TITLE: PREPARATION OF MOBILE PHASE

1.0 PURPOSE:

To lay down procedure for HPLC Mobile Phase Preparation.

2.0 SCOPE:

This procedure is applicable to the all HPLC mobile prepared at Discovery Laboratories Pvt. Ltd.

3.0 RESPONSIBILITY:

3.1 Analyst- QC

3.2 Executive-QC

4.0 DEFINITIONS:

Nill

5.0 PROCEDURE :

5.1 Analyst shall ensure the cleanliness of the glass ware before preparation of mobile phase.

5.2 All glass ware shall be washed thoroughly with DM Water before usage.

5.3 Lot shall be allotted to each preparation of Mobile phase traceability.

5.4 The lot number shall be allotted as given below

MPYYXXX

MP : This indicates Mobile phase

XXX : This indicates Numerical serial number

YY : This indicates the current year

5.5 Weigh/Measure the each component of the mobile phase separately

5.6 Degas each solvent and buffer by sonication and then filter each component of the mobile phase separately through 0.45µ filter

5.7 Mix the individual solvent and buffer as per the specified proportion.

5.8 Adjust the pH of the mobile phase whenever specified (i.e. before or after mixing of individual component) between ± 0.05 unless otherwise specified.

5.9 Sonicate the mobile phase for 10 minutes or more as required.

5.10 All weights and preparation entries shall be done in the mobile phase preparation log book Format No. QC-050-FM-107

5.11 After preparation of Mobile phase shall be transferred into a suitable glass bottles.

5.12 Details on the label shall be entered and affixed on the bottle Format No. QC-050-FM-108

5.13 Prepared MP shall be used within 48 hours as applicable. On observation of any turbidity or foreign particles the mobile phase shall be discarded.

5.14 **Procedure for Mobile Phase Validation :**

5.14.1 Prepare the mobile phase as per the test procedure and keep on bench top in well closed condition.

5.14.2 Evaluate the system suitability parameters as per the test procedure at initial, after 24 hours and after 48 hours.

5.14.3 The mobile phase is considered stable if all the system suitability is within the specified limit.

5.15 **Frequency**

5.15.1 Mobile phase is to be prepared two days after preparation, if mobile phase validation is not done

5.15.2 In case if sequence is required to be run in continuation for more than 24n hours & sufficient mobile phase is available in the reservoir then sequence can be allowed to run by demonstrating system suitability of analysis by injecting bracketing standard.

5.15.3 For stability Validated mobile phase –As per Frequency indicated

6.0 FORMATS / ANNEXURE(S):

6.1 Mobile Phase Label : QC050-FM108

6.2 Mobile phase preparation record : QC050-FM109

7.0 CHANGE HISTORY:

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	A.Navya	S.Prasad	Ch.Mahendar reddy
Department	Quality Control	Quality Control	Quality Assurance

TITLE: PREPARATION OF MOBILE PHASE

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	17.03.2017	New SOP is introduced	---

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	A.Navya	S.Prasad	Ch.Mahendar reddy
Department	Quality Control	Quality Control	Quality Assurance