PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Stability of Volumetric Solutions	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Evaluation of Stability of standardized Volumetric Solution and to confirm the Expiry period of the Volumetric Solution.

2.0 SCOPE:

This procedure is applicable for the identifying stability and use before period of standardized volumetric solution prepared in QC department.

3.0 RESPONSIBILITY – Execution - Executive QC
Checking - Assistant Manager QC.

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 Prepare and standardize the volumetric solutions as per their respective Standard test procedure.

5.2 Stability Study of Volumetric Solution shall be carried out for three preparations of each standardized Volumetric Solution.

5.3 Executive and above shall perform the stability studies for Volumetric Solutions.

5.4 Stability of Volumetric Solution shall be checked for one month period only.

5.5 The analysis shall be carried out after every 7 days as per their respective protocols.

5.6 The Volumetric Solution is considered to be stable till the RSD of Normailty / Molarity is with in 0.5% of the initial value and no turbidity or any sedimentation appears in the solution.

5.7 Standardization shall be performed in three sets at each step.

5.8 With the help of collective data, Expiry Date / Use Before Date of the volumetric Solution shall be assigned.

5.9 Quality Control Department shall prepare respective Protocol for stability of volumetric solution.

5.10 This Protocol shall be prepared on the approved format on A-4 size paper as per Annexure-I with the font Type Times New Roman, and font size as below:

Content	Font Size	Type
Headings	12	Bold
Sub headings	12	Normal
Header	12	Bold
Footer	10	Normal

5.11 All the Protocols shall be written in clear, unambiguous language, easy to understand and

easy to use

5.12 Describe the table of contents and its details stepwise.

5.13 Each protocol shall have unique number. Once a number is allocated to any Protocol, the same number shall not be repeated to other Protocol.

5.14 Protocol No. shall be alphanumeric identification no**.** having 10 characters which are as VSP/YY/XX

Where:-

V = Volumetric

S = Solution

P = Protocol

/ = Separator

XXX = Corresponds to Sr. number starting from 001 continuously to have details of total Volumetric Solutions in Quality Control laboratory .

YY = Corresponds to the last two digit of year in which Volumetric Solution is prepared.

For example: VSP/23/001

5.15 Asst. manager shall check the protocols for their correctness.

5.16 Pre Approval of the protocol shall be taken from Manager QA & QC.

5.17 After pre approval of protocol, the master copy shall be submitted to QA documentation cell.

5.18 QA department shall issue a photocopy by stamping on the backside of each page as an “OPERATIONAL COPY FOR PHOTOCOPYING”

5.19 QC shall use a photocopy of operational copy to check the stability of respective solution.

5.20 Concern person shall issue the photocopy for usage purpose.

5.21 Maintain the issuance record of volumetric solution stability protocol as per Annexure-II

5.22 Any change in Protocol shall be done through change control procedure.

6.0 SAFETY & PRECAUTIONS:

Not Applicable

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7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

RSD : Relative Standard Deviation

Annexure-I: Protocol For Stability of Volumetric Solution

Annexure-II: Issuance record of protocol for stability of volumetric solution

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ANNEXURE-I

PROTOCOL FOR STABILITY OF VOLUMETRIC SOLUTION

SOLUTION NAME: _____

STRENGTH:_____

	PROTOCOL FOR STABILITY OF VOLUMETRIC SOLUTION	**Page 2 of Y**
PROTOCOL NO. :	**EFFECTIVE DATE:**	

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	PROTOCOL FOR STABILITY OF VOLUMETRIC SOLUTION	**Page 3 of Y**
PROTOCOL NO. :	**EFFECTIVE DATE:**	

Details of the content should be written in sequence:

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ANNEXURE-II

VOLUMETRIC SOLUTION STABILITY PROTOCOL ISSUANCE RECORD

Name of the Volumetric Solution:

S.No.	Name of Volumetric Solution Protocol	Issued By/Date	Received By /Date	Remarks