



## STANDARD OPERATING PROCEDURE

**Title:** Operation and Cleaning of High Pressure High Vacuum Autoclave

<b>SOP No.:</b>		<b>Department:</b>	Production
		<b>Effective Date:</b>	
<b>Revision No.:</b>	00	<b>Revision Date:</b>	
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### 1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of High Pressure High Vacuum Autoclave.

### 2.0 SCOPE:

This SOP is applicable for Operation and Cleaning of High Pressure High Vacuum Autoclave, ID No.:....., Make: **Machin Fabrik**, Capacity: **675 liter** Production Area of 3 Piece section.

### 3.0 RESPONSIBILITY:

Operating Person – Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

HPHV	High Pressure High Vacuum
Ltd.	Limited
No.	Number
QA	Quality Assurance
RPM	Rotation per Minute
SOP	Standard Operating Procedure
VLT	Vacuum Leak Test

### 6.0 PROCEDURE:

#### 6.1 Equipment Description :

- 6.1.1 The autoclave is a horizontal, HPHV, double door, rectangular type steam sterilizer with vertical sliding double door.
- 6.1.2 The sterilization chamber is made up of SS sheet, which is welded with U-profile SS jacket.
- 6.1.3 The sterilization chamber is providing with two vertical sliding doors, which are also made up of SS reinforced with support structure.
- 6.1.4 Both doors will be opens with pneumatic cylinder.
- 6.1.5 Both the doors having interlocking system, which prevent opening of both door at the same time.
- 6.1.6 Compound gauges are located on both the side.



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**6.1.7** Sterilization chamber of autoclave is insulated with glass wool, which helps in reducing the heat loss to the environment and ensuring uniform distribution of temperature inside the chamber.

**6.1.8** Autoclave has control panel, Vacuum pump, pressure gauges, five internal probes for temperature monitoring and control (Four inside the chamber, one in drain), pressure transducer for chamber pressure monitoring and recording, steam generator as the part of machine.

<b>Equipment</b>	HPHV Steam Sterilizer
<b>Id Number</b>	.....
<b>Make</b>	Machin Fabrik
<b>Sr. No.</b>	.....
<b>Chamber size</b>	750 (w) x 750 (h) x 1200 (d) mm
<b>Chamber volume</b>	675 liters
<b>Working pressure</b>	up to 2.2 kg/cm <sup>2</sup> (g)
<b>Working temperature</b>	Up to 134 <sup>0</sup> c
<b>MOC Chamber</b>	SS 316L
<b>MOC jacket</b>	SS 304

