PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

PERFORMANCE QUALIFICATION PROTOCOL FOR HPHV STEAM STERILIZER

EQUIPMENT ID. No.	
LOCATION	**Unit Preparation Room**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

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PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

1.0 PROTOCOL– APPROVAL:

PREPARED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OPERATING MANAGER (QUALITY ASSURANCE)			
HEAD (ENGINEERING			
HEAD (PRODUCTION)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

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2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all test parameters meet the pre-defined acceptance criteria.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the HPHV Steam sterilizer, installed in Unit Preparation & sterilization room.
- This Protocol will define the methods and documentation used to qualify the HPHV Steam sterilizer.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol.

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Review, the Performance Qualification Protocol. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Performance Qualification Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Analytical Support (Microbiological Testing/Analysis).
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence. • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

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5.0 EQUIPMENT DETAILS:

Equipment	HPHV Steam Sterilizer
Id Number	…….
Make	Machine Fabric
Sr. No.	5112/3213/17
Chamber size	600 (w) x 600 (h) x 900 (d) mm
Chamber volume	324 liters
Working pressure	Up to 2.2 kg/cm^2 (g)
Working temperature	Up to 134^0C
Location of Installation	Unit Preparation area

6.0 EQUIPEMENT DESCRIPTION:

- The Sterilizer manufactured by **M/s. Machin fabrik Industries Pvt. Ltd.,** is designed for the best possible adaptation to the needs of the customer.
- The High Pressure High Vacuum Sterilizer has been an unique Sterilization System offered by **M/s. Machinfabrik Industries Pvt. Ltd.,** as it can be efficiently used to perform two types of sterilization processes; viz:
    - **Standard Program**
    - **HPHV**

The identification for any leakage & penetration of steam can be tested by the following methods:

A) Chamber Leak Test (Cold)

B) Chamber Leak Test (Hot)

C) Bowie Dick Test

- As the name suggests the above two processes achieve sterilization with the help of Steam.

STANDARD STEAM STERILIZER:
Standard Program is a jacketed pressure vessel. The Standard Program cycle is initiated by introducing steam into the jacket. This essentially aids in preheating the chamber and effective utilization of heat energy.

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The Standard Displacement Program process is made up of three phases viz:-

a. Heat Up

b. Sterilization Hold

c. Exhaust (Cooling)

When the pressure inside the jacket is reached up to a particular set pressure. Steam is introduced into the chamber & chamber Air pockets are removed through the chamber condensate line. This will ensure uniform steam distribution and penetration in the chamber. The equipment is provided with steam traps & air vent system in chamber condensate line to ensure maximum removal of air pockets and steam condensate along with some wet steam vapors.

As the chamber temperature reaches to set sterilization temperature, the control system then control's the chamber temperature till the end of sterilization time.

After the sterilization hold time is completed, steam from the chamber is exhausted to bring down the chamber pressure up to the set Process End Pressure (close to atmospheric pressure).

The sterile load is then unloaded in the sterile area.

HIGH PRESSURE HIGH VACUUM STEAM STERILIZATION:

The High Pressure High Vacuum Steam Sterilization cycle process is used to sterilize & dry the load.

The High Pressure High Vacuum Steam Sterilization cycle consists of following phases viz:-

a. Vacuum Steam Pulsing

b. Heat up

c. Sterilization Hold

d. Vacuum drying

e. Sterile Air In (Vacuum break)

This process is initiated by introducing steam into the jacket. This essentially aids in preheating the chamber and effective utilization of heat energy. In this process initially vacuum is created & then steam is introduced in the chamber up to the set value. These pulses are created 3 to 4 times to remove the air pockets. Almost 95% removal of air is ensured from chamber. The steam & vacuum pulsing not only ensures removal of air pockets and cold spots but also ensures uniform temperature distribution & penetration.

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The vacuum is created with the help of water ring type vacuum pump.

After completion of fixed no. of pulses, the chamber temperature reaches to set sterilization temperature. The control system then control's the chamber temperature till the end of sterilization time.

