MINUTES OF 234th MEETING OF CENTRAL LICENSING BOARD HELD ON Thursday, 27th February, 2014

A. LICENSING DIVISION

B. QUALITY CONTROL

C. QUALITY ASSURANCE

DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD.

MINUTES OF 234th MEETING OF CENTRAL LICENSING BOARD HELD ON 27th FEBRUARY, 2014.

234th meeting of the Central Licensing Board (CLB) was held on 27th February, 2014 in the committee room of Ministry of National Health Services, Regulations & Coordination, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP, Islamabad.

Following members attended the meeting: -

Sr. #	Name & Designation	Status
1.	Mr. Faqeer Muhammad Shaikh, Director, Drug Licensing, DRAP, Islamabad.	Chairman
2.	A.Q Javed Iqbal, Director (QA), as representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad.	Member
3.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
4.	Mr. Atta-Ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Baluchistan.	Member
5.	Mr. Zahir Ali Shah, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa (K.P), Peshawar. (Mr. Dil Nawaz, Deputy Director, Directorate General of Health Services, K.P attended meeting on behalf of Chief Drug Inspector, K.P.)	Member
6.	Dr. Syed Jamshed Kazmi, Pharmaceutical Production Expert	Member
7.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
8.	Syed Jawed Yousaf Bukhari, QC/QA Expert	
9.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
10.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
11.	Mr. Abdul Malik Ghauri, J.S-I as Law Expert nominated by Secretary, Ministry of Law and Justice, Government of Pakistan, Islamabad.	
12.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
13.	Mr. Shakeel Irfan, Representative of PPMA.	Observer
14.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
15.	Mr. Asif Akhai, Representative of PCDA	Observer

The Chairman CLB welcomed the honorable members of this Apex Forum & participants of the meeting. The meeting started with the recitation of verses from the Holy Quran. The Chairman and the members of the Board briefly introduced themselves.

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled.

Dr. Ahmed Mehmood Mumtaz, CQC/DDG (E&M), Mr. Khalid Mahmood, DDC (Lic.), Mr. Zaheeruddin M. Baber DDC (Q.C.), Mr. Adnan Faisal Saim, DDC (Q.A.) and Mr. Salateen Waseem Philip ADC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

2. Secretary, CLB presented the agenda and started proceedings of the Board as follows:-

A. LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 233rd MEETING**

The Central Licensing Board formally confirmed the minutes of 233rd meeting held on 30-31 December, 2013.

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

The Board considered the following cases of Grant of New Drug Manufacturing Licenses in the light of recommendations by respective panel of experts/inspectors and decided as under: -

S #	Name of the firm	Type of License/ Date of Inspection	Decision of CLB
1	M/s Ali Noor Industries, 8-KM, Depalpur Road, Okara.	**(Formulation)** Fresh Grant Due to non submission of application for renewal of DML within prescribed time of sixty days after validity of DML	**Approved the Grant of DML with following Sections: -** **Sections (04)** 1. Cotton Wool. 2. Bandage. 3. Crepe Bandage. 4. Gauze.
2	M/s Herbion Pakistan (Pvt) Ltd, Industrial Triangle, Kahuta Road, Islamabad.	**(Formulation)**	**Approved the Grant of DML with following Sections: -** **Sections (05)** 1. Plaster 2. Syrup (General) 3. Capsule (General) 4. Tablet (General) 5. Cream/Ointment (General)
3	M/s. Ashraf Surgical Cotton Bandage, Chak No. 5/4-1, Okara.	**(Formulation)**	**Approved the Grant of DML with following Sections: -** **Sections (03)** 1. Cotton Wool. 2. Bandage Type-II. 3. Crepe Bandage.
4	M/s. Genesis Pharmaceutical (Pvt) Ltd, 25-Sunder Industrial Estate, Lahore.	**(Formulation)**	**Approved the Grant of DML with following Sections: -** **Sections (02)** 1. Capsule (General) 2. Tablet (General)

5	M/s. Vision Pharmaceuticals, Plot No. 22-23, Industrial Triangle, Kahuta Road, Islamabad.. **Remarks**: - The firm intends to retain their same DML No.000517 (Formulation) shifted from existing premises at Plot No. 224 St.No.1, I-10/3, Industrial Area, Islamabad to their new location at Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad in the name and style of M/s Vision Pharmaceuticals. It is a case of shifting / grant of Drug Manufacturing License No.000517 (Formulation). The firm will not conduct its Formulation operations at their previous site after grant / shifting. The manufacturing of Dry Powder Injection (General) shall not be conducted in future at old premises.	**(Formulation)**	**Approved the Grant of DML** from existing premises at Plot No. 224 St.No.1, I-10/3, Industrial Area, Islamabad to their new location at Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad in the name and style of M/s Vision Pharmaceuticals with same DML No. 000517 and following Section & conditions: - **Section (01)** 1. Large Volume & Small Volume parenterals. **Conditions** • Cessation of manufacturing operations and surrendering of existing DML. • The firm will not conduct its Formulation operations at their previous site at Plot No. 224 St.No.1, I-10/3, Industrial Area, Islamabad after grant / shifting of DML at new site. • The manufacturing of Dry Powder Injection (General) shall not be conducted in future at old premises at Plot No. 224 St.No.1, I-10/3, Industrial Area, Islamabad.
6	M/s. Jaskon Pharmaceuticals (Pvt) Ltd, Plot No.50, Punjab Industrial Estate Sunder, Lahore.	**(Formulation)**	**Approved the Grant of DML with following Sections: -** **Sections (04)** 1. Capsule (General) 2. Tablet (General) 3. Sachet (General) 4. Oral Dry Powder Suspension (General)

7	M/s Aurik Pharmaceuticals, Plot No. 6&7, St No. S-9, National Industrial Zone, Rawat, Rawalpindi. **Section (01)** 1. Tablet (General). **Remarks**: • Out of four members, two members namely Prof. Gul Majeed Khan and Ch.Zeeshan Nazir, Area FID, Islamabad has recommended the grant of DML. • One member, Dr. Tariq Siddique has **Not Recommended** and rated the firm **Unsatisfactory**. • One member namely Mr. Khalid Mahmood DDC (Lic) has signed report with following remarks: o The manufacturer was advised to get ready for re-inspection during active production. o Only tablet (General) is recommended for consideration of CLB. o The Capsule section is not recommended. o Further, Area FID is requested to collect the purchase invoices of equipment.	**(Formulation)**	Mr. Gul Majeed Khan and Mr. Khalid Mahmood who were members of panel inspection team briefed the Board about proceedings of inspection. The Board was apprised that one inspection panel member Dr. Tariq Siddique DDC has signed the inspection report as **Unsatisfactory** & **Not Recommended** the grant of DML due to observations as pointed out as under: - • The performance of Reverse Osmosis Water Treatment Plant was not demonstrated by the technical staff. • The quality of water, online conductivity and pH was not determined because the pH meter in laboratory of quality control was not found functional. • Although HVAC and manometers have been installed yet the relative humidity was beyond the limits and pressure cascade was not at par. Both of the aspects need up gradation and are unsatisfactory. • Double pass reverse osmosis water treatment plant described above, could not be evaluated up till now by the under signed. • Equipment / Machinery in QC Section was new but the installation and performance was not at par. SOP's were tried accordingly but desirable performance could not be achieved. • UV Spectrophotometer seemed to be new but despite all efforts the performance of the equipment could not be successfully demonstrated by the technical staff. • HPLC, Dissolution Apparatus and pH meter were not found functional and could not show the reproducibility. • The management was given the ample opportunity to cope the deficiencies but efforts went in vain. • Since fundamental equipment of the laboratory were not found functioning properly despite being the new ones, the grading ranks unsatisfactory. • In view of the critical deficiencies, unfortunately I may not be able to recommend the grant of license to AURIK Pharmaceuticals, Rawat, Rawalpindi. **The Board after thorough discussion and in the light of above shortcomings rejected the grant of DML.**

Item-III **GRANT OF ADDITIONAL SECTIONS.**

The Board considered following cases of Grant of Additional Sections of already licensed units in the light of recommendations by respective panel of experts/inspectors and decided as under: -

S #	Name of the firm	Type of License	Decision of CLB
1	M/s Vega Pharmaceuticals (Pvt) Ltd, Pharma City, 30-KM, Multan Road, Lahore.	**Formulation**	**Approved the Grant of following Additional Section:-** **Section (1)** 1. Cream / Ointment (Steroidal)
2	M/s D-Maarson Pharmaceuticals, Plot No.17, St No. SS-2, RCCI, Rawat, Rawalpindi.	**Formulation**	**Approved the Grant of following Additional Sections:-** **Sections (2)** 1. Bolus (Veterinary) 2. Liquid Vials Injectable General (Veterinary)
3	M/s Ray Pharma Private Limited, SITE, Ext, Karachi.	**Formulation**	**Approved the Grant of following Additional Sections:-** **Sections (3)** 1. Oral Dry Powder Suspension (General). 2. Cream / Ointment / Gel (General). 3. Ophthalmic Drops Sterile (General).
4	M/s MKB Pharmaceuticals Private Limited, Industrial Estate, Hayatabd, Peshawar.	**Formulation**	**Approved the Grant of following Additional Sections:-** **Sections (2)** 1. Sachet (General). 2. Oral Dry Powder Suspension (General).
5	M/s Novartis Pharma Pakistan Limited, Petro Road Jamshoro Sindh.	**Formulation**	**Approved the Grant of following Additional Section:-** **Section (1)** 1. Tablet (General)
6	M/s Surge Laboratories (Pvt) Ltd, 10-Km Faisalabad Road, Bikhi, District Sheikhupura **DML No. (000484)**	**Formulation**	**Approved the Grant of following Areas:-** 1. Finished Goods Warehouse / Packing Hall. 2. Packaging Material Store. 3. Utilities Area (Blow Fill Seal Machine, Boiler Room)