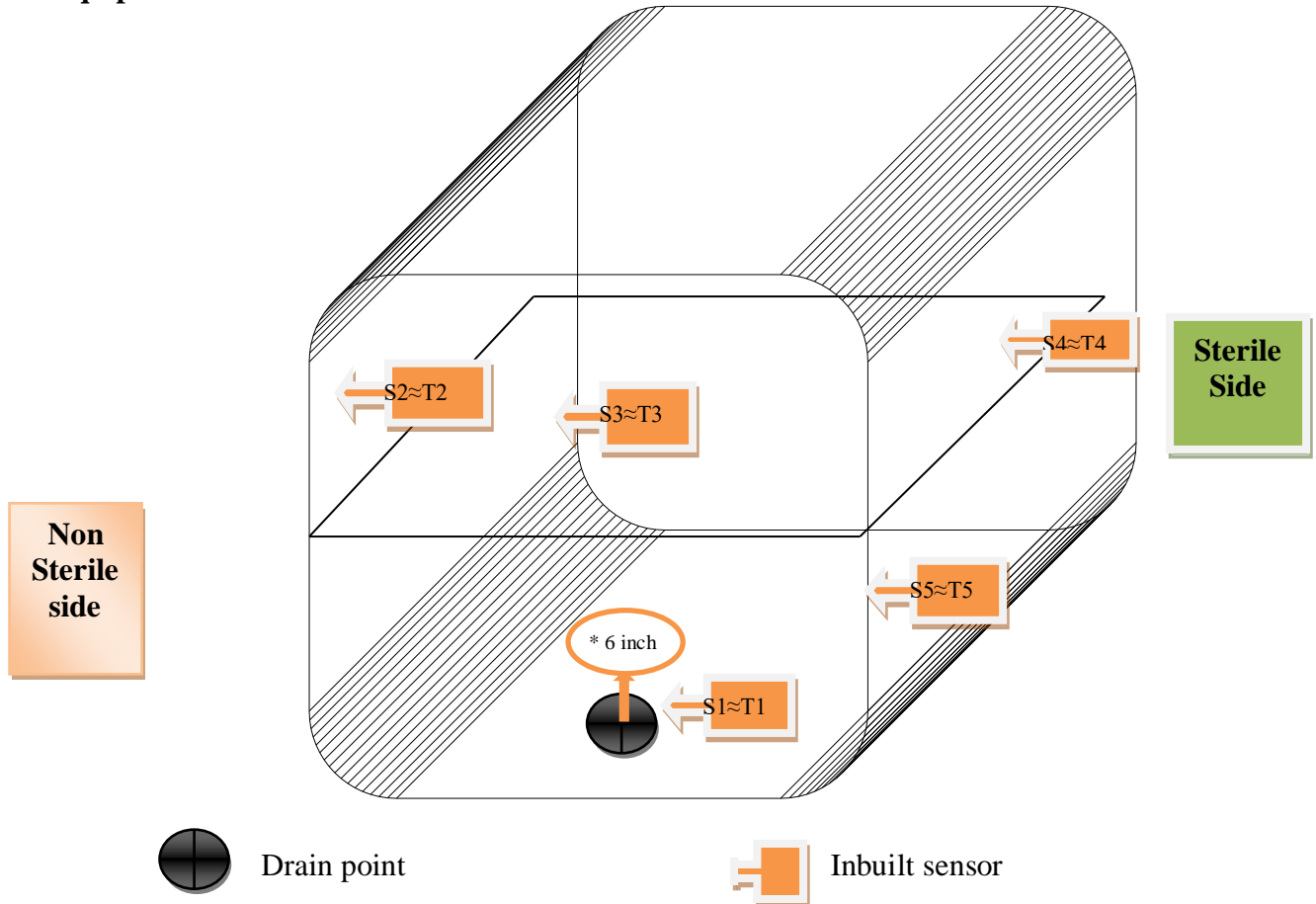


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**6.2 Equipment Details:**



**Figure:** Location of inbuilt Temperature Sensors

Sensor No.	Location in the Chamber
S1	In the drain of the autoclave chamber. T1
S2	Left side near non-sterile side door, Inbuilt Sensor T2
S3	Left side near sterile side door Inbuilt Sensor T3
S4	Right side near non-sterile side door, Inbuilt Sensor T4
S5	Right side near sterile side door, Inbuilt Sensor T5
* Bowie Dick kit should place above 6 inch height drain point sensor	



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### 6.3 Instruction:

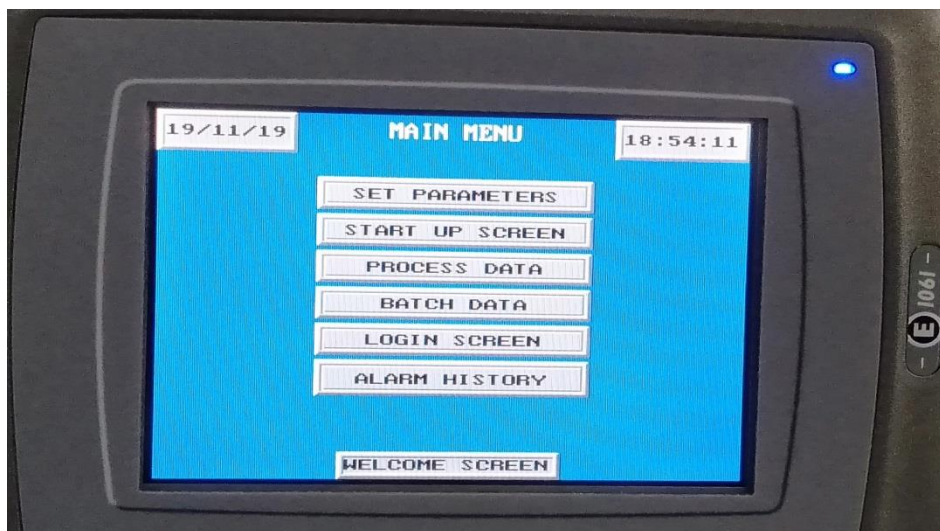
- 6.3.1 Soft water supply is available for Vacuum pump.
- 6.3.2 Compressed air supply is available at appropriate utility location.
- 6.3.3 Air pressure is 6.0 to 8.0 kg/cm<sup>2</sup> (Approx).
- 6.3.4 Pressure of Pure Steam supply is of 2.2 kg/cm<sup>2</sup> (Approx).
- 6.3.5 Check and ensure that sufficient paper is loaded in strip chart recorder and printer.
- 6.3.6 Ensure the Autoclave unloading side door of sterility area is closed.
- 6.3.7 Before every autoclave cycle, ensure that the Emergency key is release.

### 6.4 Preparation of Load for Sterilization:

After cleaning and drying of material which is to be sterilized like feeding hopper, machine parts and other filling dropper fixing & capping assembly wrap them into decron bag/tyvek bag as per **Annexure no. V**

### 6.5 Operation of Autoclave:

- 6.5.1 Switch “ON” the Main power supply of Machine and Printer.
- 6.5.2 Display appears as below after switching ON:
- 6.5.3 Press **MAIN MENU**.



