No. 42301-4073978-7
 | 1. Mr. Amin Muhammad S/O Mr. Badar ud Din CNIC NO. 42301-0816444-3
2. Mr. Adnan Hirani S/O Mr. Amin Muhammad CNIC NO. 42301-8515591-3
3. Mr. Ali Shah S/O Mr. Amin Muhammad CNIC No. 42301-4073978-7
 |

**Case No.22. CHANGE OF MANAGEMENT OF M/S LEGACY PHARMACEUTICALS (PVT) LTD., PESHAWAR.**

M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad,Peshawar under DML No. 000632 by way of formulation has submitted request for change in management of the firm as per Form-29 along with prescribed Fee Challan of 50,000/- as under:-

|  |  |  |
| --- | --- | --- |
| **Previous management**  | **Interim management**  | **New Management**  |
| 1. Hameed Ullah S/o Ubaid Ullah CNIC No.17301-1670020-1
2. Bashirullah S/o Ubaid Ullah CNIC No.17301-1670011-5
3. Aminullah S/o Ubaid Ullah CNIC No.17301-1670053-7
 | 1. Hameed Ullah S/o Ubaid Ullah CNIC No.17301-1670020-1
 | 1. Bashirullah S/o Ubaid Ullah CNIC No.17301-1670011-5
2. Aminullah S/o Ubaid Ullah CNIC No.17301-1670053-7
 |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and endorsed the change of management M/s Legacy Pharmaceuticals (Pvt) Ltd., Plot No.111, Industrial Estate, Hayatabad,Peshawar under DML No. 000632 by way of formulation as under ;

|  |  |  |
| --- | --- | --- |
| **Previous management**  | **Interim management**  | **New Management**  |
| 1. Hameed Ullah S/o Ubaid Ullah CNIC No.17301-1670020-1
2. Bashirullah S/o Ubaid Ullah CNIC No.17301-1670011-5
3. Aminullah S/o Ubaid Ullah CNIC No.17301-1670053-7
 | 1. Hameed Ullah S/o Ubaid Ullah CNIC No.17301-1670020-1
 | 1. Bashirullah S/o Ubaid Ullah CNIC No.17301-1670011-5
2. Aminullah S/o Ubaid Ullah CNIC No.17301-1670053-7
 |

**Case No. 23 REQUEST FOR CONVERSION OF SECTION FROM TABLETS (HORMONES) INTO TABLETS (STEROID HORMONES)SECTION UNDER LICENSING NO. 000295 (FORMULATION).**

The Central licensing Board in its 257th meeting held on 24-25th January, 2018approved the Tablets (Hormones). Now M/s Pacific Pharmaceuticals Ltd, Lahore has applied for conversion of Tablets (Hormones) into Tablets (Steroid Hormones)**.**

**Decision by the Central Licensing Board in 269th meeting:**

The Board consided and approved change in nomenclature of the section from Tablets (Hormones) into Tablets (Steroid Hormones).

**Case No. 24 REQUEST FOR CONVERSION OF HORMONES SECTIONS INTO STEROID HORMONES SECTIONS UNDER LICENSE NO. 000872 (FORMULATION).**

The Central licensing Board in its 256thmeeting held on 9 & 10th November, 2017 approved the Tablet (Hormone) (Human), Capsule (Hormone) (Human) and Ampoule (Hormone) (Human). Now M/s Pharmasol (Pvt) Ltd, Lahorehas applied for conversion of Tablet (Hormone) (Human), Capsule (Hormone) (Human) and Ampoule (Hormone) (Human) into Tablet (Steroid Hormone) (Human), Capsule (Steroid Hormone) (Human) and Ampoule (Steroid Hormone) (Human) respectively.

**Decision by the Central Licensing Board in 269th meeting:**

The Board consided and approved change in nomenclature of the section from Tablet (Hormone) (Human), Capsule (Hormone) (Human) and Ampoule (Hormone) (Human) into Tablet (Steroid Hormone) (Human), Capsule (Steroid Hormone) (Human) and Ampoule (Steroid Hormone) (Human) respectively

**Case No.25. WITHDRAWAL OF EFFERVESCENT TABLET GENERAL SECTION OF M/S HIRANIS PHARMACEUTICALS (PVT) LIMITED, PLOT NO. E-145 TO 149 NORTH WESTERN INDUSTRIAL ZONE, KARACHI.**

M/s Hiranis Pharmaceuticals (pvt) limited, Plot No. E-145 to 149 north western industrial zone, Karachi, under DML No. 000785by way of formulation has submitted request for withdrawal of effervescent tablet general section

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved cancellation of effervescent tablet general section in the name of M/s Hiranis Pharmaceuticals (pvt) limited, Plot No. E-145 to 149 north western industrial zone, Karachi. Drug Registration Board be informed accordingly.

**Case No. 26 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S MEDICURE LABORATORIES, KARACHI**

M/s Medicure Laboratories, F/109, S.I.T.E, Hub River Road, Karachi, had applied for renewal of DML No. 000034 by way of formulation for the period of 30-04-2015 to 29-04-2020 on 05-05-2015.

