



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Dyno Mill	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
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### 1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation of DYNO MILL (ECM AP 2).

### 2.0 SCOPE:

This procedure is applicable to Cleaning and Operation of DYNO MILL (ECM AP 2) located in manufacturing 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 Switch Off the mains of the Dyno Mill.

5.1.2 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer, as per SOP.

5.1.3 Enter the cleaning start time in equipment usage log sheet SOP.

5.1.4 Remove the powder deposited on machine by wet lint free cloth.

5.1.5 Clean the control panel with lint free cloth.

5.1.6 Clean the outside part of Dyno Mill cover, motor cover, and drain pan using dry lint free cloth.

5.1.7 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the production officer/QA Officer, as per SOP.

5.1.8 Record the cleaning completion time in equipment usage log sheet as per SOP.



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### 5.2 “TYPE B” CLEANING:

**Change over of product with different actives / colour / descending potency or after maintenance of contact parts.**

- 5.2.1 Affix dully filled “TO BE CLEANED” status label on equipment with date and signature of the Production Officer, as per SOP.
- 5.2.2 Enter the cleaning start time in equipment usage log sheet as per SOP.
- 5.2.3 After completion of batch flush the Dyno Mill with the purified water till water comes free from product residue.
- 5.2.4 Then circulate the purified water about 30 minutes. Then check the rinsing result to check the previous product residue.
- 5.2.5 If the rinsing result is not satisfactory repeat the cleaning procedure until the result is satisfactory.  
**Note:** 1. Check and ensure the drained liquid (rinse water/Solvent) should be free of product.  
2. Grinding container to be depressurized before dismantling.
- 5.2.6 Switch Off the mains of the Dyno Mill.
- 5.2.7 Loosen the 3 cap nuts and remove from studs together with the washers.
- 5.2.8 Pull on the lock pin. Then hold the grinding container at the outlet elbow and pull it few centimeters in the direction out side.
- 5.2.9 Grinding beads, product residue and rest of liquid phase run into the drain pan.
- 5.2.10 Loosen the tri clamp lock and loosen the product inlet with pressure gauge. Clean the SS pipes of product inlet with the purified water.
- 5.2.11 Hold the grinding container at the outlet elbow, pull out carefully in the direction of out side until the lock pin engages.
- 5.2.12 Allow the product to drip off the Dyno accelerators.
- 5.2.13 Pull the lock pin upward, then swing grinding container slowly and carefully aside until the lock pin engages,
- 5.2.14 Drain the remaining grinding beads from the grinding container and into the drain pan.
- 5.2.15 Loosen the tri clamp lock and loosen the product outlet with temperature gauge. Clean the SS pipes of product outlet with the purified water.
- 5.2.16 Clean the grinding cylinder, pulling device and contact surface with sufficient quantity of purified water.
- 5.2.17 Clean the guide rails of the pulling device with sufficient quantity of purified water.
- 5.2.18 Clean the rinsing tank with the purified water.



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5.2.19 Clean the Dyno accelerator, grinding container with grinding cylinder and WAB separation system with the sufficient quantity of purified water.

5.2.20 Detach the external product outfeed and clean with sufficient quantity of purified water to remove the any residue of previous product.

5.2.21 **Grinding Beads Cleaning:**

5.2.21.1 Clean the grinding beads with flushing of purified water.

5.2.21.2 After cleaning visually check cleanliness of the grinding beads.

5.2.21.3 Filter and separate the grinding beads with muslin cloth. Dry the grinding beads at room temperature in the General Wash clean area/ particular cubicle in hanging condition and after drying store in the SS container with status label having product name and batch no.

5.2.22 Clean the body, platform with wet lint free cloth followed by dry clean lint free cloth.

5.2.23 **Silicon graded tubes Cleaning:**

5.2.23.1 Remove the product inlet & outlet tubes from the nozzles of the Solution feed vessel.

5.2.23.2 Dip these tubes into purified water.

5.2.23.3 Scrub the outer surface of silicon graded tubes with wet lint free cloth followed by dry lint free cloth.

5.2.23.4 Dry the silicon graded pipes in General Wash clean area in inverted U-shaped hanging condition and after drying, store in polybags or shrink wrap the tubes by close the open ends with status label having product name and batch number.