- 6.5.4 Enter login ID and password by selecting the “LOGIN SCREEN” in HMI.
- 6.5.5 Enter details by selecting the “BATCH DATA” in HMI.



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**6.5.6** Select the program which has to be run as given below table:

PROGRAM	FREQUENCY	LOAD
VACUUM LEAK TEST	Daily	Empty
BOWIE DICK TEST	Weekly $\pm$ 2days	Empty
STANDARD PROCESS I	As per requirement	Orientator Load
STANDARD PROCESS II	As per requirement	Liquid Chemical
HPHV PROCESS I	As per requirement	Garment Load (Inner / Boiler)
HPHV PROCESS II	As per requirement	M/C parts Load, Filtration accessories, Mfg. Accessories, Mfg. filtration Load

**6.5.7** Select the required program by selecting the “START UP SCREEN” in HMI.



**6.5.8** Take the printout of selected cycle and check the parameter and batch details.

**6.5.9** Take the printout of initial temperature and pressure on strip chart paper and press the “Record” button & enter two times to record the data of temperature and pressure.

**6.5.10** Load the articles in Autoclave chamber as per following load pattern and pictorial from the Component preparation area side.



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**6.5.11** Open the supply of the utility like Compressed air, pure steam & Vacuum line.

**6.5.12** Use sterilization indicator for confirmation of the articles sterilization.

**6.5.13** The door of autoclave will open when temperature reaches less than 90<sup>0</sup>C.

**6.5.14** Check and verify the respective graph with strip chart as well as dot-matrix printer graph.

### **6.6 Operation of Strip Chart Recorder:**

**6.6.1** To start strip chart recorder open the cover and push the blue key in below right corner wait till initialization.

**6.6.2** After initialization temperature reading of 5 sensors and pressure reading of one sensor shall be displayed on screen.

**6.6.3** Push the [MENU] key for approx. 3 second main screen shall be displayed. To forward the chart paper press [FEED] key.

#### **6.6.4 To start the recording:**

**6.6.4.1** Press [FUNC] key one time [Func=Print out] shall be displayed on screen.

**6.6.4.2** Press [CH UP] key two times and immediate [REC] key recording shall be started.

#### **6.6.5 Note:**

**6.6.5.1** If strip chart recorder graph does not come with any reason in that case cycle shall be verified and accepted with temperature mapping print.

**6.6.5.2** If temperature mapping print does not come with any reason in that case cycle shall be verified and accepted with strip chart recorder graph.

**6.6.5.3** If VLT cycle is not meeting acceptance criteria in that case immediately inform to engineering department and after rectification of problem VLT cycle shall be run again till Complies the VLT cycle.

**6.6.5.4** If any overshoot observed in HPHV cycle in that case cycle shall be consider valid as there is no impact on sterilization process.

**6.6.5.5** All cycle shall be run as per validated load pattern

#### **6.6.6 Interpretation of strip chart recorder graph:**



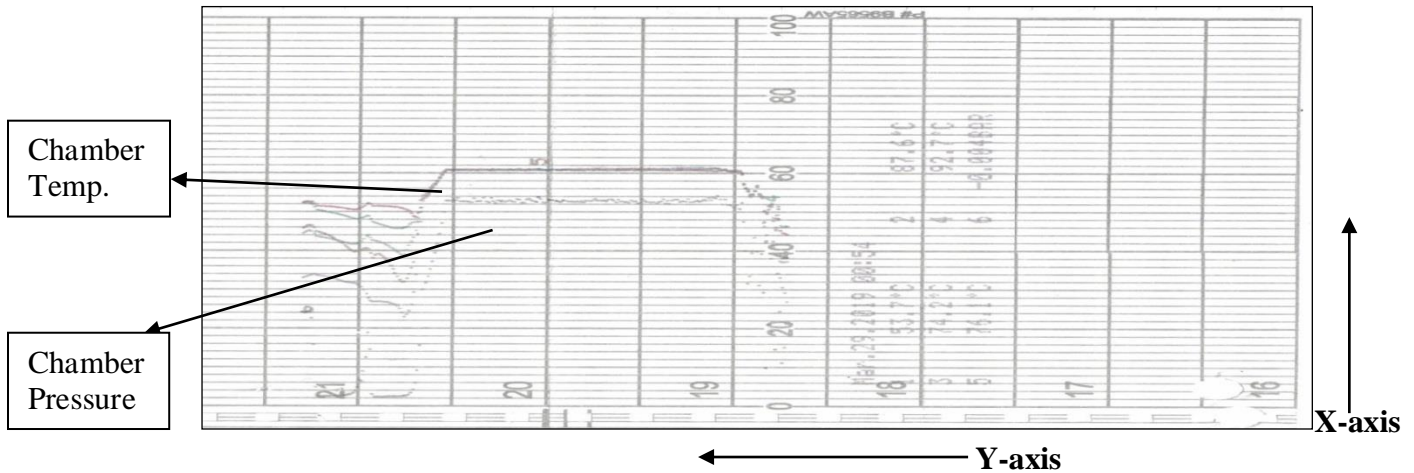
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Strip chart of Autoclave showing HPHV cycle

X axis = Temp. (°C)  
1 Div. = 4°C  
Y axis = Time. (Min)  
1 Div. = 10 min.

### 6.7 Selection of Cycle:

#### 6.7.1 Vacuum Leak Test:

6.7.1.1 Start the Vacuum Leak Test cycle as per following parameter for vacuum leak test of autoclave:

6.7.1.2 Acceptance **Criteria:** Actual vacuum leakage should be not more than **0.013 bar**.

**Frequency:** Daily

#### 6.7.2 Bowie Dick Test:

6.7.2.1 Start the Bowie Dick Test cycle as per parameter to check the air removal from chamber of autoclave:

6.7.2.2 **Acceptance criteria:** The Bowie-Dick Test Indicator should show a **uniform color change** from **Sky Blue to Black**.

6.7.2.3 No change, Non-Uniform Change and or Air Entrapment (bubble) Spot on the Test Pack indicates inadequate air removal from the sterilization chamber, if test not complies then repeat the process with new Bowie Dick Kit.



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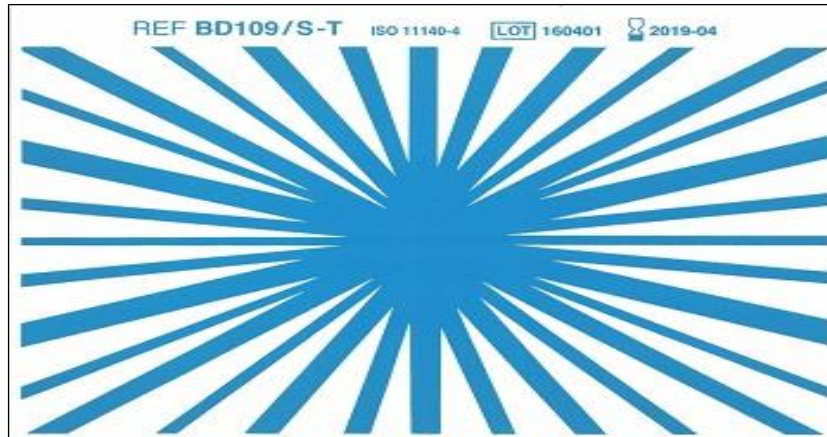
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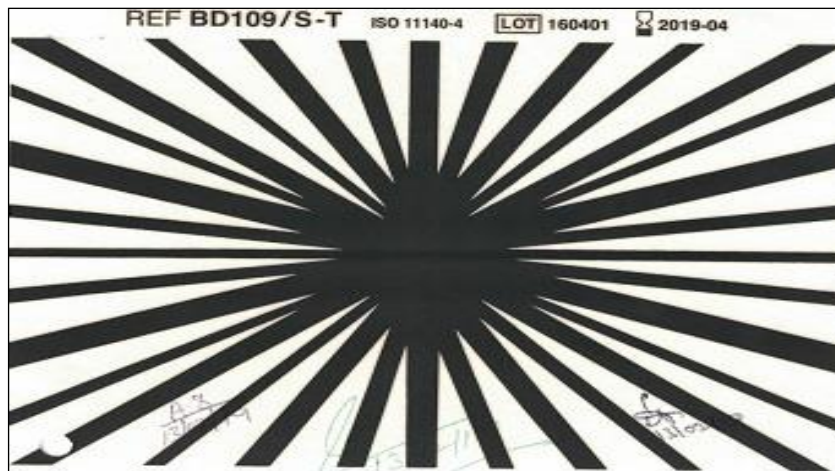
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**Bowie Dick kit  
Before Heat Expose**



**Representation of Bowie Dick kit before Heat Expose**

**Bowie Dick kit  
After Heat Expose**



**Representation of Bowie Dick kit after Heat Expose**

**Frequency:** Weekly  $\pm 2$  day.

### 6.7.3 STANDARD Process -1:

6.7.3.1 Start the STANDARD Process -1 as per parameter to sterilized the material:

6.7.3.2 Orientator Load : Load pattern No.- I

### 6.7.4 STANDARD Process -2:

6.7.4.1 Liquid Load : Load pattern No.- XII

6.7.4.2 Place (affix) the chemical indicator near drain (cold point of the HPHV), before start of sterilization cycle, in each load, to ensure the proper sterilization of subjected article.





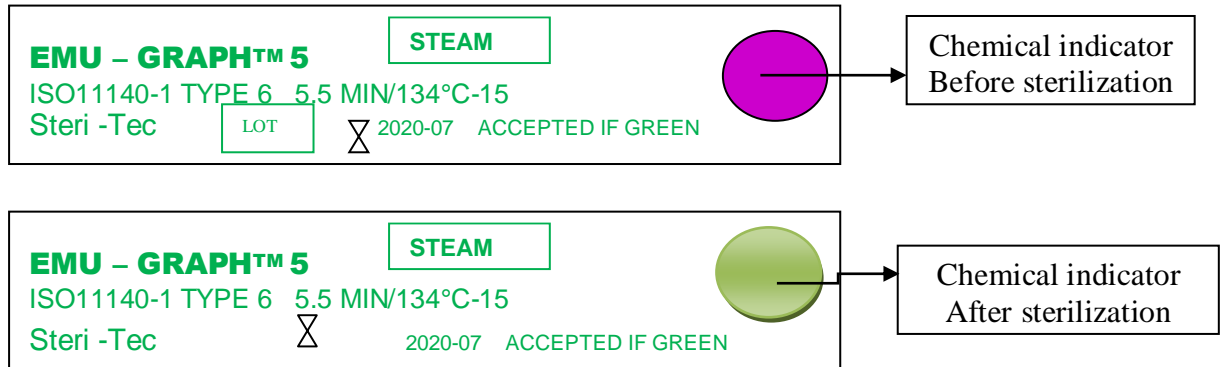
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### 6.7.5 HPHV process-1:

6.7.5.1 Start the HPHV Process 1 as per parameter Annexure III & IV to sterilized and dried the material:

6.7.5.2 Garment Load (Minimum) :- Load Pattern No.- II

6.7.5.3 Garments Load (Maximum) Load Pattern No.:- III

### 6.7.6 HPHV process 2 :

6.7.6.1 Start the HPHV PROCESS 2 as per Annexure No.- III & IV parameter to sterilized and dried the material:

6.7.6.2 Filling Machine Part & Accessory Load (Minimum): Load Pattern No:- IV

6.7.6.3 Filling Machine Part & Accessory Load (Maximum): Load Pattern No:- V

6.7.6.4 Filtration accessories: Load Pattern No:- VI

6.7.6.5 Filtration accessories: Load Pattern No:- VII

6.7.6.6 Filtration accessories: Load Pattern No:- VIII

6.7.6.7 Mfg. accessories load: Load Pattern No:- IX

6.7.6.8 Manufacturing filtration load (minimum): :- X

6.7.6.9 Manufacturing filtration load (minimum): :- XI

6.7.7 Check the print on the printing paper strip chart record paper.

6.7.8 Enter the details in the log book for each load.

6.7.9 After completion of the cycle, confirm the sterilization print and then unload the articles from the sterile side under the class 100 aseptically.

6.7.10 Transfer the articles through mobile LAF to work station.

6.7.11 **Estimation of F0 Value:**



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The actual observations obtained during the heat penetration studies at different temperature sensing locations are compiled in the table and the observed temperature shall be subjected for calculation of F<sub>0</sub> values at that particular location.

The lethality factor calculations are done by using the following formula and the computed (during the sterilization period) are given in the following table.

F<sub>0</sub> = dt ∑ 10<sup>(T-121)/Z</sup> ..... (a)

F<sub>0</sub> = dt ∑ (Sum of lethality factors).

Where,

dt = time interval between successive temperature measurements.

T = observed temperature at that particular time (as per the actual temperatures recorded).

Z = change in the heat resistance of *Geobacillus stearothermophilus* spores as temperature is changed (as Per COA).

6.7.12 F<sub>0</sub> Value for Biological Indicators:

The biological F<sub>0</sub> value for biological indicator strip exposed during the sterilization can be calculated as follows.

F<sub>0</sub> = D<sub>121</sub> (log A – log B)..... (b)

Where,

D <sub>121</sub>	D value of the biological indicator at 121°C.
A	Experimental Biological indicator concentration or spore population.
B	Desired level of sterility (SAL- 10 <sup>-6</sup> ).

Acceptance criteria of F<sub>0</sub> = 30 or above

6.8 Cleaning of High Pressure High Vacuum Autoclave :

- 6.8.1 Carry out the cleaning of the Autoclave from the Loading side. Do not open the both doors of autoclave at the same time off outside body of the HPHV Autoclave with wet sponge.
- 6.8.2 Wipe off all the pipe connections.
- 6.8.3 Take out drain cover screen; Scrub it thoroughly using nylon brush and 0.1% SLS Solution Wash it with water thoroughly.
- 6.8.4 Clean the chamber and door with, hot water and Nylon Brush. Wash thoroughly with Purified Water followed by final rinse with WFI.
- 6.8.5 Wash the trolleys and shelves with Purified water. Finally rinse it with WFI.



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**6.8.6** Cleaning Record of High Pressure High Vacuum Autoclave and entry done in Annexure No.-II.

**Frequency: Once in a day or when are required.**

**6.8.7** *Note: Sterilized items should be used before 24 hours from the time of their sterilization and sterilized garments should be used before 48 hours from the time of their sterilization.*

### 6.9 Precaution During Power Failure:

**6.9.1** If power failure occurs for few moment, which is not going to affect the sterilization hold time then continue the cycle and complete the load.

**6.9.2** If power failure occurs for a long time, due to which sterilization hold time of the load broken, then abort the cycle and again start the sterilization cycle. Refer SOP no. HPD/079 "Handling of Power Failure of Parenteral Blocks".

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Record of HPHV Steam Sterilizer	.....
Annexure-II	Load Detail Check Before Loading Into The Autoclave	.....
Annexure-III	Details of Set Parameter	.....
Annexure-IV	Pictorial Representation of Validated Load Pattern	.....
Annexure-V	Pictorial representation for preparation of load before sterilization	.....

**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:

- SOP: Handling of Power Failure of Parenteral Blocks

### 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-III DETAILS OF SET PARAMETER

S.No.	Parameter	Set parameter for VLT	Set Parameter for Bowie Dick	Set Parameter Standard Process-1	Set Parameter Standard Process-2	Set Parameter HPHV Process-1	Set Parameter HPHV Process-2
1.	Pre Vacuum	-0.700 Bar	-0.600 Bar	0.000 Bar	0.000 Bar	-0.600 Bar	-0.600 Bar
2.	Delay before hold	3 Min.					
3.	Vacuum Hold time	10 Min.					
4.	Acceptable Leakage	0.013 Bar					
5.	Pre pressure		0.500 Bar	0.000 Bar	0.000 Bar	0.500 Bar	0.500 Bar
6.	No. of pre pulse		03 Nos.	0 Nos.	0 Nos.	3 Nos.	03 Nos.
7.	Pre Pressure UP		0.700 Bar	0.700 Bar	0.700 Bar	0.700 Bar	0.700 Bar
8.	Pre Pressure Down		0.300 Bar	0.300 Bar	0.300 Bar	0.300 Bar	0.300 Bar
9.	No. of Positive pulses		05 Nos.	05 Nos.	05 Nos.	05 Nos.	05 Nos.
10.	Pre pressure Down Final		0.600 Bar	0.600 Bar	0.600 Bar	0.600 Bar	0.600 Bar
11.	Small valve SP		120.0°C	120.0°C	120.0°C	120.0°C	120.0 °C
12.	Ster. Hold temp.		121.4°C	121.4°C	121.4°C	121.4°C	121.4°C
13.	Ster. Hold time		660 Sec.	30 Minute	45 Minute	30 Min.	30 Min.
14.	Temp. Control Band		0.2°C	0.2°C	0.2°C	0.2°C	0.2°C
15.	Overshoot temp.		124.0°C	124.0°C	124.0°C	124.0 °C	124.0°C
16.	Ster. Stop temp.		120.9°C	120.9 °C	120.9 °C	120.9°C	120.9 °C
17.	Ster. Reset temp.		120.5°C	120.5°C	120.5°C	120.5°C	120.5°C
18.	Post Vacuum Start Pressure					0.200 Bar	0.200 Bar
19.	Post Vacuum					-0.600 Bar	-0.600 Bar
20.	Vacuum Hold time					05 Min.	05 Min.
21.	Post Pressure					-0.200 Bar	-0.200 Bar
22.	No. of Post Pulses					3 Nos.	02 Nos.
23.	Process End Pressure	-0.030 Bar	0.030 Bar	0.030 Bar	0.030 Bar	-0.030 Bar	-0.030 Bar
24.	Print interval	60 Sec	60 Sec	60 Sec		60 Sec	60 Sec






