STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Operation and Cleaning of Encapsulation Machine	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

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

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Encapsulation Machine used in Soft Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Executive/Officer – Production

4.0 ACCOUNTABILITY:

Head – Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
IPA	Isopropyl Alcohol
LLP	Light Liquid Paraffin
Ltd.	Limited
OSD	Oral Solid Dosage
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure
v/v	volume by volume

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Ensure that the area & machine is clean.

6.1.2 Take the line clearance from QA as per “Line Clearance” SOP and enter the details in BMR.

6.1.3 Fill the required details on the status board.

6.1.4 Ensure that the temperature and humidity of area is within limit as specified in respective BMR.

6.1.5 Operator shall set the die roller and segment as specified in respective BMR.

6.1.6 Set the temperature of spreader boxes as specified in respective BMR before feeding the gel mass flow.

6.1.7 Start the supply of gelatin mass to the spreader box and wait till, it fill up with gel mass.

6.1.8 Check the temperature of drum as specified in respective BMR.

6.1.9 Start the machine and set the ribbon between die roll.

6.1.10 Lubricant system shall be start automatically.

6.1.11 Check the ribbon thickness as per specified in respective BMR.

6.1.12 Set the temperature of segment as specified in respective BMR.

6.1.13 Gradually apply pressure to the Die roll and observed the cutting of slug.

6.1.14 Put ½ kg LLP in hopper.

6.1.15 If cutting and sealing is OK then start injection for capsule filling.

6.1.16 Set the stroke as per requirement of fill weight.

6.1.17 Draw the capsules from each segment holes in sequence.

6.1.18 Check the fill weight of capsule as specified in respective BMR.

6.1.19 If fill weight of capsule is within limit then open return pipe & take remaining quantity of LLP in outside.

6.1.20 Pour the QC approved paste / medicament in hopper.

6.1.21 If sealing of capsule is OK then start the set up valve.

6.1.22 Officer/Executive Production shall take the filled capsules for weight variation from each hole of segment.

6.1.23 Officer/Executive Production shall check the in-process parameters as specified in respective BMR and take the approval from QA.

6.1.24 After approval from QA, run the machine and record the observations in respective BMR.

6.1.25 Enter the details in “Machine Utilization Record”.

6.2 CLEANING:

6.2.1 For Product Changeover (Type B Cleaning):

6.2.1.1 Switch “OFF” the main.

6.2.1.2 Remove the ribbon from both side drums by starting the machine.

6.2.1.3 Dismantle the spreader boxes, pump, die roll & segment and transfer to washing area.

6.2.1.4 Clean the above parts with plenty of potable water by using 2.0% v/v Extran MA-02 solution then finally wash with purified water.

6.2.1.5 Wipe the parts with dry lint free cloth and finally mop with 70% v/v IPA solution.

6.2.1.6 After mopping put the die roll & segment in a change part box and place it in change part room.

6.2.1.7 Clean the medicament hopper & medicament return pipe by using 2.0% v/v Extran MA-02 with plenty of potable water then finally wash with purified water.

6.2.1.8 Wipe the medicament hopper with dry lint free cloth.

6.2.1.9 Officer/Executive QA shall check visually & collect the swab sample with intimation slip cum analysis report and send to QC for analysis.

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

6.2.1.11 If the QC report shows positive identification then repeat the above procedure.

6.2.1.12 Wipe the drum & entire surface of Encapsulation machine with lint free cloth using 70% v/v IPA solution.

6.2.1.13 Affix a status label as “Cleaned”.

6.2.1.14 Enter the cleaning details in “Machine Utilization record”

6.2.2 For Batch Changeover (Type A Cleaning):

6.2.2.1 Rinse the hopper with light liquid paraffin and drain it.

6.2.2.2 Take 2 kg of liquid paraffin in hopper, start the encapsulation machine and recirculate the liquid paraffin through pumps and pipeline.

6.2.2.3 Open the return valve and drain the recirculated liquid paraffin.

6.2.2.4 Wipe the machine with dry lint free cloth.

6.2.2.5 Mop the machine with 70% v/v IPA solution.

6.2.2.6 Affix the label as “Cleaned” on the machine.

6.2.2.7 Enter the cleaning details in “Machine Utilization record”.

6.2.3 Frequency of cleaning:

6.2.3.1 Type-B Cleaning shall be done in following cases:

(a) Product to Product Change over.

(b) After 5 batch of the same product.

(c) After any Maintenance of Product Contact Parts.

(d) If cleaned equipment is kept idle more than 72 hours.

(e) If Dirty equipment is kept idle more than 24 hours.

(f) Changeover of one Batch to Next Batch of the same Product with Descending Potency.

(g) In case of colour change.

6.2.3.2 Type-A Cleaning shall be done in following cases:

(a) Changeover from one Batch to Next Batch of the same Product with Same Potency.

(b) Changeover from one batch to next Batch of the same Product with Higher Potency.

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:

Not Applicable.

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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