



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down the procedure for the Cleaning and Operation of Automatic Capsule filling machine (AF-25 T).

2.0 SCOPE:

This procedure is applicable to the cleaning and operation of automatic capsule filling machine (AF-25 T) in production department.

3.0 RESPONSIBILITY:

Technical Associate : Operation and cleaning of the machine.

Officer/ Executive Production : Supervision

Head Production : SOP Compliance

IPQA : Line Clearance

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 "TYPE A" CLEANING

This is a cleaning procedure for change over from one batch to next batch of the same product, same potency.

5.1.1 Affix dully filled "TO BE CLEANED" status label on equipment with date and signature of the Production Officer as per SOP.

5.1.2 Enter the cleaning starting time in equipment usage log sheet as per SOP.

5.1.3 Remove the adhered material on the machine by using vacuum cleaner.

5.1.4 Record the cleaning activity in equipment usage log sheet as per SOP.

5.1.5 Dismantling and assembling as per operating procedure 5.3 and 5.4.

5.1.6 Replace the "TO BE CLEANED" status label with "CLEANED" status label with date and signature of the Production Officer/QA Officer.

5.2 "TYPE B" CLEANING

This is a cleaning procedure for Change over of product with different actives/colour/ascending potency/descending potency or after maintenance of contact parts.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.2.1 Follow the procedure from step 5.1.1 to 5.1.3.
- 5.2.2 Dismantle the vacuum pot & collect the powder from vacuum pot with the help of dust extractor or vacuum cleaner.
- 5.2.3 Send the filter bag of vacuum pot/ vacuum cleaner to the filter cleaning area for cleaning in a virgin polybag affix with "To Be Cleaned" label.
- 5.2.4 Transfer the all dismantled parts as per point 5.7 & vacuum pot to respective cleaning area in a virgin poly bag affix with "TO BE CLEANED" label.
- 5.2.5 Clean the dismantled parts of the machine using 10-12 liter of purified water with nylon brush.
- 5.2.6 Apply a jet of purified water so as to ensure the complete removal of the previous product.
- 5.2.7 Finally rinse the cleaned parts with the 20-30 liters of purified water.
- 5.2.8 Dry the bush by using compressed air.
- 5.2.9 Wipe the machine surface with wet duster soaked in purified water.
- 5.2.10 Dry the dismantled parts with a dry lint free duster.
- 5.2.11 Wipe all cleaned dismantled parts with 70% v/v IPA solution and transfer all the cleaned parts to the respective cubicle in virgin poly bag with "CLEANED" label.
- 5.2.12 Assemble the all parts to the machine & affix "CLEANED" label on machine with date and signature of the Production Officer/ QA officer.
- 5.2.13 Ensure that the area is cleaned as per SOP No.
- 5.2.14 Record the cleaning activity end time of machine in equipment usage log as per SOP No.
- 5.2.15 The cleaned equipment is idle for 72 hours, after this period Wipe all the parts of equipment with 70% v/v IPA solution before use and should be a counter sign on previous "CLEANED" label by production & QA officer with date as per SOP No.
- 5.2.16 Record the cleaning activity of machine in equipment usage log as per SOP.
- 5.2.17 Ensure that the area is cleaned as per SOP.
- 5.2.17 Perform the cleaning and record in cleaning checklist of annexure I

5.3 Frequency

- 5.3.1 Type 'A' cleaning is applicable after completion of every batch of same product, same potency and of similar product with ascending potency. If same product is processed for more than seven days then follow the procedure of type – B cleaning.
- 5.3.2 Type 'B' cleaning is applicable in case of change over of product with different actives / color / descending potency or after maintenance of contact parts or same product is run for more than seven days cleaning Type - B done after completion of batch.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.3.3 Cleaning is applicable in case of at the end of working day, dedusting of machine with vacuum cleaner or dry by lint free cloth.

NOTE: After Type - B cleaning, if machine is not used within 72 hours, clean the machine “before use”, with the lint free duster dipped in 70% v/v IPA solution followed by dry lint free duster and dully sign the “CLEANED” label again. Record the activity in equipment usage log sheet as per SOP.

5.4 SETTING FOR PELLETS 1, POWDER AND PELLETS 2

5.4.1 Assembling and setting

5.4.1.1 Assemble the clean and dry accessories in the following manner.

5.4.1.2 Remove the ‘CLEANED’ status label and affix ‘UNDER PROCESS’ label on the machine.

5.4.2 Upper and lower bush assembler

5.4.2.1 Assemble cap and body bushes at station no 3.

5.4.2.2 Insert the cap and body bushes in to the slots of cap and body bush holder plate.

5.4.2.3 Fix the clamping plates by tightening the square head bold.

5.4.2.4 Check alignment of cap bush and body bush at station 2 and 6

CAUTION: Do not tighten the screws excessively as it can damage the Clamping plates.

5.4.3 Loading station

5.4.3.1 Assemble the loading parts in the following sequence.

5.4.3.2 Assemble the rectifier blocks on the locating dowel pins in tighten the screws

5.4.3.3 Assemble the horizontal blade assembly.

5.4.3.4 Assemble the Teflon guide block over the horizontal blade.

5.4.3.5 Turn the machine hand wheel until the shaft is at its lowest position; fix the magazine on the shaft, so that the vertical blades are in line with the center of the rectifier sets, tighten the bolt firmly.

5.4.3.6 Align the reservoir holes with the dowel pins of mounting plate and clamp by the knobs.

5.4.3.7 Place the capsule hopper on reservoir and tighten the knobs.

5.4.3.8 Allow the capsule to fall into the rectifier slot. Rotate the hand Wheel until the horizontal push blades move the capsules forward. Loosen the nut for mounting the horizontal blade assembly and adjust the horizontal blades such that the point of vertical blades is within **2-3 mm** from cap end of the capsules. Retighten the assembly.

5.4.4 Pellets – 1 Station

5.4.4.1 Assemble the dosator.

5.4.4.2 Fix the head on the dosator then fit the sensor to sense the low Pellets level.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.4.4.3 Assemble the Pellet-1 hopper.

5.4.4.4 Set the Pellet filling weight with the help of screw provided.

5.4.4.5 Fit the Pellet cup at the space provided.

5.4.5 Dosing station

5.4.5.1 The powder-filling device consists of a blend hopper, stirrer, blend delivery tube, powder level sensor, powder tub and dosing disc.

5.4.5.2 Unscrew the screws of tamping pins holding plate and remove the tamping pins individually from the tamper (if required), If tamping pins are removed, replace them with tamping pins as per requirement. Keep the holding plate in position and tighten the screws.

5.4.5.3 Keep the stationary disc on mounting and fit the Teflon scraper on it.

5.4.5.4 Fit the dosing disc on the disc holder by three hexagonal bolts.

5.4.5.5 Fit the wiper assembly on the two pillars provided for reciprocating shaft and tighten it by Allen bolts and check the gap between wiper block and dosing disc (**It should not be more than 0.15 mm**)

5.4.5.6 Fit the guide plate for tamping pins holder assembly on the two reciprocating shafts and tighten it by two hexagonal bolts provided on the two sides of the plate.

5.4.5.7 Insert the tamping pin holders in the guide plate.

5.4.5.8 Loosen the bolts of the dosing disc. Check the alignment of dosing disc and fit the tamper by tightening the fixing bolts.

5.4.5.9 Fit the blend hopper on holding plate by tightening the knobs.

5.4.5.10 Fit the stirrer on the shaft inside the hopper by tightening the knob.

5.4.5.11 Fit the acrylic cover and powder level sensor and check the movement of dosing disc in manual mode.

5.4.5.12 Assemble the delivery tube to the powder hopper.

5.4.6 Pellets – 2 Station Pneumatic filling

5.4.6.1 Assemble the dosator.

5.4.6.2 Fix the head on the dosator then fit the sensor to sense the low Pellets level.

5.4.6.3 Assemble the Pellet-2 hopper.

5.4.6.4 Set the Pellet filling weight with the help of screw provided.

5.4.6.5 Fit the Pellet cup at the space provided.

5.4.7 Unopened Capsule Removal Station

5.4.7.1 Set when Pellets – 1 and/ or Powder filling done. When Pneumatic filling of Pellets done the it replaces with Pellets – 2 assembly.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.4.7.2 Fix the assembly and collection box for unopened capsule in the slot provided.

5.4.8 Filled capsule locking station

5.4.8.1 Rotate the machine by hand wheel and bring the sector plate to its bottom most position.

5.4.8.2 Unscrew all four closing pins.

5.4.8.3 Reassemble the new closing pins on the mounting plate.

5.4.8.4 Align the closing pins with the gauge provided with respect to cap and body bush holders.

5.4.8.5 Adjust the capsules closing plate position up or down to get the desired lock (closed) length.

5.4.8.6 In case of Pellet filling assembly first we assemble the dosator and lower hopper and upper hopper.

Note: Before starting of filling activity check whether all the guards of the machine is fitted properly and then only switch 'ON' the mains of the machine.

Caution: Ensure correct assembly by moving the hand wheel manually to check free movement of all loading parts, dosing parts and other moving parts and then switch 'ON' the mains.

5.4.9 In case of any abnormal sound from the machine during its operation, stop the machine and report to maintenance department.

5.5 SETTING FOR MICRO TABLETS

5.5.1 Assembling and setting

5.5.1.1 Assemble the clean and dry accessories in the following manner.

5.5.1.2 Remove the 'CLEANED' status label and affix 'UNDER PROCESS' label on the machine.

5.5.2 Upper and lower bush assembler

5.5.2.1 Assemble cap and body bushes at station no 3.

5.5.2.2 Insert the cap and body bushes in to the slots of cap and body bush holder plate.

5.5.2.3 Fix the clamping plates by tightening the square head bolt.

5.5.2.4 Check alignment of cap bush and body bush at station 2 and 6.

CAUTION: Do not tighten the screws excessively as it can damage the Clamping plates.

5.5.3 Micro Tablet Inspection Setting

5.5.3.1 Switch on the system, after loading the applications main menu appear on screen.

5.5.3.2 Press the login button. Enter access code and password.

5.5.3.3 Main screen shows the Inspection, Model, Admin, Demo, TRB Shoot, Help, Sign Out, and Quit functions.

5.5.3.4 Press Model, here for Inspection and new model creation for Teach and for delete the existing teach.

5.5.3.5 In the Teach window setting of Filled Camera and Empty Camera done as follows-



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.5.4 Setting for Filled Camera

- 5.5.4.1 After selecting the filled camera screen shows the selection of image input to the system, by Grab and by External.
- 5.5.4.2 In **Step 1** grab the image and draw field of view as much as required.
- 5.5.4.3 The pixel information of the micro tablet in the FOV is read and used for the comparison with images acquired during run time.
- 5.5.4.4 After drawing FOV, **Step 2** Set tracks, in this step, FOV image alone will appear in image Pellet and a message will appear pop up indicating "Please SET Track".
- 5.5.4.5 Draw track on image then press 'Search'. If you get all tracks, go to next step else draw tracks manually and press 'Set'.
- 5.5.4.6 For setting tracks draw a rectangular area on the image. Draw rectangular area for all the images, then press 'Search'.
- 5.5.4.7 Right click on the tracks to name it.
- 5.5.4.8 Draw cavity on image then press 'Search' if you do not get all cavities then draw cavity manually and press 'Set'.
- 5.5.4.9 **Step 3: Set Pocket** after creating cavity, in Step 2 draw pockets around any one tablet/ capsule in this step for reference and then press Search button. Now the program will search similarly patterns and draw pockets around every tablet / capsule.
- 5.5.4.10 **Step 4: Colour Thresholding**
- 5.5.4.11 Draw a ROI inside the tablet.
- 5.5.4.12 Adjust Sliders to completely cover the tablets with red color. To threshold a single object, double click on the pocket and then adjust sliders. Press fine tune to adjust the threshold in all 3-planes simultaneously.
- Note:**
1. In this process make sure that all the tablets separated from background are fully covered by RED color. If not then do Low/ High Sider or Click on Fine tune.
 2. Never set the minimum object area so high that the object in the Micro Tablet is no longer marked.
- 5.5.4.13 **Step 5: Tolerance Setting** here set the tolerance limit of Micro tablets.
- 5.5.4.14 **Step 6: Particle Properties** here check the properties and on pressing OK the properties window closed and a pop up appears for confirmation to save the particle properties.
- 5.5.4.15 After that 'Model Teaching complete, Please the empty camera' window appear. Click on OK to complete teaching the model.

5.5.5 Setting for Empty Camera



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.5.5.1 Select the Empty mode operation.
- 5.5.5.2 After selecting the Empty camera screen shows the selection of image input to the system, by Grab and by External.
- 5.5.5.3 Grab the image and draw field of view as much as required.
- 5.5.5.4 Draw a FOV.
- 5.5.5.5 After drawing FOV, Set tracks, FOV image alone will appear in image Pellet and a message will appear pop up indicating "Please SET Track".
- 5.5.5.6 Draw Track on image then press 'Search'. If you get all track go to next step else draw tracks manually and press 'Set'.
- 5.5.5.7 Assign the capsule tracks name on the tracks.
- 5.5.5.8 Draw the cavity on image then press 'Search'.
- 5.5.5.9 Make the ROI on the background (other than tablets). Then press next till it gets disable.
- 5.5.5.10 Then adjust sliders to completely cover the background with orange color.
- 5.5.5.11 To threshold a single tack, double click on the track and then adjust sliders.
- 5.5.5.12 Press fine tune to adjust the Thresholding in all 3-planes simultaneously.
- 5.5.5.13 Press next to save the Teaching parameters. Then press OK.
- 5.5.5.14 Teaching of Second camera (Empty camera) completed. Then main screen appear.
- 5.5.6 Loading station**
- 5.5.6.1 Assemble the loading parts in the following sequence.
- 5.5.6.2 Assemble the rectifier blocks on the locating dowel pins in tighten the screws.
- 5.5.6.3 Assemble the horizontal blade assembly.
- 5.5.6.4 Assemble the Teflon guide block over the horizontal blade.
- 5.5.6.5 Turn the machine hand wheel until the shaft is at its lowest position; fix the magazine on the shaft, so that the vertical blades are in line with the center of the rectifier sets and tighten the bolt firmly.
- 5.5.6.6 Align the reservoir holes with the dowel pins of mounting plate And clamp by the knobs.
- 5.5.6.7 Place the capsule hopper on reservoir and tighten the knobs.
- 5.5.6.8 Allow the capsule to fall into the rectifier slot. Rotate the hand Wheel until the horizontal push blades move the capsules forward. Loosen the nut for mounting the horizontal blade assembly and adjust the horizontal blades such that the point of vertical blades is within 2-3 mm from cap end of the capsules. Retighten the assembly.
- 5.5.7 Feeding station for Micro Tablets**
- 5.5.7.1 The Micro TFA is to be fitted at station 3 of the machine.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

5.5.7.2 The Micro TFA device consists of a tablets hopper, feeding disc (has through holes on it as per desired numbers of Micro tablets are to be filled in the capsule as per BMR), Bottom Disc, Rest plate, indexing sensor, air distributor, NFD exit chute of the attachment.