 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 23rd February, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. To submit late fee for submission of DML renewal application i.e. Rs.5,000/- per day for 06 days = Rs.5,000x6=Rs.30,000/-.
2. No objection certificate for Central Research Fund (CRF) by Statistical Officer DRAP, Islamabad
3. Legal status of the firm along with details of ownership, attested copies of CNIC’s.
4. List of total section of the firm and their letters of grant which were approved in meetings of Central Licensing Board.
5. Complete documents of technical persons i.e QC Incharge and Production Incharge according to Performa (enclosed).

 The firm submitted their reply on 4th March, 2016. After evaluation of the submitted documents, Final reminder was issued on 7th December, 2017 to the firm with following shortcomings: -

1. Prescribed fee of Rs. 50,000/- for change of management / directors.
2. Detail of all partners / Directors of firm’s letter head alongwith CNIC copies.
3. Approval / Grant letters of all repacking drugs for which renewal of DML is applied alongwith fee of Rs, 5,000/- per drug / product.
4. Complete set of duly attested documents for Proposed Production Incharge and Quality Control Incharge (as per check list).
5. Nothing due certificate regarding CRF from STO (Updated).
6. Approval letters of sections issued by the Central Licensing Board and if not available then submit master layout plan for Regularization of manufacturing facility.
7. **All documents should be duly attested.**

 Firm submitted documents on 22nd December, 2017 in reply to Final Reminder but following documents are still deficient /short and application for renewal of DML is still incomplete.

1. Nothing due certificate regarding CRF from STO (Updated).
2. Approval letters alongwith prescribe fee of Rs. 5,000/- per product for re-packing item / Products.
3. Complete set of duly attested documents for Proposed Production Incharge Ms. Zubia Kawal as her total post qualification experience is less than 10 years which does not fulfill the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) Rules 1976 in term of relevant experience.
4. Resignation / retirement of earlier Quality Control Incharge.
5. Resignation or termination letter of appointee from the previous firm / promotion letter / transfer letter from the same firm (Quality Control Incharge).
6. Job acceptance letter by the appointee (Quality Control Incharge).
7. Undertaking as whole time employee on stamp paper (Quality Control Incharge).
8. Prescribed fee of 10,000/- for Production Incharge and Quality Control Incharge.

**Proceedings and Decision of Central Licensing Board in 259thmeeting**

 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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Medicure Laboratories, F/109, S.I.T.E, Hub River Road, Karachi, Drug Manufacturing Licence No000034 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

 In response to show cause notice Dated: 08-05-2018 firm has submitted documents which are evaluated and renewal application is still found to be deficient of following documents :

1. Nothing due certificate regarding CRF from STO (Updated).
2. Approval letters for re-packing item / Products are not provided. Firm has submitted fee of Rs.20000/-(challan forms not retained by STO (DRAP) for renewal of four (04) repacking items namely Methly salicylate, sodium bicarbonate, Zinc Oxide and sodium citrate but at the time of application for renewal of DML firm claimed that it possess 16 repacking items.
3. Clarify status regarding approval of QC incharge as Previously firm submitted documents of Miss. Shaista Bano as Proposed QC Incharge and firm was advised to submit documents for approval of QC Incharge. In response firm has now claimed that Mr.Sohail Pervez is appointed as a QC incharge since Januaury 1970 and is still continuing his said role/position.The firm has also submitted Undertaking in this regard. Neither approval letter nor the complete set of attested documents of Mr. Sohail Pervez are submitted. Prescribed fee for change of QC incharge is also not submitted.
4. Complete set of duly attested documents for new Production Incharge as Ms. Zubia Kawal (Proposed Production Incharge) has total post qualification experience less than 10 years which does not fulfill the requirements of Rule 16 of Drugs (Licensing, Registering and Advertising) Rules 1976 in term of relevant experience

The firm is called for personal hearing vide letter dated 31st July, 2018.

**Proceedings and Decision of Central Licensing Board in 265thmeeting**

Mr. Ahmed Hassan (General Manager) and Shabbir Hussain Shah (Managing Partner) of the firm appeared before the Central Licensing Board and presented documents and requested for giving one month time for submission of documents. However, the Board after scrutiny of the documents directed the firm to submit certified copies of the same at the earliest. The Board after hearing the representative of the firm decided to defer the case till next meeting of Central Licensing Board.

The firm has submitted the required documents for completion of application for renewal of DML and application for renewal of DML is complete.

**Decision by the Central Licensing Board in 269th meeting:**

The Baord considered and ratified the decision taken by the Chirman, Central Licensing Board

**CASE NO.27. CORRECTION IN THE NAME OF M/S VETEC LABORATORIES, PLOT NO. 20, LANE S-5, RCCI, INDUSTRIAL AREA, RAWAT, ISLAMABAD.**

**Case Background**

The Board considered and approved the grant of Drug Manufacturing License by way of formulation in its 267th meeting of Central Licensing Board held on 31st December, 2018 in the name of M/s Vetec Laboratory, Plot No. 20, S-5, RCCI, Rawat.