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### ANNEXURE-IV

#### PICTORIAL REPRESENTATION OF VALIDATED LOAD PATTERN

S.No.	Pictorial Representation of Validated Load Pattern in Operation and Cleaning of High Pressure High Vacuum Autoclave	Load Configuration	No. of Articles				
1.		<b>Orientator Load (Load pattern No.- I) (Standard Process-I)</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Orientator</td> <td style="width: 20%;">01 Nos.</td> </tr> </table>	Orientator	01 Nos.		
Orientator	01 Nos.						
2.		<b>Liquid Chemical Load (Load pattern No.- XII) (Standard Process-II)</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Liquid Chemical</td> <td style="width: 20%;">01 Nos. (1 Liter)</td> </tr> </table>	Liquid Chemical	01 Nos. (1 Liter)		
Liquid Chemical	01 Nos. (1 Liter)						
3.		<b>Minimum Garment Load (Load pattern No.- II) (HPHV Process -1)</b>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Antistatic Sterile Inner Garments (Lower+ upper +cap + booties) + Boiler Suit + Head Gear + Booties + Eye Goggles</td> <td style="width: 20%;">05 + 05 set</td> </tr> <tr> <td>Mopping pads</td> <td>06 Nos.</td> </tr> </table>	Antistatic Sterile Inner Garments (Lower+ upper +cap + booties) + Boiler Suit + Head Gear + Booties + Eye Goggles	05 + 05 set	Mopping pads	06 Nos.
Antistatic Sterile Inner Garments (Lower+ upper +cap + booties) + Boiler Suit + Head Gear + Booties + Eye Goggles	05 + 05 set						
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4.		<p style="text-align: center;"><b>Maximum Garment Load (Load Pattern No.:- III) (HPHV Process -1)</b></p> <table border="1"><tr><td>Antistatic Sterile Inner Garments (Lower+upper+cap+booties) + Boiler Suit + Head Gear +Booties+ Eye Goggles</td><td>20 + 20 set</td></tr><tr><td>Mopping pads</td><td>10 Nos.</td></tr></table>	Antistatic Sterile Inner Garments (Lower+upper+cap+booties) + Boiler Suit + Head Gear +Booties+ Eye Goggles	20 + 20 set	Mopping pads	10 Nos.														
Antistatic Sterile Inner Garments (Lower+upper+cap+booties) + Boiler Suit + Head Gear +Booties+ Eye Goggles	20 + 20 set																			
Mopping pads	10 Nos.																			
5.		<p style="text-align: center;"><b>Machine parts Load (Minimum) (Load Pattern No.:- IV) (HPHV Process -2)</b></p> <table border="1"><tr><td>Autoclavable Pen</td><td>01 No.</td></tr><tr><td>SS Forceps</td><td>02 Nos.</td></tr><tr><td>Scissor</td><td>02 Nos.</td></tr><tr><td>Silicon Tubes in SS container (NMT 2 mtr.)</td><td>02 Nos.</td></tr><tr><td>Cable Ties</td><td>10 Nos.</td></tr><tr><td>IPA Bottle</td><td>02 Nos.</td></tr><tr><td>Autoclavable Paper</td><td>06 Nos.</td></tr><tr><td>Bio Barrier Paper</td><td>04 Nos.</td></tr><tr><td>Mopping Pad</td><td>04 Nos.</td></tr></table>	Autoclavable Pen	01 No.	SS Forceps	02 Nos.	Scissor	02 Nos.	Silicon Tubes in SS container (NMT 2 mtr.)	02 Nos.	Cable Ties	10 Nos.	IPA Bottle	02 Nos.	Autoclavable Paper	06 Nos.	Bio Barrier Paper	04 Nos.	Mopping Pad	04 Nos.
Autoclavable Pen	01 No.																			
SS Forceps	02 Nos.																			
Scissor	02 Nos.																			
Silicon Tubes in SS container (NMT 2 mtr.)	02 Nos.																			
Cable Ties	10 Nos.																			
IPA Bottle	02 Nos.																			
Autoclavable Paper	06 Nos.																			
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### Machine parts Load (Maximum) (Load Pattern No.:- V) (HPHV Process -2)

Manifold Filling	01 No.
Filling Needle – Filling Machine Nozzle Mounting Bracket	06 Nos.
Silicon Tubes in SS container (NMT 2 mtr.)	31 Nos.
Chute – Sterilized Bottles	01 Nos.
Hopper – Dropper	01 Nos.
Chute – Dropper	01Nos.
Dropper Pressing Assembly	08 Nos.
Hopper – Screw Cap	01 Nos.
Chute – Screw Cap	01 Nos.
Capping Head Assembly	08 Nos.
Nut of Hoppers	08 Nos.
Scissor	02 Nos.
SS Forceps	08 Nos.
Nitrogen Gas Flushing Nozzles	13 Nos.
SS connector	06 Nos.
SS jug	04 Nos.
Autoclavable Pen	02 Nos.







