



STANDARD OPERATING PROCEDURE

Department: Quality Control	SOP No.:
Title: Degassing of Solutions	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down the procedure for degassing the solution.

2.0 SCOPE:

This SOP is applicable for degassing of solutions used as medium for dissolution and for mobile phase used in analysis. This procedure is adopted from USP for de-aeration of dissolution medium. This procedure is also applicable for solutions used in other tests where degassing is prescribed.

When degasser instrument is used for degassing of solution, the instrument SOP shall be followed.

3.0 RESPONSIBILITY:

Executive, Officer – Quality Control Department.

Head – Quality Control Department.

4.0 PROCEDURE:

4.1 For Degassing of Dissolution medium.

4.1.1 Prepare the dissolution medium as per the Standard test procedure.

4.1.2 Heat the medium with gentle stirring to a temperature of about 41°C. (Ensure that the medium is not over heated).

4.1.3 Filter with stirring, under vacuum through a 0.45-micron porosity membrane into a suitable filtering flask.

4.1.4 After the filtration is over, seal the flask with a plug and continue applying vacuum with stirrer ON.

4.1.5 Apply vacuum for 5 minutes or as per requirement of the medium (taking care that no bubbles generate from the bottom of the flask)

4.1.6 Transfer the required amount of medium to the dissolution vessel by pouring gently along the sides of jars, taking care that air bubbles are not generated.

4.1.7 Ensure the temperature of the medium does not fall below $37.0 \pm 0.5^{\circ}\text{C}$ prior to initiation of the test.



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4.2 For Degassing of Mobile phase:

- 4.2.1 The mobile phase shall be prepared as per the individual standard test procedure.
- 4.2.2 The mobile phase shall be first mixed well by manual or mechanical stirring.
- 4.2.3 Filter the mobile phase under vacuum using a suitable filter of porosity of 0.45 micron or as specified in the individual standard test procedure.
- 4.2.4 After the filtration is over, seal the flask with a plug and continue applying vacuum with stirring for 5 to 10 minutes.
- 4.2.5 Sonicate the mobile phase for 15 to 30 minutes or as per the individual standard test procedure.
- 4.2.6 Ensure that the mobile phase is not overheated during sonication by adding cool water or replacing the hot water in the sonicator.
- 4.2.7 When the procedures recommend the degassing of individual component and mixing, degas accordingly and mix.

4.3 For degassing of solutions other than dissolution media and mobile phases, sonicate for about 5 minutes by intermittent stirring or shaking or as specified in the individual standard test procedure.

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

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

7.0 ABBREVIATION (S)/DEFINITION (S):

SOP : Standard Operating Procedure

USP : United states Pharmacopoeia

°C : Degree Celsius

QC : Quality Control

QA : Quality Assurance



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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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	—