



SOP: LFA 00068
SOP For Automatic Capsule Filling Line

Alastair Sanderson

31/08/16

1 Objective

Process for operating an Automatic Capsule Filling Line

2 Scope

This is applicable to the Automatic Capsule Filling Production Department.

3 Responsibility

Executed Operation and Production Chemist

Checking Production Pharmacist and Up

4 Accountability

Head of the Department for Production/ Assigned Designee

5 Procedure

- 5.1. The production department should ensure the cleanliness of the production area and the machine, affixing a "cleaned" label to the equipment.
- 5.2. AIR DISPLACEMENT UNIT (ADU)
 - 5.2.1. Before starting the machine, check to make sure that proper fitment is done for hosepipe and cover to the cylindrical chamber of the machine.
 - 5.2.2. Push the "ON" green button on the Direct on Line (DOL) starter to start the machine.
 - 5.2.3. De-dust the filter bag after every twenty to thirty minutes by shaking the bag up and down.
 - 5.2.4. Once the batch is done push the "OFF" red button on the Direct on line (DOL) starter to stop the unit.
 - 5.2.5. Clean the machine as per the SOP.
- 5.3. SORTER ELEVATOR
 - 5.3.1. Before starting the machine check if the sorting plate is the correct size.
 - 5.3.2. Mount the sensors on the hopper of the capsule filling machine.
 - 5.3.3. Place the hopper to the sorting plate gate and closed it, load the hopper with the empty capsules.
 - 5.3.4. Switch the auto mode to on and open the hopper gate to the specified level.
 - 5.3.5. Switch the isolator on, the power button will turn to green and glow.
 - 5.3.6. To start the loading cycle, push the elevator on button (Green button). The air button will start first and after few seconds, the vibrator motor will start.
 - 5.3.7. To prevent the capsules from clogging, open the hopper gate to the maximum.
 - 5.3.8. Once the entire batch is completed, switch off the isolator switch.

5.3.9. Remove the empty capsules and clean the machine as per the SOP

5.4. AUTOMATIC CAPSULE FILLING MACHINE

- 5.4.1. Check that the machine and line is clean
- 5.4.2. Check the cubicle and ensure that it is clean as per the SOP
- 5.4.3. Check that the appropriate capsule size is fitted as per the BMR and request for line clearance from the QA personnel
 - 5.4.3.1. Turret Assembly - cap and body bushes
 - 5.4.3.2. Empty Capsule Loader Assembly - Horizontal Blade, Magazine, Vertical Blade, Rectifier Block
 - 5.4.3.3. Powder filling device - Wiper block, Dosing disc and Tamping pin
 - 5.4.3.4. Capsule Closing Assembly - Capsule Closing pins
 - 5.4.3.5. Capsule Ejection Assembly - Ejection Guide plate
- 5.4.4. Check and make sure that all line machines are connected to the central machine
- 5.4.5. Check that all machine doors are closed
- 5.4.6. Affix label indicating the product name and batch details to the machine
- 5.4.7. Check that all electrical connections are connected and turn on the main machine
- 5.4.8. Check that the emergency switch is released
- 5.4.9. Switch the compressed air supply on and turn the control knob to the "ON" position
- 5.4.10. The MMI will display the main screen on PLC
- 5.4.11. Choose the right level by pressing the login key
- 5.4.12. Press the "PREV" and then press "NEXT SCREEN" key to display the MMI
- 5.4.13. Enter the following details: Operator and Product name, sample size, batch number. sample base, empty capsule weight, set weight, tolerance, batch number
- 5.4.14. Go back to the Main menu and press the "NEXT SCREEN" to display the MMI

- 5.4.15. Place the cursor to the :SAFETY” and then enter in the BYPASS mode
- 5.4.16. Choose ”MODE” as per the BMR and ”FLAP OPENING” as per the sample size
- 5.4.17. Go back to the Main menu and then press the ”AUTO LINE” to display the MMI
- 5.4.18. Choose the ”Auto Line” mode and then enter the status of all the line machines to ”AUTO” mode
- 5.4.19. Press the ”DRIVE ON” and then switch all the line machines manually
- 5.4.20. Choose the Auto line (all) in ”AUTO” mode
- 5.4.21. Check and make sure that the hand wheel is in the out position
- 5.4.22. Place the empty capsule of the required size as per the BMR to the empty capsule hopper
- 5.4.23. Go back to the Main screen and press the F3- ”LOAD ON/OFF” to place the empty capsule from the magazine to the rectification block
- 5.4.24. Adjust the magazine with vertical push blade assembly, horizontal push blade assembly and vacuum block to load and separate the capsules. Gather the empty capsules used for the setting and then place it in the rejected capsule bin
- 5.4.25. Put the mixture to the powder hopper and set the powder mixing mode timer in the main screen
- 5.4.26. Set the fill wet as per the BMR by adjusting the tamping pin height and powder bed height
- 5.4.27. Press the ?DRIVE ON? key and let the machine run for five minutes. Take the weight difference on the checkweigher. If the variation is within the limit as per the BMR run the machine. Ensure that the machine is in safe mode
- 5.4.28. Gradually rotate the speed control knob clockwise to increase the speed of the machine
- 5.4.29. After completing the batch, fully rotate the speed control knob anti-clockwise and then press the ”DRIVE OFF” key

