



**STANDARD OPERATING PROCEDURE**

<b>Department:</b> Production	<b>SOP No.:</b>
<b>Title:</b> Operation & Cleaning of Filling, Dropper Fixing & Screw Capping 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 a procedure for Operation and Cleaning of Filling, Dropper Fixing and Screw Capping Machine.

**2.0 SCOPE:**

This SOP is applicable for Operation and Cleaning of Filling, Dropper Fixing and Screw Capping Machine (Make: **Snowbell**) in the Eye and Ear Drop Line at .....

**3.0 RESPONSIBILITY:**

Officer / Executive - Production

**4.0 ACCOUNTABILITY:**

Head - Production

**5.0 DEFINITIONS:**

Not Applicable

**6.0 PROCEDURE:**

**6.1 PRECAUTIONS:**

- 6.1.1** Ensure that proper electric supply are provided to the machine.
- 6.1.2** Operate machine with all guards in place.
- 6.1.3** Avoid filling the hopper to its full capacity.
- 6.1.4** Use silicone tubing as per the category of the product.
- 6.1.5** Ensure nitrogen supply is "ON"

**6.2 MACHINE SETTING :**

- 6.2.1** Adjust the transferring star wheel for smooth run of vials on conveyor.
- 6.2.2** Adjust the vibrator bowl for flowing freely from the vibratory bowl feeder to the dispenser by rotating the knob.



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- 6.2.3 Adjust the height of chute as per vial by rotating the knob and inlet & outlet star wheel. Adjust the filling needle at proper height w.r.t. vial size in filling machine nozzle mounting bracket.
- 6.2.4 Adjust required height of the dropper pressing head w.r.t. vial size.
- 6.2.5 Adjust the Torque and height setting of the Capping Head.
- 6.2.6 Assembled the storage hopper to the bowl for vial, dropper fixer & screw caps & also assembled the transfer pipe to the orientator.
- 6.2.7 Assemble the “Manifold” to the needles with silicon tubes & another end of Manifolds is attached to the filling vessel.
- 6.2.8 Now start the machine by inching switch and check the volume as per specification.

### 6.3 MACHINE OPERATION:

- 6.3.1 Ensure the availability of utility.
- 6.3.2 Switch “ON” the main MCB of machine and start the LAF unit.
- 6.3.3 Open the valve of compressed air, nitrogen gas & check the pressure inside pressure gauge.
- 6.3.4 Switch “ON” the power supply of machine & check status of PLC. It should be as:
- 6.3.5 Touch the forward point screen display as follow.



- 6.3.6 Enter the user Id and password.



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6.3.7 Touch the auto mode.



6.3.8 Auto mode screen display as follow “homing mode done should be in screen”



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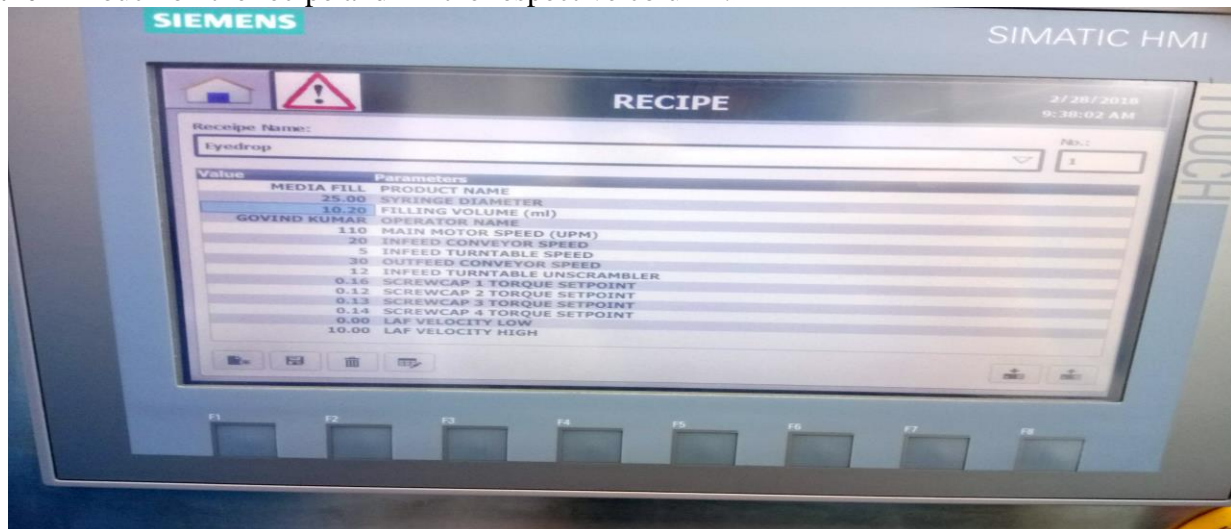
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6.3.9 Touch the home button.

6.3.10 Touch on the recipe and fill the respective column.



6.3.11 Save the recipe. And go back to the auto mode throughout the home page.

6.3.12 Click the start button.





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- 6.3.13** Before touching the filling key press filling inch button which is provided in the front of machine for setting of vial, N2 Gas Nozzles pre & post and filling nozzles.
- 6.3.14** Check volume of 1<sup>st</sup> to 8<sup>th</sup> vials according to the pack size. If the volume of vials is not according to the pack size than and adjust the volume.
- 6.3.15** Perform Challenge test of sensors before start of operation and after any break-down of machine.
- 6.3.16** Record the details of sensors challenge test in **Annexure-I**.
- 6.3.17** Record the operation details in Format F01-00 Titled “**Equipment Log**” of SOP.
- 6.3.18** To avoid the Spillage by oozing of solution from the vial during post purging of Nitrogen, Nitrogen pressure will be set in between 0.2 to 0.4 Kg/cm<sup>2</sup>.

## 7.0 ABBREVIATIONS:

SOP	Standard Operation Procedure
WFI	Water for Injection
Ltd.	Limited
LAF	Laminar Air Flow
PLC	Program Logic Controller
MCB	Miniature Circuit Breaker





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### ANNEXURE-I

	<b>PRODUCTION</b>
	<b>SENSOR CHALLENGE TEST RECORD</b>

**Frequency:** Before Start of Operation and After Machine Break-Down

Date	Product Name	Batch No.	Sensor Details	Status (Ok / Not Ok)	Done By Sign & Date	Checked By Sign & Date	Verified By Sign & Date	Remarks
			No Vial No Filling Sensor					
			No Vial No Nozzle Sensor					
			No Nozzle No Capping Sensor					
			Counter Sensor					
			Rejection Sensor					
			Compressed Air Pressure Low Sensor					
			Nitrogen Pressure Low Sensor					
			Vacuum pressure Low Sensor					
			Air Velocity Sensor					
			ORABS Sensor					