



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1.0 OBJECTIVE:

To lay down a Procedure for Operation & Cleaning of Automatic Capsule Filling Machine (AF-150 T) & it's Accessories.

2.0 SCOPE:

This SOP is applicable for Operation & Cleaning of Automatic Capsule Filling Machine (AF-150T) used in Hard Gelatin Capsule Section.

3.0 RESPONSIBILITY:

Officer / Executive Production

4.0 ACCOUNTABILITY:

Head Production

5.0 ABBREVIATIONS:

BMR	Batch Manufacturing Record
IPA	Isopropyl Alcohol
Ltd.	Limited
PLC	Programme Logic Controller
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

6.0 PROCEDURE:

6.1 OPERATION:

6.1.1 Ensure that the machine, its accessories & area is clean.

6.1.2 Ensure that the AHU is "ON".

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

6.1.4 Fill the required details on the status board.

6.1.5 Setting of Sorter Elevator:

6.1.5.1 Dismantle of sorting plate:



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.1.5.1.1 Open the four mounting screws.

6.1.5.1.2 Fix the lifting handles in the tapped holes.

6.1.5.1.3 Lift the feeding tray & place it at proper place.

6.1.5.2 Fitting of new sorting plate:

6.1.5.2.1 Place the sorting plate carefully by matching the fixing holes on the feeding tray.

6.1.5.2.2 Clamp the plate with the four mounting screws.

6.1.5.2.3 Select the machine in manual mode by turning the level control knob to manual position.

6.1.5.2.4 Turn isolator knob to “ON” position to “ON” the machine. The green indicator will glow.

6.1.5.2.5 Press the elevator “ON” (green) push button to start the loading cycle. The air blower motor will start first and after a delay of 2 minutes the vibrator motor will start.

6.1.5.2.6 To stop the loading cycle, press the elevator off (red) push button. The vibrator motor should stop first and after a delay of 2 minutes the air blower motor should “OFF”.

6.1.6 Setting of Capsule Locking Pins:

6.1.6.1 Alignment of Individual locking pin is being done manually using a centering gauge to align the pins and tightening with nut/bolt, however the segment/set alignment is done by machine automatically.

6.1.7 Setting of Tamping pins :

6.1.7.1 Set the powder filling device and each of 18 tamping pins one by one for all 6 Piston i.e. 18x6 = 108 Nos.

6.1.7.2 Adjust Fill weight setting though tamping pins by adjusting bolt of the piston.

6.1.8 Operation Sorter Elevator:

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

6.1.8.2 Fill the hopper with empty hard gelatin capsule shells. Set the machine in auto mode by turning the level control knob to auto position.

6.1.8.3 The machine will start.

6.1.8.4 Set the flow of capsules on feeding tray by adjusting the height of gate mounted on hopper.

6.1.8.5 After completion of work switch “OFF” the machine by turning the isolator knob to “OFF” position.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.1.9 Operation of Filling Machine :

6.1.9.1 Change the following parts according to the size of the capsules

ASSEMBLY	PART TO BE CHANGED
Empty capsule loader assembly	Magazine assembly with vertical blades (2 nos.)
	Rectifier block assembly (2 nos.)
	Horizontal blade assembly (2 nos.)
Turret assembly	Cap segment (12 nos.)
	Body segment (12 nos.)
Capsule locking assembly	Locking pins (18 nos.)
Capsule ejection assembly	Ejection guide plate (1 nos.)
Powder filling device	Dosing disc (1 nos.)
	Tamping pins (108 nos.)
*Pellets filling device	Dosing chamber (1 nos.)

* Optional and install when required.