7	M/s Otsuka Pakistan Ltd, Hub Industrial Trading Estate, Lasbella, Balochistan.	**Formulation**	**Approved the Grant of changes in following areas for better GMP Compliance subject to appointment and approval of permanent QC Incharge.** 1. Plabottle 2. LDPE Molding 3. Raw Material Stores
8	M/s Indus Pharma (Pvt) Ltd, Plot No. 65/27 Korangi Industrial Area Karachi.	**Formulation**	**Approved the Grant of following Additional Section & Areas:-** **Section (01)** 1. Oral Liquid (General) **Areas Approved** 1. Packing Hall for Oral Solids. 2. In-Process Warehouse.
9	M/s Kings Pharmaceuticals, Plot No. 27, Sunder Industrial Estate, Lahore.	**Formulation**	**Approved the Grant of following Additional Section:-** **Section (01)** 1. Tablet (General)
10	M/s Hygeia Pharmaceuticals, Plot No. 295, Kahuta Road, Islamabad.	**Formulation**	**Approved the Grant of following Additional Sections:-** **Sections (02)** 1. Cream/Ointment (General) 2. Dry Powder Injection (Cephalosporin).

11	M/s Surge Laboratories (Pvt) Ltd, 10-Km Faisalabad Road, Bikhi, District Sheikhupura **DML No. (000649) Semi Basic.**	**Semi Basic**	**Approved the Grant of Additional Section with following items for microencapsulation:-** **Section (1)** Micro-encapsulation **<u>Items for microencapsulation</u>** 1) Duloxetine (enteric coated pellets). 2) Domperidone (taste masked grandules/pellets). 3) Loratidine (coated granules/pallets). 4) Levocetirizine (taste masked granules). 5) Levofloxacin (taste masked granules). 6) Ibuprofen (taste masked granules). 7) Sodium bicarbonate (coated granules). 8) Mebeverine (taste masked granules). 9) Pyridoxine (coated granules). 10) Resperidone (taste masked granules). 11) Citric Acid (coated granules). 12) Linezolid (taste masked granules). 13) Lornoxicam (enteric coated granules). 14) Ferrous Fumarate (coated granules). 15) Aceclofenac (sustain release pellets). 16) Cyclobenzaprine HCL (coated pellets). 17) Riboflavin (coated granules). 18) Doxycycline HCL (coated granules) 19) Zinc Sulfate (coated granules) 20) Itopride (sustained release pellets). 21) Itraconazole (coated pellets). 22) Orlistat (granules / micro pellets) 23) Tamsulosin HCL (coated pellets). 24) Theophylline (sustained release pellets). 25) Tizanidine HCL (sustained release pellets). 26) Famotadine (taste masked granules).

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

The Board considered the following cases of Grant of Renewal of Drug Manufacturing License in the light of recommendations by panel of experts/inspectors subject to confirmation of installation of HVAC system and updated deposition of CRF admissible under the rules and decided as under: -

S #	Name of the firm	Type of License	Decision of CLB
1	M/s Kohinoor Industries, 159-160/B, Small Industries Estate, **Sahiwal** **Remarks.** The panel recommends the renewal of DML to the firm, however sterile gauze section in area of tablet sections required approval in the layout in addition to micro lab if approved the sections may also be granted renewal of DML. However, the firm does not have facility for Sterile Tulle dressing as mentioned above.	DML No. 000197 (Formulation)	**Approved the Grant of Renewal of DML except sterile gauze and Sterile Tulle Dressing Section.**
2	M/s Umer Usman Surgical Cotton Industries, Faisalabad Road, Kot Sai Singh,Jhang.	DML No. 000361 (Formulation)	**Approved the Grant of Renewal of DML for following sections and allowed production: -** **1. Absorbent Cotton Wool** **2. Surgical Cotton Bandages** **3. Cotton Crepe Bandage**
3	M/s Delux Chemical Industries, 26/A-1, Landhi Industrial Area Karachi.	DML No. 000033 (Formulation)	**Approved the Grant of Renewal of DML.**
4	M/s Asian Continental (Pvt) Ltd, D-32, SITE-II, Super Highway, Karachi	DML No. 000643 (Formulation)	**Approved the Grant of Renewal of DML.**
5	M/s Surge Laboratories (Pvt) Ltd, 10-Km Faisalabad Road, Bikhi, District Sheikhupura.	DML No. 000649 (Semi Basic).	**Approved the Grant of Renewal of DML.**

6	M/s Ray Pharma Private Limited, SITE, Ext, Karachi.	DML No. (000642) (Formulation)	**Approved the Grant of Renewal of DML.**
7	M/s MKB Pharmaceuticals Private Limited, Peshawar.	DML No. 000617 (Formulation)	**Approved the Grant of Renewal of DML.**
8	M/s Amson Vaccine & Pharma (Pvt) Ltd, Plot No. 113, Industrial Triangle Kahuta Road, Islamabad.	DML No. 000638 (Formulation)	**On the recommendations of panel, the Board in its 233rd meeting did not approve the renewal of DML and suspended DML in all areas for a period of one month under Rule 13 of Drugs (Licensing, Registering and Advertising) Rules, 1976 for rectification of observations made during the inspection by the panel.** **Later, on the recommendations of new panel that all the observations made previously by the panel of inspectors on 26-09-2013 have been rectified by the firm, the Board accordingly approved the Grant of Renewal of DML and withdrawn the suspension of DML.**

Item No.V. **MISCELLANEOUS CASES.**

Case No.1 Closure of Pharmaceutical Unit of M/s. Vetgro Pharmaceutical (Pvt) Ltd., Lahore.

The case of M/s Vetgro Pharmaceutical (Pvt) Ltd, Lahore was placed on the agenda for consideration of the Board as under: -

Background

Federal Inspector Drugs, Lahore, had visited M/s Vetgro Pharmaceuticals (Pvt) Ltd, Multan Road, Lahore on 14-03-2013 and he has stated that firm was found closed. The FID has reported the following points in its report: -

i) The firm's three security guards were present at the main gate of the firm. They did not allow to undersigned to enter the main gate. They stated that they do not have the keys of the main building (production area). One of them Mr. Zulqarnain informed that they are employees of a security company and he is appointed here for the last seven months. He further informed that he does not know about the owners of the firms and since his duty here the firm was close and no production activity is seen.

ii) Ex Area FID Mr. Asim Rauf had also visited the firm on 01-03-2012 and found the same status. Letters have also been written to the firm to explain its position in this regard on 01-03-2012 and 17-05-2012. However, neither any reply received nor any person contacted even after the lapse of one year.

iii) Undersigned also tried best to contact the Chief Executive of the firm or any other person responsible but to vain. All the contact numbers landline/mobile as per office record is either unattended or disconnected. However, it is learnt from some other market competitors that the management has closed the firm due to some partnership/family disputes.

iv) As it appears from the above submission that the firm is not functional for more than one year and as non of the owner or any other responsible person is available and as the premises is not accessible to area FID and as the conditions of the license as per the Drug (Licensing, Registering and Advertising) Rules, 1976 are not being maintained. **It is recommended that the Drug Manufacturing License bearing No. 000650 dated 30-01-2009 issued in favor of M/s Vetgro Pharmaceuticals (Pvt) Ltd may be cancelled/ suspended under rule 12 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.**

Keeping in view the above, **Show Cause** notice was issued to the firm vide letter dated 8th May 2013. The firm was also asked to appear before the CLB in its next meeting if want to be heard in person. 3. In response Mr. Faiz Rasool Chief Executive of the firm has submitted his reply in which he has denied that the FID has contacted him and written him letters. He has further stated as under:-

a. That there are severe financial crises of the country and that there is no gas no electricity no working environment, labor problems business migrations no more investment on business to create jobs. So in this environment everyone is in problem; to meet electricity bills, wages of employees, unsustainable low production volumes, high costs of production and unaffordable circumstances and inevitable expenditures. These are the major factors that we are unable to run the factory at full momentum and capacity and at all levels. In our area light goes from 16-18 hours a day. So how can we work? It is a multimillion investment at stake because of the bad conditions of country.

b. That they have done big investment and are eager to bring up factory in full working position otherwise will shift from Pakistan.

c. That country slams massive power load shedding and all chambers of commerce have expressed serious concerns over the poor response of Government towards unprecedented energy shortage of the industry.

d. That the Show Cause notice has been issued on one and first visit of FID and false report of formal FID. I think they must be friendly with the companies rather to indulge in wrong goings. They try to create easiness to industrials to create problems.

e. That I have done nothing wrong. There is no fault on my part and I am sent show cause notice and not known to reason. I therefore request the competent authority to look into the matter sympathetically and oblige.