5.5.7.3 Using gauge pins align the holes of the escapement device with the body bush holder. The housing of the attachment has kidney shaped slots.

5.5.7.4 The gap between the divertor block and the body bush holder should be 0.5 to 1.0 mm approximately.

5.5.7.5 Spacer mounted below the housing.

5.5.7.6 Remove the existing exit chute and mount the modified exit chute.

5.5.7.7 Connect the pneumatic piping to the escapement cylinder and the other end to the solenoid valve. Connect the tubing from the cylinder for the flap on the exit chute to the solenoid valve on the pneumatic panel.

5.5.7.8 Connect the all the electrical connection of Micro TFA.

5.4.7 Unopened Capsule Removal Station

5.4.7.1 Set when Pellets – 1 and/ or Powder filling done. When Pneumatic filling of Pellets done the it replaces with Pellets – 2 assembly.

5.4.7.2 Fix the assembly and collection box for unopened capsule in the slot provided.

5.5.8 Filled capsule locking station

5.5.8.1 Rotate the machine by hand wheel and bring the sector plate to its bottom most position.

5.5.8.2 Unscrew all four closing pins.

5.5.8.3 Reassemble the new closing pins on the mounting plate.

5.5.8.4 Align the closing pins with the gauge provided with respect to cap and body bush holders.

5.5.8.5 Adjust the capsules closing plate position up or down to get the desired lock (closed) length.

5.5.8.6 In case of Pellet filling assembly first we assemble the dosator and lower hopper and upper hopper.

Note: Before starting of filling activity check whether all the guards of the machine is fitted properly and then only switch, “ON” the mains of the machine.

Caution: Ensure correct assembly by moving the hand wheel manually to check free movement of all loading parts, dosing pars and other moving parts an then switch ‘ON’ the mains.

5.5.9 In case of any abnormal sound from the machine during its operation, stop the machine and report to maintenance department.

5.6 OPERATION



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 5.6.1 After line clearance from QA, put the "UNDER PROCESS" label duly filled and signed on machine as per SOP.
- 5.6.2 Enter the start time of the batch in equipment usage log sheet as per SOP.
- 5.6.3 Switch "ON" the electric supply from the control panel.
- 5.6.4 Entire operation is performed from station nos. 1 to 8 as follows
- 5.6.4.1 **Station 1**
Empty capsule loading and separation. Capsule move vertically downward through the hole of the Magazine. One capsule at a time is released by the capsule Retainer finger to the rectifier raceway. Released capsule are Then pushed by horizontal blade assembly. Vertical push blade Then pushes the capsule further downward. The Capsule enters the cap bush and cap rests on the land of cap bush. At the same time body is sucked down into the body bush by vacuum.
- 5.6.4.2 **Station 2**
This station is made for cap and body bush alignment during size changeover.
- 5.6.4.3 **Station 3**
The body bush holder plate is fully out and the cap bush holder plate is partially up. This station is used for Mechanical Pellets or Micro tablets Filling.
- 5.6.4.4 **Station 4**
This station is used for powder filling.
- 5.6.4.5 **Station 5**
At this station any unopened (Non-separated) capsule is removed.
This station is also used for Pellet filling with pneumatic filling of Pellets.
- 5.6.4.6 **Station 6**
At this station the body bush holder plate retracts to its original position in the alignment with the cap and body bush holder plate. A capsule retainer plate moves down to approximately **0.2 to 0.5 mm** above cap domes, simultaneously the capsule closing pins moves up and pushes the bodies in to the cap and lock the capsules. A vacuum cleaning device is installed at this station to remove powder or capsule particles from the top face of the body bush and bottom face of the cap bush and top face of the closing pin holder.
- 5.6.4.7 **Station 7**
At this station the locked capsules are ejected from the bushes by ejection pins through the guide plate. Compressed air jet diverts the capsules along the exit chute
- 5.6.4.8 **Station 8**



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

This is a cleaning station to ensure that there is no powder adhering to the bushes before the next cycle.

5.6.5 Setting for weight of Powder and Pellets

5.6.5.1 Select PELLET2 at Mode B and set the weight of Pellets as required.

5.6.5.2 After setting of pellet weight then we set the weight of powder by select the POWDER at Mode A as required.

5.6.5.3 After setting Pellet and powder weight select PDR+PLT2, at the Mode B and run the machine and check the weight of capsule.

