

	<b>TITLE: OPERATION, CLEANING AND MAINTENANCE OF VERTICAL AUTOCLAVE</b>	SOP NUMBER :	SOP/PMH/009-00
		EFFECTIVE DATE :	13/03/2026
		DEPARTMENT:	Microbiology
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## 1.0 OBJECTIVE

To lay down the procedure for Operation, Cleaning and Maintenance of Vertical Autoclave.

## 2.0 SCOPE

This procedure is applicable for operation, cleaning and maintenance of Vertical Autoclave in Microbiology laboratory of Pharma Micro Hub Pvt Ltd.

## 3.0 RESPONSIBILITY

3.1 All Personnel who are operating the Vertical Autoclave in Microbiology laboratory are responsible for adherence to this procedure.

3.2 Engineering personal is responsible for maintenance of equipment.

## 4.0 ACCOUNTABILITY

4.1 Head – Microbiology/designee is accountable for overall compliance of this procedure.

## 5.0 PROCEDURE

### 5.1 Precautions:

5.1.1 Wear proper PPE while handling of Vertical autoclave.

5.1.2 Open the vertical autoclave door when the chamber pressure shows zero reading.

5.1.3 Ensure the purified water lines properly connected to vertical autoclave.

5.1.4 Ensure the Vent filter valve should be open before starting the autoclave.

### 5.2 Operation:

5.2.1 Switch on the mains power supply which is located on left side of the autoclave.

5.2.2 After few seconds the HMI screen shows manufacturer details and serial number of the vertical autoclave Refer figure-1

5.2.3 After HMI screen, immediately Home screen in the HMI shows the details like Date, Time, Name of the Recipe, parameters respective of current load. Refer figure-2

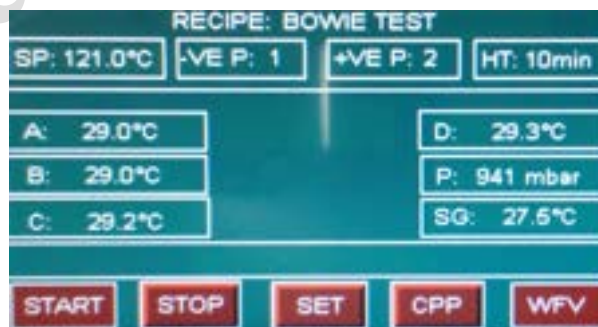


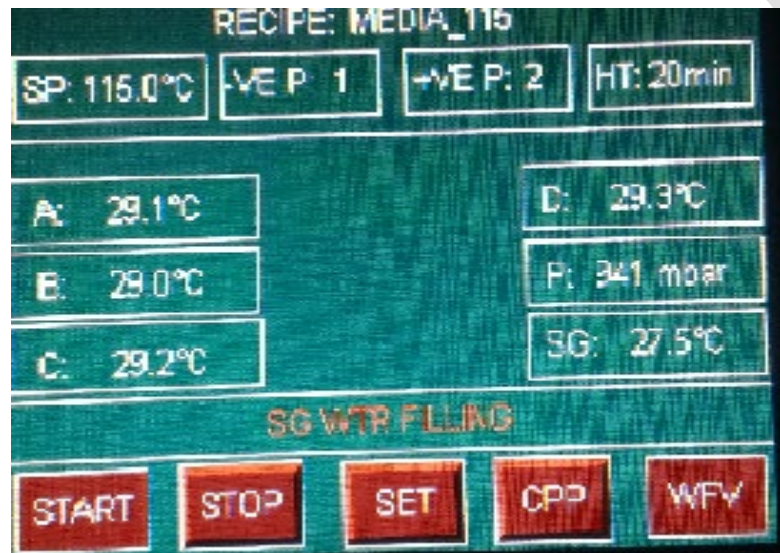
Figure-2

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5.2.4 Home screen having the below options

- a) START
- b) STOP
- c) SET
- d) CPP
- e) WFV

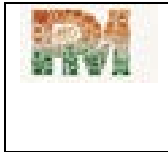
5.2.5 WFV: Select WFV option to fill the purified water to Steam generator, to stop the water filling select WFV option again to stop the water filling to steam generator. Refer figure-3



