



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Roll Compactor cum Granulator cum sifter with pneumatic system (Make-Chamunda)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

- 1.1 To lay down the procedure for the cleaning and operation of roll compactor cum granulator cum sifter with pneumatic system (Make-Chamunda).

2.0 SCOPE:

- 2.1 This procedure is applicable to the cleaning and operation of roll compactor cum granulator cum sifter with pneumatic system (Make-Chamunda) in production department.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate: Cleaning and Operation of roll compactor cum granulator cum sifter with pneumatic system.
- 3.2 Officer/Executive Production: Supervision of Cleaning and Operation of roll compactor cum granulator cum sifter with pneumatic system
- 3.3 Head Production: SOP Compliance of Cleaning and Operation of roll compactor cum granulator cum sifter with pneumatic system
- 3.4 IPQA: Line Clearance and area verification as per SOP "Cleaning and Operation of roll compactor cum granulator cum sifter with pneumatic system"

4.0 DEFINITION (S):

- 4.1 NA

5.0 PROCEDURE:

- 5.1 **"TYPE-A" CLEANING: This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.**
- 5.1.1 Put Off the mains of the roll compactor
- 5.1.2 Ensure that the hopper is empty and no powder of previous batch is present in the machine and surrounding area.
- 5.1.3 Affix dully filled "UNDER CLEANING" status label on equipment with date and signature of the Production Officer, as per SOP "Status Labeling".
- 5.1.4 Enter the cleaning start time in equipment usage log sheet SOP "making entries in equipment usage and cleaning log sheet".
- 5.1.5 Remove the powder deposited on machine by using a vacuum cleaner/compressed air/lint free cloth.



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- 5.1.6 Clean the control panel with lint free cloth.
- 5.1.7 Clean the outside part of horizontal feeding screw, vertical feeding screw and vertical feeder with auger motor cover, roller motor cover, platform, hopper using dry lint free cloth.
- 5.1.8 Dismantle lid feed hopper, sieves S.S. frame, discharge chute and the gaskets of multidisc sifter.
- 5.1.9 Clean the S.S. feed hopper S.S. frame, holding the sieve in place and S.S. wire mesh sieve with lint free cloth.
- 5.1.10 Clean the outlet chute. Rubber gasket, feed hopper tightening clamp by using lint free cloth.
- 5.1.11 Replace the “UNDER CLEANING” status label with “CLEANED “status label with date and signature of the production officer/QA Officer, as per SOP “Status Labeling”.
- 5.1.12 Record the cleaning completion time 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 / colour / ascending potency / 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 Remove the powder deposited on the machine by using vacuum cleaner.
 - 5.2.3 Dismantle the pneumatic pot & collect the powder from pneumatic pot with the help of dust extractor or vacuum cleaner.
 - 5.2.4 Remove the filter of the pneumatic pot and product pipe.
 - 5.2.5 Dismantle the front acrylic guard by loosening the bolts.
 - 5.2.6 Dismantle the compaction roller chamber, coarse granulator & fine granulator chamber by loosening bolts.
 - 5.2.7 Remove the compaction rollers and granulator swing blade.
 - 5.2.8 Remove the chamber of horizontal and vertical feeding screw followed by screw blades. In case of feeder with auger dismantle the feeder assembly by loosening the bolts.
 - 5.2.9 Remove the discharge port.
 - 5.2.10 Wash the filter of the pneumatic port and product pipe with 100 liters of purified water.
 - 5.2.11 Wash the acrylic guard, compaction roller chamber, coarse granulator and fine granulator chamber, compaction rollers, swing blades of the granulator, horizontal & vertical feeding screw chamber, In case of feeder with auger assembly and discharge pot with 300 liters of purified water.
 - 5.2.12 Dry the washed parts and filters of the pneumatic pot with compressed air.



