Registered

GOVERNMENT OF RAJASTHAN
DRUGS CONTROL ORGANISATION, SWASTHYA BHAWAN,
TILAK MARG JAIPUR

No. DC-2/A-3/ Gen.-13/2011/62 Date: 04/2/2011

All Manufacturers / All approved Testing Labs.

Subject:- GSR.780(E) dated 10-11-2008 with regard to introduction of **'GOOD LABORATORIES PRACTICES'** Schedule L-1 under the Drugs & Cosmetics Rule 1945; regarding.

Reference:- In continuation of this office Letter No. DC/D-2/2009/35 Dated 18-2-09

On the above subject please note that the provisions of Schedule L-1 that is 'GOOD LABORATORIES PRACTICES' has come into force with effect from 1st day of November 2010. For its implementation all the features of Schedule L-1 are simplified in tabular form with remark column.

You are requested to fill up the remark column of the enclosed performa to assess the existing facilities of your laboratories & submit the same within 15 days of the receipt of this letter. The improvement desired in the laboratories be done & informed accordingly. The deficiencies observed by you with respect to the said provisions be please rectified & inform so that the verification can be done by the officers.

4/2/2011
Drugs Controller,
Rajasthan, Jaipur.

01-2-11

Inspection report proforma of LABORATORIES of the Manufacturing units as per the Schedule L-1 of the Drugs & Cosmetics Act 1940 & Rules made there under

GOOD LABORATORY PRACTICES AND REQUIREMENTS OF PREMISES AND EQUIPMENTS

A- General Requirements & Premises

S.N.	Details of the requirement	Remark
1	For Laboratory management a qualified individual known as quality manager or technical manager is appointed.	
2	The laboratories is designed, constructed and maintained to prevent entry of insects and rodents besides cross contamination;	
3	Interior surface (wall, floor, and ceilings) are smooth and free from cracks, and permit easy cleaning and disinfection;	
4	Adequate provision for space and equipment for carrying out necessary test is provided & also utilities like water, power and gas;	
5	Air ventilations system is provided to ensure dust Free Environment.	
6	The laboratories is provided with adequate Lighting and ventilation, air-conditioning to maintain satisfactory temperature and relative Humidity.	
7	The facilities of drainage system & to prevent water logging in the laboratory.	
8	Tabletops is made of with acid, alkali and solvent resistant material.	
9	Adequate space with proper storage conditions in the laboratory shall be provided for keeping Reference and working standards.	
10	The air circulation is maintained in the area where sterility test is carried out as per Schedule M.	

B- Personal & Equipments

S.N.	Details of the requirement	Remark
1	Staff in the laboratory shall possess necessary qualification, proper training and shall have Adequate, experience for the assigned duties.	
2	A training record of all the personnel shall be maintained	
3	Head of the laboratory must be of high professional standing with experience in drug analysis and laboratory management.	
4	The analytical instruments shall be housed in the dust-free environment and with controlled conditions of temperature and humidity.	
5	A progress register for non-functional equipments and action for procurement of spares and accessories, monitoring thereof, shall be maintained.	
6	A Standard Operating Procedure for preventive maintenance of machine or equipment or Apparatus shall be prepared by the laboratory.	
7	Equipments such as burette, pipettes, volumetric flasks, weight boxes, thermometers, etc., shall be thoroughly checked for accuracy for Calibration before acceptance of use.	
8	Equipments, instruments giving anomalous results or defective must be labeled as 'out-of-order.	
9	Autoclaves must meet the requirements described for operations, safety and validation procedures	
10	Work involving the evolution of harmful and obnoxious vapors shall be carried out in a fume cupboard	

Chemicals and Reagents, Good housekeeping and safety

S.N.	Details of the requirement	Remark
1	All reagents and solutions in the laboratory shall be properly identified with a label.	

2	A standardization register shall be maintained,with its raw data and SOP for preparation and standardization on stock solutions, standard solutions, and volumetric solutions.	
3	Containers of stock solutions and of standard solutions shall bear the details:	
4	The storage and handling of chemicals and reagents shall be done in a manner Considering the physicochemical properties substances and the hazards involved in their use.	
5	General and specific written down instructions for safety shall be circulated to each staff member	
6	SOP for safety, house-keeping and loss prevention.	
7	Drinking, eating and smoking shall not be permitted in the laboratories.	
8	Staff must wear laboratory coats or other protective clothing including gloves and face masks and eye protection wherever required;	
9	The laboratories shall have adequate first aid kit and fire fighting equipments.	
10	Operators carrying out sterility tests shall wear sterilized garments including headgear, face masks and shoes;	
11	The staff must be educated in the first aid techniques, emergency care and use of antidotes.	
12	Safety rules in handling cylinders of compressed gases must be observed and staff must be familiar with relevant colors identification codes;	
13	Protective Precautions- 1- water showered 2- Rubber suction bulbs must be used on manual pipettes and siphons; 3- Warnings, precautions and written Instructions violent, uncontrollable or reactions. 4- Appropriate facilities for the collection, Storage and disposal of wastes. 5- Safe disposal of corrosive or dangerous Products by neutralization or deactivation. 6- Safety precautions to be adopted	

	while handling potassium cyanide and bromide; 7- SOP for handling, collection, disposal of chemical and biological wastes.	

