



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Super mill (Co mill)	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of Super mill.

### 2.0 SCOPE:

This procedure is applicable to the cleaning and Operation procedure of super mill in the production area.

### 3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation  
Production Officer / Executive : Checking Cleaning and Operation  
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 Remove "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine.
- 5.1.2 Enter the cleaning start time equipment usage and cleaning log sheet as per SOP.
- 5.1.3 Ensure that the main power supply is switched OFF.
- 5.1.4 Remove flame proof top from flame proof socket.
- 5.1.5 Open the clamp of hose pipe and de attached hose pipe.
- 5.1.6 Unscrew the nut of hopper and screen chamber and remove if any residue.
- 5.1.7 Clean the inner and outer side of the screen chamber and screen using dry lint free duster.
- 5.1.8 Visually Check the integrity of co-mill screen.
- 5.1.9 Fit the screen and tight screw properly.
- 5.1.10 Affix dully filled status label on super mill as "CLEANED" with date and signature of Production Officer verified by QA officer.
- 5.1.11 Record the cleaning completion time in equipment usage log sheet as per SOP.



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### 5.2. "TYPE B" CLEANING

**Changeover of product with different actives / color / descending potency or after maintenance of contact parts.**

- 5.2.1 Switch off the main power supply.
- 5.2.2 Remove "UNDER PROCESS" label and affix dully filled "TO BE CLEANED" label to the machine.
- 5.2.3 Remove the flame proof top from flame proof socket.
- 5.2.4 Enter the cleaning start time in equipment usage log sheet as per SOP.
- 5.2.5 Dismantle the hose pipe from hopper pipe and discharge pipe by opening the clamp.
- 5.2.6 Dismantle the hopper and screen chamber and remove screen.
- 5.2.7 Visually Check the integrity of co- mill screen.
- 5.2.8 Clean the hose pipe with flush of purified water.
- 5.2.9 Scrap the adhered material of screen with nylon scrubber using purified water.
- 5.2.10 Scrap the adhered material of agitator with nylon scrubber using purified water.
- 5.2.11 Rinse all parts with sufficiency quantity of purified water.
- 5.2.12 Clean the cleaned parts with 2% sodium Lauryl sulfate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.
- 5.2.13 After cleaning with 2% SLS rinse all parts with sufficient quantity of purified water.
- 5.2.14 Clean the control panel, flame proof top, power cables using a dry lint free cloth.
- 5.2.15 Ensure that area is cleaned as per SOP.
- 5.2.16 Wipe out the all parts of super mill with a clean dry lint free duster. Wipe with 70% v/v IPA.
- 5.2.17 Replace the "TO BE CLEANED" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.
- 5.2.18 Record the cleaning completion time in equipment usage log sheet as per SOP.
- 5.2.19 Record the cleaning activity in Annexure I.

### 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.
- 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.



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<b>Issue Date:</b>	<b>Page No.:</b>

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.

### 5.4 OPERATION:

#### 5.4.1 MACHINE ASSEMBLING:

- 5.4.1.1 Ensure that the equipment and area is cleaned. Affix ‘UNDER PROCESS’ label dully filled and signed on the equipment and record the observation in the Equipment Usage Log Sheet as per SOP.
- 5.4.1.2 Visually check the integrity of co- mill screen.
- 5.4.1.3 Fit the screen as per BMR requirement in screen chamber with gasket and tight the nut.
- 5.4.1.4 Fit the hopper with gasket and tight the nut properly.
- 5.4.1.5 Attach the hose pipe with hopper inlet and tight the clamp.
- 5.4.1.6 Attach the hose pipe with outlet and tight the clamp.
- 5.4.1.7 Fit the flame proof top in flame proof socket.

#### 5.4.2 MACHINE OPERATION:

- 5.4.2.1 Switch ON the main power supply.
- 5.4.2.2 Release the emergency.
- 5.4.2.3 Turn Control ‘ON/OFF’ switch on control panel to ‘ON’ position.
- 5.4.2.4 Set the RPM of agitator by pressing increase and decrease button.
- 5.4.2.5 Start the machine by pressing start button.
- 5.4.2.6 Check the sound to ensure that agitator should not touch the screen.
- 5.4.2.7 If sound is normal then start the pneumatic conveying system to feed the material.
- 5.4.2.8 After completion of process stop the machine by pressing stop button.
- 5.4.2.9 Turn Control ‘ON/OFF’ switch off control panel to ‘OFF’ position.
- 5.4.2.10 Switch off the power from main switch and then press the emergency.
- 5.4.2.11 Remove the flame proof top from flame proof socket.



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### 6.0 ABBREVIATION (S):

- IPA : Iso Propyl Alcohol
- SOP : Standard Operating Procedure
- No. : Number
- S.S. : Stainless Steel.
- V/V : Volume/Volume
- SLS : Sodium Lauryl Sulphate
- BMR : Batch manufacturing record

### 7.0 REFERENCES (S):

- SOP: Making entries in equipment usage and cleaning log sheet.
- SOP: Cleaning of production area.
- SOP: Status Labeling
- SOP: Cleaning and Operation of vacuum cleaner.

### 8.0 ANNEXURE (S):

- Annexure- I: Cleaning Checklist of Rapid Mixer Granulator

### 9.0 DISTRIBUTION:

- Master Copy** : Quality Assurance
- Controlled copy (S)** : Production department / Quality Assurance
- Reference copy (S)** : Production department



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### ANNEXURE I

#### CLEANING CHECKLIST OF SUPER MILL (CO-MILL)

<b>Name of the Equipment</b>		<b>Super Mill (Co-Mill)</b>	
<b>Equipment I.D. No.</b>		<b>Previous product</b>	
<b>Batch No.</b>		<b>Date</b>	

S.No.	Activity	Activity Performed
1.	Switch off the main power supply.	
2.	Open the clamp of hose pipe and de attached hose pipe.	
3.	Clean the hose pipe with flush of purified water.	
4.	Dismantle the hopper and screen chamber and remove screen.	
5.	Visually Check the integrity of co- mill screen.	
6.	Scrap the adhered material of screen with nylon scrubber using purified water.	
7.	Rinse all parts with sufficiency quantity of purified water.	
8.	Clean the cleaned parts with 2% sodium Lauryl sulfate (For 1 liter 2% Sodium Lauryl Sulphate, take 20 g Sodium Lauryl Sulphate and dissolve in 1 liter of purified water) before final rinsing of equipment/parts in case of previous product API is Efavirenz.	
9.	After cleaning with 2% SLS rinse all parts with sufficient quantity of purified water.	
10.	Clean the control panel, flame proof top, power cables using a dry lint free cloth.	
11.	Wipe out the all parts of super mill with a clean dry lint free duster. Wipe with 70% v/v IPA.	

**Note:** Put '√' mark if activity performed and put 'X' if activity not performed.

**Checked By (Prod.)**  
**Sign/Date**

**Verified By (QA)**  
**Sign/Date**