



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

1.0 OBJECTIVE:

To lay down the procedure for Cleaning and Operation of Mono block Filling and Sealing Machine.

2.0 SCOPE:

This procedure is applicable for Cleaning and Operation of Mono block Filling and Sealing Machine in liquid department.

3.0 RESPONSIBILITY:

Technical associate Production - For Execution.

Officer/ Executive Production - For verification and implementation of SOP.

Head Production - Shall ensure compliance of the SOP.

4.0 DEFINITION (S):

NA

5.0 PROCEDURE:

5.1 Cleaning

5.1.1 Check the status "TO BE CLEANED" on equipment with details filled. If next product is the same as previous product, follow batch-to-batch change over procedure. If next product is different from previous product, follow product-to-product change over procedure and follow shift end cleaning procedure at the end of day's work.

5.1.2 Batch-to-Batch change over procedure (TYPE A):

5.1.2.1 Ensure that no empty bottles from the previous batch remain in the machine.

5.1.2.2 Collect the remaining liquid of previous batch from the machine tank by opening the bottom valve and drain it. Close the bottom valve.

5.1.2.3 Collect the remaining liquid of previous batch from the transfer lines by opening the triclover clamps situated at lowest points and drain the liquid by pouring it with sufficient quantity of purified water.

5.1.2.4 Remove the glass pieces of broken bottles if any from the machine platform and wash the machine plate form with sufficient quantity of purified water.

5.1.2.5 Remove all the good and rejected bottles from the area and machine. Carry out the Reconciliation. Destroy the rejected bottles.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

5.1.2.6 Remove all the ROPP cap from the cap hopper, carry out the reconciliation and destroy the caps and mop the cap hopper using wet lint free cloth followed by dry lint free cloth.

5.1.2.7 Clean the ROPP cap sealer carefully with wet lint free cloth followed by dry lint free cloth and applies little food grade oil on it

5.1.2.8 Switch 'ON' the machine and take purified water from the SS pipe line (during recirculation of purified water through holding tank, refer point no. 5.1.2.6 of reference. SOP) and drain this water from machine tank bottom valve, piston at slow speed.

5.1.2.9 Mop the entire machine and S.S. Transfer line with clean lint free cloth.

5.1.2.10 Put the "CLEANED" status label having Unit, Department, Equipment name, Cleaned by, checked by production officer, date and finally certified by Quality Assurance (QA) as per reference SOP.

5.1.3 Shift end cleaning procedure

5.1.3.1 Stop the bottle washing from bottle washing area.

5.1.3.2 Close the Holding tank's bottom valve and disconnect the line by Putting a blank.

5.1.3.3 Switch "OFF" the lube transfer pump from the machine panel.

5.1.3.4 Switch "OFF" the machine from the machine panel and check the volume of the bottle filled in the last rounds. Reject the low volume bottles.

5.1.3.5 Collect the liquid of the batch in closed container from the machine's Tank by opening the bottom valve and transfer it to main holding tank.

5.1.3.6 Collect the liquid of the batch in closed container from the transfer line by opening the triclover clamps situated at lowest points and transfer it to main holding tank.

5.1.3.7 Switch 'ON' the machine and take purified water from the SS transfer line (as per reference SOP) and run the machine at slow speed for 5 minutes.

5.1.3.8 Drain the water completely from machine tank and transfer lines.

5.1.3.9 Mop the entire machine and S.S. Transfer line with clean lint free cloth.

5.1.3.10 Close the machine tank's bottom valve and rejoin the lines opened for drain the water.

5.1.4 Product-to-product change over procedure (TYPE B): This procedure is applicable if there is a change in product, if the next product having descending potency, if same batches have been processed for 7 consecutive days. Equipment is taken for maintenance during processing and maintenance work continues for more than 24 hrs or maintenance work involves any part, which comes in direct contact with product.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