After the completion of sterilization time, vacuum up to a pre – determined level is created in the chamber. When this vacuum level is reached, the control system ensures that the vacuum is maintained for the specified time. The vacuum created at this stage ensures drying of the load inside the chamber.

After the completion of vacuum drying time, the –ve pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

The sterilized load is then unloaded from the chamber.

A. VACUUM LEAK TEST (COLD):

- In this process initially vacuum is created up to the set level. Then it will hold as per the given delay hold time to settle down the vacuum in chamber, after that actual vacuum hold time will start to know the chamber leakage

  After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

B. VACUUM LEAK TEST (HOT) :

1) In this process steam is introduced into the jacket, this preheats the chamber. After that vacuum is created & then steam is introduced in the chamber upto set value, these pulses are repeated 3 to 4 times to remove air pockets. In heat up, exhaust & steam pulses is Repeated to for uniform temperature distribution & protection.
2) After completion of fixed no. of pulses the chamber temperature reaches to set sterilization temperature. The control system then control the chamber temperature tills the end of Sterilization time.
3) After the sterilization chamber vacuum valve open to create vacuum & help in drying.
4) Then it will hold as per the given delay hold time to settle down the vacuum in chamber, after that actual vacuum hold time will start (as per mention in HTM 2010 guideline) to know the chamber leakage. After the completion of vacuum hold time, the negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

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C. BOWIE DICK TEST :

1) In this process steam is introduced into the jacket, this preheats the chamber. after that vacuum is created & then steam is introduced in the chamber upto set value, these pulses are repeated 3 to 4 times to remove air pockets. In heat up exhaust & steam pulses is repeated to for uniform temperature distribution & protection.
2) After completion of fixed no. of pulses the chamber temperature reaches to set sterilization temperature. The control system then control the chamber temperature tills the end of sterilization time.
3) After the sterilization, Positive pressure in chamber is brought to atmospheric pressure by opening chamber exhaust valve.

7.0 REASON FOR QUALIFICATION:

- New Equipment Come in Unit Preparation.

8.0 SITE OF STUDY:

- HPHV steam sterilizer.

9.0 FREQUENCY OF QUALIFICATION:

- After any major breakdown or after major modification.
- After Change of Location.
- 6 month ± one month

10.0 PRE – QUALIFICATION REQUIREMENTS:

- Verification for availability, completeness and approval status of all the required relevant documents and observations shall be recorded in the performance qualification report.

10.1 STEAM QUALITY TEST:

- Prior to the Performance Qualification Study Pure Steam Generation and Distribution System Should be in Qualified Status.
- However the Quality of Steam parameters shall be ensured before the performance Qualification of Steam Sterilizer.

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- Steam Quality testing shall be Carried out at the steam supply line.
- Parameters like Physical, Chemical and Microbiological Test shall be Carried out from the Steam supply line to ensure Quality as per WFI Specification as below mentioned.

S.No.	PARAMETER	ACCEPTANCE CRITERIA
Physical Parameter		
1.	Non Condensable Gases	NMT 3.5%
2.	Dryness	NLT 0.90 (or NLT 0.95 for metal loads)
3.	Super Heat	NMT 25°C
Chemical Parameter		
1.	pH	5.0 -7.0
2.	Conductivity	NMT 1.3µS/cm at 25°C
3.	TOC	NMT 500 ppb
Microbiological Parameter		
1.	TVAC	NMT 10 CFU/100 ml
2.	BET	NMT 0.25 EU/ml

10.2 TEST EQUIPMENT:

S.No.	Test Instrument
1.	Duly Calibrated Data logger with calibrated sensors.
2.	Biological Indicator 10^6 spores i.e. *Geobacillus stearothermophilus* must be checked for spore population.
3.	Chemical Indicator
4.	All parts of autoclave used for measurement like temperature sensors, pressure gauges, and timers must be calibrated.

10.3 Biological Indicator Detail Should be Mentioned in Performance Qualification Report.

10.4 TEST EQUIPMENT CALIBRATION:

Review the calibration status for the test equipment (Data Logger with sensors) to be utilized and record the calibration status Performance qualification report. All Equipment/Instrumentation must

remain within the Calibration due date for the duration of Validation Study for which the item is used. If a due date potentially occurs during the testing period then the instrument must be recalibrated before it is utilized.

