PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

1.0 OBJECTIVE:

To lay down a procedure for preparation and handling procedure of Buffers, Indicator, Colorimetric solution, Limit standard solution, volumetric solutions and reagents.

2.0 SCOPE:

This SOP is applicable to all types of Buffers, Indicator, Colorimetric solution, Limit standard solution, volumetric solutions and reagents to be used in Quality Control laboratory.

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

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 General:

5.1.1 Section in charge or designee shall issue template to analyst if template is available.

5.1.2 Where template is not available raw data shall be entered in the hard book.

5.1.3 Analyst shall check the following things before preparation of any solution.

5.1.3.1 The glassware being used is clean and dried.

5.1.3.2 All required reagents are available.

5.1.3.3 All required instruments are calibrated.

5.1.3.4 Wear suitable safety appliances while making concentrated solutions of acid and alkali or any hazardous chemicals.

5.1.4 Analyst shall prepare all of Buffers, Indicator, Colorimetric solution, Limit standard solution, volumetric solutions and reagents as per respective template/reference pharmacopoeia.

5.1.5 Analyst shall enter the data of usage of primary and secondary standard in respective primary and secondary standard logbook (if applicable).

5.1.6 For differentiation of the reagents buffer ,indicators , Limit standard solutions and volumetric solutions different color labels are pasted on the respective bottles as per Annexure I – V .

5.1.7 Check the appearances of prepared solution, where very minor extraneous matter/particle are observed, filter the prepared solution through Whatman no. 41 or equivalent filter paper.

5.1.8 When higher extraneous matters, layer separation or hazy solution observed, do not use the solution and immediately inform to Manager QC.

5.1.9 Store the prepared solution into clean and dried glass/HDPE, clear/ amber bottle or as per the recommended procedure.

5.1.10 Analyst shall mention the detail of preparation on the label for each solution .

5.1.11 Coding system for indicator solution, buffer solution, test solution, general solution & volumetric solutions are as follows& shall be as follows:

Solution Name	CODING SYSTEM							
	Unique Code	2nd	3rd	4th	5th	6th	7th	8th
Indicator solution	As mentioned in Annexure VI	_	X	X	X	_	Y	Y
Buffer solution	As mentioned in Annexure VI	_	X	X	X	_	Y	Y
Test solution	As mentioned in Annexure VI	_	X	X	X	_	Y	Y
General solution	As mentioned in Annexure VI	_	X	X	X	_	Y	Y
Volumetric solutions	As mentioned in Annexure VI	_	X	X	X	_	Y	Y

Where

1) 3rd , 4th & 5th characters are serial no. , start from 001 every year in January for respective solutions.

2) 2nd & 6th characters are separators

3)7th & 8th characters are the last two digits of respective year i.e. for 2023 is 23

For Example: unique code of 0.1M NaOH is VS01
First volumetric solution of 0.1M NaOH prepared in 2023 shall be numbered as VS01- 001-23 and
Second solution of 0.1M NaOH shall be numbered as VS01- 002-23

5.1.12 Template issuance no and reagent code no will be same, analyst shall enter only reagent code no in the "Solution preparation / standardization record" register (Annexure –VII)

5.2 Solution Log book:

5.2.1 In case where template is required to issue, Manager QC or designee shall mention the "Code No.of solution", "Issued by & date" and shall mentioned "NA" in case of template is not available on the respective page for the solution allocated.

5.2.2 In case template is available analyst shall mention "NA" in column of "Preparation date", "Weight taken", " Volume made", "Standardization date", "Hard book No", and "Page No."

5.2.3 Analyst shall make entry of raw data in "Hard book" in case of template is not available.

5.2.4 Analyst shall make entry on respective page for the solution allocated.

5.2.5 Analyst shall make entry for "Code no. of solution" (As explain above), "Preparation date", "Weight taken" (Shall mention the weight and name of the chemical used for the weighing), " Volume made", "Standardization date", "Hard book no", "Page no", "Molarity / Normility" and submit the raw data to designated person for the checking.

5.2.6 Sign of designated person shall put in "Checked by/date" column.

5.2.7 In case of any odd findings shall inform to head QC or designee.

5.3 Labeling:

5.3.1 Reagent label is identification tag for the respective solution, which shall be prepared at the time of preparation and standardization of the solution.

5.3.2 After completion of standardization analyst shall prepare the label of respective solution for "Indicator" (Annexure –I), "Buffer solution" (Annexure – II), "Test solution" (Annexure -III), "General solution" (Annexure – IV), "Volumetric solution" (Annexure – V).

5.3.3 Analyst shall fill the details whichever is applicable like "Name" (Name of solution), "Code No.", "Strength", "Use before" (Date of expiry), "Prepared by", "Date of preparation", "Standardized by" (sign of analyst), "Date" (Date of standardization.

5.3.4 Analyst shall paste the label on the respective solution bottle.

5.4 Solution Expiry log book:

5.4.1 After the completion of entry in "solution log book", analyst shall immediate make entry in a "Solution expiry log" on the respective allocated page (Date at which solution will be expire) mention reference page no of corresponding solution in expiry log & vice a versa (i.e Solution preparation/standardization record.)

5.4.2 Analyst shall make entry for "Name of solution", "Code no. of solution".

5.4.3 Analyst shall daily check the "solution expiry log" for the solution to be discard and shall discard the solution as per the defined procedure.

5.4.4 After the discardation of the solution analyst shall make entry in "Discarded by/ date" column and shall get the signature of section Head.

