



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Pneumatic Stirrer	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 Pneumatic Stirrer.

2.0 SCOPE:

2.1 This procedure is applicable to the cleaning and operation of Pneumatic Stirrer in production area.

3.0 RESPONSIBILITY;

3.1 Technical Associate : Cleaning and Operation

3.2 Officer and Executive : Supervision

3.3 Head Production : SOP compliance

3.4 IPQA Person : Line Clearance

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING:

Change over from one batch to next batch of the same product and same potency and of similar product with ascending potency.

5.1.1 Replace the 'UNDER PROCESS' status label with dully filled and signed 'UNDER CLEANING' status label

5.1.2 Record the cleaning start time in the Equipment usage log sheet as per SOP, "Making entries in equipment usage and cleaning log sheet".

5.1.3 Ensure that the main air supply is turned 'OFF'.

5.1.4 Remove the air connection.

5.1.5 Wipe the main motor with a dry lint free cloth and keep it in dry place.

5.1.6 Dismantle the stirrer shaft from the motor and take it to wash area.

5.1.7 Clean the stirrer shaft with purified water and scrub the stirrer shaft with nylon scrubber to remove the adhere material of previous batch.

5.1.8 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)

5.1.9 Finally rinse the stirrer shaft with sufficient quantity of purified water.



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- 5.1.10 Ensure the cleanliness of stirrer shaft and wipe it with dry lint free cloth.
- 5.1.11 Clean the stirrer body, motor, RPM display (if applicable) with dry lint free cloth followed by wet lint free duster.
- 5.1.12 Assemble the stirrer shaft with the motor.
- 5.1.13 Replace the “UNDER CLEANING” status label with dully filled and signed ‘UNDER PROCESS’ status label.
- 5.1.14 Record the cleaning observations in the 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 / descending potency or after maintenance of contact parts.

- 5.2.1 Follow the step 5.1.1 to 5.1.9.
- 5.2.2 Wipe the stirrer shaft with 70% v/v IPA followed by clean dry lint free cloth.
- 5.2.3 Follow the step 5.1.10 to 5.1.11.
- 5.2.4 Replace the “UNDER CLEANING” status label with “CLEANED” label dully filled and signed ‘by production officer and QA officer.
- 5.2.5 Record the cleaning start time in the 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. 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, “Making entries in equipment usage and cleaning log sheet”.

5.4 Operation:

- 5.4.1 Replace the ‘CLEANED’ status label with dully filled and signed ‘UNDER PROCESS’ status label.
- 5.4.2 Record the Operation start time in the Equipment usage log sheet as per SOP, “Making entries in equipment usage and cleaning log sheet”.
- 5.4.3 Take the SS bin as per requirement for coating solution / Binder solution.



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- 5.4.4 Take the tare weight of SS bin and keep it under the Pneumatic stirrer.
- 5.4.5 Take the required quantity of solvent and transfer it to SS bin.
- 5.4.6 Start the compressed air supply by rotates the knob. Affix the power socket and on the power supply to RPM display. Display shown "0000" (if applicable).
- 5.4.7 Start the stirrer and set the rpm of stirrer by operating air controller knob. Rotate the knob clock wise to reduce the stirrer RPM and anti-clock wise to increase the RPM of stirrer. (If RPM display installed).
- 5.4.8 Speed should as such that there should be vortex formation in the solvent. Display of RPM shown the stirrer speed. (If RPM display installed).
- 5.4.9 After vortex formation in solvent add the coating material / binder slowly.
- 5.4.10 After addition of material stirring should be continued as per time specified in BMR.
- 5.4.11 After completion of stirring, stop the stirrer and remove the SS bin beneath from Pneumatic stirrer.
- 5.4.12 Record the Operation end time in the Equipment usage log sheet as per SOP, "Making entries in equipment usage and cleaning log sheet".
- 5.4.13 Put the "UNDER CLEANING" label dully filled and signed with production and QA officer.

6.0 ABBREVIATION (S):

- 6.1 SS : Stainless Steel
- 6.2 QA : Quality Assurance
- 6.3 BMR : Batch Manufacturing Record
- 6.4 SOP : Standard Operating Procedure
- 6.5 v/v : Volume/Volume
- 6.6 IPA : Iso Propyl Alcohol

7.0 REFERENCES(S):

- 7.1 SOP: Making entries in equipment usage and cleaning log sheet.
- 7.2 SOP: Cleaning of production area
- 7.3 SOP: Status Labeling

8.0 ANNEXURE(S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning Checklist of Pneumatic Stirrer		Log Book



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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 (03)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (s) for Revision	Details of revision	Effective Date
1.	00	NA	New SOP	NA	NA