Record the Calibration details in Performance Qualification Report.

10.5 CALIBRATION OF TEMPERATURE SENSORS:

- Pre & Post Calibration of Temperature Sensors

  Pre & Post calibration shall be carried out before starting and after completion of Validation activity.

10.6 PRE & POST CALIBRATION OF TEMPERATURE SENSORS:

A) PROCEDURE:

- Temperature sensors which are to be used for Qualification study shall be calibrate in Ice Bath at approximately 0°C and in High Temperature reference block at 30°C 50°C, 100°C,200°C & 350 °C prior to its usage in the qualification.
- Record the Temperature of all the sensors while putting them in ice bath after one minute of temperature stabilization.
- Put individual sensor to the slot of High temperature Reference block which is stabilized at required temperature. Record the readings at least one minute after stabilization of temperature.
- Record the Temperature for five minutes by data logger and attach the print out in Performance Qualification Report.

B) ACCEPTANCE CRITERIA:

- No temperature sensor should vary by 1°C in Ice Bath from the mean of temperatures shown by the calibrated thermometer during the data-logging period.
- No temperature sensor should vary by 1°C in High temperature reference block from the mean of temperatures shown by calibrated thermometer during data- logging period.

D) TRAINING OF EXECUTION TEAM:

- Provide the training to a team for the execution of protocol before execution of the same.
- Record of training shall be recorded in Performance Qualification Report.

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11.0 TESTS AND CHECKS:

- The autoclave will be considered validated on successful completion of the following tests.
- Vacuum Leak test
- Bowie-Dick Test
- Hot Leak test
- Empty chamber heat distribution (Standard Process) studies at 121.4°C for 30 min with temperature sensors.
- Empty chamber heat distribution (HPHV Process) studies with temperature sensors.
- Detection of cold spot.
- Loaded chamber heat penetration studies for each sterilization load of fixed loading pattern, with temperature sensors inside the innermost possible layer of the load subjected for sterilization.
- Post vacuum leak test.
- Bio-challenge studies using ***Geobacillus Stearothermophillus*** spore ampoule (containing 10^6 or more spore) during the heat penetration studies.
- Estimation of the F_0 value achieved during the sterilization hold period at each temperature sensor.
- Estimation of Desired & Actual Spore Log Reduction after each Loaded Heat Penetration cycle the documents should be available, complete and approved by respective authorities.

Load Pattern:

1. Vacuum Leak Test (3Cycles)
2. Vacuum Leak Test (Hot) (3Cycles)
3. Bowie-Dick Test (3Cycles)
4. Heat Distribution Study. Standard Process. (Empty Chamber) (3Cycle)
5. Heat Distribution Study. HPHV Process. (Empty Chamber) (3Cycle)
6. Heat Penetration Study H.P.H.V.-01 (Inner Garment Loaded Chamber) (8 dress Minimum) (3 Cycle)
7. Heat Penetration Study H.P.H.V.-01 (Inner Garment Loaded Chamber) (32 set garment with 4 surgical bin Maximum) (3 Cycle)
8. Heat Penetration Study H.P.H.V.-01 (Sterile Garment Loaded Chamber) (8 dress Minimum) (3 Cycle)

9. Heat Penetration Study H.P.H.V.-01 (Sterile Garment Loaded Chamber) (28 set garment with 4 surgical bin Maximum) (3 Cycle)
10. Heat Penetration Study HPHV Process .-01 (Pressure vessel, clamp, gasket,) (3 Cycle)
11. Heat Penetration Study HPHV Process-2. (Accessory Load) (3 Cycle)
    (Moping pad(12 Nos.), Gloves (10 Pair), Silicon Tube 2 meter (02 Nos.), Filter Housing with filter (01 Nos.) , IPA Bottles (04 Nos.), Bucket of three bucket system & SS Flexible pipe 2 meter (02 Nos.).
12. Heat Penetration Study HPHV Process-2. (Mix Load) (3 Cycle)
    Silicon Tube 2 meter (02 Nos.), Bucket of three bucket system, SS Mug 05 Liters (01 Nos.), SS Mug 02 Liters (01 Nos.), SS Mug 01 Liter (01 Nos.), IPA Bottles 04 Nos., Bio barrier Paper (1x1 meter) 04 Nos. & Eye Google (10 Nos.).
13. Estimation of the F_0 Process minimum for Heat Penetration Studies.
14. Biological/ Bacteriological evaluation of each cycle of Heat Penetration Studies.
15. Estimation of Desired & Actual Spore Log Reduction.