**Figure-3**

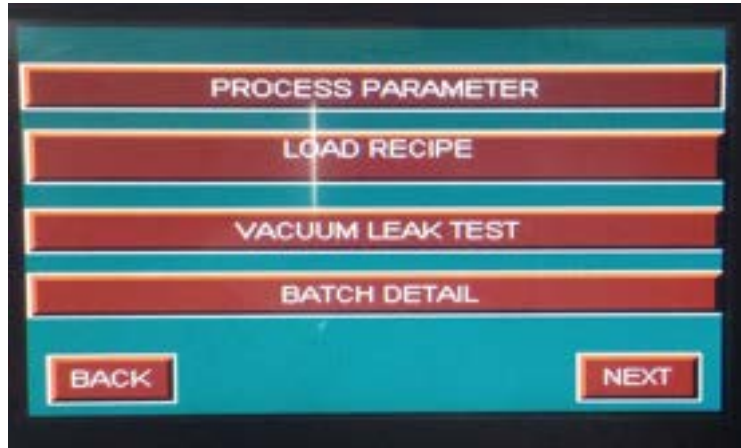
5.2.6 SET: Select the SET option to select below options. Refer figure-4

- a) Process parameter
- b) Load recipe
- c) Vacuum leak test
- d) Batch details



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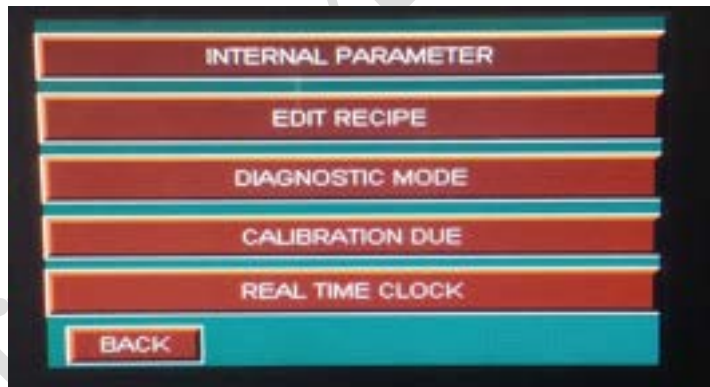
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**Figure-4**

5.2.7 Select Next key to see remaining parameters, Refer figure-5

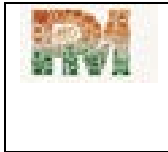
- a) Internal parameter
- b) Edit recipe
- c) Diagnostic mode
- d) Calibration due
- e) Real time clock



**Figure-5**

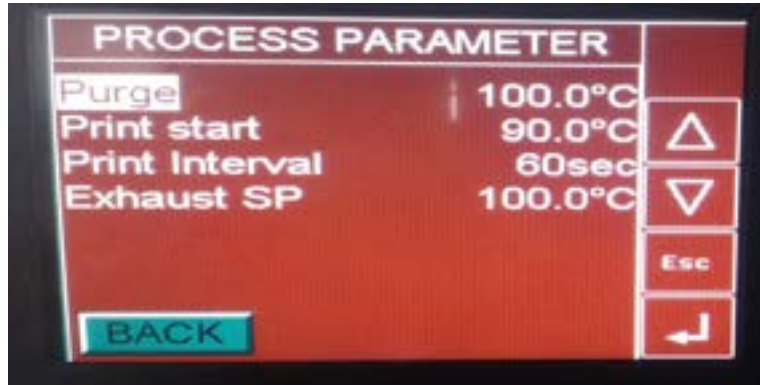
5.2.7.1 **Process parameter:** Select the process parameter to check the below parameters. Refer the figure-6

<b>Process parameters</b>	
Purge	100.0°C
Print start	90.0°C
Print interval	30 Sec
Exhaust SP	100.0°C



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**Figure-6**

5.2.7.2 To change any of the process parameter select the Up (▲)/Down (▼) navigation keys to highlight the parameter and select the (↵) to change the parameter value. Refer figure-7



