PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation of Mobile Phase for HPLC analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for preparation of mobile phase for HPLC analysis in Quality Control Department.

2.0 SCOPE:

This SOP is applicable for preparation of mobile phase for HPLC analysis in Quality Control Department.

3.0 RESPONSIBILITY:

Analyst - Quality Control responsible for the preparation of mobile phase for the HPLC analysis.

Head - Quality control or designee responsible for compliance of SOP.

4.0 PROCEDURE :

4.1 The mobile phase shall be prepared as per the procedure and testing requirement as described in respective standard test procedures.

4.2 Mobile phase quantity shall be prepare based the number of the batches to be analysis and the preparation shall be recorded in the record of analysis (Datasheet) of the one batch and this reference A. R. No. shall be recorded in respective datasheets of the other samples.

4.3 In the preparation of mobile phase, high purity solvents (HPLC grade) and reagents shall be used.

4.4 The pH of the prepared mobile phase shall be maintained with in ± 0.05 of the mentioned value in the standard test procedure.

4.5 Filter the organic solvents and buffers (aqueous phase) separately through 0.45µ nylon filter and degas under vacuum.

4.6 The required quantities of organic solvents and buffers shall be measured separately and mixed in round bottom flask / mobile phase bottle.

4.7 All buffers should be prepared freshly on the day required.

4.8 After thorough mixing, mobile phase shall be sonicated in ultrasonic bath (sonicator).

4.9 Mobile phase prepared shall be stored in screw capped glass bottles to avoid the evaporation of

organic solvents.

4.10 Label the mobile phase bottle as per Annexure-I.

4.11 The mobile phase prepared shall use within three days, which is indicated on the label.

4.12 After the date of valid up to, remaining content of mobile phase in the bottle shall be drained in washbasin under running water.

4.13 The empty used bottles shall be cleaned and dried.

5.0 ANNEXURE (S):

Annexure-I: Specimen Label for Mobile phase.

6.0 REFERENCE (S):

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

7.0 ABBREVIATION (S)/DEFINITION (S):

HPLC : High pressure liquid chromatograph

SOP : Standard Operating Procedure

µ : Micron

A. R. No. : Analytical Reference Number

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	---

ANNEXURE I
SPECIMEN LABLE FOR MOBILE PHASE

MOBILE PHASE	
Sample Name	
Test	
Composition	
Preparation date	
Valid up to	
Sign/date	