5.6.5.4 In running machine to check the individual weight firstly place the sample bag at discharge chute then select POWDER at Mode A, at the time filling of pellets stop in the capsule and we check the weight of powder in individual capsule.

5.6.5.5 After checking of individual weight again select PDR+PLT2, at the Mode B and run the machine.

Note: Ensure that at the time checking of individual weight of powder the capsule kept separate, Don't mix in the batch.

5.6.6 Start the machine in the following sequence

5.6.6.1 For machine with PLC (Touch screen).

5.6.6.2 Turn the emergency switch (red) located on the bottom left of control panel, clockwise.

5.6.6.3 Turn the control key, ON 'by turning to the right. Vacuum pump should be 'ON'.

5.6.6.4 Press the drive, 'ON' green push button to start the drive. The screen will shows

AUTOMATIC CAPSULE FILLING M/C 25 T

DRIVE RUNNING

MODE A: MODE B:

SPEED: SPM MODE:

COUNTER:

HOURS RUN:

ENCODER PRESENTCOUNT:

MACHINE READY TO USE

ALARM SCREEN	LOADING ON	ALARM RESET	NEXT
-------------------------	-----------------------	------------------------	-------------



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine

Effective Date:

Supersedes: Nil

Review Date:

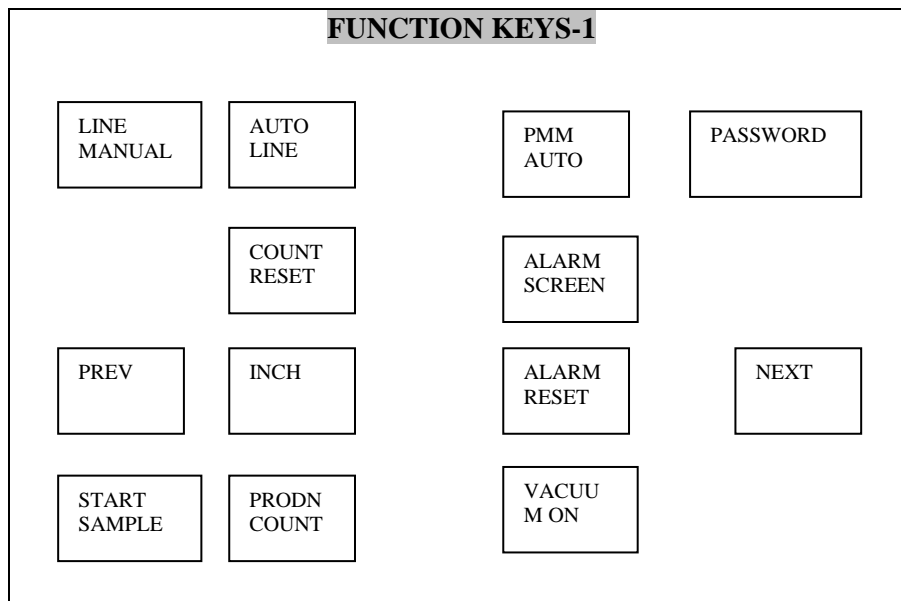
Issue Date:

Page No.:

5.6.6.5 In Mode A we select the mode of filling like POWDER, PELLETT, PDR+PLT and MICROTAB as required.

5.6.6.6 In Mode B we select the mode of filling like PELLETT2, PLT1+PLT2, PDR+PLT2 and PDR+PLT1+PLT2 as required.

5.6.6.7 Touch 'NEXT', screen will shows



5.6.6.8 **Function Key-1**

* **Password:** Four level of password to be entered

I. Operator III. Maintenance

II. Supervisor IV. Pam

To change the password touch the ' LOGIN ' and enter the password after that touch ' LOGOUT '

