



STANDARD OPERATING PROCEDURE

Department: Microbiology

SOP No.:

Title: Operation & Cleaning of Double Door Steam Sterilizer

Effective Date:

Supersedes: Nil

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1.0 OBJECTIVE:

To lay down a procedure for Operation and Cleaning of Double Door Steam Sterilizer.

2.0 SCOPE:

This SOP is applicable for Operation and cleaning of Double Door Steam Sterilizer Make: Machine Fabrik, in Microbiology Section of Quality Control.

3.0 RESPONSIBILITY:

Officer / Executive-QC.

4.0 ACCOUNTABILITY:

Head-QC

5.0 PROCEDURE:

5.1 DEFINITION:

Autoclave is an instrument/equipment for the sterilization of materials by steam under pressure. The autoclave allows steam to flow around each article placed in the chamber. The vapor penetrates cloth or paper used to package the article being sterilized. Autoclave is one of the most effective methods for destruction of all types of microorganisms, including spores. The amount of time and degree of temperature necessary for sterilization depend on the articles to be sterilized and where they are wrapped or left directly exposed to the steam.

5.2 EQUIPMENT DETAILS:

5.2.1 Name : HPHV Steam Sterilizer.

5.2.2 Make : Machine Febrik

5.2.3 ID : PC/INS/S-15/02

5.3 EQUIPMENT DESCRIPTION:

5.3.1 The autoclave is a horizontal, HPHV, double door, rectangular type steam sterilizer with vertical sliding double door.

5.3.2 The sterilization chamber is made up of SS sheet, which is welded with U-profile SS jacket.

5.3.3 The sterilization chamber is providing with two vertical sliding doors, which are also made up of SS reinforced with support structure.

5.3.4 Both door will be opens with pneumatic cylinder.



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5.3.5 Both the door having interlocking system, which prevent opening of both door at the same time.

5.3.6 Compound gauges are located on both the side (Sterile & Non sterile).

5.3.7 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.

5.3.8 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.

5.4 PRE- START UP CHECK LIST:

5.4.1 Check the water level in tube, it shall be at least half of the marked glass tube.

5.4.2 Ensure the Autoclave unloading side door of sterility area is closed.

5.4.3 The compressed air pressure should be between 6-7 kg/cm².

5.4.4 Check the steam generator pressure before starting the cycle it should be NLT 1.2 kg/cm².

5.4.5 Check the printing paper is in place for the printer and the strip chart recorder.

5.4.6 Before every autoclave cycle, ensure that the Emergency key is release.

5.4.7 Ensure that the drain valve of steam generator (Boiler) is closed.

5.4.8 Ensure that chamber is clean before loading for the next cycle.

5.5 OPERATION OF AUTOCLAVE:

5.5.1 Open the door of control panel with help of lever given on the door, switch on the MCB of main supply and then control MCB inside the control panel of autoclave.

5.5.2 Turn on the [Control On] key, Feed pump will start to feed the water inside the steam generator tank (Boiler) and as water level comes up to the specified label Feed pump will automatically get off check the water label.

5.5.3 After turning on the [Control On] key wait till the following message display on main screen. This is start up screen.



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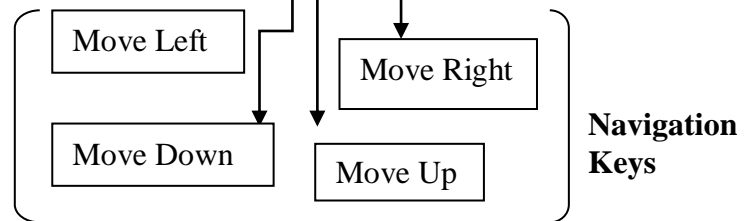
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12/09/22

12:32:00

Steam Sterilization
MFG: M/S Machine Fabrick
Industries Pvt. Ltd.

F1	F2	F3		F4	F5	F6
-	7	8	9			Back Space Enter
.	4	5	6			
0	1	2	3			



5.5.4 Switch on the heater by turning on the [Heater on] key on control panel.

5.5.5 Switch on the printer power by pressing the key inside the control panel.

5.5.6 HPHV steam sterilizer consist the following recipe for routine operation:

5.5.6.1 Vacuum leak test (once in a week)

5.5.6.2 Bowie Dick test (once in a fortnightly)

5.5.6.3 Standard process 1

5.5.6.4 Standard process 2

5.5.6.5 HPHV process 1

5.5.7 Press [F6] key following sub menu shall be displayed.

5.5.7.1 F1: Set Parameter press [F1] key to set or edit the cycle parameter.

5.5.7.1.1 F1: Vacuum leak test

5.5.7.1.2 F2: Bowie Dick test



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5.5.7.1.3 Standard Process

5.5.7.1.4 HPHV process

5.5.7.1.5 Next

5.5.7.1.6 Main

5.5.7.1.7 Select the cycle by pressing [F1 to F4] key to edit the set parameter of desired cycle if required after setting the parameter using password press [F2] key to save the set parameter and press [F6] to go on main screen.

5.5.7.2 F2: Process Data press [F2] key to check the current operating cycle process data status.

5.5.7.3 F3: Start up Screen press [F3] key to come on start screen following sub menu shall be displayed.

5.5.7.3.1 F1: Start Process.

5.5.7.3.2 F2: Print parameter

5.5.7.3.3 F3: Select Process

5.5.7.3.4 F4: Abort

5.5.7.3.5 F5: Pro end ack

5.5.7.3.6 F6: Main

5.5.7.3.7 Press [F6] key from main menu and then [F3] key cycle recipe shall be displayed on the top line of screen by pressing [F3] again and again cycle type on top line shall be changed when desired cycle displayed on top line of screen, press [F2] key to print the cycle parameter check the cycle parameter with **Annexure No-I**. If it is correct then press [F1] key to start the cycle.

5.5.7.4 F4: Batch Data press [F4] key to feed the batch data.

5.5.7.5 Sterilization cycle No.

5.5.7.5.1 Batch No.

5.5.7.5.2 Operator code

5.5.7.5.3 Quantity



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5.5.7.5.4 Print interval

5.5.7.5.5 MAIN

5.5.7.5.6 Feed the sterilization cycle number Batch number operator code before start the cycle if required to change in the print interval change the print interval.

5.5.7.6 F5: Login press [F5] key to login into the autoclave following sub menu shall be displayed.

5.5.7.6.1 F1: Login password press [F1] to login into autoclave.

5.5.7.6.2 F2: Log out press [F2] to logout.

5.5.7.6.3 F3: Edit password press [F3] to edit the password.

5.5.7.6.4 F4: Data clear press [F4] to clear the data.

5.5.7.6.5 F6: MAIN MENU

5.5.7.7 F6: Next press [F6] key to go in next screen. In next screen following parameter shall be displayed:

5.5.7.7.1 F1: Alarm History press [F1] to read the alarm history.

5.5.7.7.2 F2: Print Alarm History press [F2] to print the alarm history.

5.5.7.7.3 F3: Clear Alarm History press [F3] to clear the alarm history.

5.5.7.7.4 F4: Door Status press [F4] to check the door status following screen shall be displayed.

5.5.7.7.5 F1: Door Unlock, press [F1] to unlock the door.

5.5.7.7.6 F2: Door Lock/Acknowledge, press [F2] to lock the door media preparation room side door can be locked while opening of sterility area side door.

5.5.7.7.7 F6: Main press [F6] to come out from sub menu.

5.5.7.7.8 F6: Main Screen press [F6] to come out in main screen

5.5.8 To set the date and time in autoclave:

5.5.8.1 Press the [F1] key it will ask for password.



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5.5.8.2 Move the cursor under date of time as to be edited enter the desired value and press the enter [↵] key to save the changes.

5.5.9 Acknowledging of the Alarm:

5.5.9.1 Process data view:

T1	: 121.4	T2	: 121.9
T3	: 121.4	T4	: 121.5
T5	: 122.5	PR	: 01.098

5.5.9.2 When alarm hooter is on during the process.

5.5.9.3 Press [F1] key the list of alarm shall be displayed.

5.5.9.4 Press the down navigation key to see the message of alarm.

5.5.9.5 Press [F2] key to acknowledge the alarm and again press [F1] key to get back in process.

5.5.10 Acknowledging of the process end :

5.5.10.1 At the end of the process an MSG will be displayed on the screen.

5.5.10.2 [F1] Press [F1] key to acknowledge the process end.

5.5.10.3 [F6] main press [F6] key to come out from sub menu.

5.5.10.4 Press [F1] key to acknowledge the end process.

5.5.11 To load or unload the material from autoclave open the door by pushing [Open] button and to close by pushing the [Close] button on Autoclave near the door.

5.5.12 Operate the autoclave as per requirement and enter the details of cycle operated in **Annexure No.-II**.

5.6 OPERATION OF STRIP CHART RECORDER:

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

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



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5.6.3 To set the Date and Time:

5.6.3.1 Push [MENU] key approx 3 second until the message on display screen will change to [SET: range]. Range on display shall be blinked.

