



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Multi mill	<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 Multimill.

### 2.0 SCOPE:

2.1 This SOP is applicable to the Cleaning and Operation of Multi-mill in the 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, same potency and have similar product with ascending potency.**

5.1.1 Affix dully filled "TO BE CLEANED" status label on multi-mill with date and signature of the Production Officer as per SOP "Status Labeling"

5.1.2 Enter the cleaning starting time in equipment usage log sheet as SOP "Making entries in equipment usage and cleaning log sheet"

5.1.3 Ensure that the main power supply is switched OFF.

5.1.4 Dismantle hopper and sizing chamber with discharge chute.

5.1.5 Remove the base plate and screen.

5.1.6 Clean the dismantled parts, blades with a dry lint free duster.

5.1.7 Check the cleanness by production officer.

5.1.8 Assemble the dismantled parts of the multimill.

5.1.9 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production/QA Officer.



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5.1.10 Record the cleaning activity 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 / descending potency or after maintenance of contact parts.**

5.2.1 Follow the procedure from step 5.1.1 to 5.1.5.

5.2.2 Remove the blade assembly from the sizing chamber.

5.2.3 Clean the dismantled parts of the multi-mill using 4-5 liter of purified water with nylon brush to remove the adhered material.

5.2.4 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.

5.2.5 Clean all the above parts with 20-25 liters of purified water.

5.2.6 Clean the screen by using purified water and with a nylon brush.

5.2.7 Apply a jet of purified water so as to ensure the complete removal of traces of the previous product. Clean the blades and body with 15-20 liter of purified water.

5.2.8 Dry the screen by using compressed air.

5.2.9 Dry all the dismantled parts and the body with the help of dry lint free cloth.

5.2.10 Wipe all dismantled parts of the multimill and its body with 70% v/v IPA solution.

5.2.11 Certify the cleanliness by production officer /QA officer.

5.2.12 Assemble the multimill without the screen. Store the screen by covering with a polythene bag and label as “CLEANED” status label with date and signature of the production officer as per SOP “Status Labeling”

5.2.13 Transfer the screen to the granulation spare area and record the utilization and cleaning details in Annexure-I.

5.2.14 Ensure that the area is cleaned as per SOP “Cleaning of production area”.

5.2.15 Affix a label on multimill as “CLEANED” with date and signature of the Production Officer & QA officer as per SOP “Status Labeling”

5.2.16 Record the cleaning completion time of multimill in equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”

5.2.17 Record the cleaning activity in Annexure II.



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5.2.18 Record the screen utilization and cleaning as per 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 "Cleaning Validation"

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 Validation"

5.3.3 Cleaning is applicable in case of at the end of working day, dedusting 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 OPERATION:

#### 5.4.1 Machine setting:

5.4.1.1 Ensure that the machine and area is cleaned.

5.4.1.2 Ensure that the main switch is in "OFF" position before setting of Multimill.

5.4.1.3 Check and ensure that there is no any leakage from the sealing and gasket.

5.4.1.4 Fix all the blades in the blade housing and lock it with stud in its position.

5.4.1.5 Fix the blade housing into the shaft of main motor drive and lock it with bolt (Turn bolt anticlockwise).

5.4.1.6 Fix the required screen as per respective BMR in the frame and assemble it appropriately such that rotary blades do not rub with the frame and the screen.

5.4.1.7 Place pre-labeled cleaned SS drum with double lined polythene bag at the outlet chute.

#### 5.5 Operation of Promtech Make

5.5.1 After line clearance from QA, put the "EQUIPMENT STATUS" label duly filled and signed on machine.



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5.5.2 Enter the start time of the batch in equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”

5.5.3 Switch “ON” the electric supply and move Button’ in anti-clockwise direction to run the machine in impact forward direction and in clockwise direction to run the machine in ‘knife forward’ direction.

5.5.4 Adjust hopper vent to have desired flow rate of materials.

5.5.5 Run the machine and slowly feed the material to be crushed through the hopper.

5.5.6 Collect the crushed material into the cleaned SS drum with double lined Polythene bag.

5.5.7 After completion of operation, press ‘Red’ button to stop the machine. If there is any abnormality is observed, stop the machine and reset it.