Touch 'NEXT' screen will show

5.6.6.9 **Function Key-2**

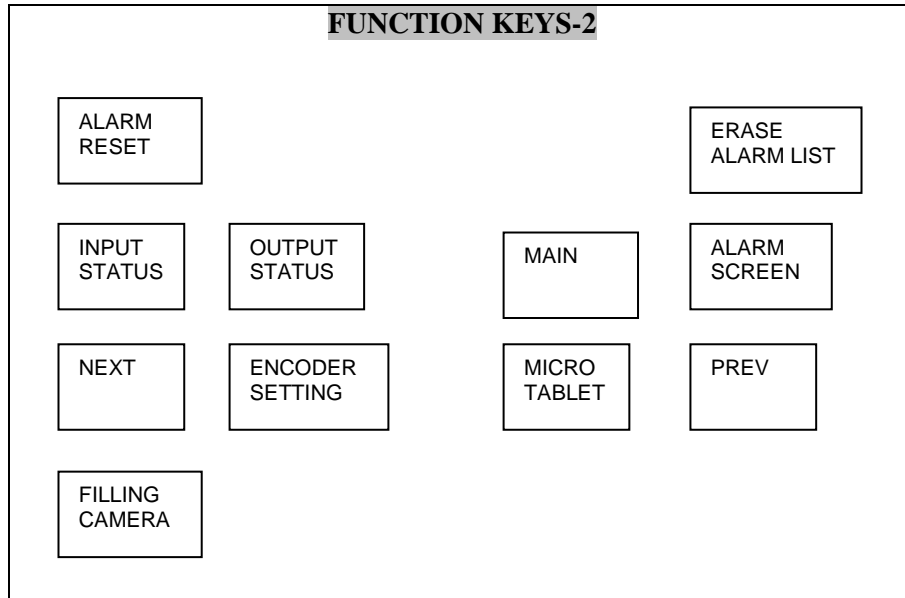


PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:



NOTE

- a. Press the drive ON/OFF push button after adjusting the speed of machine by the potentiometer knob to the desired speed.
- b. Vacuum supply should be adjusted (**limits 15”-22” of Hg**) to separate cap and body of the capsules.
- c. Compressed air required to operate the machine should be 6-7 Kg/sq. cm.

5.6.7 Dose adjustment for Powder Filling

- 5.6.7.1 Start the machine and check the weight of filled capsules.
- 5.6.7.2 If the achieved fill weight complies with specified standards mentioned in the BMR, then continue the filling operation.
- 5.6.7.3 If the fill weight needs to be re-adjusted, stop the machine and do the following.
- 5.6.7.4 To increase the fill weight adjust the tamping pins by moving downwards towards the powder bed and to decrease the fill weight adjust the tamping pins by moving upwards away from the powder bed.
- 5.6.7.5 In case of Pellet to increase the weight rotates the knob anti clock wise and to decrease the weight rotate the knob clock wise.
- 5.6.7.6 After completion of operation switch ‘OFF’ the machine in the following sequence
For machine with PLC
 - a. Press the drive OFF red push button to stop the drive.
 - b. Turn the control key, ‘OFF’ by turning to the left.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

c. Press the emergency switch (RED) located on bottom of corner of control panel.

d. Turn the main switch OFF (Situating below the working surface at the loading Side)

5.7 Dismantling

5.7.1 Loading station:

5.7.1.1 Remove the sensor from the capsule hopper assembly.

5.7.1.2 Remove the capsule hopper by unscrewing the knobs.

5.7.1.3 Remove the empty capsule reservoir by unscrewing knobs.

5.7.1.4 Dismantle the magazine, Teflon guides, pusher plate and rectifier raceway block.

5.7.4.5 Unscrew and remove the clamping plates. Push out the cap and body bushes by pressing from below.

5.7.2 Dosing station

5.7.2.1 Remove the delivery tube from the blend hopper.

5.7.2.2 Loosen the stirrer screws and remove the hopper by loosening the hopper knobs. Lift through the top acrylic cover to totally remove it from the main body.

5.7.2.3 Remove the powder sensor from the powder tub.

5.7.2.4 Remove the tamping pin holders by loosening the fixing bolts (First loosen the horizontal bolts and then the vertical bolts)

5.4.2.5 Remove the guide plate for tamping assembly by unscrewing the side bolts.

5.4.2.6 Remove the wiper assembly by unscrewing the bolt.

5.4.2.7 Remove the dosing disc by loosening the three hexagonal bolts.

5.4.2.8 Remove the stationary disc.

5.7.3 Micro tablet station

5.7.3.1 Remove the delivery tube from the tablet hopper.

5.7.3.2 Remove the hopper by loosening the hopper knobs.

5.7.3.3 Remove the Micro tablet assembly.

5.7.4 Other removable parts

Remove the following:

a. Non-separated capsule collection box.

b. Slug collection box.

c. Lower and upper bush holding plates and bushes.

b. Bush cleaning unit.

e. Capsule locking pins and locking pads.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

f. All removable acrylic guards and stainless steel guard behind loading station.

g. Exit chute.

5.8 Precaution

5.8.1 Vacuum supply should be adjusted (**limits 15''-22'' of Hg**) to separate cap and body of the capsules.

5.8.2 Ensure correct assembly by moving the hand wheel manually to check free movement of all loading parts, dosing parts and other moving parts and then switch 'ON' the mains.

6.0 ABBREVIATION (S):

PLC : Programmable logic control

'' : Inch

Cm : centimeter

Kg : Kilogram

Hg : Mercury

Mm : Millimeter

V/V : Volume/volume

IPA : Iso propyl alcohol

FOV : Field of View

ROI : Region of Interest

Micro TFA : Micro Tablet Filling Assembly

7.0 RERERENCE (S):

SOP No.: SOP for Making entries in equipment usage and cleaning log sheet.

SOP No.: Cleaning of Production Area.

