



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Preparation of Mobile Phase and Reagent (HPLC/TLC)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for preparation of Mobile Phase and Reagent (HPLC/TLC).

2.0 SCOPE:

This SOP is applicable for preparation of Mobile Phase and Reagent (HPLC/TLC) use in Quality Control Department.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 Preparation of Mobile Phase:

5.1.1 All chemicals/solvent used for preparation of mobile phase should be HPLC grade/AR grade/GR grade.

5.1.2 Preparation of mobile phase should be recorded in Annexure-I

5.1.3 All mobile phase should be filter through 0.45 micro Milli-pore filter paper while using for HPLC analysis.

5.2 Self life and labeling of HPLC water/Reagent/Mobile phase

5.2.1 All mobile phase/Miili Q water/Solvent shall be assigned of expiry date put on datasheet. Following expiry date shall be assigned.

1) Mobile Phase- 48 hrs.

2) Milli Q water- 24 hrs.



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3) Solvent – 7 days

5.2.2 If any fungal growth/ abnormality observed in mobile phase/water/solvent, it should be immediate change and make fresh.

5.2.3 Labeling of solvent/Mobile phase and solvent should be done as per Annexure II.

6.0 ABBREVIATION (S):

QCD – Quality Control Department

SOP – Standard Operating Procedure

7.0 REFERENCE (S):

8.0 ANNEXURE (S):

Annexure I - Preparation record of mobile phase

Annexure II- Labels of Mobile phase/Solvent & Water

9.0 RIVISION CARD:

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



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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ANNEXURE II

Labels of Mobile phase/Solvent & Water

Mobile Phase	
Product	:
Composition	:
Preparation on	:
Use before	:
Sign. Date	:

HPLC ACETONITRILE	
Use Before	:
Signature	:

HPLC WATER	
Use Before	:
Signature	:

HPLC METHANOL	
Use Before	:
Signature	: