



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Microbiology	<b>SOP No.:</b>
<b>Title:</b> Procedure for Operation of Vertical Autoclave (Make-Ketan)	<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 of Vertical Autoclave.

### 2.0 SCOPE:

This SOP is applicable for Operation of Vertical Autoclave for disposal of culture media, media sterilization, accessories sterilization, Garment sterilization and heat treatment of packaging material in Microbiology Section of Quality Control Laboratory.

### 3.0 RESPONSIBILITY:

Officer / Executive Microbiology

### 4.0 ACCOUNTABILITY:

Head – QC

### 5.0 ABBREVIATIONS:

ID No.	Identification Number
mins.	Minutes
Ltd.	Limited
LCD	Liquid Crystal Display
No.	Number
QA	Quality Assurance
QC	Quality Control
SOP	Standard Operating Procedure

### 6.0 PROCEDURE:

6.1 Ensure that autoclave is cleaned properly before operation.

6.2 Close the drain valve and fill sufficient purified water in the chamber to level above heater and check the water level in glass tube.

6.3 Put the metal basket inside the autoclave & load the materials to be denaturation/sterilization and tighten all the knobs firmly.

#### 6.4 OPERATION PROCEDURE:

6.4.1 Switch on the main power supply than switch on MCB that located in control unit.

6.4.2 After switch on main power supply heater will start automatically.

6.4.3 Than complete the cycle requirement with the help of display setting.

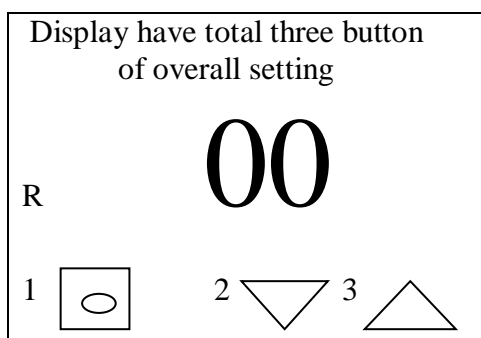


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**6.4.4** Autoclave have two display, upper side display for temperature setting and lower side display for time setting.

#### **6.5 OPERATION OF UPPER SIDE DISPLAY (TEMPERATURE SETTING):**

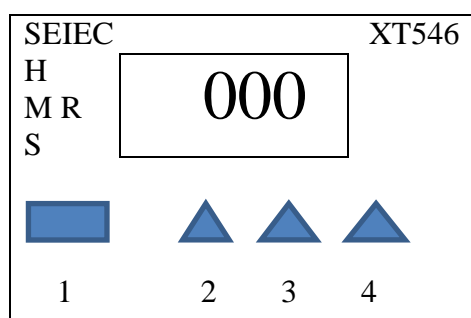


**6.5.1** Press first key with down key (second key) or up key (third key), (key number count left to right) to set the required temperature.

**6.5.2** After set the required temperature again press first key for confirm the temperature.

#### **6.6 Operation of Lower side display (Time setting).**

**6.7** Display have total four button of overall setting:



**6.7.1** Directly press key number 2, 3, 4 to set the required time, display have three digit & these three digit change through key number 2, 3, 4 respectively.

**6.7.2** After set the required time, press first number key with any one key no 2, 3 or 4 simultaneously for time confirmation.

**6.7.3** After completion of both display setting wait for sterilization temperature (121°C).

**6.7.4** Press green button for sterilization hold when temperature reaches 121°C.

**6.7.5** After completion of hold time exhaust will start.

**6.7.6** After exhaust open the autoclave when Pressure release becomes 0 Psi.



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6.7.7 Record the all timing or details in **Annexure-I**.

**6.8 DISPOSAL/STERILIZATION OF MEDIA AND ACCESSORIES :**

6.8.1 Wear Nose Mask and Hand Gloves prior to start the Destruction of Microbial Waste (used / contaminated media Petri plates, Cultures slants, Biological Indicators, Culture Suspension tubes, Tips, GPT & Media Plates and tubes) and collect all Waste Media and contaminated Glassware to Discarding Area.

