



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Preparation of Reagent Solution and Indicators	Effective Date:
Supersedes: Nil	Review Date:
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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 reagents solution and Indicators in 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 Prepare reagent solutions and indicators as per pharmacopoeia.
- 5.2 Use purified water for preparation of reagent solution and indicators.
- 5.3 Use AR grade or LR grade reagent for preparation of reagent solution or indicators.
- 5.4 Record the detail of preparation as per Annexure-I.
- 5.5 Allocate batch number for each reagent solution in the following manner
- 5.6 RS-XXXX/YY
Where as
RS - Reagent solution
- Dash
XXXX Serial number
/ - Slash
YY - Last two digit of current year



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- 5.7 All reagents solutions shall be labeled as per Annexure-II
- 5.8 Use before date of reagent solution and indicator is 3 month from the date of preparation, unless otherwise indicated in the procedure.
- 5.9 Reagent solutions must be stored in colorless/amber color glass stoppered bottles as per requirement.
- 5.10 Discard the solution immediately if any contamination, discoloration, sedimentation observed in the solution.

6.0 ABBREVIATION(S):

QCD – Quality Control Department
SOP – Standard Operating Procedure
AR - Analytical reagent
LR - Laboratory reagent

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure I: Preparation of Reagent solution & Indicator Record.
Annexure II: Label of reagent solution/Indicator.

9.0 REVISION CARD:

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



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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ANNEXURE I

Reagent Solution and Indicator label

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