



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Mini Roll Compactor	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down a procedure for Cleaning and Operation Mini Roll Compactor.

2.0 SCOPE:

This procedure is applicable to Cleaning and Operation of Mini Roll Compactor located in manufacturing area.

3.0 RESPONSIBILITY:

Technical Associate : Cleaning and Operation

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

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

5.1.5 Remove the powder deposited on machine by using a vacuum cleaner as per SOP.

5.1.6 Clean the control panel with lint free cloth.

5.1.7 Clean the outside part of Auger motor cover, roller motor cover, and platform, using dry lint free cloth.

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



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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:

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

5.2.1 Put Off the mains of the Roll Compactor.

5.2.2 Ensure that the hopper is empty and no powder of previous product is present in it.

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

5.2.4 Enter the cleaning start time in equipment usage log sheet as per SOP.

5.2.5 Remove the powder deposited on the machine by using vacuum cleaner.

5.2.6 Dismantle the hopper by loosening bolts. Raise the Auger hopper by hydraulic pump till the level is reached.

5.2.7 Wash rollers, discharge area with 25-35 liters of purified water by placing a suitable container beneath the discharge port of the Roll compactor and scrub with nylon scrubber to remove previous product residue.

5.2.8 Transfer the discharge hopper and auger hopper to respective washing area in a virgin poly bag affixed with "TO BE CLEANED" label.

5.2.9 Scrub all dismantled parts with 20-30 liters of purified water, After scrubbing clean the parts with 10-12 liters of purified water.

5.2.10 Finally rinse all the cleaned parts with the 50-60 liters of purified water.

5.2.11 Clean the body, platform, and hydraulic pump assembly of the roll compactor with wet lint free cloth followed by dry clean lint free cloth.

5.2.12 Dry the dismantle parts with lint free cloth.

5.2.13 Wipe all dismantled parts with 70% v/v IPA solution and transfer all the cleaned parts to the respective cubicle in virgin poly bag with "CLEANED" label.

5.2.14 Assemble the dismantle parts and cover the discharge port and hopper with help of a virgin polyethylene bag.

5.3 Frequency:



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5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product. 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 / 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.

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 duly sign the "CLEANED" label again. Record the activity in equipment usage log sheet as per SOP.

5.4 Operation:

5.4.1 Machine setting:

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

5.4.1.2 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.

5.4.1.3 Switch 'ON' the mains and select the mode of rotation of rollers in forward/ reverse direction by 'SELECTOR' knob. Indicator of forward/ reverse glow.

5.4.1.4 The RPM of Roller & Feeder and current consumption of Main motor & Feeder motor shows on the top.

5.4.1.5 Press 'START' button to start the rotation of rollers.

5.4.1.6 At left side on the control panel lamp indicators of Control On, Tray lift, Fwd run, Rev run, Roller, Feeder, Main motor over load and Feeder motor over load, shows, which indicates respective status.

5.4.1.7 To start the auger rotation, press 'START' button and set the RPM of rotation of auger as per given in Batch Manufacturing Record.

5.4.1.8 Fill the hopper of Roll Compactor to optimum level with pre-mix material to be compacted.

5.4.1.9 Continue feeding the material into the hopper to maintain the optimum level.

5.4.1.10 Check the hardness of collected flakes manually.

5.4.1.11 Mill the flakes using Multimill using specified screen as per the instruction given in the BMR.

5.4.1.12 If material which sticks to the roller, remove by scraper at regular interval of operation.

5.4.1.13 To stop the operation, first stop the feeding to hopper and stop auger then press the 'STOP' button to stop the roller rotation.



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- 5.4.1.14 Ensure that no any material should be inside the roll compactor.
- 5.4.1.15 Switch 'OFF' the mains.
- 5.4.1.16 Roller knob and lift knob should be open on at a time. For lift operation, roller knob should be close and hydraulic knob should be tight and for down hydraulic knob should be loose.
- 5.4.1.17 Affix 'TO BE CLEANED' label duly filled and signed on the Mini roll compactor and record the observations in equipment usage log sheet as per SOP.

6.0 ABBREVIATION (S):

- IPA : Iso Propyl Alcohol
- SOP : Standard Operating Procedure
- No. : Number
- V/V : Volume / Volume

7.0 REFERENCES (S):

- SOP: Making entries in equipment usage and cleaning log sheet.
- SOP: Cleaning of production area
- SOP: Status Labeling
- SOP: Cleaning and Operation of Vacuum cleaner

8.0 ANNEXURE (S):

- Annexure-I: Cleaning Checklist of Mini Roll Compactor

9.0 DISTRIBUTION:

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



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ANNEXURE I

CLEANING CHECKLIST OF MINI ROLL COMPACTOR

Name of the Equipment: Mini Roll Compactor

Date:

Previous product:

Batch No.:

Equipment ID No.:

S.No.	Activity	Activity Performed
1.	Remove the powder deposited on the machine by using vacuum cleaner.	
2.	Dismantle the hopper by loosening bolts. Raise the Auger hopper by hydraulic pump till the level is reached.	
3.	Wash rollers, discharge area with 25-35 liters of purified water by placing a suitable container beneath the discharge port of the Roll compactor and scrub with nylon scrubber to remove previous product residue.	
4.	Transfer the discharge hopper and auger hopper to respective washing area in a virgin poly bag affixed with "TO BE CLEANED" label.	
5.	Scrub all dismantled parts with 20-30 liters of purified water, After scrubbing clean the parts with 10-12 liters of purified water.	
6.	Finally rinse all the cleaned parts with the 50-60 liters of purified water.	
7.	Clean the body, platform, and hydraulic pump assembly of the roll compactor with wet lint free cloth followed by dry clean lint free cloth.	
8.	Dry the dismantle parts with lint free cloth.	
9.	Wipe all dismantled parts with 70% v/v IPA solution and transfer all the cleaned parts to the respective cubicle in virgin poly bag with "CLEANED" label.	

Checked By (Prod.)
Sign/Date

Verified By (QA)
Sign/Date

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