- 5.4.30. Remove the empty capsules from the reservoir and hopper. Remove the empties from the magazine, cap and body bush holder, rectifying block by using inching mode weigh and record the details in the BMR
- 5.4.31. Clean the machine as per the SOP

5.5. DEDUSTING AND POLISHING THE UNIT

- 5.5.1. Start the main machine by pressing the "ON" button
- 5.5.2. Press the red button to start the motor
- 5.5.3. Gently turn the potentiometer knob clockwise and set it at middle speed
- 5.5.4. Set the pressure regulator at $5kg/cm^2$ pressure and start the compressed air supply
- 5.5.5. Check the capsule feeding from the inlet hopper at the uniform rate
- 5.5.6. Check the polishing quality of capsules, if the quality is substandard change the polishing chamber inclination and the brush speed
- 5.5.7. Hygroscopic powder would require a steeper angle
- 5.5.8. Let the machine run for few minutes, after stop the capsule in feed
- 5.5.9. This will make sure that the capsules in the chamber will be ejected
- 5.5.10. Slowly reduce the machine speed to zero and then switch the motor and main supply
- 5.5.11. Clean the machine as per the SOP of the company

5.6. COMPACT AIR DISPLACEMENT UNIT

- 5.6.1. Ensure that the hose pipe is properly fitted and the cover of the cylindrical chamber before the machine starts
- 5.6.2. Press the "ON" green button on the "DOL" starter to start the unit machine
- 5.6.3. Dedust the machine's filter bag every twenty to thirty minutes by moving the shaker up and down

5.6.4. After the batch completed. Push the "OFF" red button on the DOL starter to stop the machine

5.6.5. Clean the machine as per SOP of the company

5.7. MINI FILLED CAPSULE SORTER

5.7.1. Ensure that the change parts are of correct size as per the BMR

5.7.2. Switch the main supply on

5.7.3. To start the Plate sorter, keep the Regulator knob at 0 position and switch the toggle switch on

5.7.4. Gently turn the knob clockwise and set it at mid position. Make sure that the sorter plate do not make any rattling noise, if there's noise, decrease the voltage

5.7.5. To start the Drum Sorter, press the green button. Check the Drum Sorter rotation and should be clockwise in in direction

5.7.6. If the forward movement of the capsule in the sorting plate is slow and capsules are starting to clog, increase the vibration slowly, turn the regulator knob clockwise to increase the vibration

5.7.7. The sorting plate would also sort the loose caps sorting diametrically defective or oversize capsules and sent to the Drum Sorter

5.7.8. After the batch is finished, check that no capsules are still inside the machine

5.7.9. Rotate the regulator knob to full anti-clockwise and also switch off the plate sorter toggle switch

5.7.10. Remove any clogged capsules from the Drum Sorter and switch the Sorter off

5.8. EMPTY CAPSULE SORTER

5.8.1. Switch the main supply on by toggling the switch

5.8.2. Turn the dimmer clockwise until the digital voltammeter displayed "Operating Voltage" to choose the size of the capsule

5.8.3. The ECS setting for the capsule size is as follows:

5.8.3.1. Take 500 filled capsules of the specified batch weight and add 25 unfilled capsules, 10 loose caps and body of the same size

- 5.8.3.2. Mix all of the capsules thoroughly and set the voltage at 80 volts
- 5.8.3.3. Slowly load the capsule in the carpet form in the ECS hopper
- 5.8.3.4. Increase the voltage slowly at 3V every interval. All 25 empty capsule, 10 loose cap and body of the same capsule size will be collected in the collection box (Voltage X). Gradually increase the voltage a 3V in every interval and check that some filled capsule will start collected in the collection box along with all the empty capsule, loose cap and the same body size capsule (Voltage Y)
- 5.8.3.5. Set the dimmer stat voltage $Z = \frac{X+Y}{2}$
- 5.8.3.6. The (Z) will be the operating voltage for the said filled capsule size
- 5.8.3.7. Repeat the same process 5 times at X and Y voltage to check that the operating voltage is working
- 5.8.3.8. The Req. ECS voltage for the said filled capsule size will be added to the BMR after doing validation for the first 3 batch. Always start the batch at the set ECS voltage for the specific product
- 5.8.4. After the batch is completed, rotate the dimmer stat anticlockwise and switch the toggle switch
- 5.8.5. Remove the empty capsules and clean the machine as SOP
- 5.8.6. After the batch is completed, place a "TO BE CLEANED" label and document it in the Equipment Log Book

6 Abbreviations

SOP Standard Operating Procedure

ECS Empty Capsule Sorter

ADU Air Displacement Unit

SE Sorter Elevator

DP Dedusting and Polishing Unit

CADU Compact Air Displacement Unit

MCS Mini Filled Capsule Sorter