



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Air Jet Micronizer

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 Air Jet Micronizer.

2.0 SCOPE:

2.1 This procedure is applicable to Cleaning and Operation of Air Jet Micronizer located in manufacturing area.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation of equipment.
3.2 Production Officer / Executive : Execution of cleaning and operation of equipment.
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.
5.1.2 Enter the cleaning start time in equipment usage log sheet SOP.
5.1.3 Shake the all six filter bags to de-dust and Switch OFF the power supply.
5.1.4 Remove the ruminants of the previous batch from the equipment and the area with vacuum cleaner.
5.1.5 Allow sucking the powder attached with the wall and return riser using vacuum cleaner.
5.1.6 Clean the feeding hopper, fine filter chamber and product container from outside using a dry clean lint free duster.
5.1.7 Clean the product container with dry lint free cloth to remove any leftover material.
5.1.8 Affix dully filled status label on Micronizer as "CLEANED" with date and signature of Production Officer verified by QA officer.



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

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 Dismantle the Solenoid valve, Air tank receiver then top box.

5.2.3 Remove the all filter bags and clean all the filter bags as per SOP.

5.2.4 Pull out the product container and dismantle the cone portion.

5.2.5 Dismantle the connecting pipe of jet mill assembly to fine filter chamber and dismantle jet mill assembly.

5.2.6 Dismantle the screw feeder (feed hopper, trough, screw and agitator paddle above the screw).

5.2.7 Dismantle the interconnecting ducting.

5.2.8 Rinse all the above parts with 30-40 liters of purified water.

5.2.9 Scrub the fine filter chamber and dismantle parts with a nylon scrubber using purified water.

5.2.10 Scrub the supporting arm and trolley with a nylon scrubber using purified water.

5.2.11 Rinse the fine filter chamber and product container with 10-15 liters of Purified water.

5.2.12 Scrub the outside of the Air Jet Micronizer with a nylon scrubber using 20-30 liters of purified water.

5.2.13 Finally rinse the all cleaned parts with the sufficient quantity of purified water.

5.2.14 Clean the utility cables limit switches and control panel with a dry lint free duster.

5.2.15 Transfer the clean Micronizer filter bags to respective granulation area for the drying of filter bag.

5.2.16 Operate the FBD at an inlet temperature of 65° C until the out let temperature is achieved 63°C to 65°C. Ensure the bags are completely dried. Record the same in to the equipment log book. Remove the bags and transfer it to the granulation spare area.

5.2.17 Wipe out the body of Micronizer, fine filter bag chamber and trolley with a clean dry lint free duster.

5.2.18 Wipe all the above parts with 70% v/v IPA solution.

5.2.19 Reassemble the dismantled cleaned parts.

5.2.20 Replace the "UNDER CLEANING" status label with the "CLEANED" status label with date and signature of Production Officer and QA Officer.

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

5.2.22 Record the observation in cleaning checklist.



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5.2.23 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, 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.

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.

5.3.3 Cleaning (De-dusting of machine with vacuum cleaner and dry lint free cloth) is applicable in case of at the end of working day.

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.

Ensure cleanliness of area and the equipment. Record the observations in the equipment usage log sheet.

5.4.2 Affix 'EQUIPMENT STATUS' label duly filled and signed on the equipment.

5.4.3 Open the lock of control panel. Turn main switch to 'ON' position. Open the main air valve, reading on main air pressure gauge will start increasing. Ensure the Compressed air pressure should be between 6 - 8 Kg / cm².

5.4.4 Set the product feed rate with the speed controller knob from 0% - 100% as required or describe in the BMR as the micronized powder will become coarser with increasing feed rates and finer with increasing operating pressure and vice-versa.

5.4.5 Open the gate valve supplying air to the feed jet so that the pressure comes to around 6 kg/ cm².

5.4.6 Check the presence of a vacuum at the feed hopper with a polythene bag.

5.4.7 Let the air run through for a period of 60 seconds and check for air leakage caused by incorrect fastening all over the system.

