



## STANDARD OPERATING PROCEDURE

**Title:** Procedure for Operation and Cleaning of Liquid Filling Machine with Filling Reservoir

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 6

### 1.0 OBJECTIVE:

To lay down procedure for Operation and Cleaning of Liquid Filling Machine with filling reservoir.

### 2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of Liquid Filling Machine with filling reservoir.

### 3.0 RESPONSIBILITY:

Officer / Executive- Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

BPCR	Batch Processing Control Record
Ltd.	Limited
PL	Production Liquid
Pvt.	Private
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

#### 6.1 OPERATION :

- 6.1.1 Ensure that the liquid filling machine and its surrounding area is clean.
- 6.1.2 Ensure the nozzles are attached with reservoir through food grade silicon tube.
- 6.1.3 Set the nozzles in the machine and adjust the height as per size of bottle.
- 6.1.4 Fill the reservoir with liquid.
- 6.1.5 'ON' the machine by rotating the main key to 'ON' position from side panel.
- 6.1.6 'ON' the conveyer by pressing conveyer 'ON' switch.
- 6.1.7 'ON' the filling machine by pressing 'ON' switch.
- 6.1.8 Set the fill volume by adjusting the knob as per desired volume mentioned in BPCR.
- 6.1.9 Check the fill volume from the individual nozzle with the help measuring cylinder, It should be within limit as defined in BPCR.
- 6.1.10 Run the machine only after approval by QA.
- 6.1.11 Use mouthpiece and hand gloves during filling of bottles.



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6.1.12 Machine must bear status label during processing. After completion of filling clean the Machine.

6.1.13 Maintain the operation record in Equipment usage log book.

### 6.2 CLEANING :

#### 6.2.1 Batch to Batch Change Over / Shift End Cleaning (A Type Cleaning):

6.2.1.1 After completion of batch remove the inprocess label and affix “ to be cleaned” label Remove all residue of previous product

6.2.1.2 Clean the reservoir with purified water and again fill it with purified water pass the purified water through nozzles by running the machine for approx. 5 minutes.

6.2.1.3 Clean the external surface and conveyer with purified water using wet lint free cloth followed by dry lint free cloth and dry with Compressed Air.

6.2.1.4 A type cleaning shall be valid for 24 hrs for using the silicon tube, If not used within 24 hrs than it should be cleaned as per B type cleaning procedure before further use.

6.2.1.5 Affixed “CLEANED” STATUS label to the machine.

6.2.1.6 Record the cleaning activity in equipment log.

#### **A-Type cleaning is to done for:**

-Batch to batch changeover of same product/same color.

-Change over to from lower strength to higher strength.

*Note: In case the reservoir tank is not empty and having the batch bulk, the reservoir tank shall be covered with stretchable poly bag to avoid any contamination and cleaning of the piston & silicon tubes shall be carried out with the help of separate container by taking purified water as mentioned in Point No.6.3.2*

#### 6.2.2 Product to Product Change Over (B-Type Cleaning):

6.2.2.1 After completion of batch remove the” in process label” and affix “to be cleaned” label Remove all residue of previous product.

6.2.2.2 Clean the reservoir with purified water and again fill it with purified water pass the purified water through nozzles by running the machine for approx. 5 minutes.

6.2.2.3 Freshly prepared 2% Extran solution and filled in reservoir them leave for 30 minute in reservoir.

6.2.2.4 Switch ‘ON’ the machine and allow 2% v/v Extran solution to run through nozzles.



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**6.2.2.5** Finally pass the hot purified water through Silicon Tubes through running filling machine Nozzles.

**6.2.2.6** Clean the external surface and conveyer with purified water and using wet cloth followed by dry lint free cloth and dry with Compressed air.

**6.2.2.7** Cleaned the silicon tubes as per cleaning procedure of silicon tube define in SOP No. HPL/028.

**6.2.2.8** Affixed the status label as 'CLEANED'.

**6.2.2.9** Maintain the cleaning record in Equipment log book.

### **B-Type cleaning is to be done for**

- Product change over
- Change over to lower strength of same product
- After 24 hours of A-Type cleaning before use.
- After maintenance of major breakdown.
- Change over to upper strength of different colour.
- If the equipment is not use within 72 hours than clean the machine before use.
- After 3 batch of same campaign.

