



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Coating Solution Preparation Tank (100 Liters)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

**Vernacular SOP:** No

### 1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Coating Solution Preparation tank (100 liters).

### 2.0 SCOPE:

2.1 This SOP is applicable to the Cleaning and Operation of Coating Solution Preparation tank (100 liters) in Production Department.

### 3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation of coating solution preparation tank

3.2 Officer and Executive: Supervision of Cleaning and Operation of coating solution preparation tank

3.3 Head Production : SOP compliance

### 4.0 DEFINITION (S):

4.1 NA

### 5.0 PROCEDURE:

#### 5.1 "TYPE A" CLEANING:

**This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.**

5.1.1 Ensure that the main power supply is turned 'OFF'.

5.1.2 Wipe the equipment with a dry lint free cloth, if required rinse the tank with purified water.

5.1.3 Replace the 'TO BE CLEANED' status label with dully filled and signed 'UNDER PROCESS' status label.

#### 5.2 "TYPE B" CLEANING:

**This is a cleaning procedure for Changeover of product with different actives / color / ascending potency / descending potency or after maintenance of contact parts.**

5.2.1 Follow the procedure from step no. 5.1.1 to 5.1.2.

5.2.2 Dismantle the impeller of stirrer from main shaft.

5.2.3 Take the impeller into coating wash area.

5.2.4 Rinse the impeller with purified water.

5.2.5 Scrub the impeller till all the adhered residues of previous product get softened. Use IPA 70 % v/v in case adhered material do not scrubbed out.

5.2.6 Flush enough purified water till all the visible residues of previous product are washed away.



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- 5.2.7 Cover the stirrer motor of solution preparation tank with double poly-bag.
- 5.2.8 Rinse the inner surface of coating solution preparation tank with purified water.
- 5.2.9 Flush enough purified water till all the visible residues of previous product are washed away. Use 70 % v/v IPA in case adhered material does not scrubbed out.
- 5.2.10 Wipe the outer surface of coating solution preparation tank with wet lint free cloth.
- 5.2.11 Wipe the inner and outer surface of coating solution preparation tank with dry clean lint free cloth.
- 5.2.12 Wipe the inner and outer surface of tank with 70 % v/v IPA.
- 5.2.13 Bring the cleaned stirrer and top lid from coating washing area and wipe with 70 % v/v IPA with a clean lint free cloth.
- 5.2.14 Finally clean the area as per SOP.
- 5.2.15 Affix dully filled and signed 'CLEANED' label on the equipment.
- 5.2.16 Record the cleaning observations in the Equipment usage log sheet as per SOP.

### 5.3 Frequency:

- 5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product. If same product is processed for more than a week then follow the procedure of type – B cleaning.
  - 5.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / colour / descending potency or after maintenance of contact parts or same product is run for more than seven days cleaning Type - B done after completion of batch.
- NOTE: After Type - B cleaning, if machine is not used within 72 hours, clean the machine "before use", with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP.

### 5.4 Precaution:

- 5.4.1 After completion of operation, clean the equipment within 24 hours if not in use.

### 5.5 Operation:

- 5.5.1 Ensure the cleanliness of equipment and area. Affix 'UNDER PROCESS' label dully filled and signed on the coating solution preparation tank and record the observations in the equipment usage log sheet as per SOP.
- 5.5.2 Set the time on time the timer panel by pressing 'RESET' button followed by 'SET' button and 'PGM' button.
- 5.5.3 Ensure that discharge valve is closed.
- 5.5.4 Load the material in the coating solution preparation tank as per sequence in the respective BMR.



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- 5.5.5 Press 'START' button on the motor panel. Stirrer motor will start.
- 5.5.6 Press 'STOP' button at the end of operation. Stirrer motor will stop.
- 5.5.7 Discharge the coating solution into solution tank.
- 5.5.8 Affix 'TO BE CLEANED' labels dully filled and signed on the coating solution preparation tank and record all the observations in the equipment usage log sheet as per SOP.

### 6.0 ABBREVIATION (S):

- 6.1 BMR : Batch Manufacturing Record.
- 6.2 SOP : Standard Operating Procedure
- 6.3 No. : Number
- 6.4 v/v : Volume/Volume
- 6.5 IPA : Iso Propyl Alcohol

### 7.0 REFERENCE (S):

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP: Cleaning of Production Area.

### 8.0 ANNEXURE (S):

- 8.1 Nil

### 9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (S):** Production department (02), Quality Assurance (01)
- 9.3 **Reference copy (S):** Production department (01)

### 10.0 REVISION HISTORY:

S.No.	Version No.	Change control No.	Reason(S) For revision	Details of Revision	Effective Date
01	00	NA	NA	New SOP	NA