The firm was asked to appear before the Board in its last meeting for personal hearing to clarify their position on the subject matter.

CLB taken in 233rd meeting held on 30-31 December, 2014 considered and decided as under:

"The representative of the firm was called for personal hearing in the light of previously served Show Cause Notice but no any representative attended the meeting, so Board deferred the case for final opportunity of personal hearing".

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds deferred the case for: -

- **Obtaining latest status of firm by panel comprising of Dr. Ikram ul Haq Member CLB, Ahmad Mehmood Mumtaz CQC, DDG (E&M) Lahore and Area FID, Lahore.**
- **Opinion from Law Division that the firm has been called twice for personal hearing before CLB but did not appear for personal hearing so whether CLB can decide for suspension / cancellation of Drug Manufacturing License of firm ex-parte under section 41 of Drugs Act, 1976.**
- **Last and final opportunity of personal hearing in the forthcoming meeting of CLB and personal hearing letter shall be sent through Registered Post and receipt of same shall be retained.**

Case No. 2 RENEWAL OF DML NO 000592 (FORMULATION) OF M/S SHAZAL'S PHARMACEUTICALS, HATTAR.

The case of M/s Shazal's Pharmaceuticals, Hattar was placed on the agenda for consideration of the Board as under: -

The brief background of the case is as under: -

M/s Shazal's Pharmaceuticals, Hattar applied for renewal of their DML No 000592 (Formulation) on 05-05-2011.

2. On scrutiny it was noted / observed that the application for renewal of DML 000592 (Formulation) of the firm was not submitted on prescribed Form 1-A, hence it was not tenable and was liable to be rejected as provided under rule 5(2A) of the Drugs (Licensing, Registering and Advertising) Rules, 1976. The firm was repeatedly asked to submit their application on prescribed Form-IA along with all its pre-requisites within thirty days as admissible under above mentioned Rule but the firm did not respond to DRAPs correspondence to submit complete application for renewal of their DML.

3. Mr. Muhammad Afzal- CEO / Sole proprietor of the firm informed that he leased out his factory for a period of 05 years to **Mr. Malik Mehrban** w.e.f 1st August 2011 and had stated that from then onwards all the responsibility of production in the factory laid on the new party for any dispute with Govt. Department or court if arised due to any fault in products or in any other case during period of agreement. Later on he informed on 27-12-2011that agreement of lease had been cancelled. Accordingly, a letter was issued on 05-01-2012 from DRAP to the owner of the firm Mr. Muhammad Afzal stating therein that a license is neither transferable nor assignable and Mr. Muhammad Afzal will be responsible for compliance of conditions of license and cGMP being the licensee under the provision of Drugs Act, 1976 and Rules framed there under.

4. An other letter was issued on 23-07-2013 from DRAP wherein the firm was asked to complete / rectify the shortcomings observed in the application of renewal of DML along with all the documents / information within 30 days as required under Rule 5[2A] of Drugs (Licensing, Registering & Advertising) Rules 1976 which is reproduced as under:-

> **"*On receipt of an application for renewal of a license any objection or shortcoming in the application observed by the Central Licensing Board may be notified to the applicant and he shall be given a time period of thirty days for rectification or completion of the application. In case he fails to rectify or complete the application within the specified period, the application may be rejected*"**

5. It is pertinent to mention that the case had been brought before CLB in its 232nd meeting held on 30th & 31st July 2013 while considering their case for non compliance of cGMP, wherein during proceeding of personal hearing, the owner Mr. Muhammad Afzal had committed to fulfill the requirement of renewal application on prescribed Form-IA but he failed to comply with the said commitment till date.

6. Instead of responding to DRAP's correspondence for completion of their renewal application it was informed by the owner of the firm i.e. Muhammad Afzal that he had sold his company / firm M/s Shazal's Pharmaceuticals, Hattar to **Mr. Rafi-ul-Mulk** on 01-10-2013.

7. The required period of thirty days has already been expired on 22-08-2013 but the management of the firm failed to submit the complete application within said period thus application of renewal of DML of the firm is liable to be rejected after approval of CLB and

thereby the DML would cease to exist. Furthermore, owner of the firm had already been informed vide letter dated 05-01-2012 that the license is neither heritable nor assignable but he did not pay any heed to the said instructions and he again sold the licensed/ unit M/s Shazal's Pharmaceuticals, Hattar, DML No. 000592 (Formulation) to **Mr. Rafi-ul-Mulk** on 01-10-2013.

8. In view of forgoing stated position, the application of renewal of DML is liable to be rejected as per Rule 5[2A] of Drugs (Licensing, Registering & Advertising) Rules 1976 and it is also a case of change of management, hence the new management of the firm is subjected to apply afresh for grant of DML in the light of Law Division's opinion solicited while considering the case of M/s Qamar Cotton Industries, Okara, wherein the Law Division had opined that the Drug Manufacturing License cannot be transferred even to the legal heirs of the company established under the sole proprietorship. The Law Division further opined that the license is a permissive right of an individual and could not be transferable.

9. Hence in view of Law Division referred to opinion the license is neither transferable, assignable nor heritable from Mr. Muhammad Afzal, the present owner of M/s Shazal's Pharmaceuticals, Hattar as per available record of Licensing Division of DRAP to Mr. Rafi Ul Mulk (purchaser) as requested. It is proposed that both the persons may be informed about the situation / status accordingly.

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds decided and rejected the application for renewal of DML. The Board further decided for issuance of show cause notice to the firm and personal hearing in forthcoming meeting of CLB before suspension / cancellation of DML.

Case No. 3 APPROVAL OF BUILDING LAYOUTS FOR TABLET SECTION BY DIRECT COMPRESSION METHOD.

The case was placed on the agenda for consideration of the Board as under: -

The brief background of the case is as under:-

M/s Himont Pharmaceuticals (Pvt.) Ltd Lahore have submitted layout plan for approval of **Tablet (Cephalosporin) Section – By Direct Compression Method** wherein Granulating Section is excluded.

2. As per Schedule B1 of Drugs (Licensing, Registering & Advertising) Rules 1976, for efficient operation, tablet production department is divided into following three distinct sections situated in different rooms in building layout.

i. **Granulating Section.**
ii. **Tableting Section**.
iii. **Coating Section**.

As per Schedule B a total area of not less than 900 square feet for above mentioned three sections is required for basic installation.

3. If we divide the areas of the above mentioned sections on the technical basis, Granulation process requires approximately 500-600 square feet. Tableting / Compression Section require approx. 150-200 Square Feet and coating section requires approx. 150-200 Square feet.

4. The area of Tablet (Cephalosporin) Section in proposed layout plan of the firm is 565.18 Square feet as under:

Sections	Area in Square Feet
1. Blending & Drying	225.78 Square feet
2. Compression	178.20 Square Feet
3. Coating	161.20 Square Feet
Total	**565.18 Square Feet**

1. The case of said layout plan was also referred to Division of Legal affairs, DRAP, Islamabad for their opinion. The Director Legal Affairs, DRAP, Islamabad has opined as under: -

"***The Schedule B1 was promulgated in 1976 and perhaps thereafter it has not been amended / updated to the best of my knowledge. In the meanwhile Schedule BII has been revised and dedicated / segregated facilities requirement made for some classes of drugs. Technology has also advanced and now compact areas / systems are used. It is therefore desirable that Schedule B-I is to be revised and updated***"

For a decision on the instant case Director (Lic.) may see Note: 1 at the end of Schedule B-1.

Note: 1 at the end of Schedule B-1 is as under: -

The above requirement of this schedule are subject to modifications, at the discretion of the Central Licensing Board if it is of the opinion that having regard to the nature and extent of the manufacturing operations it is necessary to relax or alter in the circumstances of a particular case.

Provided that such variation shall be recorded in writing with reasons therefore and also communicated in writing to the manufacturer for his record.

Decision of CLB

The Board after thorough discussion / deliberations and active participation of its members considered and decided as under: -

- **Deferred the instant case till finalization of amendment in Drugs (Licensing, Registering & Advertising) Rules, 1976 related to Licensing.**
- **The Board further constituted a committee on amendment of said Rules and Schedules related to Licensing as under:**

1. **Dr. Ikram-ul-Haq, Member CLB (Chairman)**
2. **Mr. Abdullah DDC/DDG-Lic (Secretary)**
3. **Director Quality Assurance and lab Testing (Member)**
4. **Syed Jaweb Yousaf Bukhari (Member)**
5. **Representative of PPMA(Member)**
6. **Representative of Pharma Bureau (Member)**
   PCDA shall submit its written recommendations if any.

TORs of Committee

- **To review comprehensively the existing Drugs (Licensing, Registering & Advertising) Rules, 1976 including Schedules related to Licensing so that inconsistencies, anomalies, gaps / grey areas may be identified and addressed accordingly.**
- **The committee shall submit its recommendations for consideration of Board within three months.**

Case No. 4 USAGE OF OLD COMPANY NAME PACKAGING /LABELING COMPONENTS BY M/S THE SEARLE COMPANY SITUATED AT PLOT NO.F-319, SITE, KARACHI DML NO.000016 (FORMULATION).

