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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 use in the Quality Control Laboratory.

3.0 RESPONSIBILITY:

Executive, Officer – Quality Control.

Head – Quality Control

4.0 PROCEDURE :

4.1 Preparation of volumetric solution:

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

4.1.2 Always use purified water or Milli Q water whenever intended for use.

4.1.3 Use analytical grade reagents.

4.1.4 Record the details of volumetric solution preparation in 'Preparation log of volumetric solution' (as per Annexure - I).

4.1.5 Assign batch number to the volumetric solution in the following manner.

VS-XXXX /YY-00 , Where,

VS : Volumetric solution

_ : Dash

XXXX : Serial number

/ : Slash

YY : Last two digits of the current year.

_ : Dash

00 : Initial Standardization number

01 : Re-standardization number

4.1.6 If the solution is not clear and contains suspended particles then filter the solution and standardise.

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4.1.7 If the solution is still hazy/turbid then Record the discard details in the Remarks column of 'Preparation log of volumetric solution'.
(As per Annexure- I).

4.2 Standardization of Volumetric solution:

4.2.1 Standardize the volumetric solution as per the respective procedure given in GTP or the respective pharmacopoeia.

4.2.2 Use primary standards of NIST grade or A. R. grade reagent for standardization.

4.2.3 Dry the primary standards or A. R. grade reagents before use, as mentioned in the respective GTP, pharmacopoeia or reference document.

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

4.2.5 The solution shall be standardized in triplicate and mean of the Molarity/ Normality value shall be calculated. Calculate the precision of all three values it should not be more than ± 0.2 % (as per Annexure -II).

4.2.6 Record the details of 'Volumetric solution preparation and standardization" in a respective validated calculation excel sheet or as per format given in annexure-II.

4.2.7 The actual molarity of the volumetric solution should not differ by ± 10% of the prescribed strength and the variation of Molarity/Normality between three readings should not be more than 1.0 %.

4.3 An authorized person shall check all the preparation and standardization details and shall ensure that the solution is prepared as per the standard procedure and sign the record.

4.4 If the actual Molarity/Normality differ from ± 10 % of the prescribed strength then discard the solution and prepare a new fresh solution. Record the discard details in the Remarks column of 'Preparation log of volumetric solution' (as per Annexure - I).

4.5 If the Variation between three Molarities/ Normality's exceeds 1.0 %, then re-standardize the solution and determine the Molarity/Normality. If again it exceeds 1.0 % then discard the same and prepare a new fresh solution. Record the discard details in the Remarks column of 'Preparation log of volumetric solution' (as per Annexure - I).

4.6 Alcoholic and Iodine solutions shall be standardised immediately before use.

4.7 Ensure the expired solutions are discarded after validity period is over and record the same in the log.

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4.8 A daily monitoring of solutions on the shelf shall be carried out by concerned personnel for verifying the validity of the solutions. In case any solution is expiring on that day or becomes turbid, same shall be removed from the shelf and destroyed and a new fresh solution shall be prepared.

4.9 Storage of volumetric solution:

4.9.1 Store all the volumetric solutions in dry and cleaned glass bottles as per the storage conditions given in the respective GTP or pharmacopoeia. Containers other than glass shall be used if prescribed in the pharmacopoeia (e.g. LDPE container).

Note: Always store light sensitive solutions in amber coloured glass bottles.

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

4.9.3 During usage if any change is observed in the physical properties of the solution, then discard the same and record in the log.

4.9.4 Store all volumetric solutions at 25 ± 2°C.

4.10 Labeling:

4.10.1 Paste a label with all details on the bottle as per Annexure–III.

5.0 ANNEXURE (S):

Annexure - I: Preparation log of volumetric solution

Annexure - II: Volumetric solution preparation and standardization record.

Annexure - III: Specimen Label for volumetric solution.

6.0 REFERENCE (S):

USP/BP/Ph. Eur./IP

SOP: Preparation, Approval, Distribution control, revision and destruction of Standard operating Procedure (SOP).

7.0 ABBREVIATION (S)/ DEFINITION (S):

A.R. - Analytical Reagent

GTP - General Test Procedure

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NIST - National Institute of Standards and Technology

USP : United State Pharmacopoeia

BP : British Pharmacopoeia

Ph. Eur. : European Pharmacopoeia

IP : Indian Pharmacopoeia

REVISION CARD

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

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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ANNEXURE I

PREPARATION LOG OF VOLUMETRIC SOLUTION

S. No	Date of Preparation	Name of Volumetric solution	B. No. / Lot No.	Quantity Prepared	Valid upto	Prepared by	Remarks

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ANNEXURE II

VOLUMETRIC SOLUTION PREPARATION & STANDARDIZATION RECORD

VOLUMETRIC SOLUTION PREPARATION & STANDARDIZATION RECORD Reference SOP……..	
Name of Volumetric solution	
Reference GTP No.	
Batch No. of Volumetric solution	
1.0 Preparation:	
Balance ID: EQ/QCD/	
Reagent : Batch No.: _____ Grade : _____ Mfr : _____	
Procedure :	
Prepared By/ date:	Checked By / Date:
2.0 Calculation for Standardization:	

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STANDARDIZATION					
Balance ID:					
Primary Standard: Batch No.: _____ Grade : _____ Mfr : _____					
Primary standard drying procedure :					
1st Titration		2nd Titration		3rd Titration	
Weight (g)	Titer volume (mL)	Weight (g)	Titer volume (mL)	Weight (g)	Titer volume (mL)
Calculation (1):		Calculation (2):		Calculation (3):	
Molarity/Normality:		Molarity/Normality:		Molarity/Normality:	
Variation (NMT 1.0 %) :			Precision :(NMT 0.2 %) :		
Average Molarity / Normality :			(± 10 % of the Prescribed Strength)		
Due date of Re-standardization:					
Standardized By/Date:		Checked By/Date:			

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ANNEXURE III
SPECIMEN LABLE FOR 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:	Restandardisation B.No.
Normality/Molarity:	Normality/Molarity:
Sign/Date:	Sign/Date:
Storage condition	At 25°C ± 2°C