5.2.24 Dry the cleaned parts with lint free cloth.

5.2.25 Wipe all cleaned parts with 70% v/v IPA solution.

5.2.26 Assemble the dismantle parts and cover the discharge port.

5.2.27 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the production officer/QA Officer, as per SOP.

5.2.28 Record the cleaning completion time in equipment usage log sheet as per SOP.

5.2.29 Clean the area as per SOP.

**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 seven days then follow the procedure of type – B cleaning.



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5.3.2 Type 'B' cleaning is applicable in case of change over 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.

5.3.3 Cleaning is applicable in case of at the end of working day, dedusting of machine with 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 Machine setting:

5.4.1 Ensure 'CLEANED' label duly filled and signed is affixed on the equipment.

5.4.2 Ensure cleanliness of area and the equipment. Record the observations in the Equipment usage log sheet as per SOP. Affix 'UNDER PROCESS' label duly filled and signed on the equipment.

5.4.3 After ensure the cleanliness of the equipment swivel grinding container until lock pin engages. Then push the grinding container into the machine. The control panel of the Dyno mill shown below.

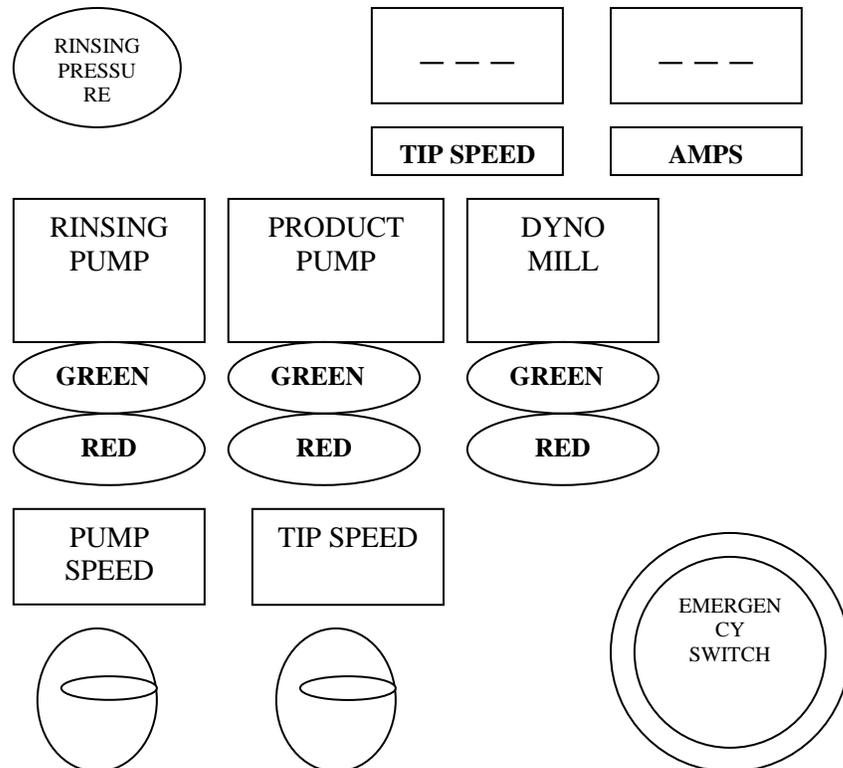


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- 5.4.4 Place the O-ring and then lock the Dyno assembly with the 3 cup nuts. Tighten the nuts to fit properly.
- 5.4.5 Fit the tri clamp lock and attach the product inlet with pressure gauge. At pressure gauge set the lower and upper limit of the pressure required for the grinding process. Beyond the limit machine stops.
- 5.4.6 Then fit the tri clamp lock and attach the product outlet with temperature gauge. At temperature gauge set the upper limit for the temperature of product. Beyond this limit machine stops.
- 5.4.7 Attach the product inlet and outlet pipes with clamp to the assembly.
- 5.4.8 Attach the chilled water supply inlet and outlet to the assembly. Ensures that the chilled water supply must be minimum 1.5 to 3.5 kg/cm<sup>2</sup>.
- 5.4.9 Verify the screen for filter the beads visually for its integrity.