- 5.1.4.1 Cleaning of Bottle Filling and cap sealing Machine.
- 5.1.4.2 Switch 'OFF' the machine from panel and collect remaining liquid of previous batch from machine SS transfer line in a SS container, add sufficient quantity of purified water in it and drain the liquid.
- 5.1.4.3 Remove all the good and rejected bottles from the area and machine. Carry out the Reconciliation. Destroy the rejected bottles. Remove all the ROPP cap from the cap hopper, carry out the reconciliation and destroy the caps and mop the cap hopper using wet lint free cloth followed by dry lint free cloth. Clean the ROPP cap sealer carefully with wet lint free cloth followed by dry lint free cloth and applies little food grade oil on it.
- 5.1.4.4 Switch 'ON' the machine and take purified water in the hopper of the machine through SS transfer line (during recirculation of purified water through holding tank, Reference SOP) and run the
- 5.1.4.5 machine to drain out all the water along with the traces of product.
Dismantle the motor, movable paddle stirrer, star wheel, bottle guide and cap plungers of the machine and take the stirrer, star wheel, bottle guide it to wash area for cleaning with the help of trolley.
- 5.1.4.6 Clean the paddle stirrer and change parts thoroughly with the help of nylon brush and sufficient quantity of purified water. Dry the paddle stirrer and change parts with the help of compressed air and take the change parts to the change parts and primary packing material storage room in trolley and kept them in the designated change parts cupboard in a virgin polybag or shrink wrap them with dully signed cleaned label or kept aside for assemble.
- 5.1.4.7 Fill the hopper of the machine with hot purified water(60°-70°C) through the S.S transfer line (during recirculation of purified water through holding tank, Reference SOP) and drain the water from the machine bottom valve ,Valve No.24 (For Holding Tank- I) and from valve No.30 (For Holding tank –II) at slow speed for 5 minutes.
- 5.1.4.8 Dismantle the piston and nozzle of the machine and dip the piston and nozzles in hot purified water at 60°- 70 °C for 30 minutes and clean them thoroughly with the help of nylon brush and purified water.
- 5.1.4.9 Dry the change parts and If Required apply little food grade oil on piston rod to avoid rusting and store in the change parts cupboard in a clean virgin polybag with cleaned label or kept a side for assemble the parts.
- 5.1.4.10 Clean the machine liquid tank with purified water and rubbing it with lint free cloth till it is visually clean and drain water from bottom valve, again rinse the tank with 10 liter of purified water & Inform the QA to collect swab/rinse water sample if required and drain the water completely from bottom valve.
- 5.1.4.11 Rinse the machine table with purified water and drain out all the water.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

- 5.1.4.12 Remove all the water from machine with compressed air.
- 5.1.4.13 Mop the machine, machine change gaurd and ss batch transfer line with wet lint free cloth followed by dry lint free cloth.
- 5.1.4.14 Check that all the surfaces of the parts of mono block filling and sealing Machine are visually clean and dry.
- 5.1.4.15 Reassemble all accessories and parts dismantled for the cleaning purpose as per the required bottle size.
- 5.1.4.16 Assemble the stirrer with the motor and place the paddle stirrer in machine buffer tank.
- 5.1.4.17 Put 'CLEANED' status label having Unit, Department, Equipment name, Cleaned by, Checked by Production Officer, Date and finally certified by Quality Assurance (QA) as per reference SOP.

5.2 Machine set up and operation

5.2.1 Filling machine

The machine consists of the following parts.

- ◆ Synchronized bottle feeder.
- ◆ Slat conveyor belt.
- ◆ Bottle actuating device.
- ◆ Bottle star plate for feeding and discharging.
- ◆ Eight numbers of filling heads.
- ◆ 'No bottles no fill' liquid level sensor.
- ◆ Movable paddle blade stirrer.
- ◆ Variable speed pulley drives arrangement.

5.2.2 Sealing machine

5.2.2.1 The Sealing unit consist of the following parts:

- Eight Numbers of sealing head
- Center star plate and bottle guide.
- Bottle discharge star plate and bottle guide.
- Sealing head height adjustment assembly.
- Cap feeder with chute.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production

SOP No.:

Title: Cleaning and Operation of Mono block Filling and Sealing machine

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

5.2.3 Panel board and PLC –description

5.2.3.1 0 ▼ : On each press

1 . Main bottle / minute.

