



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of 51- Station Double Rotary Compression Machine	Effective Date:
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1.0 OBJECTIVE:

To lay down the procedure for the Cleaning and Operation of De-dusting and Polishing machine (ANCHOR).

2.0 SCOPE:

This procedure is applicable to the Cleaning and Operation of De-dusting and Polishing machine (ANCHOR) in production department.

3.0 RESPONSIBILITY:

Technical Associate: Operation

Officer/ Executive Production: Supervision

Head Production: SOP Compliance

IPQA: Line Clearance

4.0 DEFINITION (S):

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 "TO BE CLEANED" 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 polisher 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 "TO BE CLEANED" status label with "CLEANED" 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 end time of machine 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/colour/ ascending potency/descending potency or after maintenance of contact parts.

5.2.1 Follow the procedure from step 5.1.1 to 5.1.6

5.2.2 Dismantle the hopper, feed chute, drive cover of polishing chamber, rotary gland, baffle cover, perforated tube, net and delivery chute.

5.2.3 Transfer the all dismantled parts in respective cleaning area, in virgin polybag affix with "TO BE CLEANED" label.

5.2.4 Clean the dismantled parts of the polisher using 15-20 liter of purified water with nylon brush.

5.2.5 Clean all the dismantled parts with 40-50 liters of purified water.

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

5.2.7 Dry the brush by using compressed air.

5.2.8 Wipe the lower cover of the polisher with the wet duster soaked in purified water.

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

5.2.10 Wipe all dismantled parts of the polisher and its lower cover, panel with 70% v/v IPA solution.

5.2.11 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production Officer as per SOP.

5.2.12 Ensure that the area is cleaned as per SOP.

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

5.2.14 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. If same product is processed for more than a week (three days for granulation area), and then follow the procedure of type – B cleaning.

5.3.2 Type 'B' cleaning is applicable in case of product change over or same product is run for a week which ever is earlier.

5.4 OPERATING PROCEDURE:



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5.4.1 **Assembling and setting:**

De-dusting and Polishing machine consist of:

- a. Net assembly
- b. Perforated tube and brush assembly

5.4.1.1 **Assembling of net assembly:**

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

5.4.1.2 **Assembling of perforated tube and brush assembly:**

- 5.4.1.2.1 Hold the brush shaft vertically and slide the perforated tube and net assembly over the shaft.
- 5.4.1.2.2 Locate the infeed end Baffle Cover in the perforated tube.
- 5.4.1.2.3 Assemble the delivery end baffle cover on the brush shaft, locating it in the perforated tube.
- 5.4.1.2.4 Place the assembly in the baffle trough, locating the infeed end bearing in the rear bearing support.
- 5.4.1.2.5 Place the cover on the trough & fix it with the locks.
- 5.4.1.2.6 Assemble the pulley on the shaft and mount the belt.
- 5.4.1.2.7 Connect the rotary Gland to the shaft and air pipe to the coupling.
- 5.4.1.2.8 Mount the in feed chute.
- 5.4.1.2.9 Rotate the spiral brush by rotating the belt by hand in the anticlockwise direction (looking from motor end) and ensure the free movement.
- 5.4.1.2.10 Fit the drive cover and clamp with the clamp.
- 5.4.1.2.11 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 main supply and put ON the main selector switch on Operating Panel. (As shown in figure).

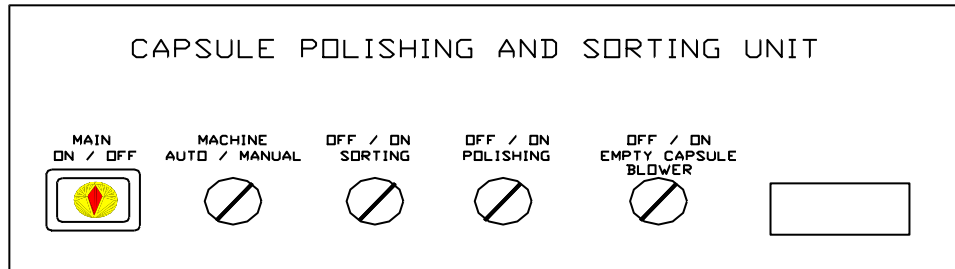


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Main Switch : Main ON / OFF switch

Selector Switch : To start the machine in auto / manual mode

Selector Switch : To start / stop the capsule polishing machine

Selector Switch : To start / stop the Filled capsule sorter machine

Selector Switch : To start / stop the blower for unfilled capsule separator

5.4.2.3 Switch "ON" the switch for Polishing.

5.4.2.4 Slowly turn the VFD 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.

5.4.2.7 After stoppage of capsule in feed at the end of the production, 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 infeed chute, Drive Cover & cover of the Polishing Chamber by unlocking the locks.

5.4.3.4 Remove the Rotary Gland from the brush shaft.

5.4.3.5 Take the perforated tube assembly out of the trough & hold it in pulley down position. Remove the bearing from delivery end & remove the baffle cover of the same end.

5.4.3.6 Hold the shaft down vertically & in pulley down position. Then remove the perforated tube from top.

5.4.3.7 Remove the nylon spacer & delivery end lock from shaft.

5.4.3.8 Rotating the brush anticlockwise disengage it from the infeed end lock & slide it off gently from the



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shaft.

- 5.4.3.9 Remove the pulley by holding the shaft upside down.
- 5.4.3.10 Take out the spring from perforated tube assembly by slowly rotating & pulling it out.
- 5.4.3.11 Remove the net from the perforated tube.
- 5.4.3.12 Lift the trough from trough support & take out the delivery chute.

6.0 ABBREVIATION (S):

- SOP : Standard operating procedure
- SS : Stainless Steel
- IPA : Iso Propyl Alcohol
- Q.A. : Quality Assurance
- V/V : Volume/ Volume
- VFD : Variable Frequency Device

7.0 REFERENCE(S):

- SOP: Making entries in Equipment usage and Cleaning Log Sheet.
- SOP: Cleaning Of Production Area.
- SOP: Status Labeling

8.0 ANNEXURE(S):

NA

9.0 DISTRIBUTION:

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