The case of M/s The Searle Company Karachi, DML No000016 (Formulation) was placed on the agenda for consideration of the Board as under: -

Brief Background:

The Central Licensing Board in its 232nd meeting discussed the case of M/s The Searle Company Karachi, regarding using of their premises for manufacture of Drugs. The Board decided to get the facilities of M/s Searle Pakistan Limited, Karachi at Korangi site inspected by a panel as this site is reportedly used for manufacturing nutraceutical products as informed by Mr. Salim Isharat Chief Drug Inspector, Sindh (Member CLB). The Board further decided to get the inspection of two separate premises of M/s Searle Pakistan Limited in Karachi i.e. Korangi Industrial area and S.I.T.E Karachi by panel of experts to ascertain the status of licenses of these Sites and check production activities being carried out at these two sites. In compliance a panel was constituted who submitted its report as under:

i) The panel consisting of Syed Javed Yousaf Bukhar, Mr. Qaiser Muhammad Chief Drug Inspector Sindh, Syed Hakim Masood, Area FID, SITE, Karachi and Abdul Rasool Shaikh FID-III.

Summary of the report of licensed unit of M/s The Searle Company situated at Plot No.F-319, SITE, Karachi DML No.000016 (Formulation).

The panel as above inspected the license premises and observed that the firm is engaged in the manufacturing of registered pharmaceutical products and the firm is still using packaging / labeling components with old company name in few products as was witness during the inspection. It is worth to mention that the name of the company has been changed with effect from 29&30-07-2013

The panel advised the firm to voluntarily stop the packaging material bearing the name of previous company and such finished products shall be hold for not to be sold till the approval of CLB for utilization of the balance / remaining packaging inventories with old company name. The Management assured the panel that they will get the approval from the Competent Authority to utilize their remaining inventories of few packaging components. Under Schedule B(II) 6.3.4 states that out dated or obsolete primary packaging material or printed packaging material shall be destroyed and its disposal be recorded. M/s Spencer Pharma Karachi was also not permitted to use their old printed packaging material after the change of the name as Rules are very clear to deal with such matters. The firm has violated the said provision of the Rules and a show cause notice / warning as the Central Licensing Board deem appropriate may be issued and the hold stock using old printed packaging material may be destroyed.

The Central Licensing Board in its 233rd meeting held on 30-31 December, 2014 has considered the subject matter and decided as under: -

"The Board in the light of panel inspection report of M/s. Searle Company, Plot No.F-319, SITE, Karachi (DML No.000016-Formulation) decided to destroy the available packaging /labeling components bearing old company name (The Searle Pakistan Ltd.,) under Schedule-B(II)6.3.4 in the presence of panel. A show cause notice and personal hearing on violation of conditions of Drug Manufacturing License shall be issued to the firm and case shall be presented before CLB in its next meeting".

Accordingly, a panel has been constituted for the destruction of available packaging /labeling components bearing old company name (The Searle Pakistan Ltd.,) and the same has been conveyed to DDG (E&M), and area FID, Karachi.

As per above decision of CLB a Show Cause Notice has been issued and further firm has been called for personal hearing, please.

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds decided for panel inspection for confirmation of using packing / labeling components bearing old company name. The Board further decided to refer the complete case to Registration Board for its consideration / decision to recall the products of the said firm bearing old company name (The Searle Pakistan Ltd.,).

Case No. 5 GRANT OF ADDITIONAL SECTION OF M/S WINSFIELD PHARMACEUTICAL, HATTAR.

The case of M/s Winsfield Pharmaceutical, Hattar was placed on the agenda as under: -

An inspection for grant of additional sections of M/s Winsfield Pharmaceutical, Hattar was conducted by panel of experts on 23-12-2010, wherein panel of experts recommended the following two additional sections: -

i). Oral Dry Suspension (General)

ii). Sachet (Cephalosporin)

2. The inspection report was presented in 226th meeting of CLB held on 31st December, 2010. In the minutes of the meeting approval of Oral Dry Suspension (General) only was recorded and other section Sachet (Cephalosporin) could not be mentioned.

3. The firm has now requested for grant of other section i.e. Sachet (Cephalosporin) which was not mentioned in the minutes of the meeting of 226th meeting of CLB but recommended by panel of experts in the said inspection report.

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds considered and deferred for panel inspection for the grant of additional section Sachet (cephalosporin).

Case No. 6 **RENEWAL OF DML OF M/S KATRINA PHARMACEUTICAL INDUSTRIES (PVT.) LTD., SHEIKHUPURA.**

The case of M/s Katrina Pharmaceutical Industries (Pvt) Ltd, Sheikhupura was placed on the agenda as under: -

M/s Katrina Pharmaceutical Industries (Pvt) Ltd, Sheikhupura was inspected by a panel of experts on 14.12.2007 for renewal of Drug Manufacturing License wherein panel did not recommend renewal of license. Firm was served with the show cause notice and owner of the firm was given personal hearing in 212th meeting of the board held on 26.05.2008 and undertook before the Board that he will suspend the production with immediate effect and will ready for re-inspection after one month.

2. The CLB in its 212th meeting decided to grant one month time for improvement of the facility. The FID Lahore conducted inspections on 30.05.2008, 08.07.2008 and then on 15.06.2009 wherein he reported that at the time of inspection the entire manufacturing facility was closed and no production activity was in progress. No technical person was present no compliance of their undertaking regarding rectification and up-gradation was made by the firm even after laps of a period of one year. The FID also recommend that the license of the firm may be suspended as the firm has not done any compliance with reference to previous inspection report and renewal of their DML was also not recommended by the Panel of inspectors. The Board in its 218th meeting held on 30-06-2009 decided to issue final show cause notice and call the management for personal hearing before the next meeting of the Board. The firm was served with show cause notice and advised to appear before CLB for personal hearing in person on 31-07-2009.

3. The firm applied for renewal of their DML for the period of 14-12-2009 to 13-12-2014 in time. The panel was constituted on 25th February 2011 but the inspection by the panel was not carried out. However, Area FID and ADC Lahore conducted an inspection of the firm on 8th February 2012 and reported that the whole of the plant was dismantled and the installation HVAC was in process and the management informed that they are non-operational from the last three and half years because the financial constraint. Area FID Lahore vide letter dated 28-11-2012 requested for reconstitution of the panel as new members of the CLB have been nominated.

4. The Federal Inspector of Drugs, Lahore conducted the inspection of M/s Katrina Pharmaceutical Industries (Pvt.) Ltd., Seikhupura on 04-03-2013 to check the status and GMP compliance of the firm. The contents of inspection report of the FID are as under: -

a. That at the time of inspection the firm was closed and no production activity was in process. Only two watchmen were there and one watchman Mr. Ata Ullah has given the statement that the factory is closed for the past many months. It is also pertinent to mention that Dr. Sheikh Akhtar Hussain, Federal Inspect of Drugs at that time, also inspected the fm on 15.6.2009 and at that time the manufacturing facility was also found closed. It was reported that no compliance of the firm's undertaking regarding rectification was made by the firm even after the lapse of one year. He recommended that the license of M/s Katrina Pharma may be suspended as the firm has not done any compliance and the renewal of their DML was also not recommended by the panel
b. The firm was again inspected by Abdul Rashid Sheikh, Federal Inspector Drugs, Lahore as the management has requested for deferment of inspections because of their installation of HVAC system and other renovation and installation of HVAC

was in process. The management informed at that time that they are non-operational from the last three and half years because of financial constraints.

c. Mr. Afzal Hameed, Chief Executive of the firm informed telephonically that HVAC system has not been installed yet due to some payment problems.
d. The renewal of DML of the firm was not recommended, however another panel was constituted but now the Board have been reconstituted under Drugs Regulatory Authority of Pakistan, therefore, reconstitution of panel is required. The factory is closed for the last five years; hence the matter may be submitted to Licensing Board for further necessary action, please.

5. Keeping in view the above, Show Cause notice was issued to the firm vide letter dated 8th November 2013. The firm was also asked to appear before the CLB in its next meeting if want to be heard in person.

6. The firm has been asked to appear before the Board for personal hearing in this meeting and clarify their position on the subject matter. Submitted for consideration of the Board in the light of above background of the case as the renewal of DML of the firm is due last two periods.

7. CLB in its 233rd meeting held on 30-31 December, 2014 considered the above case and decided as under: -

- The representative of the firm was called for personal hearing in the light of previously served Show Cause Notice but no any representative attended the meeting.

- Board after through discussion decided to suspend the manufacturing license under Rule 8(14) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 till rectification of shortcomings and verification thereof by panel. The Board further decided to give another opportunity of hearing in the light of previous show cause notice.

8. The above decision of CLB for suspension of DML of firm could not be conveyed due to anomaly of mentioning rule position in the decision as instead of relevant Rule 13 of the Drugs (Licensing, Registering and Advertising) Rules, 1976; Rule 8(14) of the Drugs (Licensing, Registering and Advertising) Rules, 1976 has inadvertently been mentioned. However, the firm has been called for personal hearing as per above decision of CLB.