- 6.1.9.2** Ensure that machine is clean.
- 6.1.9.3** Ensure that all safety guards are properly fitted.
- 6.1.9.4** Ensure that the minimum required air pressure is 6 kg/cm².
- 6.1.9.5** Ensure that all the emergency switch is in release condition.
- 6.1.9.6** Ensure that all the accessories are ready and properly connected to the machine.
- 6.1.9.7** Turn the main “ON/OFF” knob to “ON” position, placed at rear panel.
- 6.1.9.8** Turn the control “ON/OFF” knob to the right.
- 6.1.9.9** Set the machine in manual mode. Push in the hand wheel located on the left hand side of the operating panel and turn clockwise to ensure that all parts are moving freely & there is no rubbing.
- 6.1.9.10** Push out the wheel.
- 6.1.9.11** Check the functional keys on PLC, all should be green. If any key is red then check that part/accessory & correct it.
- 6.1.9.12** After conforming that all the functions are OK then press the inch key to operate the machine in inch mode.
- 6.1.9.13** Press the drive on (green) push button to on the machine.
- 6.1.9.14** Control the speed of the machine by rotating the speed control knob.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 6.1.9.15** Collect the sample in sample collection box and check the in process parameters as specified in BPR.
- 6.1.9.16** After approval by QA run the machine and other accessories also i.e. dedusting & polishing machine, mini filled capsule sorter & empty capsule sorter.
- 6.1.9.17** After completion of filling and polishing, sorting simultaneously or end of shift slowly reduce the speed of machine.
- 6.1.9.18** Push the drive “OFF” (red) push button.
- 6.1.9.19** Turn the control “ON/OFF” knob to the left.
- 6.1.9.20** Switch “OFF” the mains.
- 6.1.10 Operation of De-dusting & Polishing Machine:**
- 6.1.10.1** Switch on the mains of the machine by pushing the toggle switch downwards. The main “ON” (red) indicator will glow.
- 6.1.10.2** Then press the push button (red) to start motor. The motor “ON” (green) indicator will glow.
- 6.1.10.3** Slowly rotate the speed control knob clockwise and set it at middle speed.
- 6.1.10.4** Start compressed air supply and set the pressure regulator at 5 kg/cm².
- 6.1.10.5** Start vacuum pump.
- 6.1.10.6** Check the polishing of the capsules. If the quality is not satisfactory then vary the speed of the brush.
- 6.1.10.7** After completion of work slowly reduce the speed of the machine to zero after 3 minutes.
- 6.1.10.8** Stop the motor by pushing the toggle switch upwards.
- 6.1.10.9** Stop the air supply.
- 6.1.10.10** Switch “OFF” the vacuum cleaner after 5 minutes.
- 6.1.11 Operation of Mini Filled Capsule Sorter:**
- 6.1.11.1** Change the Sorter Plate & Drum Sorter as per size of capsules.
- 6.1.11.2** Turn the isolator switch to “ON” position. The green indicator will glow.
- 6.1.11.3** “ON” the vibrator by pushing the red indicator type toggle switch.
- 6.1.11.4** Set the speed of vibrator by turning the knob clockwise.
- 6.1.11.5** Press the green push button to “ON” the drum sorter.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.1.11.6 Start the flow of capsules from de-dusting & polishing machine.

6.1.11.7 Observe the capsule movement in the sorting plate. If the movement is slow and the capsules start clogging, then increase the vibration slowly by turning the regulator knob clockwise.

6.1.11.8 Empty the reservoirs of powder & diametrically defective capsules (inside drum sorter) at regular interval.

6.1.11.9 After completion of work stop the machine following the order:

6.1.11.9.1 Ensure that all the capsules have moved forward to sorter drum.

6.1.11.9.2 Rotate the vibrator control knob fully anticlockwise and switch “OFF” the red indicator type toggle switch.

6.1.11.9.3 Ensure that all the capsules in the drum get sorted.

6.1.11.9.4 Press the red push button to “OFF” the Drum Sorter.

6.1.11.9.5 Turn the isolator switch to “OFF” position.

6.1.12 Operation of Empty Capsule Sorter:

6.1.12.1 Switch “ON” the mains.

6.1.12.2 Turn the dimmer stat clockwise & set 120 for size “2” capsules, 140 for size “1” capsules & 160 for size “0” on voltmeter display.

6.1.12.3 The empty capsules get collected in the reservoir & good capsules get collected in the double polythene placed in SS container.

6.1.12.4 After completion of work turn the dimmer stat fully anticlockwise.

6.1.12.5 Push the toggle switch to “OFF” position to “OFF” the blower.

6.1.12.6 Enter the operation details in “Machine Utilization Record”.

6.1.12.7 Affix the label as “To be cleaned”.

6.1.13 Initial machine setting check points:

6.1.13.1 Manually Set the capsule cap and body segment by using centering gauge.

6.1.13.2 Check the alignment of locking pin using centering gauge.

6.1.13.3 Set the powder filling device and each of 18 tamping pins one by one for all 6 Piston i.e. 18x6 = 108 Nos.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

- 6.1.13.4 Adjust Fill weight setting though tamping pins by adjusting bolt of the piston.
- 6.1.13.5 Once the machine is set run the machine and check capsules for any leakage, damage, denting on capsule's Cap and Body.
- 6.1.13.6 Open the capsule body and cap and check for any damage on body and cap.
- 6.1.13.7 After the machine setting run the capsule machine at manual mode and collect capsules from any two opposite segments and open these capsules and check for any damage of capsules cap and body to ensure proper setting of locking Pins.
- 6.1.13.8 Run the machine at normal speed / optimum speed and collect few capsules i.e. Not less than 30 capsules and open these to check for any damage to cap and body to ensure proper setting of locking Pins every two hours during the filling process or earlier, if machine settings are changed.
- 6.1.13.9 Shake 30 capsules vigorously by holding between the Gloved Palms while keeping the palms hollow, then check the capsule for leakage of powder etc. every 30 min. If require check the capsule by opening and take necessary corrective actions.
- 6.1.14 **Important:**
 - 6.1.14.1 If any problem is observed, inform to engineering department for corrective action.
 - 6.1.14.2 Always use mouthpiece & surgical hand gloves.
 - 6.1.14.3 Containers containing capsules & powder must be closed & must have identity slip.