SOP No.: Status Labeling

8.0 ANNEXURE (S):

Annexure I : Cleaning Checklist

9.0 DISTRIBUTION:

Master Copy :Quality Assurance

Controlled copy (S) :Production Department, Quality Assurance

Reference copy (S) :Production Department



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE I

CLEANING CHECKLIST OF AUTOMATIC CAPSULE FILLING MACHINE (AF-25 T) AND OTHER INLINE MACHINES

Name of the Equipment		Automatic Capsule Filling Machine (AF-25 T)	
Equipment I.D. No.		Previous product	
Batch No.		Date	
S.No.	Activity		Activity Performed
1.	Remove the adhered material on the machine and inline machines with the help of vacuum cleaner and dry lint free cloth.		
2.	Remove the empty capsule hopper sensors, Empty capsule Hopper and base plate. Dismantle capsule reservoir box, magazine, rectifier block, Capsule separation vacuum pipeline and its sieve ring.		
3.	Dismantle S.S cover of blend hopper, Hopper for blend (By unscrewing nuts), Hopper pipe, Driving Stirrer, Powder filling sensor, Acrylic covers of Dosing disc and Scrapper. Also Remove Tamping pins from piston blocks, tamping pin guide plate and wiper plate.		
4.	Remove the powder sensor from dosing disc. Dismantle dosing disc (By unscrewing nuts), Chamber ring and PU pipes. Also remove the blend from the dosing disc in case of powder filling and Remove Pellet filling sensor. Dismantle Pellet assembly (Pellet hopper assembly and pellet dozer) and remove the pellets from the pellet dozer in case of pellet filling.		
5.	Dismantle unopened Capsule collection box, pellet collection box, locking station and its PU pipes. Remove filled capsule exit chute with acrylic guard.		
7.	Remove segment Cleaner, Cap bush and body bush holder and Cap bush and body bush.		
8.	Keep the dismantled parts on SS pallets with covering of fresh polybags and affix the "TO BE CLEANED" label and transfer the same in to the washing area.		
9.	Remove the "TO BE CLEANED" label before start the cleaning activity in the washing area and clean all the above parts with 120- 170 liters of purified water with using jet cleaner and scrub with nylon scrubber.		
10.	Again wash all above parts with 30-50 liters purified water. Finally rinse all these parts with 20-30 liters of purified water.		



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

11.	Dismantle all the parts of sorter elevator (SE-100) like delivery pipe, hopper, acrylic plate, delivery chute, sorting plate etc & put the all dismantled parts in virgin polybag affix with "To Be Cleaned" label & transfer them to respective cleaning area.	
12.	Remove the "TO BE CLEANED" label and clean the dismantled parts of the SE-100 using 40-50 liter of purified water and intermittent rubbing with nylon brush. Again clean all the dismantled parts with 20-25 liters of purified water. Apply a jet of purified water to finally rinse the parts with 10-15 liters so as to ensure the complete removal of the previous product.	
13.	Dismantle all the parts of mini capsule sorter (MCS-100) like sorting plate, spacer and sorting drum and keep on cleaned pallets affixed with "TO BE CLEANED" label and transfer to the washing area. Remove the "TO BE CLEANED" label and clean the dismantled parts of the MCS-100 using 60-80 liter of purified water and intermittent rubbing with nylon brush. Again clean all the dismantled parts with 20-25 liters of purified water. Apply a jet of purified water with 10-15 liters for final rinsing so as to ensure the complete removal of the previous product.	
14.	Dismantle the parts of De-dusting and polishing machine (DP-100) like perforated tube, de-dusting brush, cover of brush and keep on the cleaned pellet affixed with "TO BE CLEANED" label and transfer to the washing area. Remove the "TO BE CLEANED" label and clean the dismantled parts using 80-100 liter of purified water and intermittent rubbing with nylon brush. Again Clean all the dismantled parts with 20-25 liters of purified water. Apply a jet of purified water with 10-15 liters for final rinsing so as to ensure the complete removal of the previous product.	
15.	Dismantle the parts of Empty capsule sorter (ECS-100) hopper, vertical pipe, air diverter and capsule guide pipe and keep on the cleaned pellet affixed with "TO BE CLEANED" label and transfer to the washing area.	
15.	Remove the "TO BE CLEANED" label and clean the dismantled parts of the machine (hopper, vertical pipe, air diverter and capsule guide pipe) using 20-25 liters of purified water and intermittent cleaning with nylon brush. Again clean all the dismantled parts with 10-15 liters of purified water. Apply a jet of purified water with 5-10 liters for final rinsing so as to ensure that the no remnant present of the previous product.	