2. idle, cycle

3. wash cycle- No

Enter- Yes

4. No bottle/No cap-Not applicable.

5. Cycle –auto mode.

Cycle-Manual.

F1 : Help.

F2 : Reset Counter.

F3 : Reset fault.

F4 : Time setting.

ESC : Exit.



PHARMA DEVILS

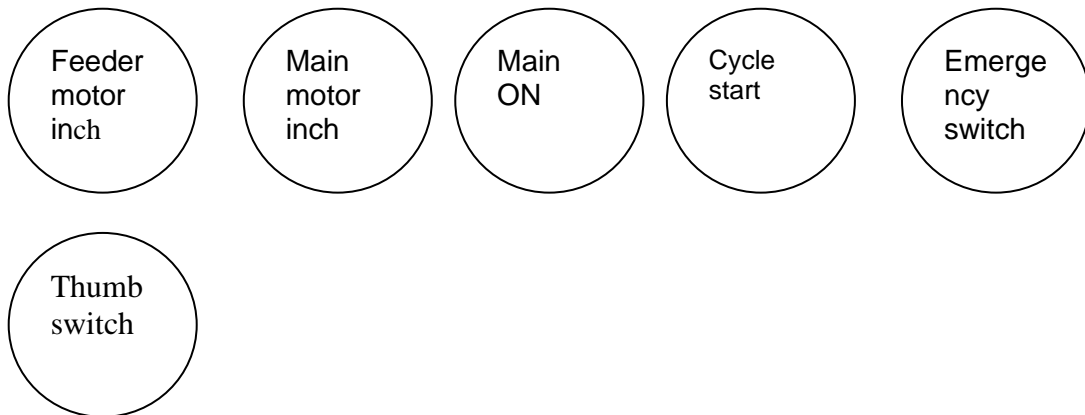
PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

5.2.3.2

PLC PROGRAMME				7	8	9
DIGIPACK VR-120 COUNT-				4	▲ 5	6
				◀1	2	3 ▶
F1	F2	F3	F4	ESC	0 ▼	ENT



5.2.3.3 Connect the Panel Board and PLC with main plug.

5.2.3.4 Switch ON the Main.

5.2.3.5 Indication lamp should glow and on the PLC screen DIGIPACK VR-120 should be displayed.

5.2.3.6 On pressing the **cycle start push button** Green lamp should glow in push button and conveyer should start first and then main motor should run after a predetermined time.

5.2.3.7 On pressing the **main motor Inch push button** only the main motor should start at low predetermined speed until the push button is been pressed. As the Inch push button is released main motor should stop.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

5.2.3.8 On pressing **Emergency stop push button** complete operation of the machine should stop. Red indication lamp should blink and 'Emergency On' message should appear on screen.

5.2.3.9 **Thumb wheel switch**

5.2.3.10 Based on the bottle dimensions and filling output required the main motor speed and the corresponding synchronized conveyer speed can be set and memorized on respective VFD. These speed can easily be selected with the help of the thumb wheel switch mounted on panel.

5.2.3.11 For example select 1-1 on thumb wheel switch which corresponds to a particular bottle size. The motor and conveyer belt should run at the set synchronized speed for this bottle size. 0-0 idle condition.

5.2.3.12 **PLC pass word** - after entering correct password status of timer should appear on screen 'Wrong password' message should appear incase entering incorrect Password.

5.2.3.13 **On pressing and opening safety doors of cabinet**

5.2.3.14 Machine should stop after opening any door of the cabinet and emergency on indicator lamp should glow. Emergency on indication on screen.

5.2.3.15 **Rear control panel**

5.2.3.16 On pressing 'UP' push button, height adjustment motor starts running and complete sealing head assembly should move Up. This is used for setting different heights of the bottles.

5.2.3.17 On pressing 'DOWN' push button, height adjustment motor starts running and complete sealing head assembly should move down. This is used for setting different heights of the bottles.

5.2.3.18 On pressing 'INCH' push button, the main motor starts and machine rotates at a pre-determined speed until the inch push button is been pressed. As the button is released, main motor should stop. This is used when set the machine for different bottle sizes.