**Note:** 1. The screen used must be 1/3 the size of the slot width of the grinding beads.

2. After completion of 150 hours, discard the grinding beads.



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5.4.10 Verify the size of beads with the certificates and Feed the agitator beads 65% of the Dyno mill capacity. Calculate the agitator bead quantity with the help of following formula-

Quantity = Volume of grinding chamber (1.90 liter) X Bulk density of Beads (depends on average bulk density of beads) X 65

5.4.11 Record the grinding beads uses in Annexure II.

5.4.12 Load the calculated quantity to the Dyno mill with the help of SS funnel.

5.4.13 Open cover of rinsing liquid tank and fill with purified water.

### 5.5 Machine Operation:

5.5.1 Connect the circulation pipe with the Dyno mill.

5.5.2 Make the suspension in the container as instructed in the batch manufacturing record.

5.5.3 Start the rinsing pump. Then start the product pump. The product to be grind is pumped from SS Container via the product inlet in to the grinding container.

5.5.4 Set the pump speed as required. Value shown at the dial gage from 1 to 10 and for RPM multiply with the 30 to get the RPM of the pump speed. Set the RPM as required for the product and check the flow rate manually it is up to 60 liter per hour.

5.5.5 Then set the tip speed minimum 6 meter/sec to maximum 12 meter/sec.

5.5.6 Then press "DYNO MILL" to start the machine.

5.5.7 Grinding of product starts.

5.5.8 At the grinding container outlet the grinding beads are separated from the product by means of the WAB separation system. Axially and across the screen surface the grinding beads return to the DYNO accelerator.

5.5.9 Then rinse entire loop with the purified water/ solvent for 20-30 seconds present in the batch for complete removal of product from the Dyno mill.

5.5.10 After completion of process press the Red switch to stop the machine.

5.5.11 Affix 'TO BE CLEANED' label duly filled and signed on the Dyno Mill and record the observations in equipment usage log sheet as per SOP.

5.5.12 Record the operation completion time in equipment usage log sheet as per SOP.

### 5.6 Precautions:



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5.6.1 In the situation where the safety of the operating personnel or the mill is threatened, press the EMERGENCY STOP push button to stop the mill. Once activated, the EMERGENCY STOP push button can only be unlock with the key.

### 6.0 ABBREVIATION (S):

IPA : Iso Propyl Alcohol  
Q.A. : Quality Assurance  
SOP : Standard Operating Procedure  
No. : Number  
S.S. : Stainless Steel.  
V/V : Volume / Volume  
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

### 8.0 ANNEXURE (S):

Annexure – I: Cleaning Checklist  
Annexure – II: Grinding Beads Uses Log Sheet

### 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 DYNO MILL (ECM AP 2)

<b>Name of the Equipment</b>	DYNO MILL (ECM AP 2)		
<b>Equipment ID No.</b>		<b>Previous product</b>	
<b>Batch No.</b>			

S.No.	Activity	Activity performed
1.	After completion of batch flush the Dyno Mill with the purified water till water comes free from product residue.	
2.	Then circulate the purified water about 30 minutes. Then check the rinsing result to check the previous product residue.	
3.	If the rinsing result is not satisfactory repeat the cleaning procedure until the result is satisfactory.	
4.	Switch Off the mains of the Dyno Mill.	
5.	Loosen the 3 cap nuts and remove from studs together with the washers.	
6.	Pull on the lock pin. Then hold the grinding container at the outlet elbow and pull it few centimeters in the direction outside.	
7.	Grinding beads, product residue and rest of liquid phase run into the drain pan.	
8.	Loosen the tri clamp lock and loosen the product inlet with pressure gauge. Clean the SS pipes of product inlet with the purified water.	
9.	Hold the grinding container at the outlet elbow, pull out carefully in the direction of outside until the lock pin engages.	
10.	Allow the product to drip off the Dyno accelerators.	
11.	Pull the lock pin upward, then swing grinding container slowly and carefully aside until the lock pin engages,	
12.	Drain the remaining grinding beads from the grinding container and into the drain pan.	
13.	Loosen the tri clamp lock and loosen the product outlet with temperature gauge. Clean the SS pipes of product outlet with the purified water.	
S.No.	Activity	Activity performed
14.	Clean the grinding cylinder, pulling device and contact surface with sufficient quantity of purified water.	



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**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.