**Figure-7**

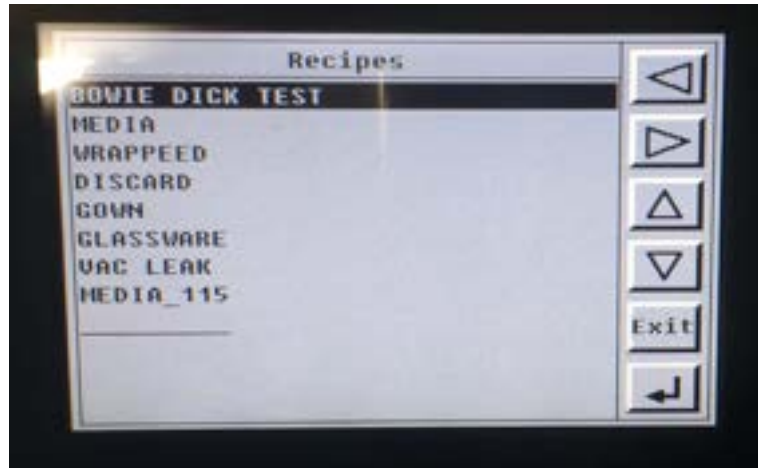
5.2.7.3 Select ESC option and Back option to leave the screen

5.2.7.4 **Load recipe:** Select the “load recipe” to select the desired recipe, following types of recipes available in the recipes. Refer figure-8

- Bowie dick test
- Media
- Wrapped
- Discard
- Gown
- Glassware
- Vac leak
- Media\_115

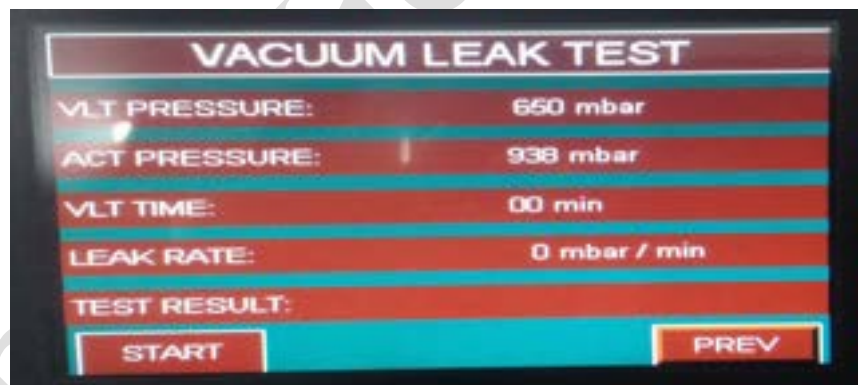
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5.2.7.5 Load recipe shall be select by using the Up (▲)/Down (▼) navigation keys to highlight the parameter and select the (↵) to select the load recipe. Select Exit key to back to the main screen. Refer figure-8



**Figure-8**

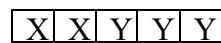
5.2.7.6 **Vacuum Leak Test:** Select “Vacuum Leak Test” to select the Vacuum leak test and select START option to start the Vacuum leak test. Refer figure-9





**Figure-9**

5.2.7.7 Acceptance criteria for Vacuum leak test is NMT 25 mbar per minute.

5.2.7.8 **Batch details:** Select the Batch details key and enter the details like Operator ID and load Number. Operator ID shall be Employee ID and Load number is XXYYY pattern. Refer figure-10

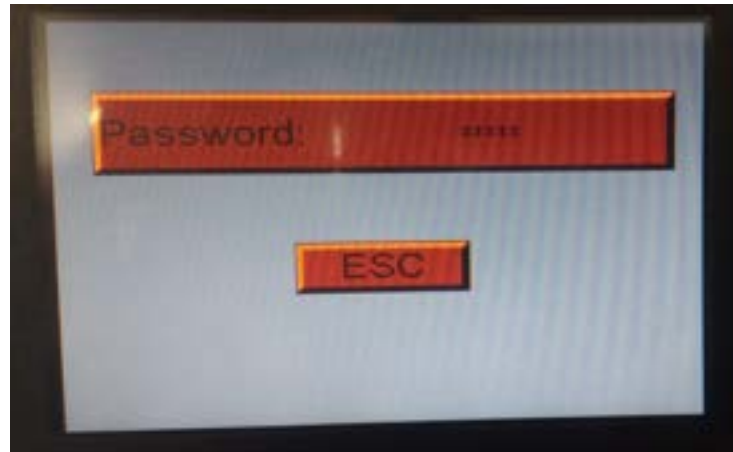




  
 Last 2 digits of year

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5.2.7.9 “XX” indicates the last two digits of the year and “YYYY” indicates the serial number of the load for example “16001” is the load number, then 16 indicates the year 2016, 001 is first load in 2016 year.

