



SOP: LFA 00067

SOP For Automatic Capsule Filling Machine

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1 Objective

To provide the operating procedure for Automatic Capsule Filling Machine.

2 Scope

Includes the operating procedure for Automatic Capsule Filling Machine.

3 Responsibility

By Operation and Production Chemist

4 Accountability

Production Manager

5 Procedure

- 5.1. Check to make sure that all equipment and the production area is clean. Check that the "cleaned" label is affixed to the equipment.
- 5.2. Record the observation in the Equipment Usage Log.
- 5.3. Remove the "cleaned" label and place the "under process" label.
- 5.4. Request for line clearance certificate from the Process Quality Assurance.
- 5.5. Precautions/Warnings:
 - 5.5.1. Do not operate the machine without all the protective gears in its proper position.
 - 5.5.2. Do not bypass any safety equipment/switches.
 - 5.5.3. Do not add, delete, convert or modify anything in the machine.
 - 5.5.4. Do not clean, repair, lubricate or adjust the machine while it is in operation.
 - 5.5.5. It is important to switch the "main switch" off before any installation, assembly, dissemble, maintenance or cleaning is done.
 - 5.5.6. Do not de-activate any safety switch that is installed in the machine.
 - 5.5.7. Use a soft dry cloth to clean the control panel and the equipment surface.
 - 5.5.8. Checking of the safety equipment should be carried out when the machine is in automatic mode.
 - 5.5.9. Safety system must be checked out weekly.
 - 5.5.9.1. The main supply can be cut off from the main power switch on the pendant.
 - 5.5.9.2. Check to see if the emergency button on the pendant is functioning correctly.
 - 5.5.9.3. Check that the emergency switch located in the rear of the metallic safety cover of the machine is functioning correctly.
 - 5.5.9.4. The equipment should stop if any of the safety feature is open (front, rear, left and right safety switches).

5.6. Assembly

5.6.1. Sorter-Cum-Elevator

- 5.6.1.1. Check that the sorter-cum-elevator is connected to the capsule hopper of the machine.
- 5.6.1.2. Empty capsules should be loaded to the hopper
- 5.6.1.3. Remove any defective capsule and arrange them diametrically, ensuring that only the correct sized capsule goes to the hopper for easy continuous feed.

5.6.2. Capsule Orientation and Loading

- 5.6.2.1. Fix the cams in the main shaft by tightening the keys.
- 5.6.2.2. Adjust the Capsule Release Pin Block height so that capsule falls in the raceway slot properly.
- 5.6.2.3. The capsules move into seven vertical tracks in an uneven manner but are rectified with the body facing downward to the bushes in the segments.
- 5.6.2.4. Capsules are separated via vacuum where the body moves in the lower segment while the cap remains in the upper segment.
- 5.6.2.5. There are two loading stations, which load and separate fourteen capsules at a time.
- 5.6.2.6. For proper filling, the dosing plate and bottom segment should be arranged in such a way that the hole in the dosing plate is aligned to the holes in the bottom segment.
- 5.6.2.7. The punch guide plate should be adjusted so that it allows the punches to move freely into the holes in the dosing plate.
- 5.6.2.8. Check and set the penetration of the punches to achieve the required fill weight.
- 5.6.2.9. To avoid downtime, choose the appropriate thickness of the dosing disc.
- 5.6.2.10. Set the air pressure so that it pushes the capsule to the rejection box.

5.6.3. Powder Filling

- 5.6.3.1. The powder filling is then placed in the drug-filling hopper where it would be transfer to the powder tub by the stirrer. The level of the powder tub is automatically controlled.

5.6.3.2. The tamping device would form a line of formulation at an interval of five tamping in the dosing disc. The sixth tamping would eject the formulation to the capsule's body.

5.6.3.3. The thickness of the dosing disc depends on the density, fill weight and properties of the drug formulation.

5.6.4. Optional Pellet Filling Device

5.6.4.1. To obtain the precise fill weight, adjust the volume of the dosing chamber. (Pellet filling is based on the volumetric principle.)

