



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of De-dusting and Polishing Machine (DP-100)	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 De-dusting and Polishing machine (DP-100).

2.0 SCOPE:

2.1 This procedure is applicable to the Cleaning and Operation of De-dusting and Polishing Machine (DP-100) in Production Department.

3.0 RESPONSIBILITY:

- 3.1 Technical Associate : Cleaning and Operation of machine
3.2 Officer/ Executive Production: Supervision of Cleaning and Operation
3.3 Head Production : SOP Compliance
3.4 IPQA : SOP Compliance and Line Clearance

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 Affix dully filled "UNDER CLEANING" status label on equipment with date and signature of the Production Officer as per SOP.
5.1.2 Enter the cleaning starting time in equipment usage log sheet as per SOP.
5.1.3 Ensure that the main power supply is switched off.
5.1.4 Remove the adhered material on the DP-100 by using vacuum cleaner.
5.1.5 Clean all the dismantled parts with lint free cloth.
5.1.6 Clean the perforated tube, feed hopper and cover of trough by using lint free cloth.
5.1.7 If the same product is processed for more than a week, then follow the procedure of cleaning as followed during product change over as per 'Type B' cleaning.
5.1.8 Replace the "UNDER CLEANING" status label with "UNDER PROCESS" status label with date and signature of the Production Officer as per SOP.



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5.1.9 Clean the area as per SOP.

5.1.10 Record the cleaning activity 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/ascending potency / descending potency or after maintenance of contact parts.

5.2.1 Follow the procedure from step 5.1.1 to 5.1.6.

5.2.2 Transfer the all dismantled parts in respective cleaning area, in virgin polybag affix with "To Be Cleaned" label.

5.2.3 Clean the dismantled parts of the DP-100 using 5-7 liter of purified water with nylon brush.

5.2.4 Clean all the dismantled parts with 30-40 liters of purified water.

5.2.5 Apply a jet of purified water so as to ensure the complete removal of the previous product.

5.2.6 Dry the brush by using compressed air.

5.2.7 Wipe the lower cover of the DP-100 with wet duster soaked in purified water.

5.2.8 Dry the dismantled parts with a dry lint free duster.

5.2.9 Wipe all dismantled parts of the DP-100 and its lower cover, panel with 70% v/v IPA solution.

5.2.10 Affix label on DP-100 as "CLEANED" with date and signature of the Production Officer/QA officer as per SOP.

5.2.11 Ensure that the area is cleaned as per SOP.

5.2.12 Record the cleaning activity end time of machine in equipment usage log as per SOP.

5.2.13 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use. And should be a counter sign on previous "CLEANED" label by production & QA officer with date 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 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.

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.



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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 OPERATING PROCEDURE:

5.4.1 Assembling and setting:

De-dusting and Polishing machine consist of:

- a. Brush assembly
- b. Net assembly
- c. Perforated tube

5.4.1.1 Assembling of brush assembly:

- 5.4.1.1.1 Mount the infeed end lock on the brush shaft and tighten the grub screw. Position the lock such that the grub screw is tightened on the notch provided on the shaft. Slide the spiral brush on the brush shaft to the infeed end and lock it in the feed end lock. Ensure that the end of brush has properly entered and groove of the lock.
- 5.4.1.1.2 Check the integrity of the bristles of the spiral brush before assembling.
- 5.4.1.1.3 Put the infeed end baffle cover from the delivery end. Ensure that the bristles of the brush are completely out of the baffle cover.
- 5.4.1.1.4 Mount the delivery end lock on the shaft.
- 5.4.1.1.5 Insert the open end of the brush in the groove of the lock properly.
- 5.4.1.1.6 Press the lock in , to compress the brush and holding the in-feed end of the brush, turn the delivery end lock clockwise to bring the grub screw position over the notch provided on the shaft .tighten the grub screw to keep the brush in position.
- 5.4.1.1.7 Mount the delivery end nylon spacer on the shaft by tightening the grub.

5.4.1.2 Assembling of net assembly:

- 5.4.1.2.1 Form a cylindrical shape of the net by joining the Velcro attachment longitudinally.
- 5.4.1.2.2 Insert the hinge pin in the eyelet provided in the net.
- 5.4.1.2.3 Slide the net into the perforated tube with the hinge pin properly positioned in the channel of the perforated tube.
- 5.4.1.2.4 Ensure that the net has a snug fit with the perforated tube.
- 5.4.1.2.5 Insert the spring slowly by rotating it in to the net, taking care that the spring does not cross the in feed.

5.4.1.3 Assembling of perforated tube and brush assembly:



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- 5.4.1.3.1 Hold the brush shaft vertically and slide the perforated tube and net assembly over the shaft.
- 5.4.1.3.2 Assemble the delivery end baffle cover on the brush shaft, locating it in the perforated tube.
- 5.4.1.3.3 Assemble the timer pulley on to the brush shaft and fix it with grub screw over the notch provided on the shaft.
- 5.4.1.3.4 Place the assembly in the trough locating the infeed end bearing in the split-bearing block.
- 5.4.1.3.5 Mount the delivery end bearing on the hexagonal bush, and bush on the shaft. Locate the delivery end bearing on the split bearing block.
- 5.4.1.3.6 Place the cover on the trough and fix it with the clamps.
- 5.4.1.3.7 Connect the rotary gland to the brush shaft and the air pipe to the coupling.
- 5.4.1.3.8 Mount the infeed hopper.
- 5.4.1.3.9 Ensure free movement of the spiral brush by rotating the belt manually in clockwise direction (Looking from the motor end).
- 5.4.1.3.10 Fit the drive cover and fix with clamps.
Fix the ADU suction pipe to the machine.

5.4.2 OPERATION:

- 5.4.2.1 Remove the CLEANED status label and affix 'UNDER PROCESS' label on the machine.
- 5.4.2.2 Switch "ON" the toggle switch. The mains 'ON' (red) LED will glow indicating power supply to the machine.
- 5.4.2.3 Press the red push button to start the motor. The 'MOTOR ON' (green) LED will glow indicating power supply to the motor.
- 5.4.2.4 Slowly turn the potentiometer knob clockwise and set it at middle speed.
- 5.4.2.5 Start feeding the capsules from the inlet hopper at uniform rate.
- 5.4.2.6 Check polishing quality of the polished capsules. If the quality is not satisfactory then vary the polishing chamber inclination and the speed of the brush.
After stoppage of capsule in feed at the end of the production run let the de-dusting and polishing machine run for additional 2-3 minutes to ensure that all the capsules from the polishing chamber has been come out.

5.4.3 DISMANTLING:

- 5.4.3.1 Switch 'OFF' the toggle switch to stop power supply
- 5.4.3.2 Remove the infeed hopper.
- 5.4.3.3 Remove the drive cover by removing the clamp.



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- 5.4.3.4 Remove the timer belt from the timer pulley.
- 5.4.3.5 Remove the cover of trough.
- 5.4.3.6 Remove the perforated tube and brush assembly from the trough.
- 5.4.3.7 Remove the brush shaft from the perforated tube.
- 5.4.3.8 Remove the net assembly from the perforated tube.
- 5.4.3.9 Remove the ADU suction pipe from the machine.

6.0 ABBREVIATION(S):

- 6.1 SOP : Standard operating procedure
- 6.2 SS : Stainless Steel
- 6.3 MCS : Mini capsule Sorter
- 6.4 IPA : Iso Propyl Alcohol
- 6.5 V/V : Volume/ Volume
- 6.6 LED : Light emitting diode

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):

- 8.1 NA

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 (01)

10.0 REVISION HISTORY:

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