It is submitted that the correct name of the firm is as under:-

|  |
| --- |
| M/s Vetec Laboratories, Plot No. 20, Street S-5, RCCI, Rawat.  |

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved the correction as under

|  |
| --- |
| M/s Vetec Laboratories, Plot No. 20, Street S-5, RCCI, Rawat.  |

**Case No.28. SITE VERIFICATION REPORT OF ALBRO PHARMACEUTICALS (PVT) LTD, DISTRICT KASUR.**

 A site verification report of **M/s Albro Pharmaceuticals (Pvt) Ltd, Khewat No. 197/180, Khatooni No. 345, District Kasur** has been received. The inspection was conducted by Mr. Asim Rauf Additional Director (E&M) DRAP, Lahore and Ms. Uffaq Tanveer, FID Lahore on 29-10-2018. The recommendations of the inspection report are as under: -

*“The site was located in the industrial Estate Kasur. Out side the said site three were three brick klins, within the vicinity of the plot, the view point of the firm was consider following reasoning.*

1. *Environmental Department Kasur issued letter for suitability.*
2. *Environmental control is done with HVAC system, then minimizing contamination form out side.*
3. *Government is committed to shift present brick klins to environmental trendily in near future.*

*The panel gave a through consideration to the location and view point of the firm above. Panel also deliberated that proper HVAC after installation keeps to achieve the desired level of conditions of atmosphere in terms of cleanliness temperature, humidity etc.*

***Keeping in view of above situation, review of documents provided by the firm, the role of HVAC and the present status of Industrial Zone of the site, Panel recommends the suitability of the site.***

*However panel also recommends to take proper risk assessment report from the manufactures, in case three brick kilns are not removed before start of operations”.*

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved the site for establishment of Pharmaceutical Unit as recommended by the panel. The Board also approved that assessment report as recommended by the panel shall be carried by the firm and submitted with the recommendation of Additional Director, Drug Regulatory Authority of Pakistan, Lahore.

**Case No. 29 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BIO FINE PHARMACEUTICALS (PVT) LTD, MULTAN.**

M/s Bio Fine Pharmaceuticals (Pvt) Ltd, 74-Industrial Estate, Multan had applied for renewal of DML No. 000334 by way of formulation for the period of 19-07-2014 to 18-07-2019 on 09-07-2014.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 3rd November, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form – 29 from the S.E.C.P.
2. Details of Management / Directors / Partners of company.
3. Attested CNIC copies of all Management / Directors / Partners.
4. Approval letters of Quality Control / Production Incharge also mention (if any changes).
5. Any change in management / Directors / Partners also mention (if any changes) then documents for approval.
6. NOC for Central Research Fund.

The firm submitted their reply on 24th January, 2016 and final reminder dated 3rd May, 2018 was issued to the firm with following shortcomings: -

1. Nothing due certificate regarding CRF from STO (updated).
2. Updated Form-29 duly attested from S.E.C.P along with CNIC copies of all directors.
3. Prescribed fee of Rs.50,000/- for change ofthe management.
4. Proof of all sections issued by the Central Licensing Board.
5. All documents should be duly attested.

Reply of the firm is still awaited and application for renewal of DML is incomplete as of today.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

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) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why the application for renewal of DML No. 000334 by way of formulation of M/s Bio Fine Pharmaceuticals (Pvt) Ltd,
74-Industrial Estate, Multan may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The firm submitted shortcomings in the application for renewal of DML and Chairman Central Licensing Board passed orders for revocation of Show Cause notice upon completion of application for renewal of DML.

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and ratified the decision taken by the Chairman, Central Licensing Board.

**Case No.30. CITI PHARMA (PVT) LTD UNDER DRUG MANUFACTURING LICENCE NO. 000429 (SEMI BASIC MANUFACTURE)**

 The DML No. 000429 (Semi Basic Manufacture) was issued to M/s Citi Pharma (Pvt) Ltd located at 3.5-Km, Head Balloki Road, Phool Nagar Kasur. The firm then claimed in the application for renewal of DML that the correct address of the firm is “3-Km, Head Balloki Road, Phool Nagar Kasur” and they have mistakenly mentioned the address as “3.5-Km, Head Balloki Road, Phool Nagar Kasur”. Additional Director (E&M), DRAP, Lahore was requested to verify / identify the correct physical address of the firm for further proceeding their application. Now Mr. Ajmal Sohail Asif, FID, DRAP, Lahore has verified that the firm was situated at 3-Km, Head Balloki Road, Phool Nagar, Kasur as measured from start of the road of Phool Nagar to Main gate of the firm through vehicle odometer.

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved the correct address to be mentioned on Licence as under:

M/s Citi Pharma (Pvt) Ltd .,3-Km, Head Balloki Road, Phool Nagar, Kasur under DML No. 000429 (Semi Basic Manufacture)

**Case No.31** **RENEWAL OF DRUG MANUFACTURING LICENSE NO. (000209) (FORMULATION) OF M/S CHIESI PHARMACEUTICALS (PVT) LTD [FORMERLY M/S JAMSON PHARMACEUTICALS LABS], MULTAN.**

M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multan was issued the License No. 000209 (Formulation) the application for renewal of DML is not received.It is pertinent to mention that Rule 5 (6) of Drug (L, R & A) Rule, 1976 states *“if an application of renewal is made after the expiry of the period of validity of License but within 60 days of expiry, the License shall continue in force on payment of additional surcharge of Rs. 5,000/- per day the application is delayed and thereafter until orders are passed on such application”.* But in this case the application for renewal of DML for the period 27-06-2014 to 26-06-2019has not been received till date. Moreover, Federal Inspector of Drugs, Lahore has reported that he has visited the premises of the firm and no any person was available and gate was locked. He knocked the door many times but no any response was received. Moreover, no any corresponding record or any status of the firm is available in his office file regarding availability of its DML. Therefore, DML No. 000209 (Formulation) M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multan may be declared as invalid hence cancelled.