5.5.8 Enter the completion time in Equipment Usage Log Sheet SOP “Making entries in equipment usage and cleaning log sheet”.

### **5.6 Operation of Anchor Mark Make:**

5.6.1 After line clearance from QA, put the “EQUIPMENT STATUS” label duly filled and signed on machine.

5.6.2 Enter the start time of the batch in equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”

5.6.3 Switch “ON” the electric supply from the control panel.

5.6.4 Press the ‘BLUE’ button for ‘FORWARD’ direction and ‘GREEN’ button for ‘REVERSE’ direction.

5.6.5 ‘POT METER’ controls RPM of the machine in forward and reverse directions; turn pot meter CLOCKWISE direction to increase and ANTICLOCKWISE direction to decrease the RPM of the machine.

5.6.6 Set the RPM of machine as required and it is shown on RPM meter.

5.6.7 If machine is overloaded ‘OVER LOAD, button blink. Adjust the machine and restart the operation.

5.6.8 Adjust hopper vent to have desired flow rate of materials.

5.6.9 Run the machine and slowly feed the material to be crushed through the hopper.



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- 5.6.10 Collect the crushed material into the cleaned SS drum with double lined Polythene bag.
- 5.6.11 After completion of operation, press 'Red' button to stop the machine. If there is any abnormality is observed, stop the machine and reset it.
- 5.6.12 Enter the completion time in Equipment Usage Log Sheet SOP "Making entries in equipment usage and cleaning log sheet".

### 5.7 Operation of Bectochem

- 5.7.1 Affix the "EQUIPMENT STATUS" label dully filled and signed on the machine as per SOP "Status Labeling"
- 5.7.2 Enter the start time of the batch in the equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet"
- 5.7.3 Switch "ON" the electric supply and press green push button to switch "ON" the machine and rotate REV/ FORW switch in clockwise direction to run the machine in impact forward direction, rotate button in anticlockwise direction to run the machine in 'REVERSE' direction.
- 5.7.4 Rotate the 'POT METER' knob in clockwise direction to increase the RPM, which is displayed on the monitor.
- 5.7.5 Adjust hopper vent to have desired flow rate of materials.
- 5.7.6 Run the machine and slowly feed the material to be milled through the hopper.
- 5.7.7 Collect the milled material into the cleaned SS container with double lined polythene bag.
- 5.7.8 After completion of operation, press 'RED' push button to stop the machine and put 'TO BE CLEANED' status label.
- 5.7.9 Enter the completion time in Equipment Usage Log Sheet as per SOP "Making entries in equipment usage and cleaning log sheet".

### 5.8 Operation of Gansons

- 5.8.1 Affix the "EQUIPMENT STATUS" label dully filled and signed on the machine as per SOP "Status Labeling"



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5.8.2 Enter the start time of the batch in the equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”

5.8.3 Switch “ON” the electric supply and press green push button to switch “ON” the machine and rotate REV/ FORW switch in clockwise direction to run the machine in impact forward direction, rotate button in anticlockwise direction to run the machine in ‘REVERSE’ direction.

5.8.4 Rotate the ‘POT METER’ knob in clockwise direction to increase the RPM, which is displayed on the monitor.

5.8.5 Adjust hopper vent to have desired flow rate of materials.

5.8.6 Run the machine and slowly feed the material to be milled through the hopper.

5.8.7 Collect the milled material into the cleaned SS container with double lined polythene bag.

5.8.8 After completion of operation, press ‘RED’ push button to stop the machine and put ‘TO BE

5.8.9 CLEANED’ status label

Enter the completion time in Equipment Usage Log Sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.