5.6.4.2. The dose volume is controlled by the fixed dose container and the movable slider block; in order to adjust the fill weight, simply adjust the knob, which controls the threaded spindle.

5.6.4.3. The displacement of the slider block is recorded by the dial gauge that has at least a count of 1 micron for exact dose setting; this unique design prevents damage to the pellets during filling.

5.6.4.4. The capsules will pass through the polishing and sorter machine, which also sorts out damaged, empty and underweight capsules.

5.6.5. Capsule Closing and Ejection

5.6.5.1. Capsules will be closed and locked through the closing pins; the length of the capsule can be adjusted using a fine screw arrangement.

5.6.5.2. Change the closing pin size when capsule size changes.

5.6.5.3. Capsules that are filled and closed will be ejected by the ejection pin and will fall through the exit chute.

5.6.5.4. Before the next cycle start, the empty bushes is cleaned by compressed air and vacuum.

5.7. Operations

5.7.1. Switch on the main switch.

5.7.2. Do a dry run before running the machine in auto or manual mode. Run the machine for one complete rotation of the turret assembly by turning the wheel that is by the motor shaft.

- 5.7.3. When in auto mode, the machine will automatically check the machine condition before starting.
- 5.7.4. In the control panel, one can see the following options ? auto, alarm, product, sample and select.
- 5.7.5. In auto function screen, one can see the following options ? start, stop, time reset, product report, weight setting, and alarm status and data entry. Sample setting will be selected as per the batch requirement.
 - 5.7.5.1. Start: Pressing this key will start the machine in auto mode. The blower and vacuum pump will also start with the machine.
 - 5.7.5.2. Stop: Pressing this key will stop the machine.
 - 5.7.5.3. Time Reset: Pressing the key for three seconds will reset the machine's running time.
 - 5.7.5.4. Alarm Status: Pressing this key will display the alarm status screen and the alarm type.
 - 5.7.5.5. Product Report: Pressing the key will show the total production, day production and number of capsules/hour.
 - 5.7.5.6. Data Entry: Pressing the key will show the parameters in the screen.
 - 5.7.5.7. Weight setting: Pressing the key will display the ?WT SET? which shows the acceptable limit of weight variation, number of capsules on average and the time where samples are taken out.
 - 5.7.5.8. Sample Setting: Pressing F8 will show the sample-setting screen. Another screen will show the following keys ? take sample, auto manual, auto, manual, tare, and motor on/off. Choose the option required and sample by weight operation will start.

5.8. Capsule Sorter

- 5.8.1. The filled capsules will pass through the capsule sorter.
- 5.8.2. Two types of sorter:
 - 5.8.2.1. Loose capsule (Plate sorter)
 - 5.8.2.2. Diametrically defective capsule sorting (Drum sorter)

- 5.8.3. Place the regulator knob to the zero position and switch the on to start the sorting through the plate sorter.
- 5.8.4. Slowly turn the knob clockwise and set it to the middle section. This would start the plate sorter to vibrate. If the plate starts making rattling noise, reduce the voltage.
- 5.8.5. For drum sorter, push the green button. The rotation of the drum sorter should be clockwise when looking from the end.
- 5.8.6. The capsule flow can be started. Personnel can start the capsule filling machine.
- 5.8.7. The capsules will then move in the sorting plate. If the movement is slow and capsules are clogging, increase the vibration slowly by turning the regulator knob clockwise.
- 5.8.8. The capsules will then move forward. Those with loose caps will fall through the hole in the sorting plate and will be sent to the drum sorter.
- 5.8.9. The capsules will rotate in the drum sorter and those with oversized diameter will be trapped in the sorting plate and the good ones will pass through the ECS100.
- 5.8.10. The good capsules will be sent to the ECS 100 while the defective ones will be removed by a nylon brush located at the top of the drum sorter. The defective capsules are collected in a tray and are manually removed in an interval.
- 5.8.11. Place ?To be cleaned? label on the machine.
- 5.8.12. Clean the Automatic Capsule Filling Machine as per the company?s SOP.
- 5.8.13. Records: Log Book

6 Abbreviations

SOP Standard Operating Procedure