**Proceedings and Decision of Central Licensing Board in 262ndmeeting**

The Board considering the facts on the record and after thread bare deliberation decided to serve Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 6 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multan under DML No. 000209 by way of formulation may not be declared cancelled by Central Licensing Board.

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

The Show Cause notice dated 26th July 2018 was issued to the M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multan

The show cause notice of M/s Chiesi Pharmaceuticals (Pvt) Ltd [Formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multan, is returned back with the remarks “دریافت کر نے پر معلوم ہوا ہے کہ فیکٹری عر صہ دراز سے بند ہےلہزا واپس جا ئے”.

Licensing Division requested to the Additional Director (E&M), DRAP, Lahore to ensure delivery and receiving of aforesaid letter to the applicant.

Mr. Abdul Rashid Shaikh, Area FID, Lahore forwarded the reply of M/s Chiesi in which the firm has stated that we M/s Chiesi Pharmaceuticals (Pvt) Ltd, 60/1A,XX, Phase-III, Commercial Zone, Khayaban-e-Iqbal, Lahore, 54000, Pakistan established since 1987 being the sole agent of Chiesi Farmaceutici S.p.A, 26/A, Vial Palermo, Parma, Itlay in Pakistan do hereby affirm that we do not own any manufacturing facility here by in Pakistan.

Moreover, Mr. Abdul Rashid Shaikh, Area FID, Lahore informed that the undersigned visited the premises of M/s Jamson Pharmaceuticals Labs, Multan on 18-10-2018, to check the production status of the firm. At the time of visit, a person namely Mr. Ali Khan, introduced him-self as Security Guard was was found available there. He informed name of the new owner of the premises as Mr. Tahir Ameer, Mobile No. 0300-9243826. He further informed that no any production activity was being carried on. The Federal Inspector of Drugs contacted the said Mr. Tahir Ameer, who informed that his brother, namely Mr. Mashood Ameer had purchased this property and now M/s Jamson Pharmaceuticals, exists no more at this premises. Hence, in view of above, the FID suggested that the DML No. 000209 of M/s Jamson Pharmaceuticals Labs, 88-B, Industrial Estate Multan may be cancelled after following the due legal and codal course of procedure.

**Decision by the Central Licensing Board in 269th meeting:**

The Board considering the facts on the record and after thread bare deliberation decided to cancel the Drug Manufacture Licence No. 000209 by way of formulation in the name of M/s Chiesi Pharmaceuticals (Pvt) Ltd [formerly M/s Jamson Pharmaceuticals Labs], 88-A, Industrial Estate, Multanunder Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule, 5(2A) and Rule 6 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

**Case No.32** **ADDITIONAL SECTION OF M/S NOVARTANA PHARMACEUTICALS (PVT) LTD, LAHORE UNDER DRUG MANUFACTURING LICENSE NO. (000738)**

 M/s Novartana Pharmaceuticals (Pvt) Ltd, Lahore has stated that the Central Licensing Board in its 267th held on 31st December, 2018 as considered and approved one additional section i.e. Liquid Injectable Ampoule / Vial (General) Section. Furthermore, the firm intimated that section of Ampoule and Vial have been approved as ONE section whereas Ampoule and Vial have separate area and production facilities as two separate sections the firm has requested to re-consider and issue amended letter for following sections:

1. Liquid Ampoule (General) Section.
2. Vial (SVP) (General) section.

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved approval of section as under :

1. Liquid Ampoule (General) Section.
2. Vial (SVP) (General) section.

**Case No.33. NONCOMPLIANCE OF SUB RULE (14) OF RULE 19 OF THE DRUGS (LICENSING, REGISTRATION AND ADVERTISING) RULE, 1976**