5.5 Machine Operation:

5.5.1 Start Feed the powder in to the milling chamber.

5.5.2 Switch ON main power supply.



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5.5.3 Bag shaking on and ON the air drum pressure.

5.5.4 Then switch ON main air supply valve.

5.5.5 Start the ROTOR then FEEDER by pressing green push button on the control panel.

5.5.6 The powder almost instantly micronized and gets carried over into the product collector.

5.6 Product Unloading

5.6.1 After sufficient quantity of powder has passed through machine, enough to fill at least 75% of the volume of the vessel close the butterfly valve.

5.6.2 Open the clamp just below the butterfly valve. Move away the product collecting container.

5.6.3 Transfer the micronized product to the SS container or SS bin, lined by double polythene bag.

5.6.4 Attach the empty vessel in place clamped it. Then open the butterfly valve.

5.6.5 If process is over then after removing the product from the machine put the TO BE CLEANED status label on the machine.

5.7 Precaution

5.7.1 During assembly of the milling chamber ensure that the Jet Ring is placed with the O-ring Groove facing UPWARDS.

5.7.2 Switch OFF the power before opening the screw Feeder.

5.7.3 Carry out the dismantling and reassembling gently. Do not use excessive force to make the parts fit.

5.7.4 Drive the Screw Feeder drive motor only through frequency controller. Do not connect the Motor directly to the Mains.

6.0 ABBREVIATION (S):

6.1 IPA : Iso Propyl Alcohol

6.2 Q.A. : Quality Assurance

6.3 SS : Stainless Steel.

6.4 SOP : Standard Operating Procedure

6.5 v/v : Volume/Volume

6.6 BMR : Batch Manufacturing Record

7.0 REFERENCES (S):

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

7.2 SOP: Cleaning and utilization of FBD/FBP Finger Bag / RMG /Air Jet Micronizer Filter Bag.



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8.0 ANNEXURE (S):

Annexure no.	Title of Annexure	Format No.	Mode of execution
Annexure-I	Cleaning checklist of Micronizer		Logbook

9.0 DISTRIBUTION:

9.1 **Master Copy** : Quality Assurance

9.2 **Controlled copy (S)** : Production department (2), Quality Assurance (1)

9.3 **Reference copy (S)** : Production department (1)

10.0 REVISION HISTORY:

S.No.	Version No.	Change Control No.	Reason (S) For revision	Details of Revision	Effective Date
1.	00		New SOP	NA	



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ANNEXURE I CLEANING CHECKLIST OF AIR JET MICRONIZER

Name of the Equipment	AIR JET MICRONIZER		
Equipment ID No.		Previous product	
Batch No.		Date	

S.No.	Activity	Activity performed
1.	Shake the filter bag to Dedust and Switch OFF the power supply.	
2.	Dismantle the Solenoid valve, Air tank receiver then top box.	
3.	Remove the filter bag and net from the cam and clean the bag.	
4.	Pull out the product container and dismantle the cone portion.	
5.	Dismantle the connecting pipe of jet mill assembly to fine filter chamber and dismantle jet mill assembly.	
6.	Dismantle the screw feeder (feed hopper, trough, screw and agitator paddle above the screw).	
7.	Dismantle the interconnecting ducting.	
8.	Rinse all the above parts with 30-40 liters of purified water.	
9.	Scrub the fine filter chamber and dismantle parts with a nylon scrubber using purified water.	
10.	Scrub the supporting arm and trolley with a nylon scrubber using purified water.	
11.	Rinse the fine filter chamber and product container with 10-15 liters of Purified water.	
12.	Scrub the outside of the Micronizer with a nylon scrubber using 20-30 liters of purified water.	
13.	Finally rinse the all cleaned parts with the sufficient quantity of purified water.	
14.	Clean the utility cables limit switches and control panel with a dry lint free duster.	
15.	Transfer the clean Micronizer filter bag to respective granulation area for the drying of filter bag.	
16.	Wipe out the body of Micronizer, fine filter bag chamber and trolley with a clean dry lint free duster.	
17.	Wipe all the above parts 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.