



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Preparation of Reagent Solutions and Indicators	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for preparation of reagent solutions and Indicators.

2.0 SCOPE:

This SOP is applicable to preparation of reagent solutions and Indicators in Quality control Department.

3.0 RESPONSIBILITY:

Executive/ Officer-Quality Control
Head of Department-Quality Control

4.0 PROCEDURE:

- 4.1 Prepare reagent solutions and indicators as per pharmacopoeia or as per standard test procedure.
- 4.2 Use purified water or Milli Q water for preparation of reagent solution and indicators.
- 4.3 Use AR grade or LR grade reagent for preparation of reagent solution or indicators.
- 4.4 Record the detail of preparation as per Annexure - I.
- 4.5 Allocate batch number for each reagent solution in the following manner
- 4.6 RS-XXXX/YY
Where as
RS Reagent solution
- Dash
XXXX Serial number
/ Slash
YY Last two digit of current year
- 4.7 All reagents solutions shall be labeled as per Annexure-II
- 4.8 The self life of reagent solutions and indicator solutions is 3 month from the date of preparation, unless otherwise mentioned in the procedure.
- 4.9 Reagent solutions must be stored in colourless/amber colour glass stoppered bottles or other



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Preparation of Reagent Solutions and Indicators	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

suitable container as per requirement.

- 4.10 Before use of the solution, if any abnormality found, like decolouration, sedimentation etc. observed in the solution, discard and record the same in the preparation logbook as per Annexure - I .
- 4.11 The solution shall be discarded immediately after the validity date is over and the same shall be recorded in the remark column of the Annexure - I.
- 4.12 A daily monitoring of the solution on the shelf shall be carried out by a concerned personnel for verifying the validity of the solution .In case any solution is expiring on that day, same shall be removed from the shelf and destroyed. In its place fresh solution shall be placed for use.

5.0 ANNEXURE (S) :

Annexure I : Preparation of Reagent Solution & Indicator Record.

Annexure II : Specimen label for Reagent Solution/Indicator .

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S)/DEFINITION (S):

AR - Analytical reagent

LR - Laboratory reagent



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Preparation of Reagent Solutions and Indicators	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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

STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Preparation of Reagent Solutions and Indicators	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE II
SPECIMEN LABEL FOR REAGENT SOLUTION / INDICATOR

Reagent solution /Indicator	
Name of solution	
Batch No.	
Date of preparation	
Prepared By	
Use before	