PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation and Standardization of Volumetric Solution	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Preparation and Standardization of volumetric solution.

2.0 SCOPE:

This SOP is applicable for Preparation and Standardization of volumetric solution in the Quality Control Department.

3.0 RESPONSIBILITY:

Executive, Officer – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Preparation of volumetric solution:

5.1.1 Prepare the volumetric solution as per respective pharmacopoeia or General test procedure.

5.1.2 Use fresh purified water.

5.1.3 Use analytical grade reagents.

5.1.4 Record the details of the volumetric solution preparation in preparation log of volumetric solution as per Annexure-III

5.1.5 Assign the batch number of volumetric solution in following manner

VS-XXXX /YY-00, where as

VS : Volumetric solution

XXXX : Serial number

/ : Slash

YY : Last two digit of the current year.

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_ : Dash

00 : Initial Standardization

01 : for Restandardization

5.1.6 Record all the calculation and results in calculation sheet and preparation record as per Annexure-I. Take the signature of authorized person in the record.

5.1.7 Before signing the record, authorized person should check all the calculation are correct and should ensure that solution are prepared as per standard procedure.

5.2 Labeling:

5.2.1 Transfer the volumetric solution from the volumetric flask to clean and dry stoppered bottle.

5.2.2 Put a label with all detail as per Annexure - II

5.3 Storage of volumetric solution:

5.3.1 Store all the volumetric solution in dry and cleaned glass bottles. Store light sensitive solutions in amber colour glass bottles.

5.3.2 Use the prepared solution within one month or as indicated on label.

5.3.3 During usage any change in physical properties of the solution observed, discard the same.

5.3.4 Store all volumetric solution at 25 ± 2 °C.

5.4 Standardization of Volumetric solution:

5.4.1 Standardize the volumetric solution as per respective procedure given in pharmacopoeia.

5.4.2 Use primary standard or A.R. grade reagent for standardization.

5.4.3 Keep separate A.R. grade reagent for standardization purpose.

5.4.4 The solution shall be standardized in duplicate and mean of the Molarity / Normality value shall be calculated.

5.4.5 The accuracy should not differ +10 % of the prescribed strength and the variance Molarity / Normality between two reading should not be more than 1.0 %.

5.5 Frequency of re-standardization:

5.5.1 Every 15 days ± 3 days for all solution, unless otherwise indicated on the label.

5.5.2 Discard the volumetric solution after expiry period

5.6 **Mobile Phase Preparation:**

5.6.1 Mobile phase preparation record for HPLC and TLC should be recorded as per annexure-V.

6.0 ABBREVIATION(S):

QCD - Quality Control Department

SOP - Standard Operating Procedure

A.R. - Analytical Reagent

7.0 REFERENCE(S):

IP

8.0 ANNEXURE(S):

Annexure- I: Preparation & Standardization of volumetric solution.

Annexure - II: Label format.

Annexure - III: Preparation of volumetric solution record.

Annexure-V: Data sheet for the preparation of mobile phase

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9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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ANNEXURE I

Preparation & Standardization of Volumetric Solution	
Name of Volumetric solution	
GTP No.	
Reference SOP No.:	**Page No.:** 5 of 7

Preparation:	
Prepared By/ date:	**Checked By / Date:**
Calculation for Standardization:	
Acceptance Criteria: ± 10% of prescribed strength.	

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STANDARDIZATION (Initial)			
Reagent		Lot No.	
Weight (1)	Titer Volume	Weight (2)	Titer Volume
Calculation 1:		Calculation 2:	
Molarity / Normality	1:	2:	**Avg.:**
Variance (NMT 1.0%)		Due date of Re-standardization	
Batch no. of Volumetric solution			
Standardized By/ Date:		Checked By/ Date:	

RE-STANDARDIZATION			
Reagent		Lot No.	
Weight (1)	Titer Volume	Weight (2)	Titer Volume
Calculation 1:		Calculation 2:	
Molarity / Normality	1:	2:	**Avg.:**
Variance (NMT 1.0%)		Due date of Re-standardization	
Batch no. of Volumetric solution			
Re -Standardized By/ Date:		Checked By/ Date:	

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ANNEXURE II

VOLUMETRIC SOLUTION	
Name of Volumetric Solution	
Date of Preparation	
Sign /Date	
Valid up to	
Date of standardization	
Due date of Restandardization	
Initial Standardisation B.No.:	Restandardization B.No.:
Normality / Molarity:	**Normality / Molarity:**
Sign /Date:	**Sign /Date:**