11.1 VACUUM LEAK TEST :

11.1.0 Objective

To verify the Leakage in Sterilization Chamber during Vacuum Hold when the Sterilization Chamber is empty.

11.1.1 Procedure

- Operate the equipment as per SOP of “operation & cleaning of HPHV Steam sterilizer”
- Set the following parameters

Pre Vacuum	=	- 0.700 Bar
Delay before Hold	=	3 Minute
Vacuum Hold Time	=	10 Minute
Acceptable Leakage	=	NMT 0.013 Bar
Process End Pressure	=	-0.030 Bar

- Check the pressure of the chamber initially.
- Record the pressure of the chamber after three min. of getting start the autoclave.
- Record the pressure of the chamber after ten min. of getting start the autoclave.
- Measure the difference between the pressures.

- Calculate the difference of pressure per min.
- Each Cycle Should be Performed at three time

11.1.2 Acceptance Criteria

Actual vacuum leakage should be not more than **0.013 Bar.**

Evaluation of Result: If Actual vacuum leakage is not within the specified limit, check the Gasket & other joints of the chamber. If the Minimum vacuum leakage is not achievable, Gasket shall be changed or any other appropriate measures be taken to achieve the acceptance criteria.

11.2 HOT LEAK TEST:

11.2.0 Objective

- To verify the Leakage in Sterilization Chamber during Vacuum Hold when the Sterilization Chamber is hot & empty.

11.2.1 Procedure

- Operate the equipment as per SOP of "operation & cleaning of HPHV Steam sterilizer"
- Set the following parameters

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of pre pulses	To repeat the vacuum pressure pulses	3 Nos.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	05 Min
Over Shoot Temperature	To indicate through the alarm when there is excess temp in the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature	120.9 ºC

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Parameter	Purpose	Set Value
Sterilization Reset Tem.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.5 ºC
Post Vacuum start Pressure	To exhaust the steam from chamber & to start the vacuum pump	0.200
Post Vacuum	To achieve set level of vacuum	-0.500
Vacuum Drying time	To achieve set level of vacuum	15 min
Delay before hold	To stabilize the vacuum	5 min
Vacuum Hold Time	To maintain the desired vacuum level up to particular time	10 min
Acceptable Leakage	Limit beyond witch leakage not acceptable	0.013 Bar
Process End Pressure	To end the process & allow to unload the material	0.030 Bar

- After completion of Cycle collect thermograph from the multipoint temperature recorder of the steam sterilizer and attach in Performance Qualification Report.
- Each Cycle Should be Performed at three time
- Note down the Vacuum hold start pressure and Vacuum hold end pressure
- Difference of these two will give the actual leakage.

11.2.2 Acceptance Criteria

Actual vacuum leakage should be not more than **0.013 Bar.**

11.3 BOWIE-DICK TEST:

11.3.0 Objective

- To ensure that the Vacuum Pulses applied before the Sterilization Hold Period are sufficient to remove the Entrapped Air or Non-Condensable Gases so as to facilitate rapid and even Steam Penetration into all parts of the load and maintaining these conditions for the Specified Temperature Hold Time (660 Sec. at 121.4°C).

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- If air is present in the chamber, it will collect within the Bowie-Dick Test Pack as a Bubble. The indicator in the region of the Bubble will be of different color as compared to the color on the remaining part of the test paper, because of a lower temperature, lower moisture level or both. In this condition the cycle parameters to be reviewed and the normal sterilization cycles to be modified accordingly.

