STANDARD OPERATING PROCEDURE

Title: Operation and Cleaning of Semiautomatic Capsule Filling Machine

SOP No.:		**Department:**	Production
		Effective Date:	
Revision No.:	00	**Revision Date:**	
Supersede Revision No.:	Nil	**Page No.:**	1 of 4

1.0 OBJECTIVE:

To lay down a Procedure for Operation and Cleaning of Semi Automatic Capsule Filling Machine.

2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Semi Automatic Capsule Filling Machine used 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
DT	Disintegration Time
IPA	Isopropyl Alcohol
Ltd.	Limited
NLT	Not Less Than
PSI	Per Square Inch.
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SA	Semi-Automatic
SOP	Standard Operating Procedure
v/v	Volume by volume

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Ensure that the machine and surroundings 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 the temperature and humidity of area is within limits as specified in BMR.

6.1.5 Fill the required details on the status board.

6.1.6 Change the parts of machine as per size of capsule.

6.1.7 Open the compressed air line and adjust the air pressure should be NLT 3.0 kg/cm² with controlling valve.

6.1.8 Fill the powder hopper with bulk powder.

6.1.9 Fill the capsule hopper with empty hard gelatin capsules.

6.1.10 Open the vacuum line by switching on the vacuum pump and vacuum should be NLT 300 mm of Hg.

6.1.11 Switch "ON" the mains and Switch "ON" the machine.

6.1.12 Fix the empty capsules loading ring on the platform.

6.1.13 Press the green switch, to start the machine, mounted on control panel.

6.1.14 Adjust the chute leave so that capsules fall freely into the plate.

6.1.15 After the plate is filled with empty capsules, rotate 1 or 2 times so that cap and body of the capsules are separated in the plate.

6.1.16 Lift the upper plate and fix the lower plate on the powder-filling platform.

6.1.17 Switch 'ON' the powder table.

6.1.18 The hopper will be adjusted on the "body" plate and powder will be filled in capsule body.

6.1.19 Remove excess powder from the plate with SS scrapper.

6.1.20 Put the cap plate on the body plate.

6.1.21 Fix the loading ring on the pigging unit.

6.1.22 Insert the complete plate on the capsule locking zone. This will activate the switch and compressed air will lock the body and cap of the capsules.

6.1.23 Check the weight of the capsules. Adjust the weight of the fill powder by changing the speed of the body plate with the help of shifting gears.

6.1.24 Officer/Executive Production shall check the initial in-process parameters as per specified in BMR.

6.1.25 Machine shall be run after approval from QA and record the in-process observation in respective BMR.

6.1.26 After the completion of the process, affix the status label" To be cleaned".

6.1.27 Enter the operation details in "Machine Utilization Record"

6.2 CLEANING:

6.2.1 For Product Changeover (Type B Cleaning):

6.2.1.1 Switch 'OFF' the machine, air and vacuum.

6.2.1.2 Preliminary clean the powder with vacuum cleaner.

6.2.1.3 Take the drug hopper, filling plates brush, scrapper etc. to washing area.

6.2.1.4 Clean the above thoroughly with potable water.

6.2.1.5 Wash the drug hopper, loader and filling plates, lock and die, brush, scrapper etc. with 10.0 ltr. Solution of 2.0% v/v Extran MA-02 followed by wash with potable water.

6.2.1.6 Finally wash with purified water.

6.2.1.7 Clean the outer parts of the machine by clean dry lint free cloth.

6.2.1.8 Check the drug hopper and filling plates, loader, lock & die etc. visually, then send swab test intimation slip cum analysis report to Officer / Executive QA to take swab sample.

6.2.1.9 Officer / Executive QA shall collect the swab sample and send to QC department for Analysis.

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

6.2.1.11 If report shows positive identification then repeat above procedure.

6.2.1.12 Mop all the parts with 70% IPA.

6.2.1.13 Assemble the machine after approval by QC.

6.2.1.14 Affix the label as "Cleaned".

6.2.1.15 Enter the cleaning details in "Machine Utilization Record".

6.2.2 For Batch Changeover (Type A Cleaning):

6.2.2.1 Clean all the parts with clean dry lint free cloth.

6.2.2.2 Enter the cleaning details in "Machine Utilization Record".

6.2.3 Frequency of Cleaning:

6.2.3.1 Frequency of cleaning as per step-**6.2.1**

(a) Product to Product Changeover.

(b) After 10 batch of the same product.

(c) After any Maintenance of Product Contact Parts.

(d) 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**

(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:

Operating Manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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