POLICY ON GOOD QUALITY CONTROL LABORATORY PRACTICES

INTRODUCTION:

This document provides the policy for Good Laboratory Practices to be followed to obtain reliable and reproducible results meeting regulatory standards with effective usage of time, manpower and resources.

SCOPE:

This policy is applicable to all the activities performed in Quality Control Laboratory.

POLICY DETAILS:

- ✧ Quality Control Laboratories shall be separated from Production areas and Warehouse. Premises shall be built and maintained to suit the operations being carried out. Adequate ventilation, air filtration and exhaust systems shall be provided, where appropriate.
- ✧ There shall be adequate number of personnel qualified by appropriate education, training and / or experience to perform and supervise the tasks assigned.
- ✧ Written procedures/specifications shall be available for all the activities carried out in Quality Control laboratory. Adequate system shall be available for reporting of analytical test results, calibration results, results of different studies conducted in the laboratory etc. All laboratory documents shall be stored and retrieved as per written procedures.
- ✧ Safe working conditions and practices shall be ensured in the laboratory. Accidents shall be handled as per written procedures.
- ✧ All analytical instruments and equipments used in the laboratory shall be installed, qualified, calibrated and maintained as per written procedures. Software used in the Quality Control laboratory shall be qualified.
- ✧ Backup of Electronic Data generated in the laboratory and restoration verification of the same shall be performed as per written procedures.
- ✧ Valid laboratory reagents, chemicals, indicators and volumetric solutions shall be prepared (as applicable), maintained and stored as per the written procedures.
- ✧ Laboratory Reference Standards shall be maintained, qualified (as applicable), stored and used as per the written procedures.
- ✧ Quantitative and semi-quantitative analytical test procedures for drug substances (API’s), Raw materials, API- starting materials, intermediates, excipients and drug products (formulations) shall be validated / verified, as applicable.
- ✧ Transfer of analytical methods shall be performed to qualify the receiving laboratory.
- ✧ Sampling of all API, API starting materials, Raw materials, Excipients, Ancillary materials, Packaging materials, Intermediates, water and steam condensate shall be performed using appropriate sampling accessories.
- ✧ Retention sample from each batch of Raw materials, API’s, Excipients, Intermediates, packaging material (printed
- ✧ / primary) and Drug products (formulations) shall be maintained under recommended conditions as per SOP of “Retention Samples”, for future reference.
- ✧ All the samples received for analysis in the laboratory shall be analysed as per

approved specifications. While performing the tests, instructions for use and storage of laboratory reagents, volumetric solutions, reference standards, culture media etc. shall be followed. The instruments / equipments shall be used within the permitted range and as per the written operating procedures. The analytical data shall be reviewed and Certificate of analysis shall be prepared for required consignment.

- ✧ All non-conformances observed in the laboratory [e.g. Out-of-specification (OOS), Out of Trend (OOT), Laboratory incidences, Deviations and Excursion in temperature and humidity (in case of Walk-in chambers / incubators)] shall be investigated, evaluated, documented and reported to relevant competent authorities, wherever applicable.
- ✧ Cleaning validation of the laboratory glassware and sampling accessories shall be performed as per defined frequency.
- ✧ Stability Studies of all own manufactured drug substances, intermediates and drug products shall be performed for establishment of recommended storage conditions, retest periods (for drug substances and intermediates), and shelf-life (for drug products).
- ✧ Visual Inspection of Drug substances and Drug products shall be performed.
- ✧ Different types of studies such as Forced Degradation Study, Temperature and Humidity Distribution Study, Photostability Study, Deactivation Study (wherever applicable) etc. shall be performed and documented as per written procedures.
- ✧ Change control procedure shall be applied to all changes done in the laboratory i.e. addition / revision / deletion / transfer related to product, documents, system, facility, equipment, instrument, others.
- ✧ Training related to employee's functions as well as on cGMP and GLP shall be imparted as per defined frequency by qualified individuals.
- ✧ Internal audits shall be performed in accordance with an approved schedule by designated competent persons other than in-charge of the laboratory in order to verify compliance with the Quality Control system.
- ✧ Audit of contract laboratory wherein samples of Raw Materials, Packaging Materials, Active Pharmaceutical Ingredients, Excipients, Intermediate and Drug Products are sent for analysis shall be performed to ensure GMP compliance of specific operations occurring at the contract laboratory.

AMENDMENT AND WAIVER :

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

DEFINITION: Not applicable.

ABBREVIATIONS:

API	:	Active Pharmaceutical Ingredient
cGMP	:	current Good Manufacturing Practice
EU	:	European Union
FDA	:	Food and Drug Administration
GLP	:	Good Laboratory Practices
ICH	:	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
SOP	:	Standard Operating Procedure

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WHO : World Health Organization

REFERENCES:

ICH Q7A : Good Manufacturing Practice for active pharmaceutical ingredients. WHO : A WHO guide to Good Manufacturing Practice (GMP) requirements.
EudraLex Volume 4 : EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary use.
Indian FDA : Schedule M and L. (Drugs and cosmetics act, 1940 and rules, 1945).