



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Capsule Polishing Machine	Effective Date:
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1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Capsule Polishing Machine.

2.0 SCOPE:

This SOP is applicable for operation and cleaning of capsule polishing machine in hard gelatin capsule section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

AHU	Air Handling Unit
BMR	Batch Manufacturing Record
Ltd.	Limited
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION OF CAPSULE POLISHING MACHINE:

- 6.1.1 Ensure that the machine and surrounding area is clean.
- 6.1.2 Take line clearance from QA as per "Line clearance" SOP and enter the details in BMR.
- 6.1.3 Ensure that the AHU is "ON".
- 6.1.4 Ensure that the temperature and humidity of area is within limits as specified in BMR.
- 6.1.5 Affix the status label on the machine.
- 6.1.6 Load the filled capsules in hopper of polishing machine.



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- 6.1.7 Switch "ON" the mains.
- 6.1.8 Switch "ON" the machine.
- 6.1.9 Start the brush by pushing the brush button.
- 6.1.10 Start the vacuum pump by pushing the green button.
- 6.1.11 Adjust the speed of vibrator by rotating vibrator control knob.
- 6.1.12 Prior to start-up ensure that, all the accessories, connection, fasteners are tight & the timing bell is properly tightened, there is no interference during operation.
- 6.1.13 Check the direction of rotation of all the units' i.e. capsule polishing motor.
- 6.1.14 Ensure uniform capsule feed to polishing inlet chute as excessive feed may block the path, which result in capsule damaged.
- 6.1.15 Gradually vary the polishing motor to vary the nylon brush speed. Check some capsules for polishing quality. If found not satisfactory, vary the speed to get better polishing quality.
- 6.1.16 Collect the polished capsule through exit valve in labeled double polyethylene bag.
- 6.1.17 After completion the work, switch "OFF" the brush, vacuum pump and mains.
- 6.1.18 Maintain the operation record in "Machine Utilization Report".

6.2 CLEANING OF CAPSULE POLISHING MACHINE:

6.2.1 For product to product change over:

- 6.2.1.1 Switch "OFF" the mains electric supply to the machine.
- 6.2.1.2 Dismantle the hopper, cover of polishing brush, filter bag of ADU, and transfer to washing area.
- 6.2.1.3 Wash the above parts with potable water by using 2% Extran MA-02 solution.
- 6.2.1.4 Wash with potable water.
- 6.2.1.5 Finally rinse with purified water and dry the all parts by using dry lint free cloth.
- 6.2.1.6 Clean the machine with clean wet cloth.
- 6.2.1.7 Clean the machine with dry lint free cloth.
- 6.2.1.8 Check the polishing brush, filter bag, cover visually and then send swab test intimation cum analysis report to QA for collect the swab sample.
- 6.2.1.9 Officer / Executive QA shall collect the swab sample and send to QC for Analysis.



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6.2.1.10 Use the polishing machine after receiving swab test intimation slip cum analysis report from QC showing negative identification.

6.2.1.11 If report shows positive identification than repeat the procedure of step **6.2.1.3 to 6.2.1.10**.

6.2.1.12 Mop all the parts with 70% IPA.

6.2.1.13 Reset the machine after QC approval.

6.2.1.14 Affix a label as “Cleaned”.

6.2.1.15 Maintain the cleaning record in “Machine Utilization Report”.

6.2.2 For batch to batch change over:

6.2.2.1 Clean the hopper and machine outer part with clean and dry lint free cloth.

6.2.2.2 Maintain the cleaning record in “Machine Utilization Report”.

6.2.3 Frequency of Cleaning:

6.2.3.1 Frequency of cleaning as per step-6.2.1

6.2.3.1.1 During product to product change over.

6.2.3.1.2 After 5 batch of the same product.

6.2.3.1.3 After major maintenance work involving the contact part of the equipment.

6.2.3.1.4 When new equipment or equipment after any modification is received.

6.2.3.1.5 Changeover of one Batch to Next Batch of the same Product with Descending Potency.

6.2.3.2 Frequency of cleaning as per step-6.2.2

6.2.3.2.1 During batch to batch change over.

7.0 ANNEXURES:

Not Applicable

ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance
- Controlled Copy No. 02 Production
- Master Copy Quality Assurance



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9.0 REFERENCES:

Operating Manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By