



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

|   |                        |
|---|------------------------|
| <b>Department:</b> Production                                       | <b>SOP No.:</b>        |
| <b>Title:</b> Cleaning and Operation of Filling and Sealing Machine | <b>Effective Date:</b> |
| <b>Supersedes:</b> Nil  | <b>Review Date:</b>    |
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**Vernacular SOP:** No

### 1.0 OBJECTIVE:

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

### 2.0 SCOPE:

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

### 3.0 RESPONSIBILITY:

3.1 Technical associate Production - For Execution.

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

3.3 Head Production - Shall ensure compliance of the SOP.

### 4.0 DEFINITION (S):

4.1 NA

### 5.0 PROCEDURE:

#### 5.1 Cleaning

5.1.1 Check the status "UNDER CLEANING" on equipment with details filled. If next product is the same as previous product or have ascending potency of identical active pharmaceutical ingredient, follow batch-to-batch change over procedure. If next product is different from previous product, follow product-to-product change over procedure, If same bulk is to be packed in different packing batch then Follow batch change over from the single bulk and follow shift end cleaning procedure at the end of day's work for which next shift or day is not working and product is pending for filling..

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

5.1.2.1 Remove the glass pieces/ Cap/ bottles (if any) from the machine and its platform and ensure that there is no material remain in the machine which may interfere in cleaning of the machine. Carry out the reconciliation of the packing material and reject the rejected packing material.



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- 5.1.2.2 Connect the flexible drain pipe to the bottom drain of the machine's platform and drain the remaining liquid of the product from the buffer tank. Close the bottom valve of the buffer tank after complete removal of the liquid from the tank.
- 5.1.2.3 Collect the remaining liquid of previous batch/product from the transfer lines by opening the triclover clamps situated at lowest points and drain the liquid into the drain of the wash area followed by the purified water.
- 5.1.2.4 Connect Pipe to the purified water supply pipe line and wash the machine platform, change part & conveyor belt with sufficient quantity of purified water by opening the valve of purified water supply.
- 5.1.2.5 Close the water supply and place the pipe aside, allow to drain the water from the machine. LOGIN in the PLC to the USER 3 and select Operation and then select the CIP on the screen.
- 5.1.2.6 The screen shows as –
- 5.1.2.7 Set the machine speed to 50 bottle / min and start the cleaning by toughing "CIP START" option and run the CIP system for 10 min. After completion of cleaning process select "CIP STOP" to stop the process.
- NOTE:** The purified water comes from the SS pipe line (during re circulation of purified water through holding tank, refer reference. SOP) and drain this water from machine buffer tank bottom valve also by opening and closing the valve for proper cleaning.
- 5.1.2.8 Dis-mental the flexible pipe (product level pipe of buffer tank) and clean it in the wash area and reassemble. Clean the nozzles of flexible pipe with the help of purified water. Allow to drain the water from the buffer tank from the bottom valve.
- 5.1.2.9 Switch OFF the machine through panel and completely drain the water from the buffer tank through bottom valve and close the valve after complete drainage.
- 5.1.2.10 Dry the entire machine with the help of compressed air.
- 5.1.2.11 Disconnect the flexible drain pipe to the bottom drain of the machine's platform and transfer it to the wash area for cleaning.
- 5.1.2.12 Mop the cap hopper using wet lint free cloth followed by dry lint free cloth.
- 5.1.2.13 Clean the ROPP cap sealer / Screw cap sealer carefully with wet lint free cloth followed by dry lint free cloth and applies little food grade oil on it
- 5.1.2.14 Mop the entire machine and S.S. Transfer line with clean lint free cloth.



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5.1.2.15 Put the “CLEANED” status label duly signed by production officer with date and finally checked 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 Check the volume of the bottle filled in the last rounds. Reject the low volume bottles.

5.1.3.5 Stop the machine from the PLC.

5.1.3.6 Collect the liquid of the batch in container from the machine’s Tank (By attaching flexible pipe to the valve of buffer tank) by opening the bottom valve and from the transfer line by opening the triclover clamps situated at lowest points and transfer it to main holding tank.