5.2.3.19 **Direction of rotation** – Machine should rotate clock wise direction and bottle movement should be from left to right direction.

5.2.3.20 **No bottle- No fill** – when machine is running normal the bottle present sensor senses the S. S sleeve of each nozzle. And rocker arm slide forward to open the filling valve to fill the bottle . In case of no bottle for filling below filling nozzle, bottle absent sensor will sense S.S sleeve and will retract rocker arm and filling valve will kept closed.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

5.2.3.21 The following different message signals should be displayed on screen for stoppage of machines during operation.

- ◆ ‘Emergency ON’- if emergency push button is pressed , or cabinet door
- ◆ safety switch open.
- ◆ ‘Cap hopper empty’- if there is no cap in hopper or in front of sensor.
- ◆ ‘Liquid tank empty’ – if there is no liquid in tank.
- ◆ ‘Machine jammed’ – if bottle present and absent sensor are tripped at a time.

5.2.4 Machine Set Up

5.2.4.1 Ensure that Bottle filling and sealing Machine is cleaned.

5.2.4.2 Fix change parts if required as per bottle size.

5.2.4.4 Machine set up with Holding Tank – I :-

5.2.4.4.1 Attach the transfer line to holding tank – I through lube pump.

5.2.4.4.2 Attach the HT-1A end to the A end of transfer line of filling, Sealing machine and HT-1B end to B end of transfer line of the filling, sealing machine through SS Pipeline.

5.2.4.5 Machine set up with Holding Tank – II :-

5.2.4.5.1 Attach the transfer line to holding tank – II through lobe pump.

5.2.4.5.2 Attach the HT-2A end to the A end of transfer line of filling, Sealing machine and HT-2B end to B end of transfer line of the filling, sealing machine through SS Pipeline.

5.2.4.6 Ensure that SS Transfer line is clean and dry. Do this by opening the triclover Clamps situated at lower level in the line.

5.2.4.7 Open the drain valve of liquid tank to ensure it is dry and close it.

5.2.4.8 After line clearance from Q. A. put “UNDER PROCESS” label on the machine.

5.2.5 Operation

5.2.5.1 Open the air valve and check that it is not less than 5 Kg/cm².

5.2.5.2 Connect the Lube pump with panel.

5.2.5.3 Connect the PLC with main plug, Switch ON the PLC.

5.2.5.4 First Start the conveyor belt.

5.2.5.5 After 5 seconds start the machine.

5.2.5.6 Start cap-feeding Machine for the continuous feeding of Caps.

5.2.5.7 Start providing the washed bottles to filling machine conveyor from bottle washing area.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

- 5.2.5.8 Set the guide rails as per the bottle so that the neck of the bottle moves below the nozzles freely and with minimum clearance.
- 5.2.5.9 Set the nozzles at the center of the respective bottles.
- 5.2.5.10 Set the diving stroke and position such that the top position is about 20 to 40 mm above bottleneck and lower position depending on the frothing characteristics of the liquid. The diving stroke can be adjusted with the help of the wheel provided at the front, below the conveyor.
- 5.2.5.11 Adjust the 'NO' bottle sensor.
- 5.2.5.12 Transfer the liquid to be filled in the S.S feeding tank through SS pipe lines from storage tank.
- 5.2.5.13 Start the movable paddle blade stirrer from the switch provided on machine. The movable stirrer should be start for suspension product only. Set the stirrer frequency / RPM (10 frequency \approx 192 RPM) through VFD.
- 5.2.5.14 Set the filling rate of the machine from the main panel of the machine.
- 5.2.5.15 Adjust the volume of the liquid filled per stroke. For this Loosen the Ram Shaft nut and turn the adjustment screw clockwise to increase the volume and anticlockwise to decrease the volume. Tighten the Ram Shaft nut and never start the machine when ram shaft nut is loose.
- 5.2.5.16 Check the volume of all the eight nozzles with calibrated volumetric cylinder. The frequency of checking the volume should be as per the respective Batch Production Record.
- 5.2.5.17 Screw tight the bottles having less/More volume than the set range of volume and keep such bottles in the recovery tray.
- 5.2.5.18 After filling the bottles moves to sealing machine through center star wheel.
- 5.2.5.19 The sealed bottle unload through second star wheel to conveyor belt.
- 5.2.5.20 If the machine is stopped during the shift for lunch break, then leave no bottle on the conveyor belt.