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

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

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

|  |  |  |  |
| --- | --- | --- | --- |
| **Sr.** | **DML No.** | **Name** | **Last Contribution Paid upto (FY)** |
|  | 000053 | M/s Risma Laboratories | 2016 |
|  | 000081 | M/s Specific Research Laboratories | 2010 |
|  | 000086 | M/s Bliss Industries (Pvt) Ltd. | 2013 |
|  | 000092 | M/s National Institute of Health Chak Shahzad Islamabad. | Never |
|  | 000099 | M/s Hussain Traders | 2006 |
|  | 000118 | M/s Standard Drug Company | 2016 |
|  | 000119 | M/s Pakistan Pharmaceutical & Chemical Laboratories (Pvt) Ltd. | 2014 |
|  | 000131 | M/s Alkemy Pharmaceutical Laboratories (Pvt) Ltd. | 2016 |
|  | 000132 | M/s Kohs Pharmaceuticals (Pvt) Ltd. | 2012 |
|  | 000137 | M/s National Absorbent Cottton Mills Co. | 2014 |
|  | 000138 | M/s Ahson Drug Co. | 2016 |
|  | 000148 | M/s Marvi Pharmaceuticals | 2016 |
|  | 000168 | M/s Gaba Pharmaceutical Laboratories | 2010 |
|  | 000197 | M/s Kohinoor Industries | 2016 |
|  | 000203 | M/s Sarco Chemical Industires | 2013 |
|  | 000209 | M/s Chiesi Pharmaceutials (Pvt) Ltd. | Never |
|  | 000244 | M/s IPP (Pvt) Ltd. | - |
|  | 000255 | M/s Pharmacare Laboratories (Pvt) Ltd. | 2016 |
|  | 000257 | M/s Medipak Ltd. | 2016 |
|  | 000259 | M/s Siza International (Pvt) Ltd. | 2016 |
|  | 000282 | M/s Gelcaps (Pakistan) Ltd. | 2013 |
|  | 000284 | M/s Getz Pharma (Pvt) Ltd. | 2014 |
|  | 000295 | M/s Pacific Pharma | 2016 |
|  | 000317 | M/s Imco Pharmaceutical Labs (Pvt) Ltd. | 2016 |
|  | 000344 | M/s Katrina Pharma Industries (Pvt) Ltd. | 2007 |
|  | 000353 | M/s Kakasian Pharmaceuticals (Pvt) Ltd | 2011 |
|  | 000362 | M/s Prime Laboratories (Pvt) Ltd. | 2016 |
|  | 000370 | M/s IPP | 2016 |
|  | 000371 | M/s Yousuf Ali Shah chemical Industries (Pvt) Ltd. | 2016 |
|  | 000373 | M/s Alpha Chemicals (Pvt) Ltd. | 2015 |
|  | 000375 | M/s Tas Pharma (Pvt) Ltd. | 2016 |
|  | 000384 | M/s Ceicil Labs (Pvt) Ltd. | 2015 |
|  | 000389 | M/s Ferroza International Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000404 | M/s Leama Chemi Pharma (Pvt) Ltd. | 2016 |
|  | 000413 | M/s Famous Pharmaceutical | 2014 |
|  | 000421 | M/s Nexus Pharma (Pvt) Ltd. | 2016 |
|  | 000423 | M/s Alza Pharmaceuticals | Never |
|  | 000428 | M/s Flow Pharma (Pvt) Ltd. | 2010 |
|  | 000429 | M/s Citi Pharma (Pvt) Ltd. | 2016 |
|  | 000433 | M/s Ahad International Pharmaceutical Limited  | 2016 |
|  | 000437 | M/s Raazee Therapeutics (Pvt) Ltd. | 2016 |
|  | 000440 | M/s Onyx Pharamaceuticals Industries | 2016 |
|  | 000446 | M/s Delta Pharma (Pvt) Ltd. | Never |
|  | 000449 | M/s Hirra Pharmaceutical Laboratories (Pvt) Ltd. | 2013 |
|  | 000451 | M/s Caylex Pharmaceuticals (Pvt) Ltd. | 2014 |
|  | 000471 | M/s Farmigea Pakistan (Pvt). Ltd. | 2016 |
|  | 000473 | M/s Shifa Laboratories (Pvt) Ltd. | 2014 |
|  | 000502 | M/s Ottoman Pharma | 2016 |
|  | 000511 | M/s CSH Pharmaceutical-North (Pvt) Ltd. | 2016 |
|  | 000512 | M/s Citi Pharma (Pvt) Ltd. | 2016 |
|  | 000536 | Rex Pharmaceuticals Pakistan | Never |
|  | 000549 | M/s Medisearch Pharmacal (Pvt) Ltd. | 2016 |
|  | 000554 | M/s Farmaceutics International | 2016 |
|  | 000593 | M/s Miracle Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000604 | M/s Ameer Pharma (Pvt) Ltd. | 2016 |
|  | 000620 | M/s Maple Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000646 | M/s Fassgen Pharmaceuticals | 2016 |
|  | 000660 | M/s Aventek Pharmaceuticals | 2015 |
|  | 000662 | M/s Sunshine Pharmaceuticals | 2013 |
|  | 000665 | M/s 3S Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000668 | M/s Asian Fibre | 2013 |
|  | 000674 | M/s Silver Surgical Complex (Pvt) Ltd. | 2015 |