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds considered and decided as under:-

- **Fresh status report by panel comprising of Dr. Ikram ul Haq, Member CLB, Ahmad Mehmood Mumtaz, CQC, DDG (E&M), Lahore and Area FID, Lahore.**
- **Opinion from Law Division that the firm has been called twice for personal hearing but did not attended for personal hearing so whether CLB can decide for suspension / cancellation of Drug Manufacturing License ex-parte under section 41 of Drugs Act, 1976.**
- **Last and final opportunity of personal hearing in the forthcoming meeting of CLB and letter shall be sent through Registered Post and receipt of same shall be retained.**

Case No. 7 RENEWAL OF DML OF M/S WESTMONT PHARMACEUTICAL, GT ROAD GUJAR KHAN, RAWALPINDI.

The case of M/s Westmont Pharmaceutical GT Road, Gujar Khan, Rawalpindi was placed on the agenda as under: -

The application for renewal of Drug Manufacturing License No. 000631 (Formulation) was issued to you on 19-06-2008 subject to certain conditions. You next renewal is due w.e.f. 18-06-2013. Whereas you have been intimated about your incomplete submission of renewal application vide DRAP's letter issued on 09th October, 2013 with the direction to furnish your complete application as per Form-1A and a reminder was issued on 12th February 2014 to submit your complete application on prescribed Form-1a but the firm failed to complete their application. The drugs (LR&A) Rules, 1976 under rule 5(2A) states as under: -

> **"On receipt of an application for renewal of a license any objection or shortcoming of the application observed by CLB may be notify to the applicant and shall be given a time period of 30 days for rectification or completion of the application. In case he fails to rectify to complete the application within the specified period the application may be rejected".**

2. Since, period of 30 days has been lapsed on 08th November 2013 however, a letter was issued on 12th February, 2014 to complete the application within seven days but till to date no response is received. Keeping in view of above it is proposed that the application of the firm may be rejected if the CLB deem appropriate, further this power may be given to the Chairman CLB so that in such cases the applications for renewal of DML which have not been completed by the licensee may be rejected after lapse of period of 30 days to strictly adhered to the provisions of the Rules.

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds decided and rejected the application for renewal of DML. The Board further decided for show cause and personal hearing in forthcoming meeting of CLB.

Case No. 8 CLARIFICATION REGARDING RECCOMMENDATIONS OF PANEL REGARDING INSPECTION OF M/S WIMITS PHARMACEUTICALS LAHORE.

The case of M/s Wimits Pharma Lahore was placed on the agenda as under: -

The case for grant of DML to M/s Wimits Pharma Lahore was considered by the CLB in its 233rd meeting. The panel of experts in its inspection report dated 26-11-2013 had recommended the liquid injection section (Ampoule Human General) along with eight sections (human & veterinary) and recommended to re-inspect liquid –Infusion Section (human) due to the observations raised during the inspection. But due to some mis-interpretation it was construed that liquid injection section (Ampoule Human General) was perhaps not recommended by the panel. Now the panel has clarified that it had also recommended liquid ampoule section (General). However, panel re-iterated that Liquid Injection section (Infusion) (human) had not been recommended.

Decision of CLB

In the light of clarification and consolidated recommendations of panel of experts and withdrawal of Vial Section by M/s Wimits Pharmaceuticals, Lahore, the Board after thorough discussion / deliberations considered and approved Liquid Injection (Ampoule Human General) Section

Case No. 9 DELEGATION OF FUNCTIONS OF THE CENTRAL LICENSING BOARD.

The case was placed on the agenda as under: -

The Central Licensing Board in its 232nd meeting approved delegation of following functions to its Chairman and Secretary for a period of one year with immediate effect under Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 in order to facilitate timely disposal of routine / day to day business of Central Licensing Board. The case is resubmitted for ratifying the functions with provision of respective Section and Rule of Drugs Act, 1976 for a period of one year again.

Sr #	Powers	Relevant Provision of Act / Rule (s)	Power delegated in 232nd meeting	Powers proposed for re-delegation
1.	Show Cause Notice regarding contravention of any of the provisions of the Drugs Act, 1976 and rules framed there under. For cancellation and suspension of DML for such period either wholly or in respect of some of the drugs to which it relates.	Section 41 and Rule 12 of Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman CLB
2.	Suspensions of Production	Section 41 and Rule 12 of Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman CLB returned back his function to CLB delegated in 232nd meeting of CLB.
3.	Lodging of FIR	Section 19(7) read with 30(b) of Drugs Act, 1976.	Chairman CLB	The function has already been delegated to Director QA/LT or all DDG(s) Provincial Headquarter or Officer Incharge of the respective Province of DRAP so shall remain as above.
4.	Approval of layout plan	Schedule "B" Section 1 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB through a committee comprising of DDG (Lic) DDC (Lic) DDC (Lic) ADC (Lic)	Chairman CLB through respective desk officer under Rule 8 (10) Drugs (Licensing, Registering & Advertising) Rules, 1976.

5.	i) Approval of change of name of a firm for licensed units/unlicensed units (after the site approval). ii) Approval of drugs (molecules) for basic and semi basic manufacturing. iii) Approval of Repacking items under Schedule D of drugs Act 1976 and Rules framed there under.	Rule 5(6) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 read with Rule 8 (10) of aforementioned Rules.	Chairman CLB	Central Licensing Board shall consider such requests in future as Chairman CLB returned back the said delegated function to Board. For powers 5(i)(ii) the inspections are mandatory before grant of any items / drugs under respective Schedule etc.
6.	Constitution / amendments in constitution of panel for inspection for grant/renewal of Drug Manufacturing License, grant of Additional Section and verification/ checking of conditions of License etc of firms.	Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 of aforementioned Rules.	Chairman CLB	Chairman Central Licensing Board.
7.	Extension in Sealing period of Licensed manufacturers where Contravention(s) is/are of Conditions of DMLs only.	Section 18(h) read with Section 19(7) of the Drugs Act, 1976 and Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman Central Licensing Board.
8.	Correction of typographical error in recording minutes of the meeting of the CLB.	Rule 8 (10) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Chairman CLB	Chairman Central Licensing Board.
9.	Issuance of Inspection Book	Rule 8(10) read with Rule 19(4) of the Drugs (Licensing, Registering & Advertising) Rules, 1976.	Secretary CLB	Secretary CLB
10.	Approval of Technical Staff Communication/ Issuance of Decisions of Central Licensing Board.	Rule 15 and 16 of the Drugs (Licensing, Registering & Advertising) Rules, 1976 read with Rule 8 (10) of aforementioned	Secretary CLB	Secretary CLB

		Rules.		
11.	Site approval.	Rule 8 (10) of aforementioned Rules.	Secretary CLB	Secretary CLB
12.	Approval of change of name of an unlicensed firm / unit (before the approval of site).	Rule 8 (10) of aforementioned Rules.	Secretary CLB	Secretary CLB
13.	Functions performed by Officers of Division of licensing in context with disposal of day to day business of Central Licensing Board regarding communication of decisions as per provisions laid down under the Drugs Act, 1976 and Rules (Drugs (LR&A) Rules, 1976) framed there under for exercising the power in implementation of rules (Drugs (LR&A) Rules, 1976).	Rule 8 (10) of aforementioned Rules.		Through respective desk officers of Division of Drug Licensing after getting approval from Chairman CLB.

Decision of CLB

The Board after thorough discussion considered and approved the delegation of power mentioned at Sr. No. 5.

Sr #	Powers	Relevant Provision of Act / Rule (s)	Power delegated in 232nd meeting	Powers proposed for re-delegation
5.	i) Approval of change of name of a firm for licensed units/unlicensed units (after the site approval). ii) Approval of drugs (molecules) for basic and semi basic manufacturing. iii) Approval of Repacking items under Schedule D of drugs Act 1976 and Rules framed there under.	Rule 5(6) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 read with Rule 8 (10) of aforementioned Rules.	Chairman CLB	Central Licensing Board shall consider such requests in future as Chairman CLB returned back the said delegated function to Board. For powers 5(i)(ii) the inspections are mandatory before grant of any items / drugs under respective Schedule etc.

Case No. 10 REFORMS IN DIVISION OF DRUG LICENSING.

The case of M/s Wimits Pharma Lahore was placed on the agenda as under: -

Division of Drug Licensing is responsible for the licensing of the drug manufacturing facilities and to perform other functions connected therewith under the Drugs Act, 1976 and Drug Regulatory Authority of Pakistan Act, 2012. It discharges its functions through Central Licensing Board, a statutory body for considering and deciding the matters of licensing of the drug manufacturing facilities.

2. After inception of DRAP, this Division has convened three meetings of Central Licensing Board to dispose-off various applications of grant of new drug manufacturing licenses, renewal of drug manufacturing licenses and miscellaneous matters.

3. Promulgation of DRAP Act 2012 urges for improvements and keeping the pace with modern world and developing countries. Such steps can be taken after availability of enough resources. At present, acute problem of office accommodation, equipments, staff and IT technology is being faced which may be addressed to achieve the goals of the authority.

4. In order to update the data / information and to improve working efficiency of Licensing Division, it is proposed that following information may be obtained from all manufacturers as under: -

i. Copy of DML granted at initial stage along with proof of sections approved.
ii. Names of Owners/Directors etc. at initial stage and if changed later, the proof of approval of same.
iii. Subsequent proof of renewal of DML.
iv. Proof of approvals of additional section(s) obtained from time to time.
v. Sections running or existing without approval.
vi. Names of presently working approved technical persons along with qualification. In case of no such approval, the proof of application submitted to DRAP for approval of Technical staff.
vii. Present status of License / Renewal.