5.4.5 In case solution is exhausted before the expiration date analyst shall make an entry in "Discarded by/ date" column on the same allocated date (page), writes the remark as "Solution is exhausted" and put initial and date (Date at which solution exhausted)

5.5 General Guidelines for volumetric solutions:

5.5.1 Analyst shall prepare all of volumetric solutions as per respective template/reference pharmacopoeia.

5.5.2 Where stabilization time is not given, stabilize the solution for one hour before standardization.

5.5.3 Carry out standardization of the solution in triplicate.

5.5.4 Check the variance between all findings, if the observation RSD is more than 1% repeat the exercise and report the observation.

5.5.5 Also find out mean molarity, which should within the ±3% of the labeled molarity.

5.5.6 In case of molarity /Normality of prepared solution found more than ± 3.0% variation, do the necessary dilutions/weight adjustments and carry out restandardization. Report the normality/molarity upto four digits after decimal.

5.5.7 Write the weight taken, code no. of used indicator, primary standard, secondary standard, water, indicator, instrument used and other which is used for the preparation/standardization (Wherever applicable) in template / hardbook.

5.5.8 Write the observed molarity/normality on the label as per (Annexure –V) and make necessary entries in hardbook/ template. Shall submit the raw data to designated person for the checking.

5.5.9 Sign of designated person shall put in “Checked by/date” column.

5.5.10 In case of any odd findings shall inform to Manager QC or designee.

5.5.11 Volumetric solution can be use within 1 month + 3days. For perchloric acid solution should be used within 15 days. In case, where extraneous matters, layer separation or hazy solution observed, do not use the solution immediately report to Manager QC.

5.6 General guideline for reagents/buffer solutions/indicators/colorimetric solution/limit test solution:

5.6.1 Analyst shall prepare all of reagents/ buffer solutions/indicators/colourometric solution/limit solution as per respective template/reference pharmacopoeia.

5.6.2 Analyst shall check the sensitivity/standardization of the solutions as per the defined procedure (Wherever applicable).

5.6.3 Analyst shall write the weight taken, code no. of used indicator, primary standard, secondary standard, water, indicator, instrument used and other which is used for the preparation/ standardization (Wherever applicable) in template/hardbook.

5.6.4 Analyst shall make necessary entries in hardbook/ template. Shall submit the raw data to designated person for the checking.

5.6.5 Sign of designated person shall put in “Checked by/date” column.

5.6.6 In case of any odd findings shall inform to head QC or designee.

5.6.7 Solution can be use within 2 month + 6days. In case, where extraneous matters, layer separation or hazy solution observed, do not use the solution immediately report to Manager QC.

5.7 General guideline for the solution discardation:

5.7.1 Discard the excess solution after expiry/ usage by diluting the solution with doubled quantity of water and than drain it into the drainage.

5.7.2 Solution can be discarded in case of specific instruction given.

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & Date
00	New	

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

No. : Number

QC : Quality Control

HDPE : High density Polyethylene

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURES:

Annexure – I : Indicator Label

Annexure –II: Buffer Label

Annexure –III: Test Solution Label

Annexure – IV: General Solution Label

Annexure – V: Volumetric Solution Label

Annexure – VI: List of Unique Number

Annexure –VII: Solution Preparation/Standardization Record

Annexure –VIII: Solution Expiry Log

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURE – I
INDICATOR LABEL

INDICATOR SOLUTION
Name : _____Code No. : _____
Strength : _____ Use before: _____
Prepared by : _____ Date :_____
Storage:

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

ANNEXURE – II
BUFFER SOLUTION LABEL

BUFFER SOLUTION
Name : _____Code No. : _____
Strength : _____ Use before: _____
Prepared by : _____ Date :_____
Storage:

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURE – III
TEST SOLUTION LABEL

TEST SOLUTION
Name : _____Code No. : _____
Strength : _____ Use before: _____
Prepared by : _____ Date :_____
Storage:

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURE – IV
GENERAL SOLUTION LABEL

GENERAL SOLUTION
Name : _____Code No. : _____
Strength : _____ Use before: _____
Prepared by : _____ Date :_____
Storage:

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURE – V
VOLUMETRIC SOLUTION LABEL

VOLUMETRIC SOLUTION
Name : _____Code No. : _____
Strength : _____ Use before: _____
Prepared by : _____ Date :_____
Standardized by:_____Date :_____
Storage:

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURE – VI

LIST OF UNIQUE NUMBER

S.No.	Solution Name	Short Name
1.	**Volumetric Solution**	
1.1		
1.2		
1.3		
2.	**Indicator Solution**	
2.1		
2.2		
2.3		
3.	**Test Solution**	
3.1		
3.2		
3.3		
4.	**Buffer Solution**	
4.1		
4.2		
4.3		
5.	**General Solution**	
5.1		
5.2		
5.3		

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURE – VII
SOLUTION PREPARATION/STANDARDIZATION RECORD

Name of solution: _____

Code No. of solution	Preparation				Protocol Issuance No.	Page No. Solution Expiry Log	Issued By & Date
	Date	Weight taken	Volume made	Prepared by			

Standardization			Morality/ Normality	Checked By & Date	Remark
Date	Protocol Issuance No.	Standardized By			

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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

ANNEXURE –VIII
SOLUTION EXPIRY LOG

Date of expiry:

Name of solution/ Page No. of solution preparation standardization record	Code No of solution	Discarded by/ date	Signature of Section Head