|  | 000690 | M/s Med Asia Pharmaceutical (Pvt) Ltd. | 2016 |
|  | 000692 | M/s Rogen Pharmaceuticals | 2015 |
|  | 000695 | M/s Injection System (Pvt) Ltd. | 2015 |
|  | 000704 | M/s Surgi Plast | 2016 |
|  | 000705 | M/s Al-Badar Manufacturing (Pvt) Ltd. | 2015 |
|  | 000709 | M/s Crespak Medical Industries  | 2016 |
|  | 000710 | M/s Medicare Disposable Industries  | 2015 |
|  | 000711 | M/s Siam Pharmaceuticals | 2016 |
|  | 000716 & 730 | M/s National Institute of Health | Never |
|  | 000726 | M/s Basel Pharmaceuticals  | 2014 |
|  | 000730 | M/s Pakistan Institute of Nuclear Sciences & Technology | Never |
|  | 000740 | M/s Unisa Pharmaceutical Industries Ltd. | 2016 |
|  | 000743 | M/s Astle Medical Devices Pakistan (Pvt) Ltd. | Never |
|  | 000746 | M/s Apex Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000749 | M/s Medella Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000757 | M/s Reign Pharmaceuticals  | 2016 |
|  | 000759 | M/s S.N.B Pharma (Pvt) Ltd. | Never |
|  | 000780 | M/s Wisdom Pharmaceutical Industry  | Never |
|  | 000788 | M/s Lasani Healthcare | Never |
|  | 000794 | M/s Ashraf Surgical Cotton & Bandages  | Never |
|  | 000795 | M/s Herbion Pakistan (Pvt) Ltd. | 2016 |
|  | 000797 | M/s Oakdale Pharmaceuticals | Never |
|  | 000809 | M/s Mission Pharmaceuticals | 2016 |
|  | 000810 | M/s Linta Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000812 | M/s Bio-Oxime Pharmaceuticals | Never |
|  | 000816 | M/s Ice Berg Pharmaceuticals (Pvt) Ltd. | Never |
|  | 000818 | M/s Zeta Pharmaceuticals | Never |
|  | 000822 | M/s Mediflow Pharmaceuticals (Pvt) Ltd. | 2016 |
|  | 000829 | M/s GT Pharma (Pvt) Ltd. | 2016 |
|  | 000831 | M/s 3N Lifemed Pharmaceuticals | Never |
|  | 000833 | Moon Pharmaceuticals | Never |
|  | 000836 | M/s Vantage Pharmaceutical | Never |
|  | 000841 | M/s Medipak Ltd. | Never |
|  | 000843 | M/s Simax Chemicals | Never |
|  | 000845 | M/s Genetics Pharmaceuticals (Pvt) Ltd | Never |
|  | 000848 | M/s Biorific Pharma | Never |
|  | 000850 | M/s Divine Pharmaceuticals | Never |
|  | 000851 | M/s Maxitech Pharma (Pvt) Ltd. | Never |
|  | 000853 | M/s Pharmedic Pharmaceutical Industries (Pvt) Ltd. | Never |
|  | 000854 | M/s Karsons Pharmaceuticals | Never |
|  | 000855 | M/s Apsis Pharmaceuticals | Never |
|  | 000856 | M/s Walt Danzay Pharmaceuticals | Never |
|  | 000857 | M/s Perk Pharma (Pvt) Ltd. | Never |
|  | 000858 | M/s Palpex Pharmaceuticals (Pvt) Ltd. | Never |
|  | 000859 | M/s University of Sargodha Pharmaceutical Laboratories | Never |
|  | 000861 | M/s Pharma Zone Chemicals (Pvt) Ltd. | Never |
|  | 000862 | M/s Briell Pharmaceuticals (Pvt) Ltd. | Never |
|  | 000863 | M/s Bio-mark Pharmaceuticals | Never |
|  | 000865 | M/s Albert Pharma (Pvt) Ltd. | Never |
|  | 000866 | M/s Inventor Pharma | Never |
|  | 000867 | M/s Evolution Pharmaceuticals (Pvt) Ltd. | Never |
|  | 000868 | M/s TN Pharmaceuticals (Pvt) Ltd. | Never |
|  | 000869 | M/s N.S Pharma | Never |
|  | 000870 | M/s Newton Health Care (Pvt) Ltd. | Never |
|  | 000871 | M/s AAA Health Pharmaceutical Laboratories | Never |
|  | 000872 | M/s Pharmasol (Pvt) Ltd | Never |
|  | 000873 | M/s Majestic Pharma | Never |
|  | 000874 | M/s winlet Pharmaceuticals (Pvt) Ltd | Never |
|  | 000875 | M/s Relizon Pharmaceuticals | Never |
|  | 000876 | M/s Multi Caps | Never |
|  | 000877 | M/s Neutro Pharma (Pvt) Ltd. | Never |
|  | 000878 | M/s MedPharm Research Lab | Never |
|  | 000879 | M/s Effort Pharmaceuticals (Pvt) Ltd | Never |
|  | 000880 | M/s Fahmir Pharma (Pvt) Ltd | Never |
|  | 000881 | M/s Liven Pharmaceuticals (Pvt) Ltd | Never |
|  | 000882 | M/s Wezen Pharmaceuticals | Never |
|  | 000883 | M/s Parkar Pharma | Never |
|  | 000884 | M/s Hi-Med Pharmaceuticals (Pvt) Ltd. | Never |