5. Above information may be collected through field offices by area FIDs on given pro-forma as under. The information so collected will be uploaded on website of DRAP and it will be helpful for future improvements.

LICENSING PROFILE OF FIRM

S No.	Title	Information	Remarks if any
1.	Name of firm		
2.	Type of License		
3.	Date of License Grant		
4.	Date of validity of License		
5.	Human / Veterinary		
6.	Sections Approved at initial grant of DML		
7.	Names of Owners/Directors/Partners/ Proprietors at initial stage and if changed later, the proof of approval of same.		
8.	Proof of Renewals		
9.	Proof of approvals of additional sections obtained from time to time		
10.	Sections running or existing without approval, if any		
11.	Names of presently working approved technical persons along with qualification. In case of no approval, the proof of application submitted to this Ministry for approval of Technical staff.		
12.	Present status of License / Renewal		
13.	Any other information, if any		

Decision of CLB.

The Board after thorough discussion considered and approved the reforms in Division of Drug Licensing for obtaining data / information as per given proforma.

Case No.11 **Cancellation of Drug Manufacturing License No. (000663) (Formulation) of M/s Al-Aju Cotton Industries Mir Pur Khas Sindh.**

The case of M/s Katrina Pharmaceutical Industries (Pvt) Ltd, Sheikhupura was placed on the agenda as under: -

Federal Inspector of Drugs Dr. Najam-us-Saquib visited M/s Al-Aju Cotton Industries on 28th June 2013 wherein the FID has reported that there was no production activity underway and premises were found closed. He has further informed that letters and reminders to the firms were issued but no reply from the firm was received. The neighboring person informed that there is no production activity since long and this premises alongwith other surrounding land has been purchased by another person namely Mr. Amjad Memon. On contact to Mr. Amjad Memon he has confirmed that he has purchased the whole land and he does not know about running a pharmaceutical unit, nor he is interested in the same. The FID has recommended for cancellation of Drug Manufacturing License of M/s Al-Aju Cotton Industries, Mirpur Khas, Sindh.

Decision of CLB taken in 233rd meeting held on 30-31 December, 2013.

The Board in light of inspection report of area FID and after thorough discussion and deliberations decided to issue Show Cause notice to M/s Al-Aju Cotton Industries, Mirpur Khas, Sindh and called the firm for personal hearing in next meeting before cancellation of DML. Board further decided to collect the DML and Inspection Book through area FID.

Decision of CLB

The Board after thorough discussion / deliberations and facts on grounds considered and deferred for final opportunity of personal hearing and collection of DML and inspection book through Area FID.

QUALITY CONTROL CASES

ITEM-I **New Cases**

S No	Title of Firm/ Medical Store & Accused Name	Offence	Brief Description
1	i). M/s Espoir Pharmaceuticals, Through its Managing Director/Owner PCSIR, Laboratories Complex Shahrah-e-Dr. Salim-uz-Zaman Sidiqui, Off University Road, Karachi ii) Muhammad Imran, Director, M/s Espoir Pharmaceuticals, PCSIR, Laboratories Complex, Shahrah-e-Dr. Salim-uz-Zaman Sidiqui, Off University Road, Karachi iii. Wazeer Ahmed, Production Incharge, M/s Espoir Pharmaceuticals, PCSIR, Laboratories Complex, Shahrah-e-Dr. Salim-uz-Zaman Sidiqui, Off University Road, Karachi iv. Juber Ali, Quality Control Incharge, M/s Espoir Pharmaceuticals, PCSIR, Laboratories Complex, Shahrah-e-Dr. Salim-uz-Zaman Sidiqui, Off University Road, Karachi (F. No. 4-08/2013-QC)	Manufacture / Sale of Un-Registered, Drugs Section 23 (1)(a)(vii) 23(1)(b) & 23(1)(h) of Drug Act, 1976	• Samples drawn from premises of M/s Espoir Pharma on 26-08-2013 by FID Karachi-III. • The Test reports issued by the Federal Government Analyst in respect of five drugs viz, Ciel Tablets, Oprits Tablets, Alive Plus Tablets, OSO-D Tablets, Callus Tablets identified Calcium, Riboflavin and Vitamin C, in these samples. • The Federal Government Analyst also give following remarks:- Since, the sample is not labeled, therefore, the information regarding composition, registration number, batch number, date of manufacturing and expiry and the manufacturer are not available, hence, the Federal Inspector of Drugs concerned may determine the legal status of the sample under guidance of the Directorate of Registration. • On the basis of clarification given by the firm, the FID further stated that herbal products were being manufactured in the premises. • Show Cause Notice dated 18-02-14 was issued to the firm and the following accused for violation of Section 23 (1)(a)(vii), 23(1)(b) & 23(1)(h) of Drugs Act 1976: i. Muhammad Imran ii. Wazeer Ahmed iii. Juber Ali • The accused and firm/their representatives have been called for personal hearing.

2	i. Qisam Khan S/o Hameed Gul Resident of Sikandar Khel, Caste Koki Khel, Ghundi Post Office, Jamrood, District Khyber Agency ii. Muhammad Nawaz S/o Arsala Khan, Resident of Sikandar Khel, Caste Koki Khel, Ghundi Post Office, Jamrood, District Khyber Agency iii. Ghafoor Afghani Resident of Shinwari Market, Block-B, Hayatabad, Peshawar (F. No. 4-12/2013-DDC(QC-I)	Manufacture/ sale of Un-registered Drugs Section 23(1)(a)(vii) & 23(1)(i) of Drugs Act, 1976	• Federal Inspector of Drugs-II, Islamabad alongwith team of FIA, raided two vehicles Reg. No. WJ.823 and ZS-907 at Daewoo Cargo Collection Point near Liaquat Bagh, Rawalpindi on 17.12.2013 and recovered number of unregistered drugs without having any warranty, drug manufacturing license. • Recovered drugs were seized and, in view of logistic and storage problem of FID office, handed over to FIA authorities for keeping in safe custody on behalf of FID. • Sample of seven drugs were also drawn for test/analysis. The Federal Government Analyst declared all the seven drugs viz, Tab Vegah, Tab Vega, Tab Ponegra, Tab Black Cobra, Inj Voren, Cap Grucid, Cap Pyricam-20 as un-registered for having Sildenafil, Diclofenac Sodium, Piroxicam and Omeprazole. • The FID lodged FIR No. 122/2013 dated 17-12-2011 with FIA authorities against Qisam Khan S/o Hameed Gul and Muhammad Nawaz S/o Arsala Khan. • The FIA authorities vide their Challan has found the above accused and Ghafoor Afghani as guilty. The Ghafoor Afghani was reported to be absconder while other accused are under arrest. • Show Cause Notice dated 18-02-2014 issued to the following accused for violation of Section 23 (1)(a)(vii) & 23(1)(i) of Drugs Act 1976: i. Qisam Khan ii. Muhammad Nawaz iii. Ghafoor Afghani • The accused /their representatives have been called for personal hearing.

ITEM-II ANY OTHER ITEM WITH PERMISSION OF CHAIR

AGENDA/WORKING PAPER FOR 234th MEETING OF THE CENTRAL LICENSING BOARD

Quality Assurance Cases (GMP)

INDEX

234th MEETING FOR CENTRAL LICENSING BOARD (GMP CASES)

Item No. I

(Old Cases of Quality Assurance)

Case No.1: M/s Medivet (Pvt) Ltd, Lahore

M/s Medivet (Pvt) Ltd, Lahore was inspected on 12.04.2013 by Mrs. Aisha Khalil, FID Lahore with reference to see/verify the GMP compliance of the firm. During the inspection, the FID has pointed out a number of shortcomings in all sections.

Action Taken by DRAP: - A show cause notice was issued to the firm on 09.05.2013 along with the direction to stop production in all sections with immediate effect.

Reply of the firm:- In response of the show cause notice, the firm had submitted that they have rectified all the shortcomings pointed out by the FID.

Following panel was constituted on 04.10.2013 for conducting the inspection of the firm.

a) Mr. Nadeem Iqbal, Member Central Licensing Board.
b) DDG (E&M) Lahore.
c) Area FID, Lahore.
d) Area ADC Lahore

The aforesaid panel inspected the firm on 10.12.2013 and concluded as under:

1. ***To allow resumption of production in the Bolus Section, Oral Liquid and Oral Powder Section.***
2. ***Not to resume production for Injectable area due to non conformance as highlighted in the report.***
3. ***Re-inspection by the same panel to review the progress regarding maintenance of GMP compliance and shifting of packaging warehouse as per undertaking the firm.***
4. ***Discontinue production of penicillin containing products till approval of dedicated facility.***

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Case No. 2:- **M/s Standard Drug Company, Hyderabad**

The inspection of M/s Standard Drug Company, Hyderabad was conducted on 22.07.2013 by Dr. Najam-us-Saquib, FID Karachi with reference to see/verify the GMP compliance. During the inspection, the FID has pointed out a number of serious GMP violations.