5.1.3.7 Remove the glass pieces/ Cap/ bottles ( if any ) from the machine and its platform and ensure that there is no material remain in the machine which may interfere in cleaning of the machine & Switch ‘ON’ the machine and take purified water from the SS transfer line ( as per reference SOP). Connect the flexible drain pipe to the bottom drain of the machine’s platform. (The cap of chute and hopper shall be packed in virgin poly bag for use in the batch in designated area.)

5.1.3.8 Follow step no. 5.1.2.4 to 5.1.2.14 for cleaning of the machine.

**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.

5.1.4.1 Follow step No. 5.1.2.1 to 5.1.2.8 of Type ‘A’ cleaning.

5.1.4.2 Dismantle the movable stirrer, star wheel, bottle guide of the machine and take them to wash area for cleaning with the help of trolley. Clean the stirrer and change parts thoroughly with the help of nylon brush and sufficient quantity of purified water. Dry them with the help of compressed air and lint free duster and take them to the change parts and primary packing material storage room with the help of trolley and kept them in the designated change parts cupboard in a virgin poly-bag or shrink wrap them with dully signed cleaned label or kept aside for assemble (If required).



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- 5.1.4.3 Clean the machine liquid tank by rubbing it with lint free cloth till it is visually clean and fill the hopper of the machine with hot purified water through the S.S transfer line (during re circulation of purified water through holding tank, Reference SOP no.). Drain the water from the machine bottom valve, Valve No.24 (For Holding Tank- I) and from valve No.30 (For Holding tank –II) .
- 5.1.4.4 Dismantle the spool, valve body, piston and nozzle of the machine and dip them in hot purified water for 30 minutes and clean them thoroughly with the help of nylon brush and purified water and dry it with lint free duster and kept it in change parts and primary packing material storage room with the help of trolley and kept them in the designated change parts cupboard in a virgin poly-bag or shrink wrap them with dully signed cleaned label or kept aside for assemble (If Required).
- 5.1.4.5 Dismantle the cap plungers from the machine (If next batch having different cap sealing ) and clean the cap sealer with wet lint free cloth followed by dry lint free cloth and apply little food grade oil on it and kept it in change part cup board.
- 5.1.4.6 Rinse the tank with 10 liters of purified water by opening the tank cover & Inform the QA to collect swab/rinse water sample (if required) and drain the water completely from bottom valve.
- 5.1.4.7 Clean the Cap Chute and head with compressed air. If required to change the cap chute and head then dismantle it and assemble other cap Chute and head as per requirement.
- 5.1.4.8 Rinse the machine table with purified water and drain out all the water.
- 5.1.4.9 Remove all the water from machine with compressed air.
- 5.1.4.10 Disconnect the flexible drain pipe to the bottom drain of the machine's platform and transfer it to the wash area for cleaning.
- 5.1.4.11 Mop the machine, machine guard and S.S. batch transfer line with wet lint free cloth followed by dry lint free cloth.
- 5.1.4.12 Check that all the surfaces of the parts of filling and sealing Machine are visually clean and dry.
- 5.1.4.13 Reassemble all accessories and parts dismantled for the cleaning purpose as per the required bottle size. If stored piston is to be assembled to the machine then clean them with the help of hot purified water before assemble on the machine.
- 5.1.4.14 Assemble the stirrer with the motor and place the stirrer in machine buffer tank.



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5.1.4.15 Put the “CLEANED” status label duly signed by production officer with date and finally checked by Quality Assurance (QA) as per reference SOP.

**5.1.5 Batch change over from the single bulk:** This procedure is applicable if there is a change in packing batch from a single Bulk.

5.1.5.1 Remove the glass pieces/ Cap/ bottles (if any) from the machine and its platform and ensure that there is no material remains in the machine which may interfere in cleaning of the machine. Carry out the reconciliation of the packing material and reject the rejected packing material.