### 5.9 Operation of SSMS Engineers:

5.9.1 Affix the “EQUIPMENT STATUS” label dully filled and signed on the machine as per SOP “Status Labeling”

5.9.2 Enter the start time of the batch in the equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.



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- 5.9.3 Switch “ON” the electric supply and press Yellow push button to switch “ON” the machine and rotate forward in clockwise direction to run the machine in “IMPACT FORWARD” forward direction, press red push button to stop the machine. Press green button to rotate the machine in anticlockwise direction to run the machine in ‘REVERSE’ direction.
- 5.9.4 Rotate the ‘POT METER’ knob in clockwise direction to increase the RPM, which is displayed on the monitor.
- 5.9.5 Adjust hopper vent to have desired flow rate of materials
- 5.9.6 Run the machine and slowly feed the material to be milled through the hopper.
- 5.9.7 Collect the milled material into the cleaned SS container with double lined polythene bag.
- 5.9.8 After completion of operation, press ‘RED’ push button to stop the machine and put ‘TO BE CLEANED’ status label.
- 5.9.9 Enter the completion time in Equipment Usage Log Sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.

### 5.10 Operation of Kapsan Pharmatech

- 5.10.1 Affix the “EQUIPMENT STATUS” label dully filled and signed on the machine as per SOP “Status Labeling”.
- 5.10.2 Enter the start time of the batch in the equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”.
- 5.10.3 Switch “ON” the electric supply then switch “ON” main of Multi-mill and press Green push button to switch “ON” the machine and rotate forward in clockwise direction to run the machine in “IMPACT FORWARD” by switch of direction on “forward” direction, press red push button to stop the machine. Press green button to rotate the machine in anticlockwise direction to run the machine in ‘REVERSE’ direction by switch of direction on “REVERSE”.
- 5.10.4 Rotate the ‘POT METER’ knob in clockwise direction to increase the RPM, which is displayed on the monitor
- 5.10.5 Adjust hopper vent to have desired flow rate of materials
- 5.10.6 Run the machine and slowly feed the material to be milled through the hopper.
- 5.10.7 Collect the milled material into the cleaned SS container with double lined polythene bag.



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5.10.8 After completion of operation, press 'RED' push button to stop the machine and put 'TO BE CLEANED' status label.

5.10.9 Enter the completion time in Equipment Usage Log Sheet as per SOP "Making entries in equipment usage and cleaning log sheet".

### 5.11 Precaution and check points:

5.11.1 Use elbow size latex gloves during handling of materials.

5.11.2 Ensure that the rotating blade do not rub with frame and the screen.

5.11.3 Do not put oil in main motor shaft with blade housing from inside.

5.11.4 Ensure that no over feeding is done in the hopper of the Multimill.

### 6.0 ABBREVIATION (S):

6.1 IPA : Iso Propyl Alcohol

6.2 SOP : Standard Operating Procedure

6.3 ml : Milliliter

6.4 BMR : Batch Manufacturing Record

6.5 SS : Stainless Steel

6.6 v/v : volume/volume

6.7 SLS : Sodium Lauryl Sulphate

### 7.0 REFERENCE (S):

7.1 SOP: Making entries in equipment usage and cleaning log sheet.

7.2 SOP: Cleaning of production area.

7.3 SOP: Cleaning Validation.

7.4 SOP: Status Labeling.

### 8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Screen Utilization and Cleaning Record		Logbook
Annexure II	Cleaning Checklist of Multimill		Logbook





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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 (19).

### 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





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### ANNEXURE II

### CLEANING CHECKLIST OF MULTIMILL

<b>Name of the Equipment</b>	<b>Multi 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	Ensure that the main power supply is switched OFF	
2	Dismantle hopper and sizing chamber with discharge chute.	
3	Remove the base plate and screen.	
4	Clean the dismantled parts, blades with a dry lint free duster.	
5	Remove the blade assembly from the sizing chamber	
6	Clean the dismantled parts of the multi-mill using 4-5 liter of purified water with nylon brush.	
7	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.	
8	Clean all the above parts with 20-25 liters of purified water.	
9	Clean the screen by using purified water and with a nylon brush.	
10	Apply a jet of purified water so as to ensure the complete removal of traces of the previous product. Clean the blades and body with 15-20 liter of purified water.	
11	Dry the screen by using compressed air.	
12	Dry all the dismantled parts and the body with the help of dry lint free cloth.	
13	Wipe all dismantled parts of the multi-mill and its body with 70% v/v IPA solution.	

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

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

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