Maintenance, calibration, and validation of equipments & Reference materials: Microbiological Cultures:

S.N.	Details of the requirement	Remark
1	All equipments, instruments and other devices used in the laboratory shall use appropriate methods and procedures for all tests or calibrations and they shall be regularly Calibrated and validated.	
2	For most of the equipments and instruments , SOP for calibration and calibration schedule be p the laboratory and a logbook shall also be prepared by each laboratory for proper documentation of calibration results.	
3	Reference material shall be traceable to agency authorized by Government of India or any other International body.	
4	The laboratory shall prepare working standard by comparing with the reference standards and shall be routinely checked for their purity	
5	Whenever, any new reference material is received by the laboratory following details are to be written- a-Source of supply; b-Code number of the reference material; c-Date of receipt; d-Batch number or identification number of the supplying agency; e-Details like assay value, water content or information provided; f-Storage condition of the material; g-Date of expiry, if any and date of manufacturing if possible.	
6	SOP for maintenance of microbial culture and sub-culture must be prepared by the laboratories.	

Quality system: & internal quality system audits, Management review:

S.N.	Details of the requirement	Remark
1	The measurements and calibrations shall fully conform to the compendia requirements and the methods demonstrably based on validation protocols are followed.	
2	Remedial action on the observations by internal and external audits are taken appropriately	
3	Documented quality policy for the organization.	
4	Internal audits are done to assure the integrity of the analysis and such audits shall be conducted periodically	
5	Each activity is audited at least once in a year.	
6	The Quality Manager shall maintain all the records of the analysis being conducted which includes test system, the type of analysis, date on which analysis is done	
7	Review yearly 1-Report or input of internal audits; 2-Matter arising from previous reviews; 3-Report of external audits, if any; 4- Surveillance report, if any; 5- Result of proficiency testing; 6-Complaints or feedback received from users of laboratory services; 7-Details of in-house quality control checks; 8-Need of amendment of the quality system and documentation; 9-Introduction training of new staff.	

. Standard operating Procedures

S.N.	Details of the requirement	Remark
1	Shall be written in a chronological order listing different steps leading to an analysis of drugs or calibration of an instrument;	
2	Shall have SOP manuals and have its periodic Review.	

3	Standard Operating Procedures for the followings are required (i) Sample handling and accountability; (ii) Receipt identification, storage, mixing and method sampling of the test and control articles; (iii) Record keeping, reporting, storage and retrieval of data; (iv) Coding of different studies, handling of data including use of computerized data system; (v) Operation of technical audit personnel in performing and reporting audits, inspections and final report reviews; (vi)Routine inspection of cleaning, maintenance, testing, calibration and standardization of instruments; (vii) Action to be taken in respect of equipment failure; (viii) Analytical data methods; (ix) Health and safety protection; (x) Data handling and storage retrieval; (xi) Health and safety protection; (xii) Animal room preparations; (xiii) Animal care; (xiv) Storage and maintenance of microbial cultures; (xv) Maintenance of sterility room (i.e. constant maintenance and monitoring of Aseptic condition room); (xvi) Use and storage of reference standards; (xvii) Procurement of stores and equipment; (xviii) Monitoring of testing of samples; (xix)Method of retention of unexpended samples, their location, maintenance and disposal; (xx)Document control; (xxi) Redressal of technical complaints; (xxii) House-keeping; (xxiii)Corrective and preventive action; (xxiv)Working procedure (test methods); (xxv)Calibration manual. (xxvi)Training manual.	

4	**Protocols and specifications archive:-** List of all the pharmacopoeias a file on patent and proprietary medicines (non-Pharmacopeia) test methods to specifications prepared and validated by the manufacturer. The test methods shall be submitted to the concerned Drug Control Authority.	
5	**Raw data-** Data integrity and security shall be maintained Original entry must be saved and the system shall trail for all data.	
6	**Storage and archival:** The residual sample shall be retained in proper storage condition for a period of one year after the final report.	
7	The laboratory must establish and maintain procedures for the identification collection, indexing, retrieval, storage, maintenance, and Disposal of all quality documents.	
8	All the raw data, documentation, SOP, protocols and final reports are to be retained and there shall be archives of orderly storage and expeditious retrieval of all raw data, documentation, protocols, interim and final report.	
9	The condition under which the original documents are stored must ensure their security and confidentiality	
10	Raw data on thermal paper might fade away with time; therefore, a photocopy of the thermal paper shall be retained in the archive.	

Note- (1) All bio-medical laboratory waste shall be destroyed as per the provisions of the Bio-Medical laboratory waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 1996.

(2) If the culture have become non-viable or mutant, proper procedure shall be followed to destroy these cultures by autoclaving under an authorized personnel for biological testing. Preferably not more than five passages may be prepared.

(3) The original equipment manufacturer's recommendations along with the experience of the laboratory staff and the use of equipment per day may also be considered while fixing the Frequency of calibration.