

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 standard.

2.0 SCOPE:

This SOP is applicable to handling of primary standard used for standardisation of volumetric solution and calibration purpose in quality control department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality control

Head – Quality Control

4.0 PROCEDURE:

- 4.1 After receipt of primary standard from suppliers, check the Grade/Class of material i.e. details given in delivery challan and verify whether same standard was indented. Enter the details in primary standard inward as per Annexure-I.
- 4.2 Check the integrity of pack before placing on designated rack.
- 4.3 Mention the 'Date of opening' on primary standard at the time of opening for use and also mention 'Use before date' on the label as per SOP for handling of reagent and chemical. All opened primary standards shall be used before 2 years from the date of opening or manufacture expiry/instruction, which ever is earlier.
- 4.4 All primary standard containers shall be stored in a designated place at room temperature (not exceeding 25°C), unless otherwise specified on the label.
- 4.5 The primary standards shall be dried before use as per the manufacturer's instructions or mention as per GTP.
- Primary standards as per Annexure II and code number of same has to be assigned subsequently as P_1, P_2, P_3respectively.

5.0 ANNEXURE (S):

Annexure – I: Primary standard inward



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Annexure – II: List of primary standard

6.0 REFERENCE (S):

SOP: Handling of usage and Destruction of Reagent & Chemical.

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating

Procedure (SOP).

7.0 ABBREVIATION (S)/**DEFINITION** (S):

GTP: General testing procedure

REVISION CARD

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



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ANNEXURE I

PRIMARY STANDARD INWARD

S.No.	Date of Receipt	Name of Primary standard	B. No./ Lot No.	Grade	Manufacturer	Mfg. Date	Exp. Date	Qty.	Packing condition (OK / Not OK)	Received by/ date	Remarks (If any)



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ANNEXURE II LIST OF PRIMARY STANDARD

S.No.	Name of Primary standard	Code No.