**6.2.2.10** Ensure that the Filling machine has CLEANED status label.

## **6.3 SANITIZATION:**

**6.3.1** Each nozzles and piston shall be dismantle from the machine and collect the nozzles & piston in container, add approx 50 liter (or sufficient qty to dip the change parts) hot purified water (80-90°C) to leave for 1 hour and clean with Teflon brush inside to remove any minute adhered particle, dry it and them assemble the machine.

**6.3.2** After that collect approx 50 liter hot purified water (80-90°C) in filling reservoir tank and kept for approx. 15 minutes in the reservoir. Maintain the sanitization record in **Annexure – I**.

**6.3.3** Collect the rinse water sample and send the sample to QC for chemical analysis.

**6.3.4** If Testing Results not complies with Reference Specification, again clean the All Dismantle Parts of Filling Machine of Hot Purified water or till satisfactory & send the Rinse sample Quality control Department.

**6.3.5** Affix **CLEANED STATUS** label to the machine.

**6.3.6** Record the sanitization activity in **Annexure-I**.

**6.3.7** Sanitization shall be carried out after every B- type cleaning.



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*Note: After every B type cleaning (Product to product change over), cleaning of the area, equipment and other accessories available in the area shall be checked by the production officer/executive as per the checkpoints mentioned in the annexure-II and same shall be verified by the IPQA person.*

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Sanitization record For filling machine (nozzles & piston) and reservoir tank	
Annexure-II	Area/equipment cleaning check list for product to product cleaning	

**ENCLOSURES:** SOP Training Record

### 8.0 DISTRIBUTION:

- Controlled Copy No. 01                      Quality Assurance
- Controlled Copy No. 02                      Production
- Master Copy                                      Quality Assurance

### 9.0 REFERENCES:

Machine manual

### 10.0 REVISION HISTORY:

#### CHANGE HISTORY LOG

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





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### ANNEXURE-II

#### AREA/EQUIPMENT CLEANING CHECK LIST FOR PRODUCT TO PRODUCT CLEANING

Previous Product		Date	Checked By	Verified By
Batch No.		Area		
S.No.	Check Points		(OK/Not OK)	(OK/Not OK)
1.	Check the Area is Visually Clean and Free from Dust Particles and ensure that there are no Previous Material/Unwanted Material.			
2.	Ensure the Equipment affix with Cleaned label.			
3.	Ensure the Cleaning of Bottle Washing (Equipment ID.....). 1. Bottle Washing machine Body 2. Turn Table 3. Conveyer Belt 4. Magnifying Glass(Visual inspection )			
4.	Filling Machine (Equipment ID.....) 1. Machine Outer body Surface 2. Nozzle 3. Piston 4. Conveyer Belt 5. Silicone Pipes			
5.	Sealing Machine 1. Machine outer body surface 2. Conveyer Belt 3. Visual inspection booth			
6.	Ensure the cleaning of the Reservoir with Stirrer (Equipment ID.....) 1. Ensure the cleaning of Inner surface and Lid 2. Manifold 3. Outer surface 4. Cleaning of Gasket and intactness 5. Stirrer Rod 6. Stirrer Body Surface 7. Propeller of stirrer			
7.	Ensure the Cleaning of Platform, wall, false ceiling, light fixture.			
8.	Ensure the Cleaning of return riser, it should be clean from the remains of previous product.			
9.	. Ensure the Cleaning of Detachable Pipe, Transfer line of the Area.			
10.	Ensure the Waste Bins are properly cleaned and Placed in Proper Place.			
11.	Ensure that other Accessories used like Measuring cylinder, Container, are cleaned and dried.			
12.	Weigh Balance If available in the area.			

**Remarks:** If found satisfactory write OK, If found Unsatisfactory write Not OK.

**Checked By Sign/Date** \_\_\_\_\_  
(Prod. Officer/Executive)

**Verified Sign/Date** \_\_\_\_\_  
(QA Officer/Executive)