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<b>07</b>		<table border="1"><thead><tr><th colspan="2"><b>Filtration Accessory Load (Load pattern No.:-VI) ( H.P.H.V Process-02 )</b></th></tr></thead><tbody><tr><td>Filter Housing(10 inch)</td><td>01 Nos.</td></tr><tr><td>SS Container(20 Litrs)</td><td>02 Nos.</td></tr><tr><td>SS Container(30 Litrs)</td><td>01 Nos.</td></tr><tr><td>SS Container (40 Litrs)</td><td>01 Nos.</td></tr><tr><td>Silicon tube (NMT 02 Mtr.)</td><td>04 Nos.</td></tr><tr><td>Scoop</td><td>02 Nos</td></tr><tr><td>Spatula</td><td>01 Nos</td></tr><tr><td>Spoon</td><td>01 Nos</td></tr></tbody></table>	<b>Filtration Accessory Load (Load pattern No.:-VI) ( H.P.H.V Process-02 )</b>		Filter Housing(10 inch)	01 Nos.	SS Container(20 Litrs)	02 Nos.	SS Container(30 Litrs)	01 Nos.	SS Container (40 Litrs)	01 Nos.	Silicon tube (NMT 02 Mtr.)	04 Nos.	Scoop	02 Nos	Spatula	01 Nos	Spoon	01 Nos						
<b>Filtration Accessory Load (Load pattern No.:-VI) ( H.P.H.V Process-02 )</b>																										
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<b>08</b>		<table border="1"><thead><tr><th colspan="2"><b>Filtration Accessory Load (Load pattern No.:-VII) ( H.P.H.V Process-02 )</b></th></tr></thead><tbody><tr><td>Cable Tie</td><td>30 Nos.</td></tr><tr><td>Autoclavable IPA bottle</td><td>10 Nos.</td></tr><tr><td>SS Mug. 1 Lit.</td><td>01 Nos.</td></tr><tr><td>SS Mug. 2 Lit.</td><td>01 Nos.</td></tr><tr><td>SS Mug. 5 Lit.</td><td>01 Nos.</td></tr><tr><td>Autoclavable Paper</td><td>06 Nos.</td></tr><tr><td>Bio Barrier Paper</td><td>04 Nos.</td></tr><tr><td>Mopping bucket</td><td>03 Nos.</td></tr><tr><td>Mopping Pad</td><td>10 Nos.</td></tr><tr><td>Mopping Head</td><td>01 Nos.</td></tr><tr><td>Mopping Handle</td><td>01 Nos.</td></tr></tbody></table>	<b>Filtration Accessory Load (Load pattern No.:-VII) ( H.P.H.V Process-02 )</b>		Cable Tie	30 Nos.	Autoclavable IPA bottle	10 Nos.	SS Mug. 1 Lit.	01 Nos.	SS Mug. 2 Lit.	01 Nos.	SS Mug. 5 Lit.	01 Nos.	Autoclavable Paper	06 Nos.	Bio Barrier Paper	04 Nos.	Mopping bucket	03 Nos.	Mopping Pad	10 Nos.	Mopping Head	01 Nos.	Mopping Handle	01 Nos.
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### Filtration Accessory Load (Load pattern No.:-VIII) ( H.P.H.V Process-02 )

SS Container (20 Litrs.)	01 Nos.
SS Container (15 Litrs.)	03 Nos.

10



### Manufacturing Accessory Load (Load pattern No.:-IX) ( H.P.H.V Process-02 )

SS Mug - 5 Lit.	2 Nos.
SS Mug - 2.5 Lit.	1 Nos.
SS Mug - 1 Lit.	2 Nos.
Air /N2/Vent filter (5 inch)	06 Nos.
Tool Box	01 Nos.
SS Spoon	04 Nos.
Silicon tubing (NMT 02 Mtr.)	02 Nos.
SS Sampling rod	01 Nos.
SS Container	03 Nos.
Measuring Cylinder(Glass)-1 Lit	01 Nos.
Measuring Cylinder(Glass)-2 Lit	01 Nos.
SS Forceps in SS Perforated Box	04 Nos.



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11		<b>Filtration Load (Minimum)</b> (Load pattern No.:-X) ( H.P.H.V Process-02 ) <table border="1" data-bbox="799 589 1485 1037"><tr><td data-bbox="799 589 1334 1037">Filter Housing(10 inch)</td><td data-bbox="1334 589 1485 1037">02 Nos.</td></tr></table>		Filter Housing(10 inch)	02 Nos.		
Filter Housing(10 inch)	02 Nos.						
12		<b>Filtration Load (Maximum)</b> (Load pattern No.:-XI) ( H.P.H.V Process-02 ) <table border="1" data-bbox="799 1187 1485 1608"><tr><td data-bbox="799 1187 1334 1413">Filter Housing (10 inch)</td><td data-bbox="1334 1187 1485 1413">02 Nos.</td></tr><tr><td data-bbox="799 1413 1334 1608">Filter Housing (5 inch)</td><td data-bbox="1334 1413 1485 1608">06 Nos.</td></tr></table>		Filter Housing (10 inch)	02 Nos.	Filter Housing (5 inch)	06 Nos.
Filter Housing (10 inch)	02 Nos.						
Filter Housing (5 inch)	06 Nos.						



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### ANNEXURE-V

### PICTORIAL REPRESENTATION FOR PREPARATION OF LOAD BEFORE STERILIZATION



**SS FILTER HOUSING**



**SCISSOR**



**IPA BOTTLE**



**CABLE TIES**



**SS JUG**



**AUTOVLAVABLE PAPER**



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**BIO BARRIER PAPER**



**TC CLAMP WITH SILICON GASKET**



**ORIENTATOR HOPPER**



**DROPPER HOPPER**



**CAPPING HOPPER**



**MANIFOLD WITH SS CONNECTOR SILICON TUBING AND FILLING NEEDLE**



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**NITROGEN PURGING  
NEEDLE**



**SILICON TUBE WITH SS TC  
NOZZLE**



**VIAL DROPPING ASSEMBLY**



**DROPPER CHUTE**



**SS JUG**



**HYDROPHOBIC DISC FILTER**



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**SS SCISSOR**



**SS FORCEP**