POLICY ON GOODS LABORATORY PRACTICES FOR MICROBIOLOGY LABORATORY

INTRODUCTION:

This document provides the policy for Good Laboratory Practices for Microbiology Laboratory.

SCOPE:

This policy is applicable to Microbiology laboratory at ……. and associated units.

POLICY DETAILS:

All Microbiology laboratories shall comply with cGMP as defined by Regulatory requirements, Local Regulatory authorities and …….

Quality Management

Management of Quality shall ensure safety, quality and efficacy of …… products and compliance with the regulations of their regulatory registrations.

Facility

- ✧ Laboratory shall be carefully designed considering the requirements of good microbiological practices and laboratory safety.
- ✧ A laboratory shall be divided into clean or aseptic areas and live culture areas.
- ✧ Areas in which sterile product samples are handled and incubated shall be maintained completely free of live cultures.
- ✧ Written procedure for Entry and Exit for Microbiology Laboratory and its critical areas shall be in place. Photographic chart of the entry exit procedure shall be displayed at the respective locations.

Personnel

- ✧ The individual responsible for the supervision of laboratory shall have appropriate education, training, and experience on activities to be carried out in laboratory.
- ✧ Laboratory shall have sufficient number of personnel for timely and proper work considering the requirement. Personnel working in the laboratory shall be appropriately qualified.

Gowning

- ✧ Personnel working in the laboratory shall wear suitable clothing which is non-shedding type, with loose fitting and comfortable to work.
- ✧ Personnel working in testing shall wear garments as required by the set procedures.

Health and Hygiene

- ✧ The general health of the personnel shall be satisfactory.
- ✧ Personnel with open wounds, any skin infection or any respiratory tract infection shall not be permitted to work in microbiology laboratory.
- ✧ Cleanliness and Hygiene of the laboratory shall be maintained at prime level.

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Cleaning and disinfection of the laboratory shall be done as per schedule.

- ✧ Written procedures for cleaning and disinfection along with preparation of disinfectant solution shall be in place.

Training

Training related to work, Hygiene and safety shall be given to each and every personnel working in the laboratory. Procedure related to training shall be in place.

Equipment and Instrument

- ✧ Equipment and Instruments used shall be of appropriate design and adequate capacity.
- ✧ Written procedures shall be in place for operation, inspection, cleaning, and maintenance of equipment and instruments.
- ✧ All the Equipment and instruments shall be adequately calibrated and/or validated as per schedules. Breakdown procedures shall be in place for equipment and instrument under maintenance.

Operation

- ✧ Duly approved schedules related to activities to be performed in the laboratory like Environment Monitoring, water analysis, Equipment / instrument calibrations and validation shall be in place.
- ✧ Laboratory shall have standard operating procedures in writing that are adequate to ensure the quality and integrity of the data generated in laboratory.
- ✧ Standard operating procedures shall be authorized.
- ✧ During Analysis under LAF / BSC, analyst should ensure microbiological activity without disrupting the aerodynamics required as per First Air principle.
- ✧ All reagents, dehydrated culture media and solutions in the laboratory areas shall be labelled to indicate identity, storage requirements, and expiration date.
- ✧ Inventory management and sample management shall be in place.

Internal Audit

Internal Audit of the laboratory shall be performed by Audit and Compliance Team from Corporate Quality Assurance as per Schedule.

Documentation

- ✧ Written procedure shall be in place for documentation in laboratory.
- ✧ Raw data, documents, protocols, and reports, generated as a result of any activity in laboratory shall be retained as per set procedures.
- ✧ Laboratory shall have proper storage system for all raw data, documentation, protocols and reports.

Safety

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During working in the microbiology laboratory safety of the staff shall be assured. Proper safety apparels shall be in place for the working staff.

AMENDMENT AND WAIVER:
The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable.

ABBREVIATIONS:

CFR : Code of Federal Regulations
cGMP : Current Good Manufacturing practices. NF : National Formulary
USP : United States Pharmacopoeia

REFERENCES:

USP 43 – NF 38 Chapter <1117> Microbiology Best Laboratory Practices.

21 CFR part 58 Good Laboratory Practices for Nonclinical Laboratory Studies.

Schedule M : The Gazette of India Extraordinary Part – II Section – 3(1) Ministry of Health and Family welfare (Department of Health) Notification New Delhi. 11th December 2001.