5.1.5.2 Connect the flexible drain pipe to the bottom drain of the machine’s platform and connect Pipe to the purified water supply pipe line and wash the machine platform, change part & conveyor belt with sufficient quantity of purified water by opening the valve of purified water supply. Close the water supply and place the pipe aside, allow draining the water from the machine.

5.1.5.3 Dry the entire machine with the help of compressed air and dismantle the change part of the machine which is not used for next part of the batch. Transfer them in the wash area for cleaning and kept them in designated place.

5.1.5.4 Disconnect the flexible drain pipe to the bottom drain of the machine’s platform and transfer it to the wash area for cleaning.

5.1.5.5 Put the “CLEANED” status label duly signed by production officer with date and finally checked 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.

- ◆ Bottle Warm shaft.
- ◆ Bottle count sensor.
- ◆ Slat conveyor belt.
- ◆ Bottle star plate and guide for feeding.
- ◆ Eight numbers of filling heads.
- ◆ ‘No bottles no fill’ liquid sensor.
- ◆ Movable stirrer.
- ◆ Bottle tilt sensor.



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### 5.2.2 Sealing machine

5.2.2.1 The Sealing unit consist of the following parts:

- Eight Numbers of sealing head (ROPP Cap sealer)
- Eight Numbers of sealing head (Screw Cap sealer)
- VFD to regulate the vibration of cap hopper.
- Center star plate and bottle guide.
- Bottle discharge star plate and bottle guide.
- Sealing head height adjustment assembly.
- Vibratory Cap feeder assembly with feeder chute.



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- 5.2.3** After line clearance from Q. A. put “UNDER PROCESS” label on the machine.  
Switch ‘ON’ the machine through panel board. The PLC of the machine will automatically on and screen will show :
- Press login on PLC screen, the screen shows login user and password. On touching the option user, the screen shows 4 different user ID.
- 5.2.3.1** (i) Administrator- This user id is for internal setting.  
(ii) User 1 - This user id is use by Technicians for machine setting.  
(iii) User 2 - This user id is use by Technicians to run the machine with selected process.  
(iv) User 3 - This user id is use by Officer for complete of setting.
- The id’s are protected with password. For password refer reference SOP.  
In user id 1 only machine MANUAL mode is active.  
In user id 2 machine will be run on auto and manual mode with selected operations.  
In user id 3 machine whole setting will be done.  
Select user 3 on Login and type password. The screen will show:  
Select SETTING, the screen will show :



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- 5.2.3.7.1 **Bottle Jam time:** Machine stop time when bottle is jammed on machine.  
**Bottle tilt time:** Machine (delay) when bottle is tilt on conveyor.  
**Low level alarm delay:** Machine stop time when liquid level on buffer tank of machine is low.  
**High level alarm delay:** Machine stop time when liquid level on buffer tank of machine is high.  
**Liquid SOV/Pump On delay:** Machine stop time when liquid is not flow through pump or solenoid valve.  
**Cap sensor OFF Delay:** Machine stop time when cap is absent on bottle.  
**No bottle M/C stop delay:** Machine stop time when No bottle on machine.  
**No Cap chute alarm delay:** Machine stop time when no cap on cap chute.  
**Machine set speed:** Machine speed.  
Set the desired delay time required to stop the machine on activating the sensor of the machine.
- 5.2.3.8 Select Home on PLC screen , then select PLC I/O, the screen shows the different Inputs and outputs of Machine





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On PLC screen ALARMS option is provided, select ALARM the screen shows :

5.2.3.9

The alarm will show on the PLC screen when any error is observed on machine with buzzer.



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5.2.3.9.1 Following different alarm signals display on PLC for any error observed on machine :

- Emergency ON- If emergency button is pressed
- Safety door open.
- Cap hopper empty.
- Low level in tank.
- High level in tank.
- Bottle tilt.
- Bottle jam.