**Decision by the Central Licensing Board in 269th meeting:**

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

**Case No. 34 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S BASEL PHARMACEUTICAL, MULTAN.**

M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan had applied for renewal of DML No. 000726 by way of Formulation for the period of 21-06-2016 to 20-06-2021 on 06-06-2016.

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 3rd October, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Form 1-A
2. Classes of Drugs
3. Dosage form of Drugs
4. Name (s) of drugs Registered / approved
5. Chang (s) in name of proprietor / director / partner (If any)
6. Detail of premises including layout plan and proof of section form CLB
7. Nothing due certificate regarding CRF from STO.
8. Resignation of earlier Production Incharge & QC Incharge.
9. Resignation of appointee Production Incharge & QC Incharge from Pervious firm.
10. Experience of QC Incharge is less than 10 year.
11. Job Acceptance / joining letter from production Incharge.

No reply was receive from the firm. Final Reminder letter was issued on 10thJanuary, 2017 to the firm for submission of following documents.

1. Form1-A duly signed and stamped.
2. Classes of Drugs.
3. Dosage Forms of Drugs.
4. Name(s) of drugs registered/Approved.
5. Detail of premises including approved master layout plan.
6. Proof of sections approved by CLB.
7. CNIC copies of All Directors/Partners.
8. Nothing due certificate regarding CRF from STO (Updated).
9. Resignation of earlier Production Incharge & QC Incharge.
10. Resignation of appointee Production Incharge & QC Incharge from Pervious firm.
11. Experience certificates of Proposed Production Incharge & QC Incharge(Not less than 10 years in relevant field)
12. Job Acceptance / joining letter from production Incharge.
13. Undertaking as whole time employee on stamp paper of both Production Incharge & QC Incharge.
14. Registration Certificate from pharmacy council of Production Incharge.
15. CNIC copy of Production Incharge.

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

**Proceedings and Decision of Central Licensing Board in 265thmeeting**

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 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why their application for renewal of M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan, under Drug Manufacturing Licence No. 000726 by way of formulation may not be rejected or Drug Manufacturing Licence may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 5th September 2018 was issued to the M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan.

The firm did not reply the show cause notice and the application for renewal of DML is incomplete till date.

A letter of Personal hearing has been issued on 18th October, 2018.

**Proceedings and Decision of Central Licensing Board in 266th meeting**

No person on the behalf of the firm appeared before the Board, therefore, the Central Licensing Board decided to serve the show cause notices to the firm through Additional Director (E&M) DRAP Lahore .

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

The firm replied to Show Cause Notice that Mr. Nadeem Khalid Proprietor of firm due to severe health issues is unable to attend personal hearing. He has further stated that the firm already closed due to maintenance work and also informed Area FID.

Furthermore, Mr. Abdul Rashid Shaikh, Federal Inspector of Drugs, Lahore, has informed that the undersigned visited the premises of M/s Basel Pharmaceuticals, Multan on 18-10-2018, to check the GMP compliance and production status of the firm. At the time of visit, Mr. Muhammad Ayoub, Security Guard was present, who opened the gate of the unit, and informed that owner of the factory, Mr. Nadeem was seriously ill, so the factory was closed since long. Mr. Nadeem was contacted in phone. He confirmed that he was seriously ill and got heart surgery. He also stated that he was not in the position to run the factory. Hence he was directed to inform to DRAP before taking any step and the production will remain stopped meanwhile.

Aletter of Personal hearing has been issued on 24thDecember, 2018.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

No Person appeared on the behalf of firm. The Board after hearing the representative of the firm and considering the facts on the record and after thread bare deliberation decided to suspend the Drug Manufacturing Licence No. 000749by way of formulation issued in the name of M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, Multan till settelemnt of codal formalities under Section 41 of the Drugs Act, 1976 read with Rule, 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 for not complying the provision of Rule 16 and Rule, 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. If the firm completes the codal formalities, the Chairman Central Licensing Board shall pass an order for revocation of suspension. However, case would be brought before Central Licensing Board in forthcoming meeting for endorsement of decision taken by the Chairman.

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

In the aforesaid minutes of meeting of Central Licensing Board, the Drug Manufacturing License No. of the firm was inadvertently typed as “Drug Manufacturing Licence No. 000749 by way of formulation” instead of “Drug Manufacturing Licence No. 000726by way of formulation”.

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved correction in the Drug Licence Number of M/s Basel Pharmaceuticals, Plot No. 227, Phase-II Multan Industrial Estate, MultanDrug Manufacturing Licence No. 000726by way of formulation. Accordingly decision taken in 267th meeting shall be communicated with corrections.

**Case No. 35 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S PRIX PHARMACEUTICA (PVT) LTD, LAHORE.**

|  |  |  |  |
| --- | --- | --- | --- |
| M/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharmacity, 30-Km, Multan Road, Lahore.DML No. 000587 (Formulation)**Period**: Commencing on 15-10-2015 ending on 14-10-2020 | 13-06-2018;10-10-2018&11-12-2018 | **Good** | 1. Dr. Ikram-ul-Haq, Member Central Licensing Board.
2. Mr. Anjum Pervaiz, Consultant, Registration and Licensing, PDCU, Govt. of Punjab.
3. Ms. Uzma Barkat, Federal Inspector of Drugs, Lahore.
4. Ms. Sara Mehreen, Assistant Director, DRAP, Lahore.
 |
| **Recommendations of the panel: -**In the light of the inspection conducted by the panel and based on the findings, the panel of inspectorsrecommended grant of renewal of Drug Manufacturing License by way of formulation ofM/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharmacity, 30-Km, Multan Road, Lahore, for the following veterinary sections:1. Bolus Section (Veterinary).
2. Oral General Powder Section (Veterinary).
3. Oral Powder Section (General Antibiotic)
4. Oral Liquid Section (Veterinary)
5. Liquid Injectable Section (General) (Veterinary)
6. Oral Powder Section Penicillin (Veterinary).

