



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Oscillating Granulator	Effective Date:
Supersedes: Nil	Review Date:
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Vernacular SOP: No

1.0 OBJECTIVE:

1.1 To lay down a procedure for Cleaning and Operation of Oscillating Granulator.

2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Oscillating Granulator located in manufacturing area.

3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation

3.2 Production Officer / Executive: Checking cleaning and operation

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 Remove "EQUIPMENT STATUS" label and affix dully-filled "UNDER CLEANING" label to the machine as per SOP "Status Labelling".

5.1.2 Enter the cleaning start time in equipment usage log sheet SOP "Making entries in equipment usage and cleaning log sheet".

5.1.3 Remove the remainants of the previous batch from the equipment and the area with vacuum cleaner as per SOP "Cleaning and operation of vacuum cleaner".

5.1.4 Clean the inner and outer surface with lint free dry cloth.

5.1.5 Affix dully filled status label on Oscillating Granulator as "CLEANED" with date and signature of Production Officer verified by QA officer as per SOP "Status Labeling".

5.1.6 Record the cleaning completion time in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".



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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 5.1.4.
- 5.2.2 Dismantle the deflector and funnels from the machine and put on the SS pallet.
- 5.2.3 Dismantle the sieve tensioning bars of both sides.
- 5.2.4 Unbolt the movable head with the knob and draw the head towards you.
- 5.2.5 Take out the rotor, passing it through the opening of the movable on the housing and then take it out through the top, tilting it.
- 5.2.6 Rinse the all the above dismantled parts with sufficient purified water.
- 5.2.7 Clean the rotor with 5-8 liters of purified water by scrubbing with nylon scrubber.
- 5.2.8 Clean all the dismantled parts with 50-60 liters of purified water.
- 5.2.9 Clean the sieve by using purified water with a nylon brush.
- 5.2.10 Apply a jet of purified water so as to ensure the complete removal of the previous product.
- 5.2.11 Finally rinse the all the above parts with 30-40 liters of purified water.
- 5.2.12 Dry the sieve by using compressed air.
- 5.2.13 Wipe the body of the Oscillating Granulator with wet duster soaked in purified water.
- 5.2.14 Dry all the dismantled parts with a dry lint free duster.
- 5.2.15 Wipe all the dismantled parts of the sifter and its body with 70% v/v IPA solution.
- 5.2.16 Record the cleaning activity in Annexure I "Cleaning Checklist of Oscillating Granulator".
- 5.2.17 Replace the "UNDER CLEANING" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer as per SOP "Status Labeling".
- 5.2.18 Record the cleaning completion time in 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, same potency and of similar product with ascending potency. If same product is processed for more than a seven days 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.



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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 Machine setting:

5.4.1 Ensure ‘CLEANED’ label duly filled and signed is affixed on the equipment.
Ensure cleanliness of area and the equipment. Record the observations in the equipment usage log sheet as per SOP “Making entries in equipment usage and cleaning log sheet”. Affix “EQUIPMENT STATUS” label duly filled and signed on the equipment as per SOP “Status Labeling”.

5.4.2 Mounting of the Rotor:

- 5.4.2.1 Dismantle the deflector and funnels from the machine and put on the SS pallet.
- 5.4.2.2 Dismantle the sieve tensioning bars of both sides.
- 5.4.2.3 Unbolt the movable head with the knob and draw the head towards you.
- 5.4.2.4 Draw the rotor from the top in the opening of the movable head on hosing. Set it in position on the pentagon shaft of the fixed head and push back the movable head in its initial position.
- 5.4.2.5 Push the movable head inside and tighten the knob.

5.4.3 Mounting of the Sieve:

- 5.4.3.1 Slip the sieve in the interior of the machine.
- 5.4.3.2 Put the sieve tension bars in their place, passing the upturned edges of the sieve in the slots of the two tension bars.
- 5.4.3.3 Stretch the sieve slightly, rotating the sieve tensioning bars towards the exterior of the machine.
- 5.4.3.4 Stretch the sieve up to the contact with the rotor.
- 5.4.4 Fix the deflector and funnels at the respective place and tighten the bolt.
- 5.4.5 Start the machine slowly to check the proper fitting of all the parts.
- 5.4.6 If noise occurs release the one notch to stop the noise.

5.5 OPERATION:



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- 5.5.1 After line clearance from QA, put the "EQUIPMENT STATUS" label duly filled and signed on machine as per SOP "Status Labeling".
- 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 from the control panel.
- 5.5.4 Press the 'GREEN (Granulator ON)' push button to start the Oscillating Granulator and 'RED (Granulator OFF)' push button for stop the Oscillating Granulator.
- 5.5.5 'GRANULATOR SPEED' knob controls RPM of the machine; turn knob CLOCKWISE direction to increase and ANTICLOCKWISE direction to decrease the RPM of the machine.
- 5.5.6 Set the Oscillating Granulator speed as per requirement by the property of the product and it is shown on GRANULATOR RPM.
- 5.5.7 Adjust hopper vent to have desired flow rate of materials.
- 5.5.8 Run the machine and slowly feed the material to be crushed through the deflector.
- 5.5.9 Collect the material into the cleaned SS drum with double lined Polythene bag.
- 5.5.10 After completion of operation, press 'Red' button to stop the machine. If there is any abnormality is observed, stop the machine.
- 5.5.11 At the end of operation affix 'UNDER CLEANING' label duly filled and signed on the machine and record all the observation in equipment usage log sheet as per SOP "Making entries in equipment usage and cleaning log sheet".

5.6 Precaution and check points

- 5.6.1 Use elbow size latex gloves during handling of materials.
- 5.6.2 Ensure that the rotating pentagon shaft do not rub with frame and the screen.
- 5.6.3 Ensure that no over feeding is done.

6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 V/V : Volume/Volume
- 6.3 SOP : Standard Operating Procedure



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7.0 REFERENCES (S):

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

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of Execution
Annexure - I	Cleaning Checklist of Oscillating Granulator		Log Book

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled copy (S):** Production department (02 Nos.) Quality Assurance (01 Nos.)
- 9.3 **Reference copy (S):** Production department (02 Nos.)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason(s) for revision	Details of revision	Effective Date
01	00		New SOP	NA	



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ANNEXURE I

CLEANING CHECKLIST OF OSCILLATING GRANULATOR

Name of the Equipment		OSCILLATING GRANULATOR	
Equipment ID. No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity performed
1.0	Dismantle the deflector and funnels from the machine and put on the SS pallet.	
2.0	Dismantle the sieve tensioning bars of both sides.	
3.0	Unbolt the movable head with the knob and draw the head towards you.	
4.0	Take out the rotor, passing it through the opening of the movable on the housing and then take it out through the top, tilting it.	
5.0	Rinse the all the above dismantled parts with sufficient purified water.	
6.0	Clean the rotor with 5-8 liters of purified water by scrubbing with nylon scrubber.	
7.0	Clean all the dismantled parts with 50-60 liters of purified water.	
8.0	Clean the sieve by using purified water with a nylon brush.	
9.0	Apply a jet of purified water so as to ensure the complete removal of the previous product.	
10.0	Finally rinse the all the above parts with 30-40 liters of purified water.	
11.0	Dry the sieve by using compressed air.	
12.0	Wipe the body of the Oscillating Granulator with wet duster soaked in purified water.	
13.0	Dry all the dismantled parts with a dry lint free duster.	
14.0	Wipe all the dismantled parts of the sifter 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.