



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Roll Compactor	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

Vernacular SOP: No

1.0 OBJECTIVE:

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

2.0 SCOPE:

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

3.0 RESPONSIBILITY:

3.1 Technical Associate : Cleaning and Operation of Roll Compactor

3.2 Officer and Executive : Supervision of Cleaning and Operation of Roll Compactor

3.3 Head Production : SOP compliance

3.4 IPQA Person : Line Clearance and verification.

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 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.

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, platform, hopper using dry lint free cloth.



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Department: Production	SOP No.:
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Issue Date:	Page No.:

- 5.1.8 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”
- 5.1.9 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:**
Changeover of product with different actives/color/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 “UNDER CLEANING” status label on equipment with date and signature of the Production Officer, as per SOP “STATUS LABELING”.
- 5.2.4 Enter the cleaning start time in equipment usage log sheet as per SOP “MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET”.
- 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 30 –40 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 “UNDER CLEANING” 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 the all cleaned parts with the 50-60 liters of purified water.
- 5.2.11 Clean the body, platform, 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.
- 5.2.14 Transfer all the cleaned parts to the respective cubicle in virgin poly bag with “CLEANED” label.
- 5.2.15 Assemble the dismantle parts and cover the discharge port and hopper with help of a virgin polyethylene bag.



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Department: Production	SOP No.:
Title: Cleaning and Operation of Roll Compactor	Effective Date:
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Issue Date:	Page No.:

5.2.16 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”

5.2.17 Record the cleaning completion time in equipment usage log sheet as per SOP “MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET”.

5.2.18 Clean the area as per SOP “CLEANING OF PRODUCTION AREA”.

5.3 Frequency

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 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.

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 and Operation (CIP):

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.

5.4.2 Place the cleaned IPC to the outlet port of Roll Compactor and connect with the help of silicon sleeve. Replace clean label of IPC with ‘EQUIPMENT STATUS’ label.

5.4.3 Place the IPC with premixed material above the hopper of Roll Compactor using L & P device and connect with the help of silicon sleeve.

5.4.4 Switch ‘ON’ the mains and select the mode of rotation of rollers in forward direction by “FORWARD/ REVERS SWITCH (R/F)” knob.

5.4.5 Press ‘START’ key to start the rotation of rollers.

5.4.6 To start the auger rotation, press ‘START’ key and set the RPM of rotation of auger as per given in Batch Manufacturing Record.

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



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Department: Production	SOP No.:
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Issue Date:	Page No.:

- 5.4.8 Continue feeding the material into the hopper to maintain the optimum level.
- 5.4.9 Check the hardness of collected flakes manually.
- 5.4.10 Mill the flakes using Multi-mill using specified screen as per the instruction given in the BMR.
- 5.4.11 If material which sticks to the roller, remove by scraper at regular interval of operation.
- 5.4.12 To stop the operation, first stop the feeding to hopper and stop auger then press the 'STOP' key to stop the roller rotation.
- 5.4.13 Ensure that no any material should be inside the roll compactor.
- 5.4.14 After completion of process switch 'OFF' the mains.
- 5.4.15 Affix 'UNDER CLEANING' label duly filled and signed on the Roll Compactor and record the observations in equipment usage log sheet as per SOP "MAKING ENTRIES IN EQUIPMENT USAGE AND CLEANING LOG SHEET".
- 5.4.16 Record the cleaning 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 IPA : Iso Propyl Alcohol
- 6.2 SOP : Standard Operating Procedure
- 6.3 No. : Number
- 6.4 S.S. : Stainless Steel.
- 6.5 V/V : Volume / Volume
- 6.6 L & P : Lifting and positioning Device.
- 6.7 BMR : Batch Manufacturing Record

7.0 REFERENCES (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 OF ROLL COMPACTOR		Log Book



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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)

10.0 REVISION HISTORY:

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



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ANNEXURE I

CLEANING CHECKLIST OF ROLL COMPACTOR

Name of the Equipment	ROLL COMPACTOR		
Equipment ID No.		Previous product	
Batch No.		Date	

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 30 –40 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	Clean the body, platform, hydraulic pump assembly of the roll compactor with wet lint free cloth followed by dry clean lint free cloth.	
7	Finally rinse the all cleaned parts with the 50-60 liters of purified water.	
8	Dry the dismantle parts with lint free cloth.	
9	Wipe all dismantled 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.