



STANDARD OPERATING PROCEDURE

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|--|------------------------|
| Department: Quality Control | SOP No.: |
| Title: Handling and Usage of Reagents and Chemicals | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for handling & usage of reagents & chemicals.

2.0 SCOPE:

This SOP is applicable to handling & usage of reagents & chemicals in Quality Control Department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

- 5.1 After receipt of Reagents and Chemicals from suppliers, check the Grade/Class of material like Reagents / Solvents items against the details given in delivery challan and verify whether same Reagent /chemical was indented.
- 5.2 Check the integrity of pack before placing on rack.
- 5.3 Arrange the chemicals in dedicated place in the quality control laboratory and affix the received labels as per Annexure-I.
- 5.4 Receipt of reagents, solvent and acids and issuance records should be recorded as per Annexure II.
- 5.5 Assign shelf life 5 years, whenever expiry is not mentioned. Maintain the date of opening on Chemical /Reagent, Solvent bottle at the time of opening for use and also mention use before date on the label as per Annexure-I. All opened reagent and chemicals shall be used within 2 years from the date of opening or expiry date declared by the manufacturer, which ever is earlier.
- 5.6 Reagents shall be visually examined during their usage.
- 5.7 If any discoloration, lump formation or precipitation (in case of liquids) or any unusual appearance is observed, it shall not be used and shall be discarded.



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- 5.8 All reagents and Chemicals shall be stored at the room temperature, unless any other storage condition is specified on the label.
- 5.9 Toxic chemicals / reagents shall be identified.
- 5.10 All toxic chemicals / reagents shall be stored separately under lock and key.
- 5.11 List of all toxic chemicals shall be maintained in quality control department.
- 5.12 MSDS (Material Safety Data Sheets) of all toxic chemicals shall be maintained in quality control department.
- 5.13 Maintain the destruction record of all reagents / solvents after the expiry date or rejection due to any discoloration, lump formation or precipitate, as per Annexure –III

6.0 ABBREVIATION (S):

QCD - Quality Control Department

SOP - Standard Operating Procedure

7.0 REFERENCE (S):

NA

8.0 ANNEXURE (S):

Annexure -I Receipt & opening label

Annexure-II Stock Record of Reagents, Solvents and Acids

Annexure -III Destruction record of Reagents/Chemicals

9.0 REVISION CARD:

| S.No. | REVISION No. | REVISION DATE | DETAILS OF REVISION | REASON (S) FOR REVISION |
|-------|--------------|---------------|---------------------|-------------------------|
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PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

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ANNEXURE I
Receipt & Opening label

| Reagent | |
|--|---|
| Date of Receipt | 1 |
| Assigned Shelf life / Expiry date | 2 |
| Date of Opening | 3 |
| Use before | 4 |
| Sign. Date | 5 |