5.2.7.10 “Internal parameter”, “Edit recipe”, “Diagnostic mode” and “Real time clock” options are locked with pass word, engineering department having the privileges to access the password. Refer figure-11



**Figure-11**

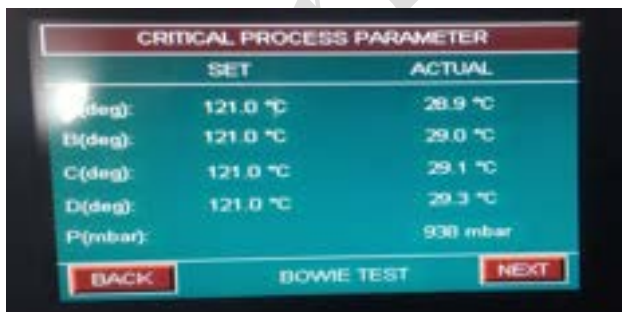
5.2.7.11 Calibration due: select this option to enter the due date of calibration of vertical autoclave.

5.2.8 Select the desired load in “Load recipe” option as per the 5.2.7.4 and 5.2.7.5

5.2.9 Close the door and turn the liver in clock wise direction to lock the vertical autoclave lid.

5.2.10 Select the “START” option to start the cycle.

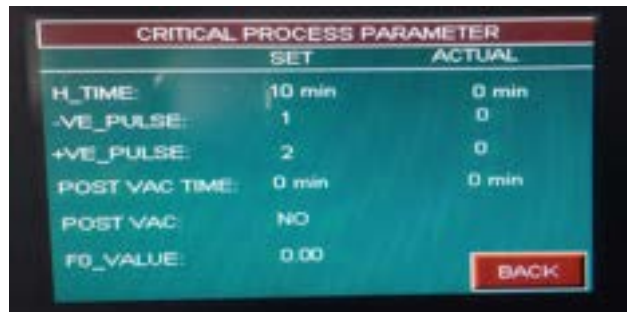
5.2.11 To check the “Critical Process Parameters” select the CPP option, to check the critical process parameters. Refer figure-12, Figure-13



	SET	ACTUAL
A(deg):	121.0 °C	28.9 °C
B(deg):	121.0 °C	29.0 °C
C(deg):	121.0 °C	29.1 °C
D(deg):	121.0 °C	29.3 °C
P(mbar):		938 mbar

BACK      BOWIE TEST      NEXT

**Figure-12**



	SET	ACTUAL
H_TIME	10 min	0 min
-VE_PULSE:	1	0
+VE_PULSE:	2	0
POST VAC TIME:	0 min	0 min
POST VAC:	NO	
FB_VALUE:	0.00	

BACK

**Figure-13**

5.2.12 In case any discrepancy observed in middle of the load the select STOP option to stop the load. After selecting the STOP option, screen shows “YES” and “NO” options, select “YES” to stop the load.

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- 5.2.13 Printer starts printing after selecting the START option.
- 5.2.14 After completion of cycle autoclave gives buzzer indication.
- 5.2.15 Open the vent valve after completion of autoclave cycle
- 5.2.16 To run the sterilize cycle after decontamination load run one empty cycle between decontamination and sterilization load.

### 5.3 **Cleaning:**

- 5.3.1 Clean the outer surface of the equipment with dry lint free mop.
- 5.3.2 In case of any spillage occurred clean the outer surface of the equipment with lint free cloth moistened with disinfectant.
- 5.3.3 Clean the chamber daily once before starting the activity with disinfectant.

### 5.4 **Maintenance and validation of Vertical autoclave:**

- 5.4.1 In case of any discrepancy observed respective to instrument or cycle inform to immediate supervisor and inform engineering department.
- 5.4.2 Preventive Maintenance shall be done as per SOP
- 5.4.3 Requalification of Vertical autoclave as SOP
- 5.4.4 Vacuum Leak Test shall be perform daily as a first load.
- 5.4.5 Bowie dick test shall be done daily once after comply the Vacuum Leak Test

## 6.0 **ABBREVIATIONS**

- 6.1 CPP : Critical Process Parameters
- 6.2 HMI : Human Machine Interface
- 6.3 NMT : Not More Than

## 7.0 **ANNEXURE (S)**

- 7.1 Annexure -1 Vertical Autoclave log book.

## 8.0 **REFERENCES**

- 8.1 NA

## 9.0 **CHANGE HISTORY**

- 9.1 New SOP

**END OF DOCUMENT**