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

16.	Dismantle the parts of filled capsule elevator (FCE-100) like delivery chute, top pipe and bottom pipe. Keep the all dismantled parts on clean SS pallet, cover it with cleaned polybag and affix the "TO BE CLEANED" label and Transfer the same in washing area. Remove the "TO BE CLEANED" labels in washing area before starting the cleaning activity. Clean the dismantled parts of the machine using 30-40 liters of purified water with intermittent rubbing by using nylon brush. Again clean all the dismantled parts with 20-25 liters of purified water with using jet cleaner. Finally rinse the dismantled parts with 10-15 liters by using jet cleaner.	
17.	Dry all the dismantled parts of machine and other inline machines by using compressed air and dry lint free cloth after cleaning activity.	
18.	Wipe out working platform, toughen glass, body and side cover (Panel) of the machine with lint free duster soaked in purified water and dry with a dry lint free duster. Clean PLC panel, all electric cables and sensors of machine with dry lint free duster. Clean area beneath the machine with duster soaked in purified water and dry with a dry lint free duster.	
19.	Wipe all the dried dismantled parts of the machine and body with 70 % v/v IPA. Keep the cleaned and dried dismantled parts on cleaned SS pallet and Transfer all the dried cleaned parts into Cleaned equipment area/Cleaned respective cubicle in virgin poly bag with duly signed "CLEANED" label.	

Note: Put '√' mark if activity performed and put 'X' if activity not performed.

Checked By (Production)
Sign/Date

Verified By (QA)
Sign/Date



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE II ECS VALIDATION

Procedure:

- 1) Take 20 filled capsules (collected after product setting) and 05 empty capsules (collected from empty capsule hopper).
- 2) Adjust voltage as required and pass 20 filled capsules along with 05 empty capsules.
- 3) Collect the empty capsules and filled capsules from respective bin and reconcile.
- 4) In Row A write the collected capsules quantity at filled collection bin and in Row B write the quantity of capsules in rejection bin.
Note: Put remarks 'ok' when filled capsules collection bin have 20 and in rejection bin 05 empty capsules, if not put 'not ok' in remarks.
- 5) Voltage should be so that empty capsules will be rejected and filled capsules should not be rejected.
- 6) Set the voltage range such that the empty capsules will go to rejection bin.

DATE:		PRODUCT NAME:				BATCH NO.:		
S.No.	SET VOLTAGE	OBSERVATION				DONE BY	CHECKED BY	REMARKS
		NO OF CAPSULES INTRODUCED FOR TEST		CAPSULES RECOVERED AFTER TEST				
		FILLED CAPSULES	EMPTY CAPSULES	NO OF CAPSULES AT FILLED CAPSULE COLLECTION BIN (A)	NO OF CAPSULES AT REJECTION BIN (B)			

Lower Limit Voltage: - _____ Higher Limit Voltage: - _____

Done By (Production): - _____ Verified By (QA): - _____.

- Note:**
- 1) Freeze the limit of ECS voltage for individual product after completion of three batches.
 - 2) Destroy the entire used capsule during ECS challenge and validation test.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

ANNEXURE III CHALLENGE TEST OF ECS

Procedure:

- 1) Take 20 filled capsules (collected after product setting) and 05 empty capsules (collected from empty capsule hopper).
 - 2) Set the voltage as limit obtained from ECS validation and pass 20 filled capsules along with 05 empty capsules.
 - 3) Collect the empty capsules and filled capsules from respective bin and reconcile.
 - 4) Write the collected capsules quantity at filled collection bin in A and quantity in rejection bin in B.
Note: Put remarks 'ok' when filled capsules collection bin have 20 and 05 empty capsules in rejection bin, if not put 'not ok' in remarks.
- Frequency:** Start of operation. Repeat the test 03 times for each operation.
- 5) Voltage should be so that empty capsules will be rejected and filled capsules should not be rejected.
 - 6) In-process for ECS voltage is to be performed after 01 Hours alternately by production and QA.

DATE:		PRODUCT NAME:				BATCH NO.:		
		*Lower Limit Voltage:				*Higher Limit Voltage:		
S.No.	SET VOLTAGE	OBSERVATION				DONE BY	CHECKED BY	REMARKS
		NO OF CAPSULES INTRODUCED FOR TEST		CAPSULES RECOVERED AFTER TEST				
		FILLED CAPSULES	EMPTY CAPSULES	Nos. OF CAPSULES AT FILLED CAPSULE COLLECTION BIN (A)	Nos. OF CAPSULES AT REJECTION BIN (B)			
Start of operation Date: _____		20	5					
Start of operation Date: _____		20	5					
Start of operation Date: _____		20	5					

In-process for Voltage of ECS

Date	Time	Observed Voltage	Checked By	Remarks

- *Note: 1) Limit obtained after 03 validation batches.
2) Destroy the entire used capsule during ECS challenge and validation test.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Automatic forming, Filling and Sealing machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

ANNEXURE IV CAPSULE CHANGE PARTS UTILIZATION RECORD

Change part size: _____

Product Name	Dosing Disk	Tamping Pins	Pellet Dozer	Magazine assembly	Bush assembly	Locking units	Sorting plates (SE-100 & MCS-100)	Sorting Drum	Issued By/Date	Issued for Batch No.		Submitted By/ Date	Received By/ Date	Remarks
										From	To			

Put (√) or (X) for change part selection

Dimensions of the dosing disk shall be mentioned in Remarks column