Select HOME, Logout from current user and Select user 1 on Login. Select

**5.2.4** OPERATION , the screen shows:



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- 5.2.4.1 Machine manual mode is active : Take the change parts as per required bottle size and set the change parts piston , nozzle , warm shaft, Inlet and discharge star wheel and inlet and discharge guide on machine. Set the machine by selecting the switch towards inch mode and green button to move the machine forward.  
Check the air valve it should NLT4 Kg/cm<sup>2</sup>. Set the speed of the machine on PLC for
- 5.2.4.2. setting of machine. Set the machine as per requirement.  
Start providing the washed bottles to filling machine conveyor from bottle washing
- 5.2.4.3 area.  
Set the guide rails as per the bottle so that the neck of the bottle moves below the nozzles
- 5.2.4.4 freely and with minimum clearance.  
Adjust the 'NO' bottle sensor. set the nozzles at the center of the respective bottles.
- 5.2.4.5 Check the no bottle no fill sensor, when machine is running normal the bottle present sensor senses the S.S sleeve of each nozzle and piston slide forward to open the filling
- 5.2.4.6 valve to fill the bottle .In case no bottle for filling the bottle sensor senses the sleeve and will retract piston and filling valve will kept close.  
Set the Cap hopper with cup bridge as per requirement of batch ( Set Hopper bridge for ROPP CAP / HDPE CAP as per requirement )
- 5.2.4.7 Set the cap chute and head as per requirement of batch ( 25mm or 28mm cap chute)  
Set the cap plunger (ROPP CAP or HDPE CAP) as per requirement (ROPP Cap plunger with 25 mm die or 28 mm die) or HDPE Cap plunger with Jaw as per
- 5.2.4.8 requirement.



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5.2.4.10 Set the height of the sealing head as per bottle size. Sealing head height adjustment is provided on machine, kept the bottle with cap on the platform and adjust with the two push buttons inside the cabinet of machine. Blue colour push button for upward movement of sealing head assembly and yellow colour button for downward movement of sealing head assembly. The upward and down ward movement of sealing head to be done only on inch mode of machine.

### 5.2.4.3 **Machine set up with Holding Tank – I:**

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

5.2.4.3.2 Attach the HT-1A end to the transfer line of filling & Sealing machine and HT-1B end to the re circulation pipe line from solenoid valve of filling & sealing machine.

### **Machine set up with Holding Tank – II:**

**5.2.4.4** Attach the transfer line to holding tank – II through lube pump.

5.2.4.4.1 Attach the HT-2A end to the transfer line of filling & Sealing machine and HT-2B end

5.2.4.4.2 to the re circulation pipe line from solenoid valve of filling & sealing machine.

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

On PLC screen there are option provided CAP CLEANING and STIRRER MOTOR.

5.2.4.5 During setting of machine on Manual mode check the cap cleaning (on selecting this

5.2.4.6 on PLC, air is come out through nozzle provided for cap cleaning and there is vacuum pipe is provided after air nozzle for suction of any particle from the cap) and check the stirrer rotation by selecting STIRRER MOTOR (If Required).

After complete setting of machine logout from current user. Then select user 3. Select machine Auto. Count reset the total production count to '0' before start of filling process. Set the speed of the machine through PLC. The screen shows :

### **5.2.5 Operation**

5.2.5.1 Log out from User 3 and Login User 2. Select Operation.

5.2.5.2 Start the machine through PLC by selecting Machine auto. The speed of the machine will show on the scale on PLC screen after 1 minute of start of machine.

5.2.5.3 Start the vibrator cap hopper from the ON/OFF button situated on the panel of the vibrator cap hopper and adjust the vibration through VOL+ or VOL- button. (Switch on or off the hopper as per requirement)



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- 5.2.5.4 Transfer the liquid to be filled in the S.S feeding tank through SS pipe lines from storage tank.
- 5.2.5.5 Start the stirrer by selecting stirrer motor on buffer tank from the PLC only for suspension product.
- 5.2.5.6 Adjust the volume of the liquid filled per bottle. For this Raising up the cam track to clockwise to increase the volume and anticlockwise to decrease the volume.
- 5.2.5.7 Check the volume of all the eight nozzles with class "A" volumetric cylinder. The frequency of checking the volume should be as per the respective Batch Production Record.
- 5.2.5.8 Adjust the lock nut over the piston for fine setting of volume in individual head.
- 5.2.5.9 After filling the bottles moves to sealing machine through center star wheel.
- 5.2.5.10 The sealed bottle unload through discharge star wheel to conveyor belt.
- 5.2.5.11 If the machine is stopped during the shift for lunch break, then leave no bottle on the conveyor belt.
- 5.2.5.12 After completion of batch affix "UNDER CLEANING" label on the machine as per reference SOP.