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- 5.2.13 Finally mop the dismantled parts with dry lint free cloth.
- 5.2.14 Wipe all dismantled parts with 70% v/v IPA solution.
- 5.2.15 **Multi-deck sifter cleaning**
- 5.2.15.1 Dismantle the lid feed hopper, sieve, S.S. frame, discharge chute and the gasket.
- 5.2.15.2 Clean the S.S feed hopper, S.S frame, holding the sieve in place and S.S wire mesh sieve with lint free cloth.
- 5.2.15.3 Clean the outlet chute, rubber gasket, feed hopper tighten clamp by using lint free cloth.
- 5.2.15.4 Clean the dismantled parts of sifter using 100 liters of purified water with nylon brush to remove the adhered material.
- 5.2.15.5 Clean the sieve by using 50 liters of purified water using nylon brush.
- 5.2.15.6 Apply a jet of purified water so as to ensure the complete removal of the previous product.
- 5.2.15.7 Dry the sieve by using compressed air.
- 5.2.15.8 Wipe the body of sifter with wet duster soaked in purified water.
- 5.2.15.9 Dry all the dismantled part with lint free duster.
- 5.2.15.10 Wipe all the dismantled parts of the sifter and its body with 70% v/v IPA solution.
- 5.2.16 Assemble the dismantle parts and cover the discharge port and hopper with help of a fresh polyethylene bag.
- 5.2.17 Replace the “UNDER CLEANING “status label with “CLEANED “status label with date and signature of the production officer/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”.
- 5.2.19 Clean the area as per SOP “Cleaning of Production Area”.
- 5.2.20 Clean the cleaned part with 2% sodium lauryl sulphate (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.

Note: Frequency

- 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.
- Type ‘B’ cleaning is applicable in case of changeover 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.



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- 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”.

5.3 OPERATING PROCEDURE:

5.3.1 ASSEMBLING AND SETTING:

- 5.3.1.1 Ensure that all parts are clean and dry before assembling.
- 5.3.1.2 Ensure that the filter bag and product pipe of pneumatic port is clean and dry.
- 5.3.1.3 Assemble the vertical and horizontal feeding screw assembly, compaction rollers. If horizontal and vertical assembly is not in operation aside the assembly by moving on lifter and disconnect the power supply.
- 5.3.1.4 If feeder with auger is in operation assemble the feeder assembly by tightening the bolts and connect the power supply.
- 5.3.1.5 Assemble coarse granulator and fine granulator swinging blades desired screen as per the product and then assemble the chamber.
- 5.3.1.6 Assemble the discharge chute.
- 5.3.1.7 Attach the powder hopper with horizontal feeding screw and then attach the pneumatic pot with powder hopper.
- 5.3.1.8 Attach the filter bag of pneumatic pot.
- 5.3.1.9 In case of any abnormal sound from the machine during its operation, stop the machine and report to maintenance department.

5.3.2 OPERATION:

- 5.3.2.1 Ensure ‘CLEANED’ label duly filled and signed is affixed on the equipment.
- 5.3.2.2 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.
- 5.3.2.3 Place the cleaned Vibro sifter to the outlet port of Roll compactor cum granulator cum sifter with pneumatic system (Make-Chamunda) cum granulator cum sifter with pneumatic system (Make-Chamunda).and connect with the help of silicon sleeve. Replace clean label of Vibro Sifter with ‘EQUIPMENT STATUS’ label.



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- 5.3.2.4 Place the cleaned IPC to the outlet port of Vibro Sifter and connect with the help of silicon sleeve. Replace clean label of IPC with 'EQUIPMENT STATUS' label.
- 5.3.2.5 Place the IPC/bin with premixed material near the Roll compactor cum granulator cum sifter with pneumatic system (Make-Chamunda) cum granulator cum sifter with pneumatic system (Make-Chamunda) device and put the product pipe inside the bin.
- 5.3.2.6 Switch on the power supply of the roll compactor. Turn on the HMI by rotating the power knob clockwise.
- 5.3.2.7 There is 03 level password protection
- Operator : To start stop the machine.
 - Supervisor : To start, stop the machine and to edit batch no.
 - Manager : To start, stop the machine and to edit the machine running parameters & edit batch no.
- 5.3.2.8 Log in the system with desired password.
- 5.3.2.9 Machine in following manner: for horizontal and vertical feeding screw
Vibro sifter → Fine Granulator → Coarse Granulator → Compaction Rollers → Vertical Feeding Screw → Horizontal Feeding Screw → Pneumatic System.
- 5.3.2.10 Machine in following manner: for feeder with auger assembly
Vibro sifter → Fine Granulator → Coarse Granulator → Compaction Rollers → feeder with auger → Pneumatic System.
- 5.3.2.11 Set the timer of Pneumatic system to fills the powder hopper continuously.
- 5.3.2.12 Feeding screw (Horizontal and vertical feeding screw or feeder with auger) supply the material to the compaction roller.
- 5.3.2.13 Check the hardness of collected flakes manually from sampling point.
- 5.3.2.14 Flakes pass the coarse and fine granulator and discharge through discharge port to Vibro Sifter.
- 5.3.2.15 Sifted granules are collected in IPC/bin.
- 5.3.2.16 Stop the operation in following manner:
- 5.3.2.17 Pneumatic System → Horizontal Feeding Screw → Vertical Feeding Screw/feeder with auger → Compaction Rollers → Coarse Granulator → Fine Granulator → Vibro sifter.
- 5.3.2.18 Ensure that no any material should be inside the roll compactor.
- 5.3.2.19 After completion of process switch 'OFF' the mains.
- 5.3.2.20 Affix 'UNDER CLEANING' label duly filled and signed on the Roll compactor cum granulator cum sifter with pneumatic system (Make-Chamunda) cum granulator cum sifter with



