



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Cleaning and Operation of Linear Bottle Washing Machine	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE

To lay down the procedure for cleaning and operation of linear bottle washing Machine.

### 2.0 SCOPE

This procedure is applicable for cleaning and operation of linear bottle washing machine in Liquid department liquid department at Macleods Pharmaceuticals Ltd. Baddi (Block N2).

### 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 Shift end cleaning procedure:

5.1.1.1 Switch off the electric supply from the mains.

5.1.1.2 Close purified water supplies from their respective valves.

5.1.1.3 Close the compressed air supply.

5.1.1.4 Remove all the bottles from the machine and keep them in closed container with status label.

5.1.1.5 Open the drain valves of water storage containers and drain out all the water.

5.1.1.6 Remove all the water from machine by moping with lint free cloth.

5.1.1.7 Dry the water storage containers and Drip trays with the help of lint free cloth.

5.1.1.8 Mop the complete machine with the help of dry lint free cloth.

##### 5.1.2 Cleaning Procedure after completion of Batch :

5.1.2.1 Remove all the good and rejected bottles from the area and carry out the reconciliation. Destroy the rejected bottles.

5.1.2.2 Close purified water supplies from the valve.

5.1.2.3 Close the compressed air supply.



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- 5.1.2.4 Dismantle infeed caps, Spacer bar, bottle holder and Erector if the next product is not having the same bottle size, if 7 batches have been processed ,if batches have been processed for 7 consecutive days whichever is earlier.
- 5.1.2.5 Clean the change parts with purified water and nylon brush.
- 5.1.2.6 Dry the change parts and store them.
- 5.1.2.7 Open the drain valves of water storage containers and drain out all the water. Ensure that there is no water in the water lines .
- 5.1.2.8 Clean the water storage containers, Drip trays with purified water, and dry them with lint free cloth.
- 5.1.2.9 Set the change parts infeed caps, Spacer bar and Erector as per the required bottle size.
- 5.1.2.10 Mop the machine with dry lint free cloth.
- 5.1.2.11 Check that all the surfaces of the parts of Bottle Washing Machine are visually clean and dry.
- 5.1.2.12 Reassemble all accessories and parts dismantled for the cleaning purpose
- 5.1.2.13 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 No. QA/044
- 5.1.2.14 Protect the cleaned Bottle washing machine by covering the water storage containers with SS lid and loading and unloading sides with clean polythene bag if the equipment is not planned for use within a day.
- 5.1.2.15 Record the details of cleaning in equipment usage record sheet as per Reference SOP No. PG/178 and check the cleaning activity as per Annexure II.

## 5.2 Machine set up and operation

### 5.2.1 Machine set up

- 5.2.1.1 Ensure that Bottle Washing Machine is cleaned .
- 5.2.1.2 After line clearance from QA, put the "UNDER PROCESS" label dully filled and signed on the machine.
- 5.2.1.3 Change / fix the bottle holders as per the bottle size.
- 5.2.1.4 Set up the drum assembly, infeed guide, spacer and erecter as per the required size of the bottle
- 5.2.1.5 Air filter to be changed after every three Months and water filters for purified water to be changed when water pressure on pressure gauge comes down under 3 Kg/ cm<sup>2</sup> or if required earlier.
- 5.2.1.6 Record the change of filter as per refrence Annexure-I ( Replacement record of air filter and water filter).



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### 5.2.2 Operation

5.2.2.1 Open the valves for the purified water to fill the water containers.

5.2.2.2 Open the air valve and check the air pressure from air pressure gauge, the air pressure should be NLT 3.0 kg/ cm<sup>2</sup> and mechanical air pressure at 6 kg/ cm<sup>2</sup>.

5.2.2.3 Switch ON the main.

5.2.2.4 If no **ERROR** message display on screen then select **MANUAL MODE** and observe the machine carefully for proper functioning by starting individual items.

5.2.2.5 Press Pump 1, then Pump 2, check respective dial gauge mounted on panel. The pressure should be NLT 3.0 kg/ cm<sup>2</sup>.

#### 5.2.2.7 Wash Sequence:

##### Inside Wash:

W1	W2	W3	W4	W5	W6	W7
Air	L1	Air	L2	L3	Air	Air

##### Outside wash :

E1	E2
Water	Air

L1,E1 = From tank No.01 (Filtered purified water)

L2, L3 = From tank No. 02 (Filtered purified water)

W1-W7 = Inside air and water wash stations for bottles

E1 = External water

E2 = air wash

5.2.2.8 Switch ON/OFF Globe valves 1,2 and 3 and observe its proper functioning.

5.2.2.9 Press the key's for Pumps & Globe valves again for few seconds and switch it OFF.

5.2.2.10 Run Machine Conveyor for few minute and observe its free movement & timely movement of pins and erector.

5.2.2.11 Operate extractor(Pusher) for its proper response by pressing extractor button.

5.2.2.12 Operate feed conveyer in Manual mode so as Bottles available up to the loading drum through infeed guide.

5.2.2.13 Select AUTO mode. To start the washing operation.

5.2.2.14 Press Cycle start switch ON, Then PLC takes over Auto operation.

5.2.2.15 First Pump No. 1 Switches ON.

5.2.2.16 Then Pump No. 2 will get ON with a delay of few sec.



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5.2.2.17 Turn machine conveyer ON & then Feed conveyer will switch ON automatically.

5.2.2.18 In case of improper machine setting, the PLC may show the following faults :

- ◆ Air pressure low
- ◆ No Bottles on In feed Conveyer
- ◆ Low water level in tank
- ◆ Emergency button is pressed
- ◆ Jamming of Conveyer
- ◆ Cam Clutch slipped
- ◆ Geneva Clutch slipped.

5.2.2.19 Once error has been removed AUTO mode will work after pressing RESET button.

5.2.2.20 Start the water pumps and machine, check that water pressure is with in the range and uniform flow from all the nozzles.

5.2.2.21 Receive the empty glass bottles from store in shrink wrap.

5.2.2.22 Remove the shrink rap and load the bottles on the loading platform. Put the torn shrink Wrap in waste bin.

5.2.2.23 Put any damaged bottle in waste bin.

5.2.2.24 Washed and air dried bottles will be unloaded automatically on the other side of the machine.

5.2.2.25 After the completion of operation, Switch 'OFF' Bottle washing machine.

5.2.2.26 Affix "TO BE CLEANED" label on the machine as per refrence SOP No. QA/044.

5.2.2.27 Record the details of operation of Bottle washing machine in equipment usage log sheet as per refrence SOP No. PG/178.

### 5.3 NOTE:

5.3.1 Ensure adequate oil level by reduction gear box.

5.3.2 Ensure Mechanical air pressure in the unit is not less than 6 kg/ cm<sup>2</sup>.

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

### 6.0 ABBREVIATION (S)



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SOP: Standard Operating Procedure.

No. : Number.

NA : Not applicable.

PLC : programmable logic controller .

### 7.0 REFERENCE(S)

QA/044: Status labeling.

PG/178: Making entries in equipment usage and cleaning log sheet.

### 8.0 ANNEXURE (S)

ANNEXURE-I: Replacement record of air filter and water filter.

ANNEXURE-II: cleaning checklist of linear bottle washing 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(2)

