



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Spheronizer	<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 Spheronizer.

### 2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of Spheronizer in the production area.

### 3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Operation
- 3.2 Officer/ Executive Production: Supervision
- 3.3 Head Production : SOP Compliance
- 3.4 IPQA : 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 Ensure that all the materials of previous batch are removed from the Roll Compactor area.  
Ensure that main power supply is switched off.
- 5.1.2 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP (Status labeling).
- 5.1.3 Record the cleaning start time in equipment usage log sheet equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.1.4 Dismantle the chequered plate and pack in polybag and transfer to washing area and clean as per Type B cleaning.
- 5.1.5 Clean the dismantled parts using lint free cloth.
- 5.1.6 Clean the discharge gate and the main body of the equipment with lint free cloth.  
Assemble the dismantled part of the Spheronizer.
- 5.1.7 Remove the "TO BE CLEANED" label and affix "CLEANED" label to the machine.



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5.1.8 Record the cleaning end time in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet). After completion of cleaning process, get it checked by production officer.

### 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 Affix dully filled “TO BE CLEANED” status label on equipment with date and signature of the Production Officer as per SOP (Status labeling).

5.2.2 Ensure that the power supply is put off.

5.2.3 Dismantle the chequered plate and pack in poly bag and transfer to washing area and clean.

5.2.4 Clean the dismantled parts of the Spheronizer using 4-5 liter of purified water with nylon scrubber in washing area.

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

5.2.6 Clean the chequered plate using purified water and with a nylon scrubber.

5.2.7 Apply a jet of purified water so as to ensure the complete removal of traces of the previous product and clean the plate with 20-30 liters of purified water.

5.2.8 Dry the cleaned parts 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 Clean Spheronizer Body with lint free duster dipped in purified water.

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

5.2.12 Certify the cleanliness by Production Officer/QA officer.

5.2.13 Assemble the Spheronizer.

5.2.14 Affix a label on Extruder as “CLEANED” with date and signature of the Production Officer and QA officer.

5.2.15 If the Spheronizer is idle for 72 hours or more, then wipe all the parts of the Spheronizer with 70% v/v IPA solution before use.

5.2.16 Enter cleaning activity in ‘CLEANED’ label.

5.2.17 Record the cleaning completion activity of Spheronizer in equipment usage logbook as per SOP (Making entries in equipment usage and cleaning log sheet).

5.2.18 Record the activity in cleaning checklist Annexure I” Cleaning Checklist of Spheronizer”.

### 5.3 Frequency:



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- 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 week then follow the procedure of type – B cleaning.
- 5.3.2 Type 'B' cleaning is applicable in case of change over 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 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 OPERATING PROCEDURE:

- 5.4.1 Ensure the area and equipment is clean. Affix 'UNDER PROCESS' label duly filled and signed on the machine and record all the observations in the equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).

#### 5.4.2 Machine setting:

- 5.4.2.1 Ensure that the main switch is in “OFF” position before setting of Spheronizer.
- 5.4.3.2 Ensure that the Spheronizer is cleaned and ready for use.
- 5.4.4.3 Fix the rotary scrapper above the shaft of the motor.
- 5.4.5.4 Set the chequered plate above the scrapper with the help of SS rod.
- 5.4.6.5 Tight the chequered plate with the help of knob.
- 5.4.7.6 Cover the acrylic plate on machine.

#### 5.4.3 Operation:

- 5.4.3.1 After line clearance from QA, put the 'UNDER PROCESS' label on the machine.
- 5.4.3.2 Enter start time of the machine in equipment usage log sheet as per SOP (Making entries in equipment usage and cleaning log sheet).
- 5.4.3.3 Switch “ON “the mains from electrical panel.
- 5.4.3.4 Supply the compressed air to the machine.
- 5.4.3.5 Set the RPM of the chequered plate as mentioned in BMR.
- 5.4.3.6 Run the machine and slowly feed the extrude mass to the spheronizing chamber.



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- 5.4.3.7 Supply the compressed air to the granules to remove the excess moisture generated during the operation.
- 5.4.3.8 Allow to run the machine till spherical granules are formed.
- 5.4.3.9 After completion of the Spheronization, press knob to discharge and collect the granules in SS container lined in double lined polyethylene bags.
- 5.4.3.10 After completion of operation, switch off the machine to stop the operation.
- 5.4.3.11 Enter the completion time in equipment usage log sheet.

### 5.4.3 Precaution and check points:

- 5.4.3.1 Ensure that supply of the compressed air is not less than 4 kg/cm<sup>2</sup>
- 5.4.3.2 Do not put oil in main motor shaft housing from inside.
- 5.4.2.3 Ensure that the spheronizing chamber is not over fed.

### 6.0 ABBREVIATION (S):

- 6.1 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 v/v : Volume by Volume
- 6.4 RPM : Revolution per minute
- 6.5 SS : Stainless steel

### 7.0 REFERENCES (S):

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

### 8.0 ANNEXURE(S):

Annexure No.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Cleaning Checklist of Spheronizer		Log Book

### 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 (03)



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### 10.0 REVISION HISTORY:

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



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### ANNEXURE I CLEANING CHECKLIST OF SPHERONIZER

<b>Name of the Equipment</b>	<b>Spheronizer</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 power supply are put off.	
2.	Dismantle the chequered plate and pack in poly bag and transfer to washing area and clean.	
3.	Clean the dismantled parts of the Spheronizer using 4-5 liter of purified water with nylon scrubber in washing area.	
4.	Clean all the above parts with 20-25 liters of purified water.	
5.	Clean the chequered plate using purified water and with a nylon scrubber.	
6.	Apply a jet of purified water so as to ensure the complete removal of traces of the previous product and clean the plate with 20-30 liters of purified water.	
7.	Dry the cleaned parts by using compressed air.	
8.	Dry all the dismantled parts and the body with the help of dry lint free cloth.	
9.	Wipe all dismantled parts of the spheronizer and its body with 70% v/v IPA solution.	
10.	Assemble the Spheronizer.	

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

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

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