11.3.1 Procedure

- Operate the equipment as per SOP. on operation of HPHV Steam sterilizer
- Set the following parameters in PLC.

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 bar
Pre pressure	To break the vacuum with steam	0.500 bar
No. of pre pulses	To repeat the vacuum pressure pulses	3 Nos.
Pre pressure up	For pressure pulses to improve heat distribution	0.700 bar
Pre pressure down	For pressure pulses to improve heat distribution	0.300 bar
No. of Positive Pulses	To repeat the pulses to improve heat distribution	05 Nos.
Pre pressure down final	--	0.600 bar
Ster. Hold temp.	Sterilization	121.4°C
Ster. Hold time	To hold the sterilization period as per the set time	660 Sec.
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Ster. Stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization	120.9ºC
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.5ºC
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Place one Bowie-Dick Test Pack in the center (Near Drain) of the sterilization chamber, supported approximately 100 to 200 mm above the sterilization chamber base as given in Figure 1.

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- The printout taken during the Bowie-Dick test cycle & the Bowie-Dick test indicator should be attached in the Performance Qualification Report.
- Compile the observations made during the test for complete evaluation of the system.

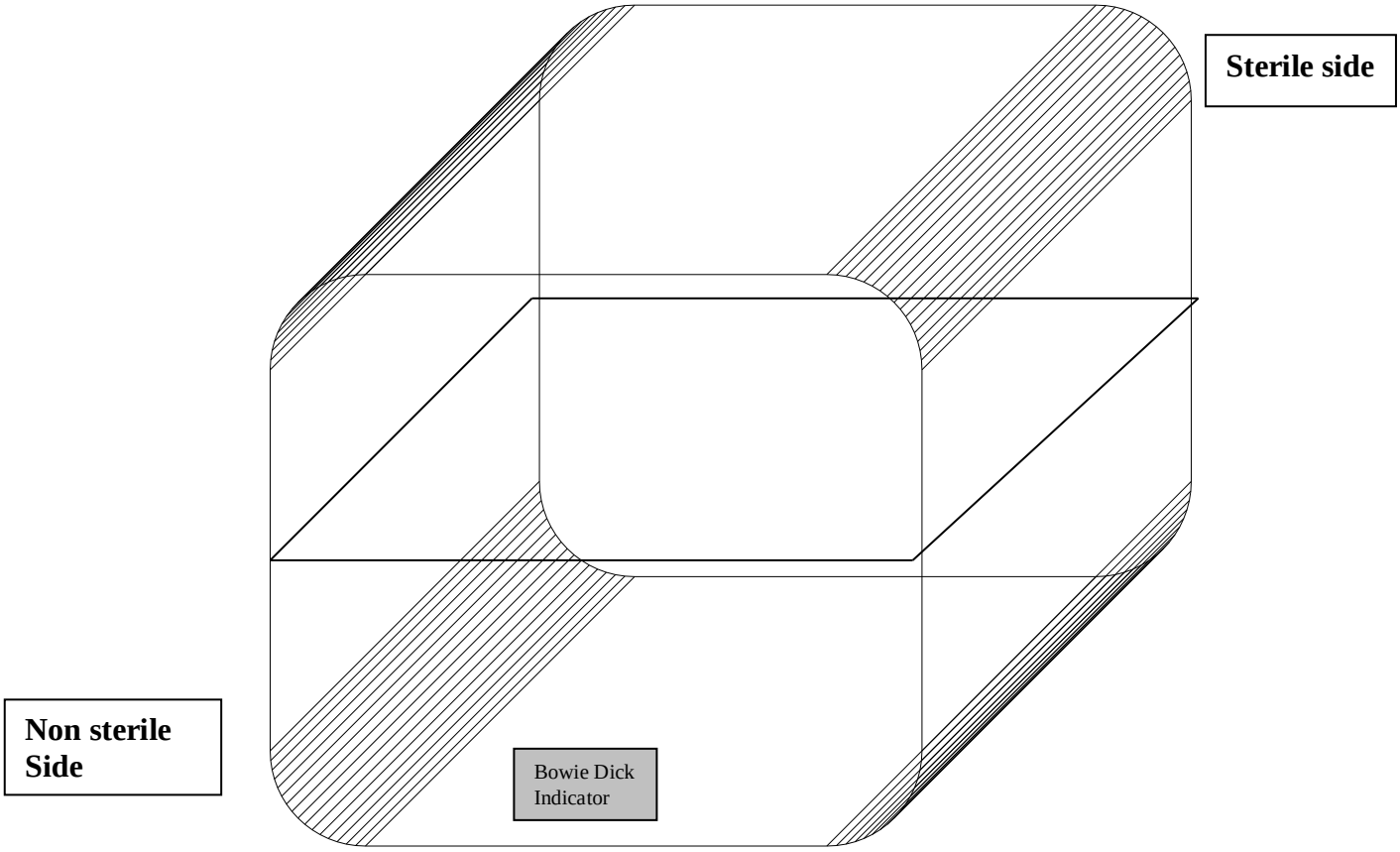

Figure 1: Location of Bowie Dick test Indicator inside the chamber at Drain Point.

11.3.2 Acceptance Criteria

The Bowie-Dick Test Indicator should show a uniform color change. No change, Non-Uniform Change and / or Air Entrapment (bubble) Spot on the Test Pack indicates inadequate air removal from the sterilization chamber.

11.3.3 Observation :

Record the observations in Performance Qualification Report.

11.3.4 Evaluation of Result

Uniform color changes of Bowie Dick test Indicator shows the absence of Entrapped air or non Condensable gases inside the chamber. In case of Entrapped air or non condensable gases inside the

chamber, vacuum leak test shall be rechecked and also check other joints. After taking proper Corrective measures, Bowie Dick Test shall be re-checked and cycle also be run again.

11.4 HEAT DISTRIBUTION STUDY FOR STANDARD PROCESS (EMPTY CHAMBER):

11.4.0 Objective

- To verify Temperature Uniformity throughout the Chamber and to locate the Cold Spot in Empty Chamber.