On the Recommendation of the FID, **that the production and QC operations should be stopped to avoid** any possible public health hazard, a show cause notice was served on 02.09.2013 with the direction to stop manufacturing in all sections immediately with the approval of the Chairman, CLB.
The firm in reply submitted the compliance report that they have made improvements as advised by the FID and they are ready for re-inspection. Accordingly the Chairman, Central Licensing Board has constituted a panel comprising Syed Jaweb Yousaf Bukhari, Member CLB, Mr. Abdul Rasool Shaikh, FID Karachi, area FID Karachi and ADC CDL to re-inspect the firm to check the GMP condition of the firm.

The panel reported that the firm has taken serious steps towards improving, renovation of the areas and addressed almost all the deficiencies and shortcomings pointed out by the FID during previous inspection and recommended that the resumption of the production may be allowed.

The case is placed before the Central Licensing Board for consideration, please.

Case No. 3:- **M/s Ambro Pharma (Pvt) Ltd, Islamabad**

M/s Ambro Pharma (Pvt) Ltd, Islamabad conducted on 17.04.2013 by Mr. Faisal Shahzad, FID-I Islamabad with reference to see/verify the GMP compliance of the firm. During the inspection, the FID has pointed out a number of serious and critical shortcomings in all sections. The FID has concluded that based on areas inspected, people met and documentation reviewed and considering the findings of inspection, the firm is operating at an unsatisfactory level and the FID recommended that the firm should stop production immediately till compliance to GMP guidelines as defined under the Drugs Act, 1976.

Action Taken by DRAP:-

Accordingly, a show cause notice was issued to the firm on 23.05.2013 along with the direction to stop production in all sections with immediate effect.

Reply of the firm:-

In reply of the show cause notice, the firm has requested that they need sometime for compliance/rectification of observations observed during inspection. After the compliance/rectification of shortcomings they will inform the area FID and Secretary Licensing Board for re-inspection/verification of the rectification before starting production.

Following panel was constituted on 01.11.2013 for conducting the inspection of the firm.

a) Dr. Gul Majeed Khan, Member Central Licensing Board.
b) Mr. Tariq Siddique DDC (Reg).
c) Mr. Sayyad Hussain Khan, DDC (LA).
d) Area FID, Islamabad

The panel could not conduct the inspection for one reason to another. The Director (QA/LT) has therefore re-constituted a panel comprising the following officers to conduct the inspection of the firm which was directed to stop production since April 2013 to check/verify the GMP compliance in all sections:

i) Deputy Director General (E&M), Islamabad.
ii) Area FID, Islamabad.
iii) Deputy Drugs Controller (QC), Islamabad

Present Position:

The above panel inspected the firm on 30.01.2014 to check/verify the improvements made by the firm and concluded that the production and testing facilities, the personnel met, their knowledge on the subject **the panel recommended the resumption of production**.

The case is placed before the Central Licensing Board for consideration, please.

Case No. 4:- **M/s Marvi Pharmaceuticals (Pvt) Ltd, Karachi**

M/s Marvi Pharmaceuticals (Pvt) Ltd, Karachi was conducted on 08.03.2013 by Dr. Shahid Hussain, FID Karachi with reference to see/verify the GMP compliance. The FID has reported that the firm is medium size and has the facilities to manufacture of Tablet, Capsules and Syrups. A renewal inspection of the firm was conducted in 2010. However, the FID has pointed out the number of observations and gross violations in all sections. The FID recommended that their Drug Manufacturing License No.000148 (By way of Formulation) may be cancelled in larger public interest.

Action Taken by DRAP:-Accordingly, a show cause notice was issued to the firm on 23.04.2013 along with the direction to stop production in all sections with immediate effect.

Reply of the Firm:-In response to the show cause notice, the firm had submitted a reply through Abbas Haider Jafri Law Associates, Advocates High Court wherein the firm has claimed that the FID has provided a false inspection report.

Consequent Action Taken by DRAP:- A letter has been sent to FID Karachi on 12.07.2013 to get his comments/views on the reply of the firm.

Comments of The FID:- The comments of the FID has been received wherein he has submitted that the allegation made by the Attorney of the firm are baseless actually based on conjecture and surmises and harassing to interfere the official duties of FID under section 18 & 19 of the Drug Act, 1976 which is also violation of the Drug Act, 1976. He further informed that his visit was lawful and inspection based on facts which are enacted with the withdrawal of suspicious samples which were sent legally to CDL Karachi.

The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013 where after considering all aspects of the case, the Board had decided including the following:-

i) A larger panel inspection will be conducted to check/verify the claim of the firm about two different premises and to check overall GMP conditions of the firm as per Schedule B-II of Drugs (L.R.A) Rules 1976 framed under the Drugs Act 1976 within 30 days.

ii) The production will remain stopped till the final approval by Central Licensing Board on receipt of the inspection report of the firm by the larger panel of experts.

Accordingly in compliance to the decision of the Board, the Chairman, Central Licensing Board has constituted a panel comprising the following to conduct the inspection of in the light of the decision of the Central Licensing Board:

i) Dr. Ali Akbar Sial, Member Central Licensing Board,
ii) Deputy Director General (E&M) Karachi,
iii) Area FID Karachi

iv) Area ADC Karachi

The panel concluded that the contents of the case may be kept on the forthcoming meeting of CLB for further action as the period of 30 days recommended by the panel for compliance of the shortcomings till that period. **Licensee is not allowed for any production activity.**

Reply of firm: The firm informed that the observations of the panel has been fully met, consequently the director QA directed the same panel to re-inspect the firm for reporting on GMP status of the firm with clear recommendations.

Action Taken by DRAP: The Director (QA/LT) has kept the above mentioned panel to conduct re-inspection of the firm in order to verify the improvements made by the firm. In this regard, letter has been issued by this section on 18.02.2014.

The firm submitted the copy of the panel report of inspection. The panel's in their report has not mentioned any observations and shortcomings which are of serious nature. The company had been closed for the last more than 03 years. However, the panel has concluded that**: In the opinion of the panel recommended that the firm be given two week period to become fully prepared, to go into production. Before they are allowed production they were respected to check the compliance with the undertaking attach herewith. At this stage a conditional resumption is forwarded to honorable CLB for favorable consideration. Over all other facilities are available as compliance were made against previous observations. Present under- taking envisage as per compliance of the Rules and the Drug Act 1976.**

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Case No. 5:- **M/s Lahore Pharma, Lahore**

M/s Lahore Pharma, Lahore was inspected on 14.03.2013 by a panel comprising of Mr. Nadeem Iqbal, Member Central Licensing Board, Mrs. Aisha Khalil, FID Lahore and Mr. Akbar Ali, ADC Lahore with reference to see/verify the GMP compliance. During the inspection, the panel has pointed out number of serious shortcomings in all sections. The panel concluded and directed the firm to stop production immediately.

Action Taken by DRAP: - A show cause notice was issued to the firm on 29.04.2013 along with the direction to stop production in all sections with immediate effect.

The case was placed before the Central Licensing Board in its 232nd meeting held on 29-30th July, 2013 wherein Mr. Muhammad Saeed, Owner of the firm appeared before the Board. He submitted the reply of the show cause notice to the Board informing that they have made improvements as suggested by the FID. They are ready for inspection and also requested to withdraw the show cause notice. The Board after thorough deliberations on the instant case took the decision accordingly on case to case basis.

Decision of CLB

i) The Board decided that the production will remain stopped till the final decision by Central Licensing Board.

ii) The Board also decided to get the firm re-inspected by a panel to verify the improvements made by the firm in the light of shortcomings identified by the area FID.

iii) ***The panel inspection report will be presented in next meeting of CLB as and when received for further consideration and decision by the Board.***

In compliance to the decision of the Central Licensing Board, the Chairman, Central Licensing Board/Director (QA/Lab Testing & Lic) has constituted a larger panel comprising the following to conduct the inspection of the firm in the light of the decision of the Central Licensing Board to check/verify the GMP compliance in all sections:

i) Mr. Ayaz Ali Khan, Member, Central Licensing Board,
ii) Mr. Zia Husnain, FID Lahore,
iii) Area FID Lahore and
iv) Mr. Akbar Ali ADC Lahore

Present Position: The FID inspected the firm before the panel inspection to check the production status and improvements made by the firm and reported that no production and QC staff was present, same situation prevails, no progress in installation of HVAC. Some production activities in cream/ointment and external liquid area were observed. Upon query, Mr. Saeed's (Owner) son showed very in appropriate behaviors with the FID. He criticized the concerned authorities for imposing the conditions/requirements of HVAC system, GMP compliance on audit proforma Schedule B-II.

Another show cause notice has been served to the firm on 20.02.2014 along with the direction to stop production, immediately.

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Item No. II

(New Cases of Quality Assurance)

Case No. 6:- **M/s National Absorbent Cotton Mills Co. Karachi**

The inspection of M/s National Absorbent Cotton Mills Co, Karachi was conducted 31.10.2013 by a panel for compliance of Drug Registration Board decision vide DRAP's letter No.F.3-20/2012-DDC (QC) dated 08.10.2013. The panel comprises of Dr. Amanullah Khan, Director DTL Quetta, Dr. Muhammad Tanweer Alam, DDG (E&M) Karachi and Mrs. Muneeza Khan, FID Karachi conducted the inspection and recommended for the *suspension of Carded Absorbent Cotton Wool for three months.* The panel has also pointed out number of other shortcomings. The panel also recommended to stop all manufacturing operations.

