



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Portable Mechanical Stirrer (Make-Remi)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Portable Mechanical Stirrer (Make-Remi).

2.0 SCOPE:

This procedure is applicable to the Cleaning and Operation of Portable Mechanical Stirrer (Make-Remi) in Production area.

3.0 RESPONSIBILITY:

Technical Associate: Cleaning and Operation

Officer and Executive: Supervision

Head Production: SOP compliance

IPQA Person: Line Clearance

4.0 DEFINITION (S):

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 'TO BE CLEANED' status label.
- 5.1.2 Record the cleaning start time in the Equipment usage log sheet as per SOP.
- 5.1.3 Ensure that the main power supply is turned 'OFF'.
- 5.1.4 Remove the speed controller connection.
- 5.1.5 Wipe the speed controller 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 Finally rinse the stirrer shaft with sufficient quantity of purified water.
- 5.1.9 Ensure the cleanliness of stirrer shaft and wipe it with dry lint free cloth.
- 5.1.10 Clean the stirrer body and motor with dry lint free cloth followed by wet lint free duster.
- 5.1.11 Assemble the stirrer shaft with the motor and connect the speed controller connection.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Portable Mechanical Stirrer (Make-Remi)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.1.12 Replace the 'TO BE CLEANED' status label with dully filled and signed 'UNDER PROCESS' status label.
- 5.1.13 Record the cleaning observations in the Equipment usage log sheet as per SOP.
- 5.1.14 If the TYPE-A cleaned equipment is not used within 12 hours, clean the equipment as per "TYPE-B" cleaning.

5.2 "TYPE B" CLEANING:

This is a cleaning procedure for Changeover of product with different actives / with different 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 'TO BE CLEANED' 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.
- 5.2.6 After completion of operation, clean the equipment within 24 hours if not in use.

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 / 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.
- 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 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.
- 5.4.3 Take the SS bin as per requirement for coating solution / Binder solution.
- 5.4.4 Take the tare weight of SS bin and keep it under the portable stirrer.
- 5.4.5 Take the required quantity of purified water and transfer it to SS bin.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Portable Mechanical Stirrer (Make-Remi)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.4.6 Start the stirrer and set the rpm of stirrer from speed controller.
- 5.4.7 Speed should be such that there should be vortex formation in the purified water.
- 5.4.8 After vortex formation in water add the coating material / binder slowly.
- 5.4.9 After addition of material stirring should be continued as per time specified in BMR.
- 5.4.10 After completion of stirring, stop the stirrer and remove the SS bin beneath from portable stirrer.
- 5.4.11 Record the Operation end time in the Equipment usage log sheet as per SOP.
- 5.4.12 Put the "TO BE CLEANED" label duly filled and signed with production and QA officer.

6.0 ABBREVIATION (S):

- SS : Stainless Steel
- QA : Quality Assurance
- BMR : Batch Manufacturing Record
- SOP : Standard Operating Procedure
- IPA : Isopropyl Alcohol

7.0 RERERENCE (S):

Nil

8.0 ANNEXURE (S):

Nil

9.0 DISTRIBUTION:

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