6.8.2 The material should be transported from the observation room to discard room through the pass box.

6.8.3 Organize the Petri plates (with the tops up) in suitable bio hazardous poly bags & then place in vertical autoclave with chemical indicator.

6.8.4 All cycle shall be run as per validated load pattern.

6.8.5 Note down the time when the temperature and pressure reached at 121 °C and 15 Psi respectively or as per validated load pattern Refer Annexure III)

6.8.6 Hold the cycle for 30 minutes (note down the Holding Time) or as per validated load pattern (Refer Annexure II). After completion of Hold Time, wait for exhaust.

6.8.7 After completion of cycle, switch “**OFF**” the Autoclave.

6.8.8 Open the Autoclave when Pressure release becomes 0 Psi. Check the status of Indicator Strip for its change in colour and take out the materials from autoclave and transfer the material into respective area with help of perforated SS Container. Collect the decontaminated autoclaved media in poly bag and send to outside party for further disposal.

6.8.9 Record the Details in Format, Titled “**Usage Log Book of Autoclave**”.

6.8.10 During cleaning of autoclave ensure that before cleaning autoclave chamber should be empty. Drain out the water and clean the instrument with 70 % IPA. Pour sufficient water to cover the heater, ensure water level is above the heater.

6.9 After completion of discarding cycle run empty cycle for 121 °C for 30 min if using for sterilization.

6.10 Heat treatment of packaging materials shall be done as per respective STP.

6.11 Record the details of Empty cycle in Format, Titled “**Usage Log Book of Autoclave**”.



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**7.0 ANNEXURES:**

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure – I	Usage Log Book of Autoclave	
Annexure – II	Validated load pattern	

**ENCLOSURES:** SOP Training Record.

**8.0 DISTRIBUTION:**

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

**9.0 REFERENCES:**

Instruction Manual

**10.0 REVISION HISTORY:**

**CHANGE HISTORY LOG**

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





**PHARMA DEVILS**  
MICROBIOLOGY DEPARTMENT

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**ANNEXURE-II**  
**VALIDATED LOAD PATTERN**

Load Pattern No.	Load Configuration	No. of Articles
1	<b>GARMENT LOAD (Hold time: 121 ° C for 30 minutes)</b>	
	Clean Room Garment	07 Set
	Mopping pad	10 Nos.
2	<b>GLASSWARE ACCESSORIES (Hold time: 121 ° C for 30 minutes)</b>	
	Filtration Assembly	15 Nos.
	Bottle 250 ml	06 Nos.
	Glass Pipette (5 ml)	05 Nos.
	Air sampler Head	01 Nos.
	Filtration Flask	01 Nos.
	Scissor	12 Nos.
	Silicone Pipe	02 Nos.
	Micropipette Tip Box (1.0 ml)	02 Nos.
	Vial Opener	04 Nos.
	Forcep	10 Nos.
	Borer	10 Nos.
Three Manifold Assembly	01 Nos.	
3	<b>AGAR MEDIA LOAD (Hold time: 121 ° C for 20 minutes)</b>	
	1000 ml bottle	14 X 700 ml media
	500 ml bottle	10 X 300 ml media
4	<b>BROTH MEDIA LOAD (Hold time: 121 ° C for 20 minutes)</b>	
	38 X 200 mm tubes	60 X 100 ml broth medium
5	<b>RVS AND GN BROTH MEDIA LOAD (Hold time: 115 ° C for 16 minutes)</b>	
	18 x 150 mm tube	200 X 10 ml medium
	38 X 200 mm tube	20 X 100 ml medium
6	<b>MIX MEDIA DISCARD LOAD (Hold time: 121 ° C for 30 minutes)</b>	
	High dispo bag with petri plate	02 Nos.
	High dispo bag with broth medium tubes	02 Nos.
7	<b>SOLID MEDIA DISCARD LOAD (Hold time: 121 ° C for 30 minutes)</b>	
	High dispo bags with petri plates	04 Nos.
8	<b>LIQUID MEDIA DISCARD LOAD (Hold time: 121 ° C for 30 minutes)</b>	
	High dispo bags with broth medium tubes or other miscellaneous items	04 Nos.