



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Coating Solution Preparation Tank	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Coating Solution Preparation Tank.

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of Coating Solution Preparation tank in Production Department.

3.0 RESPONSIBILITY:

3.1 Technical Associate: Cleaning and Operation of Coating Solution Preparation tank.

3.2 Production Officer/Executive: Checking Cleaning and Operation of Coating Solution Preparation tank

3.3 Head Production: SOP Compliance

3.4 IPQA Person: Line Clearance and verification

4.0 DEFINITION (S):

4.1 NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

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

5.1.1 Affix dully filled "UNDER CLEANING" status label on the equipment with date and signature of the Production officer as per SOP: "STATUS LABELING".

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

5.1.3 Wipe the equipment with a dry lint free cloth.

5.1.4 Clean the area as per SOP: "CLEANING OF PRODUCTION AREA".

5.1.5 Enter the cleaning start and end time of equipment in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

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.



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- 5.2.1 Follow the procedure from step no. 5.1.1 to 5.1.2.
 - 5.2.2 Dismantle the stirrer from main shaft.
 - 5.2.3 Take the stirrer and top lid with purified water.
 - 5.2.4 Rinse the stirrer and top lid with purified water.
 - 5.2.5 Scrub the stirrer and top lid with nylon brush 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 Clean the cleaned parts with 2% sodium lauryl sulfate before final rinsing of equipment/parts in case of previous product API is Efavirenz. (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water).
 - 5.2.7 Flush enough purified water till all visible residues of previous product are washed away.
 - 5.2.8 Cover the stirrer motor with double polybag.
 - 5.2.9 Rinse the inner surface of coating solution preparation tank with purified water.
 - 5.2.10 Flush enough purified water till all the visible residues of previous product are washed away. Use 70% v/v IPA in case adhered materials do not scrubbed out.
 - 5.2.11 Wipe the outer surface of coating solution preparation tank with wet lint free cloth.
 - 5.2.12 Wipe the inner and outer surface of coating solution preparation tank with dry clean lint free cloth.
 - 5.2.13 Wipe the inner and outer surface of tank with 70% v/v IPA.
 - 5.2.14 Bring the cleaned stirrer and top lid from coating washing area and wipe with 70% v/v IPA with a clean lint free cloth.
 - 5.2.15 Finally rinse the equipment with 30-40 liters of purified water.
 - 5.2.16 Finally cleaned the area as per SOP "CLEANING OF PRODUCTION AREA".
 - 5.2.17 Replace the "UNDER CLEANING" status label with dully filled "CLEANED" status label with date and signature of the production/QA officer as per SOP "STATUS LABELING".
 - 5.2.18 Enter the cleaning start and end time of equipment in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".
- 5.3 **Frequency:**
- 5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product, same potency and of similar product with ascending potency. If same product is processed for more than seven days then follow the procedure of Type – B cleaning as per SOP "CLEANING VERIFICATION".



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5.3.2 Type 'B' cleaning is applicable in case of changeover of product with different actives / color / 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 as per SOP "CLEANING VERIFICATION".

5.3.3 Cleaning is applicable in case of at the end of working day, de dusting of machine with vacuum cleaner or dry by lint free cloth.

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 "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

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 the equipment and area. Affix 'EQUIPMENT STATUS' label dully filled and signed on the coating solution preparation tank and record the observations in the equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

5.5.2 Set the time on the timer panel by pressing 'RESET' button followed by 'SET' button and 'PGM' button.

5.5.3 Ensure the discharge valve is closed.

5.5.4 Load the material in the coating solution preparation tank as per sequence in the respective BMR.

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 'UNDER CLEANING' label dully and signed on the coating solution preparation tank.

5.5.9 Record all the observations in the equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".

6.0 **ABBREVIATION(S):**

6.1 IPA : Iso Propyl Alcohol

6.2 Q.A. : Quality Assurance

6.3 SOP : Standard Operating Procedure

6.4 V/V : Volume/Volume



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6.5 No. : Number

6.6 BMR : Batch Manufacturing Record

7.0 RERERENCE (S):

7.1 SOP: Status Labeling

7.2 SOP: Cleaning in Production area

7.3 SOP: Making Entries in Equipment usage and Cleaning Log sheet.

8.0 ANNEXURE (S):

8.1 Nil

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled Copy (S):** Production Department (01), Quality Assurance (01)

9.3 **Reference Copy (s) :** Production Department (04)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	REASON (S) FOR REVISION	DETAILS OF REVISION	Effective Date
01	00	NA	New SOP	NA	NA