6.2 CLEANING:

6.2.1 Cleaning of Sorter Elevator:

- 6.2.1.1 Switch "OFF" the machine by turning the isolator switch to "OFF" position.
- 6.2.1.2 Open the lid of the hopper and remove the empty capsule shells & collect in double polythene bag.
- 6.2.1.3 Remove the capsules from sorting plate with the help of forcep.
- 6.2.1.4 Remove the capsules from ventury pipe, discharge tube & delivery chute if any.
- 6.2.1.5 Remove the capsules from collection box.
- 6.2.1.6 Clean the machine using Vacuum Cleaner.
- 6.2.1.7 Wipe the machine with clean lint free cloth and affix the label as "Cleaned"



PHARMA DEVILS

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STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.2.2 Cleaning of Filling, Dedusting & Polishing Machine, Mini Filled Capsule Sorter & Empty Capsule Sorter:

6.2.2.1 For Product Changeover (Type B Cleaning):

- 6.2.2.1.1** Switch 'OFF' the electric supply to the machine & accessories.
- 6.2.2.1.2** Dismantle all Accessories, clean with Vacuum Cleaner & take to washing area by placing in a caret.
- 6.2.2.1.3** Clean the machine platform, doors and other non removable parts with Vacuum Cleaner. Mop with 70 % isopropyl alcohol (prepare by adding 70 ml isopropyl alcohol in 30 ml purified water).
- 6.2.2.1.4** Clean the Accessories with 2% solution of Extran MA-02 using nylon brush.
- 6.2.2.1.5** Wash thoroughly with potable water followed by rinse with purified water.
- 6.2.2.1.6** Wipe the all Accessories with clean lint free cloth.
- 6.2.2.1.7** Finally mop with 70 % isopropyl alcohol.
- 6.2.2.1.8** QA shall collect the swab sample with intimation slip/ analysis report & send to QC for analysis.
- 6.2.2.1.9** Use the machine after receiving swab test intimation slip cum analysis report from QC showing negative identification.
- 6.2.2.1.10** If report shows positive identification.
- 6.2.2.1.11** Enter the cleaning details in "Machine Utilization Record".
- 6.2.2.1.12** Affix a label as "Cleaned" on the machine.

6.2.2.2 For Batch Changeover (Type A Cleaning):

- 6.2.2.2.1** Clean the holder plates & top surface of the table with a brush to remove the powder use vacuum to suck off the powder.
- 6.2.2.2.2** Clean all cap holders & body holders with nylon brush.
- 6.2.2.2.3** Clean the tamping pins with wet cloth & dosing disc by nylon brush.
- 6.2.2.2.4** Remove all the powder form the drug hopper by vacuum.
- 6.2.2.2.5** Clean all the accessories by using Vacuum Cleaner.
- 6.2.2.2.6** Finally clean all the parts with clean dry lint free cloth.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

6.2.2.2.7 Cleaning of vacuum pump & filter:

6.2.2.2.7.1 Loose the screw & open the housing cover.

6.2.2.2.7.2 Remove the powder from the housing and collect in a polythene bag.

6.2.2.2.7.3 Clean the filter with compressed air.

6.2.2.2.8 Cleaning of air displacement unit:

6.2.2.2.8.1 Agitate the filter bag by pressing the knob at the top of the assembly.

6.2.2.2.8.2 Remove the powder from the bag collect in polythene bag and destroy as per SOP “Destruction Procedure of Rejected In-process Materials and In-process Samples”.

6.2.2.2.8.3 Wash the filter bag with purified water and dry with compressed air.

6.2.2.2.9 Cleaning of filter ring of empty capsule sorter:

6.2.2.2.9.1 Remove the sorting device & open the filter ring by losing the screw.

6.2.2.2.9.2 Clean the filter ring using Vacuum Cleaner and reinstall.

6.2.2.2.9.3 Enter the cleaning details in “Machine Utilization Record”.

6.2.2.2.9.4 Affix a label as “Cleaned” on the machine.

6.2.2.3 Frequency of Cleaning: (Type B Cleaning)

6.2.2.3.1 Frequency of cleaning as per step-6.2.2.1

- (a) Product to Product Changeover.
- (b) After 5 batches of the same product or 72 hours from last cleaning operation whichever is earlier, however if 72 hours are completed during the processing then the process shall be completed in the area.
- (c) After any Maintenance of Contact Parts.
- (d) Changeover of one Batch to Next Batch of the same Product with descending potency.
- (e) In case of colour change (any strength).

6.2.2.3.2 Frequency of cleaning as per step-6.2.2.2

- (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.



STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Operation and Cleaning of Automatic Capsule Filling Machine (AF-150 T)	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

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

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

9.0 REFERENCES:

Operating Manual

10.0 REVISION HISTORY:

CHANGE HISTORY LOG