5.2.6 Shut Down

- 5.2.6.1 Ensure that all the filled bottles have been capped and there is no bottle remaining on the conveyor.
- 5.2.6.2 Ensure that there is no liquid remaining in the feed tank.
- 5.2.6.3 Switch OFF the main electric supply to the machine.



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

5.2.6.4 Affix "TO BE CLEANED" label on the machine as per reference SOP.

5.3 NOTE

5.3.1 Ensure adequate oil level by reduction gearbox.

5.3.2 Ensure air pressure in the unit is not less than **5 Kg/cm²**.

5.3.3 Lubricate daily all moving parts with food grade oil when product is coming in contact and grease for closed parts.

5.3.4 Never start the machine in reverse direction.

5.3.5 Do not drop oil on torque limitation clutch or on the vary belt.

5.3.6 The speed of machine can be varied.

5.3.7 No bottle no filling arrangement is provided to avoid spillage of liquid.

5.3.8 Direction of movement of movable paddle blade stirrer is anticlockwise direction with respect to Machine movement.

6.0 ABBREVIATION (S):

SOP : Standard operating procedure.

No. : Number

PLC: Programmable logic controller.

ROPP: Roll on Pilfer Proof.

VFD : Variable frequency Drive.

RPM : Revolution per minute.

7.0 REFERENCE(S):

SOP No.: Status labeling.

SOP No.: Cleaning and operation of 3000 ltrs holding tank.

SOP No.: Cleaning and operation of Lube transfer pump.

8.0 ANNEXURE (S):

ANNEXURE I - Cleaning checklist of Monoblock filling and sealing machine.

9.0 DISTRIBUTION:

9.1 **Master copy** : Quality Assurance

9.2 **Controlled copy (s)** : Production department, Quality Assurance

9.3 **Reference copy (s)** : Production department



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

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

ANNEXURE I

CLEANING CHECKLIST OF MONOBLOCK FILLING AND SEALING MACHINE

Name of the Equipment: Mono block filling and sealing machine. **Equipment ID. :**

Previous product: **Date:**

Batch No.

S.No.	Activity	Activity Performed
1.	Remove all the good and rejected bottles from the area and machine. Carry out the reconciliation. Destroy the rejected bottles. Remove all the ROPP cap from the hopper, carry out the reconciliation and destroy the caps and mop the cap hopper using wet lint free cloth followed by dry lint free cloth clean the hopper carefully.	
2.	Switch 'ON' the machine and take purified water in the hopper of the machine through SS transfer line and run the machine to drain out all the water along with traces of the product.	
3.	Dismantle the motor, movable paddle stirrer, star wheels, bottle guide and cap plungers of the machine and take the stirrer, star wheels, bottle guide it to the wash area for cleaning with the help of trolley. Clean the change parts thoroughly with the help of nylon brush and sufficient quantity of purified water. Dry the change parts with the help of compressed air.	
4.	Fill the hopper of the machine with hot purified water through the S.S transfer pipe and drain the water from the machine bottom valve, valve No.24 (for holding tank-I) and valve No. 30 (for holding tank-II) at slow speed for 5 minutes.	
5.	Dismantle the piston and nozzles of the machine and dip the piston and nozzles in hot purified water at 60°- 70 °C for 30 minutes and clean them thoroughly with the help of nylon brush and purified water.	
6.	Dry the change parts and apply little food grade oil on piston rod to avoid rusting .	
7.	Clean the machine liquid tank with purified water and rubbing it with lint free cloth till it is visually clean and drain water from bottom valve.	
8.	Remove all the water from machine with compressed air.	
9.	Mop the machine guard and, S.S transfer line with lint free cloth.	
10.	Check that all the surfaces of the parts of Mono block filling and sealing Machine are visually clean and dry.	

Checked By (Production)
Sign/Date

Verified By(QA)
Sign/Date

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