### 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.

### 5.3 NOTE

- 5.3.1 Lubricate the machine through pump (provided on left bottom side of machine) before start of batch.
- 5.3.2 Direction of movement of machine is clockwise direction and bottle movement should be from left to right direction.
- 5.3.3 Direction of movement of movable stirrer is anticlockwise direction with respect to Machine movement.
- 5.3.4 If Both the holding tank is filled with product and hot purified water required for cleaning of parts of filling machine then take the hot purified water from the manufacturing area through bulk transfer line.



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5.3.5 Do not run the machine in reverse direction.

5.3.6 Remove the SS cover of lubricating pipe line and lower cover of conveyor belt (During every Type B cleaning) on machine platform and clean with purified water and compressed air and refit after cleaning during every Type B cleaning.

### 6.0 ABBREVIATION (S):

6.1 SOP: Standard operating procedure.

6.2 No.: Number

6.3 PLC: Programmable logic controller.

6.4 ROPP: Roll on Pilfer Proof.

6.5 VFD: Variable frequency Drive.

6.6 RPM: Revolution per minute.

6.7 HDPE: High Density poly ethylene.

### 7.0 REFERENCE(S):

7.1 SOP No.: Status labeling.

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

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

### 8.0 ANNEXURE (S):

| Annexure no. | Title of Annexure                                  | Format no. | Mode of Execution |
|--------------|--|------------|-------------------|
| Annexure I   | Cleaning checklist of filling and sealing machine. |            | Log Book          |

### 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

### 10.0 REVISION HISTORY:

| S. No. | Version No. | Change Control No. | Reason (s) for Revision | Details of revision | Effective Date |
|--------|-------------|--------------------|-------------------------|---------------------|----------------|
|        |             |                    |                         |                     |                |



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### ANNEXURE I

#### CLEANING CHECKLIST OF FILLING AND SEALING MACHINE

**Name of the Equipment:** Filling and sealing machine.

**Equipment ID.:**

**Previous product:**

**Batch No.**

**Date:**

| S.No. | Activity  | Activity Performed |
|-------|---|--------------------|
| 1.    | Wash the machine platform, change part & conveyor belt with sufficient quantity of purified water.  |                    |
| 2.    | Start the cleaning by CIP option and run the CIP system for 10 min.   |                    |
| 3.    | Dismantle the flexible pipe (product level pipe of buffer tank) and clean it in the wash area and reassemble. Clean the nozzles of flexible pipe with the help of purified water. Allow to drain the water from the buffer tank from the bottom valve.  |                    |
| 4.    | Dismantle the movable stirrer, star wheel, bottle guide of the machine and take them to wash area for cleaning with the help of trolley. Clean the stirrer and change parts thoroughly with the help of nylon brush and sufficient quantity of purified water.  |                    |
| 5.    | Dismantle the spool, valve body, piston and nozzle of the machine and dip them in hot purified water for 30 minutes and clean them thoroughly with the help of nylon brush and purified water and dry it with lint free duster and kept it in change parts and primary packing material storage room. |                    |
| 6.    | Clean the machine liquid tank by rubbing it with lint free cloth till it is visually clean and fill the hopper of the machine with hot purified water through the S.S transfer line (during re circulation of purified water through holding tank) and drain the water from the machine bottom valve. |                    |
| 7.    | Remove all the water from machine with compressed air.  |                    |
| 8.    | Mop the machine, machine guard and S.S. batch transfer line with wet lint free cloth followed by dry lint free cloth.   |                    |
| 9.    | Check that all the surfaces of the parts of 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