Action Taken by DRAP: - A show cause notice was served to the firm on 13.01.2014 along with the direction to stop production in all sections with immediate effect.

Reply of the firm:

The firm replied that they have send lay out plan to licensing section for approval and after approval they will start work on it other improvements are going-on in the light of directions of the panel. The firm is willing to appear personally before the Board.

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Case No. 7: **M/S Sawan Pharmaceutical (Pvt) Ltd, Islamabad**

M/s Sawan Pharmaceutical (Pvt) Ltd, Islamabad was conducted on 30.12.2013 by Dr. Muhammad Fakhruddin Aamir, FID Islamabad with reference to check the GMP compliance and production activities of the firm. During the inspection, the FID has pointed out number of shortcomings in all sections. The firm was reported to manufacture tablet, capsule and injections (ampoules). The FID was not satisfy with the GMP of the firm and directed the firm to submit comprehensive plan of rectifications/improvements.

Action Taken by DRAP: - A show cause notice was issued to the firm on 03.02.2014 along with the direction to suspend manufacturing of drugs in all sections immediately till the decision of Central Licensing Board.

Reply of the firm: In response to show cause the firm has submitted compliance report for making certain improvements.

Present Position: Following panel has been requested to inspect the company on 21.02.2014 so as to check the improvements made by the firm:

i) Dr. Gul Majeed Khan, Member CLB
ii) Dr. Ahmad Mahmood Mumtaz, Chairman, Quality Control
iii) Dr. Muhammad Fakhruddian Aamir, FID Islamabad.

Recommendation of the Panel: The panel concluded that based on the areas inspected, the people met and documents reviewed, and considering the findings of the inspection M/s Sawan Pharmaceuticals (Pvt) Ltd, Islamabad has rectified most of the shortcomings observed by the FID during last GMP inspection. **The panel recommended for the resumption of production and asked the company to continue its efforts for ongoing improvement process of upgradation.**

The case is placed before the Central Licensing Board for consideration, please.

Case No. 8: **M/s Ameer Pharma (Pvt) Ltd, Lahore**

M/s Ameer Pharma (Pvt) Ltd, Lahore was inspected on 13.01.2014 and 15.01.2014 by a panel comprises by Mr. Asim Rauf DDG (E&M) Lahore, Mrs. Aisha Khalil, FID Lahore and Rana Ihsan-ul-Haq Athar, ADC Lahore to check the GMP compliance. The panel has pointed out number of shortcomings in all sections. The Panel reported that the procedures of manufacturing were not being followed, quality control staff was not strengthen, proper production schedule had not been followed keeping in view the capacity and work load in the areas. The panel further reported major critical deviations from the procedures and the firm was directed to rectify the shortcomings. The observations of the panel and quantification of the cGMP performa directed the firm to **immediately stop operational activities in the liquid Injectable section**. The GMP of the firm is rated with the scoring as poor compliance (c) 123 and even non-compliance (D) 04, fair compliance (B) 144. The scoring of GMP indicates alarming and pathetic/poor condition of GMP by the firm.

Action Taken by DRAP: -

A show cause notice was issued to the firm on 03.02.2014 along with the direction to suspend manufacturing of drugs **in the liquid Injectable section** till the decision of Central Licensing Board.

Reply of the firm:-

No reply has been received from the firm till to date.

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Case No.9: M/s Hafiz Pharma, Kamonke

M/s Hafiz Pharma Industry, Kamonke was inspected on 19.03.2013 by Mr. Abdul Rashid Shaikh, FID Lahore with reference to see/verify the GMP compliance of the firm. During the inspection the FID has pointed out some shortcomings which are as under:-

- The HVAC system was not installed.
- There was no proper and full time technical staff was available.
- Inkjet printer for in house printing of date of manufacturing date of expiry and batch number was not available.

The FID reported that as per current GMP conditions, the firm was directed to stop production of their re-packing section. **The firm agreed and also given undertaking that they will stop production of this section till the up-gradation of their section**. The FID further reported that the renewal of the firm is still pending and requested to constitute the panel for renewal of the Drug Manufacturing License.

Action Taken by DRAP: The firm was directed to stop production on 14.05.2013 by this Authority in re-packing section with immediate effect and also direct to install HVAC system in all production areas. The CEO, DRAP/Chairman, CLB constituted a panel comprising the following to re-inspect the firm for rest of production areas and quality control etc. The panel shall be authorized to stop production in any section, subject to GMP compliance.

Reply of the firm:

The firm submitted compliance report in which they acknowledged that they have stopped production in their re-packing section w.e.f. 19.03.2013 as per instruction by FID Lahore. The firm further informed that they are not in position to conduct the inspection and requested for 2 months time to completion of HVAC system.

Subsequently, a reminder was issued to the panel on 08.07.2013 wherein the panel was again directed to conduct the inspection of the firm in order to confirm the improvements made by the firm particularly installation of HVAC system.

Present Position: The said inspection is still not been conducted by the panel. However, the firm has sent a request on 19.02.2014 wherein they have informed that 6-8 weeks are required for installation of HVAC system, as they are importing from Bahrain.

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Case No. 10: M/S Chishti Pharmaceutical Industries, Chichawatni

The inspection of M/s Chishti Pharmaceutical Industries, Chichawatni was conducted on 18.08.2010 by Mr. Muhammad Arif Ch., FID Lahore with reference to see/verify the GMP compliance of the firm. The FID had pointed out number of shortcomings in all the sections and the firm was **directed to stop production immediately** by the defunct Ministry of Health. The firm was also directed to establish independent quality control laboratory which is mandatory under rule 16 of the Drugs (Licensing, Registering and Advertising) Rules, 1976.

Status of the firm
The FID has reported that the firm was directed many times to rectify the shortcomings pointed out in previous inspections and also directed to hire technical staff etc but no compliance report has been received in this regard so far.

Action Taken by DRAP: - A show cause notice was issued to the firm on 03.01.2014.

However, no reply has been received from the firm till to date.

The representative of the company has been called for personal hearing and the case is placed before the Central Licensing Board for consideration, please.

Case No. 11: **M/s Rukha Pharmaceutical & Laboratories (Pvt) Ltd, Lahore**

The inspection of M/s Rukha Pharmaceutical & Laboratories (Pvt) Ltd, Lahore conducted on 25.09.2013 by Mr. Asim Ruaf, FID Lahore with reference to see/verify the GMP compliance. During the inspection, the FID has pointed out a number of serious shortcomings which are as under:-

- Quality management system was not fully operational.
- No quality assurance manager was available.
- All SOPs available were un-signed.
- Training of staff and technical officers were not being done.
- There was no compliant cell.
- All equipments in quality control including spectrophotometer, centrifuge machine etc were not calibrated.
- HPLC was not operational.
- Conc. HCl reagent was placed and was found expired.

The FID directed the firm to attend the observations immediately and submit detail compliance report. Meanwhile, the FID asked the firm to stop all manufacturing and quality control operations.

Later on another inspection of the firm was conducted on 21.10.2013 by a panel comprising Mr. Ajmal Sohail Asif, FID Lahore and Mrs. Asif Rauf, FID Lahore to verify the improvements made by the firm. **The panel concluded that the unit** was neat and clean and equipped with necessary manufacturing and quality control facilities and **recommended to resume the operations in the premises.**

The case is placed before the Central Licensing Board for consideration, please.

(ITEM No. III)

List of Show Cause Notices Issued By QA Division for Non GMP Compliance of the Pharmaceuticals Companies

S.No.	Name of the company	Current Status
1.	M/s Drug Pharma Chemical (Pvt) Ltd, Karachi	Reply of the company received.
2.	M/s Himont Pharmaceuticals (Pvt) Ltd, Lahore	Reply of the company received. Panel constituted to verify the improvements.
3.	M/s Kohos Pharmaceutical (Pvt) Ltd, S.I.T.E, Hyderabad	Reply of the company received. Panel constituted to verify the improvements.
4.	M/s Medicraft Pharma, Peshawar	Show Cause issued. Reply of the firm is awaited.
5.	M/s Safina Pharmaceuticals (Pvt) Ltd, Lahore	Reply of the company received. Panel constituted to verify the improvements.
6.	M/s Sharooq Pharmaceuticals (Pvt) Ltd, Lahore	Reply received. Under Evaluation
7.	M/s T.G Pharma, Karachi	Reply of the company received. Panel constituted to verify the improvements.
8.	M/s Tagma Pharma (Pvt) Ltd, Lahore	Reply received. Under Evaluation
9.	M/s Metro Pharmaceutical, Rawat	Reply not received.
10.	Goodman Laboratories, Rawat	Reply received. **Personal Called**
11.	M/s Aviceena Lab, Lahore	Case under Evaluation
12.	M/s Rex Pakistan Ltd, Karachi	Old Case
13.	M/s Risma Lab, Karachi	Old Case

Item No. IV:-ANY OTHER ITEM WITH PERMISSION OF CHAIR