5.6.3.2 Push [DISP] key for set the clock, push [CH UP] key to set the desired parameter on display.

5.6.3.3 Push the [FUNC] key to adjust the cursor on clock YY/MM/DD, HH/MM/SS.

5.6.3.4 Push the [DISP] key to change in date and time value after editing date and time value.

5.6.3.5 Push the [CH UP] key two times to save the changed value of date and time.

5.6.3.6 Push the [MENU] key for approx 3 second main screen shall be displayed.

5.6.3.7 To forward the chart paper press [FEED] key.

5.6.4 To start the recording:

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

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

5.6.5 Scale reading procedure:

S.No.	Axis	Procedure
1.	X- Axis	a. 1 cm distance along X- axis (1 grid) covers 20°C temperature reading. b. 1 division in a grid representing 4°C. c. 1 cm distance along with X- axis (1 grid) covers 0.34 bar pressure. d. 1 division in a grid represents 0.07 bar. e. At X-axis "20" mark pressure is 0.00 bar. f. In strip chart recorder graph right side grid at X- axis from "20" mark shows positive pressure and left side grid shows negative pressure.
2.	Y-axis	a. 1cm distance along Y-axis (1grid) covers 10 minutes reading.

5.7 FREQUENCY:

5.7.1 Vacuum leak test - Once in a week

5.7.2 Bowie Dick test - Once in a fortnightly

5.7.3 Standard process 1- Whenever as required



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5.7.4 Standard process 2- Whenever as required

5.7.5 HPHV process 1 - Whenever as required

5.8 CLEANING OF AUTOCLAVE:

5.8.1 Daily cleaning:

5.8.1.1 Switch off MCB of autoclave inside the control panel.

5.8.1.2 Ensure that instrument having normal temperature and power point of autoclave is switched off.

5.8.1.3 Ensure that before cleaning autoclave chamber should be empty.

5.8.1.4 Clean the external surfaces of autoclave with clean and dry mop in case of tough stains use 70 % IPA.

5.8.1.5 In the cleaning of control panel do not spray any solvent.

5.8.2 Weekly Cleaning:

5.8.2.1 Clean the inner side of autoclave with WFI/purified water use hot WFI if media residue is present in the chamber.

5.8.2.2 Maintained the cleaning record as per **Annexure No-III**.

5.9 SAFETY PRECAUTION :

5.9.1 Check the Boiler pressure before start the cycle.

5.9.2 Always check the water level in the boiler before start the cycle.

5.9.3 Ensure there should not any leakage from the autoclave.

6.0 REFERENCES:

Instruction Manual

7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Details of Set Parameter	
Annexure-II	Double Door Steam Sterilizer Log	
Annexure-III	Cleaning Record of Double Door Steam Sterilizer Log	
Annexure-IV	Validated Load Patter Details of Autoclave Cycles	



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ENCLOSURES: SOP Training Record

8.0 DISTRIBUTION:

- Controlled Copy No. 01 Quality Assurance Department
- Controlled Copy No. 02 Quality Control Department
- Master Copy Quality Assurance Department

9.0 ABBREVIATIONS:

HPHV	High Pressure High Vacuum
IPA	Iso Propyl Alcohol
IPR	Intellectual Property Rights
MCB	Miniature Circuit Breaker
QC	Quality Control
SOP	Standard Operating Procedure
VLT	Vacuum Leak Test
WFI	Water for Injection

10.0 REVISION HISTORY:

CHANGE HISTORY LOG

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

ANNEXURE-I
DETAILS OF SET PARAMETER



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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
1	Pre Vaccum	-0.700 Bar	-0.600 Bar	0.000 Bar	0.000 Bar	-0.600 Bar
2	Delay before hold	3 Minute	NA	NA	NA	NA
3	Vaccum Hold time	10 Minute	NA	NA	NA	NA
4	Acceptable Leakage	0.013 Bar	NA	NA	NA	NA
5	Pre pressure	-0.050 Bar	0.500 Bar	0.000 Bar	0.000 Bar	0.500 Bar
6	No. of pre pulse	NA	03 Nos.	0 No.	0 No.	03 Nos.
7	Heat UP 1	NA	110°C	110°C	104.0°C	110°C
8	Heat UP Hold 1	NA	05 Minute	07 Minute	07 Minute	05 Minute
9	Heat UP 2	NA	115°C	115°C	109.0°C	115°C
10	Heat UP Hold 2	NA	04 Minute	05 Minute	05 Minute	04 Minute
11	Heat UP 3	NA	118°C	118°C	112°C	118°C
12	Heat UP Hold 3	NA	03 Minute	03 Minute	03 Minute	03 Minute
13	Heat UP band	NA	0.2°C	0.2°C	0.2°C	0.2°C
14	Small valve SP	NA	120.0°C	120.0°C	114.0.0°C	120.0 °C
15	Ster. Hold temperature	NA	121.4°C	121.4°C	115.4°C	121.4°C
16	Ster. Hold time	NA	1020 Sec.	20 Minute	15 Minute	30 Minute
17	Control Band	NA	0.2°C	0.2°C	0.2°C	0.2°C
18	Overshoot temperature	NA	124.0°C	124.0°C	118.0°C	124.0°C
19	Ster. Stop temperature	NA	120.9°C	120.9 °C	114.9°C	120.9 °C
20	Ster. Reset Temperature	NA	120.5°C	120.5°C	114.0°C	120.5°C
21	Post Vaccum Start Pressure	NA	NA	NA	NA	0.200 Bar
22	Post Vaccum	NA	NA	NA	NA	-0.5 00 Bar
23	Vaccum Hold time	NA	NA	NA	NA	05 Minute
24	Post Pressure	NA	NA	NA	NA	-0.100 Bar
25	No. of Post Pulses	NA	NA	NA	NA	02 No.
26	Process End Pressure	NA	0.040 BAR	0.035 BAR	0.030 BAR	-0.050 Bar
29	Print interval	60 Sec	60 Sec	60 Sec	60 Sec	60 Sec



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ANNEXURE-IV VALIDATED LOAD PATTERN DETAILS

S.No.	Type of Cycle	Load	Type of Load	Load Details
1	H.P.H.V.	Garment load	Minimum	Clean Room Garments - 03 set each in three perforated SS Containers Gloves 12 Pairs and 5 Moppers in SS Container
2	H.P.H.V.	Garment load	Maximum	Clean Room Garments - 03 set each in four perforated SS Containers Clean Room Garments - 03 set each in two perforated SS Containers Gloves 20 Pairs & 10 Moppers in one SS Container
3	H.P.H.V.	Petri plate load	Minimum	50 Petri Plates (90 mm) each in two perforated SS Containers 50 Petri Plates (90 mm) each in two perforated SS Containers
4	H.P.H.V.	Petri plate load	Maximum	50 Petri Plates (90 mm) each in four perforated SS Containers 50 Petri Plates (90 mm) each in four perforated SS Containers
5	H.P.H.V.	Accessories load	Minimum	Filtration Assembly-05 Nos. Forceps-10 Nos. Scissor-10 Nos. Membrane Filter (47 mm) -20 Nos. Three Manifold Assembly-01 Nos. Filtration flasks-01 Nos. Glass Beaker (500 ml) -02 Nos. Measuring Cylinder (100 ml) -01 Nos. Vial Opener-02 Nos. Silicon Tube-02 Nos. Air Sampler Head-02 Nos. Bottle 250 and 100 ml-15 Nos. Tubes (100 ml) -30 Nos. Glass Pipette (5 ml) -05 Nos.



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				Borer -04 Nos.
6	H.P.H.V.	Accessories Load	Maximum	Filtration Assembly-15 Nos. Forceps-20 Nos. Scissor-20 Nos. Membrane Filter (47 mm) -40 Nos. Three Manifold Assembly-01 Nos. Filtration flasks-02 Nos. Glass Pipette (5 ml) -30 Nos. Vial Opener-04 Nos. Silicon Tube-05 Nos. Air Sampler Head-02 Nos. Tubes (100 ml) -60 Nos. Micropipette Box -04 Nos. Borer -08 Nos.
7	STANDAD PROCESS	Agar Media	Minimum load	1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 500 ml Media containing in 1000 ml Flask/ Bottle. 1 X 300 ml Media containing in 500 ml Flask/ Bottle.
8	STANDAD PROCESS		Maximum load	18 X 700 ml Media containing in 1000 ml Flask/ Bottle. 10 X 500 ml Media containing in 1000 ml Flask/ Bottle.



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				4 X 300 ml Media containing in 500 ml Flask/ Bottle.
9	STANDAD PROCESS	Broth Media	Minimum load	30 X 100 ml Media containing in 38 X 200 mm tubes. 30 X 100 ml Media containing in 38 X 200 mm tubes. 30 X 100 ml Media containing in 38 X 200 mm tubes. 10 X 100 ml Media containing in 38 X 200 mm tubes. 10 X 100 ml Media containing in 38 X 200 mm tubes 10 X 100 ml Media containing in Bottle.
10	STANDAD PROCESS	Broth Media	Maximum load	60 X 100 ml Media containing in 38 X 200 mm tubes. 60 X 100 ml Media containing in 38 X 200 mm tubes. 60 X 100 ml Media containing in 38 X 200 mm tubes. 20 X 100 ml Media containing in 38 X 200 mm tubes. 40 X 100 ml Media containing in 38 X 200 mm tubes. 20 X 100 ml Media containing in Bottle.
11	STANDAD PROCESS	RVS and GN Broth Media	Standard Load	400 X 10 ml Media containing in 18 X 150 mm tubes in stand \ beaker (RVS Media) 60 X 100 ml Media containing in 38 X 200 mm tubes. (GN Broth Media)