**Decision by the Central Licensing Board in 267th meeting**The Board considered and approved the renewal of Drug Manufacturing Licence No. 000587(Formulation) in the name M/s Prix Pharmaceutica (Pvt) Ltd, Plot No. 05, Pharmacity, 30-Km, Multan Road, Lahore on the recommendations of the panel of experts for the further period of five years commencing on Commencing on 15-10-2015 ending on 14-10-2020 for following secions.1. Bolus Section (Veterinary).
2. Oral General Powder Section (Veterinary).
3. Oral Powder Section (General Antibiotic)
4. Oral Liquid Section (Veterinary)
5. Liquid Injectable Section (General) (Veterinary)
6. Oral Powder Section Penicillin (Veterinary).
 |

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

In the aforesaid minutes of meeting of Central Licensing Board, the renewal of Drug Manufacturing License tenure of the firm was inadvertently typed as “Commencing on 15-10-2015 and ending on 14-10-2020” instead of “Commencing on 16-10-2015 and ending on 15-10-2020”

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and approved correction as proposed above.

**Case No. 36 RENEWAL OF DRUG MANUFACTURING LICENCE OF M/S CEICIL LABORATORIES (PVT) LTD, LAHORE.**

M/s Ceicil Laboratories (Pvt) Ltd, 21-Km Ferozepur Road, Doolu Khurd, Lahore had applied for renewal of DML No. 000384 by way of Formulation for the period of 16-4-2016 to 15-04-2021 on 11-04-2016.

The application for the renewal of DML of the firm was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 18th October, 2016 under Rule 5{2A} of Drugs (Licensing, Registering, Advertising) Rules, 1976:-

1. Detail of management at the time Pervious renewal of DML and present renewal of DML.
2. Classes of Drugs
3. Dosage forms of drugs
4. Name(s) of drugs registered / approved
5. Attested copy of form 29
6. Section wise detail of machinery for Quality Control Lab
7. Approval letter of QC Incharge & Production Incharge
8. Detail of premises including layout plan.
9. Copy of pervious DML
10. Proof of all licensed sections as firm also possessed registration of Narcotic / Psychotropic section & steroid section
11. Nothing due certificate regarding CRF from STO.

The letter issued to the firm returned back and the area FID was requested to ensure the delivery of letter. No reply was receive from the area FID and again a reminder was issued to the Area FID. In the meanwhile Budget and Account Division DRAP, Islamabad submitted that firm has submitted CRF till 2015 and failed to submit CRF as required under Rule 12 of Drugs (L,R&A), 1976.

**Decision by the Central Licensing Board in 269th meeting:**

The Board considered and decided to issue Show Cause Notice to the firm under Section 41 of the Drugs Act, 1976 read with Rule 12 of the Drugs (Licensing, Regisering and Advertising) Rules, 1976 as to why their Drug Manuafcturing Licence No. 000384 in the name of M/s Ceicil Laboratories (Pvt) Ltd, 21-Km Ferozepur Road, Doolu Khurd, Lahore may not be suspende or cancelled or renewl of Drug Manuafcturing Licence may not be rejected for not complying the provision of Rule, 5(2A), Rule, 16, Rule 19 of the Drugs (Licensing, Registering and Advertising) Rues, 1976

**Case No. 37 APPROVAL OF PRODUCTION INCHARGE & QUALITY CONTROL INCHARGE OF M/S DIVINE PHARMACEUTICALS, LAHORE.**

M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore had applied for approval of Production Incharge & Quality control Incharge on 27-07-2018. The application for the was evaluated and a letter for following shortcomings / deficiencies was issued to the firm on 31st August, 2108.

1. Prescribed fee of Rs. 10,000/- alongwith complete set of duly documents of technical staff (as per checklist).

 The firm submitted their reply on 25th September, 2018. After evaluation of the submitted documents, final reminder was issued on 6th November, 2018 to the firm with following shortcomings: -

1. Complete set of duly attested documents of technical staff (as per checklist).

The firm has not replied to Final reminder and application for approval of Production Incharge & Quality control Incharge is incomplete.

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

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, 1976for not complying the provisions of Rule 16 and Rule 19 of the Drugs (Licensing, Registering and Advertising) Rules, 1976 as to why DML No.000850 by way of Formulation in the name of M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore may not be suspended or cancelled by Central Licensing Board.

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

The Show Cause notice dated 29th January, 2019 was issued to M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore

The firm has replied the show cause notice and application of proposed Production Incharge and Quality Control Incharge has been completed by the firm.

**A letter of Personal hearing has been issued on 19-02-2019**

**Proceedings and Decision of Central Licensing Board in 267thmeeting**

The Board after considering facts on record decided to cease the operation of Show Cause Notice issued to the firm.