PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Good Laboratory Practices	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure of good laboratory practices covering activities performed in Quality Control Laboratory.

2.0 SCOPE:

This procedure applies to Good Laboratory Practice in Quality Control Laboratory.

3.0 RESPONSIBILITY:

Analyst - Quality Control responsible for adhering to the practices while working in laboratory.

Head - Quality Control.

4.0 PROCEDURE:

4.1 Principles and objectives of Good laboratory practices

4.1.1 To ensure consistency of quality by the adoption and application of effective procedures and the keeping of comprehensive and accurate records.

4.1.2 Honesty- to perform tasks as and when required and records the results exactly as they are.

4.1.3 Accuracy- without which both time and work will be wasted.

4.1.4 Diligence- the caring attitude which binds honesty and accuracy together.

4.1.5 Every activity must be validated to ensure that it achieves its intended result.

4.2 Premises

4.2.1 Maintain the laboratory and its premises clean.

4.2.2 Maintain all instruments clean and to the extent possible covered.

4.2.3 Ensure that all the analytical balances are kept on steady platform, away from air currents and vibrations.

4.2.4 Measure and record the temperature and the relative humidity of the laboratory twice in a day.

4.2.5 Keep workbenches of laboratory clean and tidy all the time.

4.2.6 Keep the passageways clear of any obstacles to facilitate free movement.

4.2.7 Ensure that only current versions of all master documents are available in the laboratory.

4.2.8 Ensure that all instruments are qualified as per relevant protocols before putting into use.

4.2.9 Allot identification number to all analytical instruments.

4.2.10 Ensure that the instruments are in calibrated status before usage.

4.2.11 Identify 'Under Maintenance' instruments and prevent usage of the same.

4.2.12 SOPs and logbooks must be maintained at the workplace where they can be easily accessed.

4.2.13 Ensure all the liquid / gas chromatographic columns are numbered as per the relevant SOP and update the usage log of the same whenever columns are used.

4.2.14 SOP's shall cover every aspect of laboratory work.

4.2.15 All the materials and products must be tested as per their respective specification and STP.

4.2.16 All the laboratory instruments must be maintained, checked and calibrated to ensure accurate and repeatable results as per respective calibration schedule.

4.2.17 All the work areas must be kept tidy at all times and floor clear of obstructions.

4.2.18 Regular self-inspection audits shall be carried out by all the departments.

4.2.19 All the documents and procedures must be reviewed and kept up to date regularly.

4.2.20 All the records must be properly indexed and stored to allow rapid retrieval when required.

4.3 Personnel

4.3.1 Always wear the company's uniform or apron as applicable in the laboratory premises.

4.3.2 Always wear the company's footwear or shoe cover when entering it to the laboratory.

4.3.3 Do not drink or eat in the laboratory.

4.3.4 Follow entry and exit procedures wherever applicable.

4.3.5 Follow safety instructions carefully all the time.

4.3.6 Wear safety apparels and equipment as applicable in the laboratory premises.

4.3.7 It is essential that every person working in the laboratory must aware of grave consequences, which may result in ignoring safety rules. Do not wear ornaments/Accessories in laboratory premises.

4.4 Practices

4.4.1 Update the daily analytical work plan and status on relevant document. Start analysis only after issuance of test datasheet and always follow controlled copy of specification/test procedure.

4.4.2 Enter all analytical records concurrently when analysis is being carried out.

4.4.3 Protect all documents from spillage of chemicals/ solutions while performing analysis.

4.4.4 Strike the desired option, when multiple options are provided, unless specified otherwise.

4.4.5 Use only Class 'A' category volumetric glassware's (Measuring cylinder, pipettes, burettes and volumetric flasks) or calibrated Class 'B' category volumetric glassware's.

4.4.6 Clean and dry all the laboratory glassware by following the relevant SOP.

4.4.7 Store all cleaned and dried glassware in a dust free storage area.

4.4.8 Use clean and dry glassware for analysis.

4.4.9 Check the glassware for any cracks or dirt before using them.

4.4.10 To the extent possible rinse the glassware with the solvent or diluent, which is meant for analysis in case of critical test procedures such as Related Substances.

4.4.11 Label all chemicals and readymade reagents when opened update the open date and use before date.

4.4.12 At every interval of six months or Before Use, examine chemicals and readymade reagents for any change in appearance or nature (Color, lumping, clarity, and liquefaction).

4.4.13 Discard chemicals / reagents if they are found to have undergone any change during the checking.

4.4.14 Check the validity period of chemicals before use. Discard all expired chemicals with related proper documentation.

4.4.15 Check the validity period of working standards, primary standards, analytical standards, volumetric solutions, indicator solutions and limit test standard solutions before use.

4.4.16 Check the calibration status of instruments before use. Clean the instrument and put related accessories at designated place after proper cleaning.

4.4.17 Wipe the tip of the burette and pipette before dispensing (or withdrawal of) the withdrawn liquid. Do not use broken tip burettes and pipettes.

4.4.18 Store all samples at designated storage area and designated storage temperatures throughout the time it is retained in the laboratory, until their destruction. (Carry out destruction of left over samples after release of Product/Material)

4.4.19 Clean the work area before starting the analysis.

4.4.20 Replace discolored silica gel or desiccants at appropriate times.

4.4.21 Update all relevant logbooks concurrently. (Ensure chronological order is maintained while usage of more no. of instruments/equipments)

4.4.22 Label Liquid Chromatographic mobile phase bottles with proper label.

4.4.23 For products / materials where Assay need to be calculated on dried or anhydrous basis, the date of determination of LOD / Water content should be the same date on which the Assay preparations are made.

4.4.24 Label all reagents and volumetric solutions with the strength and validity period.

4.4.25 Use clean spatulas or butter papers for transferring and weighing samples.

4.4.26 Maintain sample and standard solutions under protective conditions if indicated in standard test procedures. Do not discard stock solutions until results are evaluated.

4.4.27 Handle all laboratory standards as per the instructions in the relevant SOP and the directions for use.

4.4.28 Report all incidents and failures to the supervisor as soon as possible and follow instructions.

4.4.29 Strike out any wrong entries with a single straight line, initial and date the same. Never overwrite and never use correction fluids or erasers.

4.4.30 Remove all used glassware from workbenches and send for washing after the completion of analysis.

4.4.31 Avoid spillages, and if happens initiate necessary action to clean.

4.4.32 Place all standards, reagents and chemicals at the designated storage area after use.

4.4.33 Before closing the department ensures that all the tube lights and air conditioning units are switched ‘OFF’.

4.4.34 After closing the department, handover the key to the security department.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

General Notices of USP/BP/Ph. Eur./IP

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure (SOP).

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7.0 ABBREVIATION (S)/DEFINITION (S):

SOP - Standard Operating Procedure.

STP – Standard Test Procedure

LOD – Loss On Drying

USP – United States Pharmacopoeia

BP – British Pharmacopoeia

Ph. Eur. – European Pharmacopoeia

IP – Indian Pharmacopoeia

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---