



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Quality Control | SOP No.: |
| Title: Handling of Primary Standards | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for Handling Of Primary Standards.

2.0 SCOPE:

This SOP shall be applicable for all Primary Standards which are to be used for standardisation of Volumetric Solution & Calibration of Instrument.

3.0 RESPONSIBILITY - Execution -Executive QC

Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control.

5.0 PROCEDURE

5.1 Procure the Certified Primary Standards from the approved vender by placing a purchase order.

5.2 On receipt of the Primary Standards, check the delivery as per order.

5.3 Distribute the sufficient quantity of the Primary Standards as required for one time use into predefined no. of vials as per Annexure- I (List of Primary Standards and No. of vials) & record it as per Annexure- II.(Primary standard Bin Card.)

5.4 Give the reference number to Primary Standard as follows.

PS/NN/YY/ZZ

Where PS corresponds the Primary Standard .

NN Corresponds to sr. number from 01 onward to have details of total Primary standard in Quality Control Laboratory.

YY Corresponds the last two digit of year in which Primary Standard is prepared

ZZ Corresponds the No. of vial prepared for particular Primary Standard starting from 01.

Example: First vial of Potassium Hydrogen Phthalate in year 2023 shall be numbered as PS/23/07/01



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9.0 REFERENCES:

“SOP Disposal of Expired Chemicals, Reagents, Solvents and Microbiological Medium”.

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QC : Quality Control

AR : Analytical Reagent

Ref : Reference

AC : Air condition

Sr. : Serial

ANNEXURES :

Annexure-I: List of Primary Standard & No. of vials

Annexure-II: Primary Standard Bin Card



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ANNEXURE-I LIST OF PRIMARY STANDARDS & NO. OF VIALS

| S.No. | Name of Primary Standard | Ref. No. | No. of Vial | Sr. No. | Name of Primary Standard | Ref. No. | No. of vial |
|-------|--------------------------|----------|-------------|---------|--------------------------|----------|-------------|
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| Prepared By: (Date & sign) | Checked By: (Date & sign) | Approved By: (Date & sign) |
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ANNEXURE-II PRIMARY STANDARD BINCARD :

Name of Primary Std. :
Batch No. :
Date of Preparation :
Use before :
No. of Vials prepared :
Prepared By :

| S.No. | Vial Ref. No. | Date of Issue | No. of Vial Issued | Balance Quantity | Issued By | Remarks |
|-------|---------------|---------------|--------------------|------------------|-----------|---------|
| | | | | | | |

No. of Vials remaining on Expiry :
No. of Vials destroyed :
Vials destroyed on :
Vials destroyed by :