PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production (External Preparation)	**SOP No.:**
Title: Operation and Cleaning of Stirrer	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Stirrer.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Stirrer in Ointment and Oral liquid section.

3.0 RESPONSIBILITY:

Officer / Executive – Production

4.0 ACCOUNTABILITY:

Head - Production

5.0 ABBREVIATIONS:

BMR : Batch Manufacturing Record
IPA : Isopropyl Alcohol
QA : Quality Assurance
SOP : Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Ensure the stirrer and surroundings are clean.

6.1.2 Set the stirrer on the mixing container.

6.1.3 Start the stirrer initially by inching and then allow running freely.

6.1.4 Stir the solution/suspension as per instructions given in BMR.

6.1.5 After completion of mixing switch ‘OFF’ the stirrer.

6.1.6 Detach the stirrer from the mixing container.

6.1.7 Clean the stirrer and mark the status label.

6.1.8 Close the lid of the container.

6.2 CLEANING:

6.2.1 Switch ‘OFF’ the stirrer.

6.2.2 Dismantle the stirrer rod.

6.2.3 Clean the stirrer rod with purified water using 2.0% Extran MA-02 solution.

6.2.4 Again wash the stirrer with purified water.

6.2.5 Finally rinse the stirrer with purified water.

6.2.6 Check the stirrer visually for stick particles.

6.2.7 If there is no any stick particles then stirrer is ready for use.

6.2.8 If there is any stuck particles then wash with purified water.

6.2.9 Affix status label as "CLEANED".

6.2.10 Before use, mop the stirrer with 70% IPA solution using lint free cloth.

6.3 FREQUENCY OF CLEANING:

6.3.1 Frequency of cleaning as per B Type.

6.3.2 Product to Product Changeover.

6.3.3 If cleaned equipment is kept idle for more than the hold time.

6.3.4 After 05 batch of the same product or 72 hours from last cleaning operation whichever is earlier completed in the area.

6.3.5 After any maintenance of contact parts.

6.3.6 Changeover of one batch to next batch of the same product with descending potency.

6.3.6.1 In case of colour change (any strength).

6.3.7 Frequency of cleaning as per A Type.

6.3.7.1 Changeover from one batch to next batch of the same product with same potency.

6.3.7.2 Changeover from one batch to next batch of the same product with higher potency.

7.0 ANNEXURES:

Not applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance

9.0 REFERENCES:

Not Applicable

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10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By