



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Capsule Polishing Machine	Effective Date:
Supersedes: Nil	Review 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 Soft 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 |
| IPA | Isopropyl Alcohol |
| 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.
 - 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.



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- 6.1.11 Adjust the speed of vibrator by rotating vibrator control knob.
- 6.1.12 Air push back the empty capsules to collect in reservoir.
- 6.1.13 Sort defective capsules manually and collect in separate polythene bag.
- 6.1.14 Collect the polished capsule through exit valve in labeled double polyethylene bag.
- 6.1.15 After completion the work, switch “OFF” the brush, vacuum pump and mains.
- 6.1.16 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, 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 Mop all the parts with 70% IPA.
- 6.2.1.9 Affix a label as “Cleaned”.
- 6.2.1.10 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
 - a. During product to product change over.
 - b. After 5 batch of the same product.



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- c. If cleaned equipment is kept idle more than 72 hours.
- d. If Dirty equipment is kept idle more than 24 hours.
- e. After major maintenance work involving the contact part of the equipment.
- f. When new equipment or equipment after any modification is received.

6.2.3.2 Frequency of cleaning as per step-6.2.2

- a. 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

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