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pneumatic system (Make-Chamunda).and record the observations in equipment usage log sheet as per SOP “making entries in equipment usage and cleaning log sheet”.

5.3.2.21 Record the completion time in equipment usage log sheet as per SOP “making entries in equipment usage and cleaning log sheet”.

6.0 ABBREVIATION (S):

- 6.1 PLC : Programmable logic control
- 6.2 “ : Inch
- 6.3 Cm : centimeter
- 6.4 Kg : Kilogram
- 6.5 Hg : Mercury
- 6.6 Mm : Millimeter
- 6.7 V/V : Volume/volume
- 6.8 IPA : Iso Propyl Alcohol

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: Status Labeling

8.0 ANNEXURE (S):

Annexure No.	Title of Annexure	Format No.	Mode of execution
Annexure-I	Cleaning Checklist Roll Compactor cum Granulator cum sifter with pneumatic system (Make-Chamunda)		Logbook

9.0 DISTRIBUTION:

- 9.1 **Master Copy** : Quality Assurance
- 9.2 **Controlled Copy (S):** Production department (01), Quality Assurance (01)
- 9.3 **Reference Copy (S) :** Production department (01)



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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		New SOP	NA	



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ANNEXUER I

Cleaning Checklist Roll Compactor cum Granulator cum sifter with pneumatic system (Make-Chamunda)

Name of the Equipment		Roll Compactor	
Equipment ID. No.		Previous product	
Batch No.		Date	
S.No.	Activity	Activity performed	
1.	Put Off the mains of the roll compactor		
2.	Remove the powder deposited on the machine by using vacuum cleaner.		
3.	Dismantle the pneumatic pot & collect the powder from pneumatic pot with the help of dust extractor or vacuum cleaner.		
4.	Remove the filter of the pneumatic pot and product pipe.		
5.	Dismantle the front acrylic guard by loosening the bolts.		
6.	Dismantle the compaction roller chamber, coarse granulator & fine granulator chamber by loosening bolts.		
7.	Remove the compaction rollers and granulator swing blade.		
8.	Remove the chamber of horizontal and vertical feeding screw followed by screw blades. In case of feeder with auger dismantle the feeder assembly by loosening the bolts.		
9.	Remove the discharge port.		
10.	Wash the filter of the pneumatic port and product pipe with 100 liters of purified water.		
11.	Wash the acrylic guard, compaction roller chamber, coarse granulator and fine granulator chamber, compaction rollers, swing blades of the granulator, horizontal & vertical feeding screw chamber, In case of feeder with auger assembly and discharge pot with 300 liters of purified water.		
12.	Dry the washed parts and filters of the pneumatic pot with compressed air.		
13.	Finally mop the dismantled parts with dry lint free cloth.		
14.	Wipe all dismantled parts with 70% v/v IPA solution.		
15.	Dismantle the lid feed hopper, sieve, S.S. frame, discharge chute and the gasket.		
16.	Clean the S.S feed hopper, S.S frame, holding the sieve in place and S.S wire mesh sieve with lint free cloth.		
17.	Clean the outlet chute, rubber gasket, feed hopper tighten clamp by using lint free cloth.		
18.	Clean the dismantled parts of sifter using 100 liters of purified water with nylon brush to remove the adhered material.		
19.	Clean the sieve by using 50 liters of purified water using nylon brush.		
20.	Apply a jet of purified water so as to ensure the complete removal of the previous product.		
21.	Dry the sieve by using compressed air.		
22.	Wipe the body of sifter with wet duster soaked in purified water.		
23.	Dry all the dismantled part with lint free duster.		



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24.	Wipe all the dismantled parts of the sifter and its body with 70% v/v IPA solution.	
25.	Assemble the dismantle parts and cover the discharge port and hopper with help of a fresh polyethylene bag.	
26.	Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the production officer/QA Officer, as per SOP.	
27.	Clean the cleaned part with 2% Sodium Lauryl Sulphate (for 1 litre 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.	

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

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date