- The sterilizer is capable of attaining a temperature of 121.4°C during the sterilization hold period with steam pressure of 1.1 to 1.2 Kg/cm².
- To verify that at any location(s) where the probes are placed, achieving Minimum Sterilization Temperature 121.4°C throughout the Sterilization Temperature Hold will be considered as Cold Spot.

11.4.1 EQUIPMENT/INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated sensors
- **Procedure** Insert 12 Nos. of Temperature Sensors inside the Chamber through the Validation Port of the Steam Sterilizer. Seal the validation port with Silicon Sealant to ensure no steam leakage during operation of steam sterilizer.
- Fix the Probes at the location in Sterilizer Chamber so that probes do not touch any metallic surface. Positions of Temperature Sensors are shown in Figure.
- Connect the Sensors to Data Logger, which can scan and print the actual temperature observed at different locations with respect to time.
- Set the following parameters in PLC & operate the Steam Sterilizer as per SOP and also start the data logger to record actual temperatures within the sterilization chamber with respect to time.
- Set the following parameters in PLC.

Parameter Settings for Standard Process:

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	0.000 Bar
Pre pressure	To break the vacuum with steam	0.000 Bar
No. of pre pulses	To repeat the vacuum pressure pulses	0 Nos.

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Parameter	Purpose	Set Value
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Over Shoot Temperature	To indicate through the alarm when there is excess temp in the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature	120.9 ºC
Sterilization Reset Tem.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.5 ºC
Process End Pressure	To end the process & allow to unload the material	0.030 Bar

- After completion of Sterilization Cycle collect thermograph from the multipoint temperature recorder of the steam sterilizer and attach in Performance Qualification Report.
- Download the data from data logger into the computer for data-analysis & graph preparation. Take print out & attach in Performance Qualification Report.
- Record the temperatures observed at different locations in the Performance Qualification Report
- Three cycles shall be carried out as per above Parameters and Procedure.
- Compile the data generated during the qualification, for complete evaluation of the system.

Location of Temperature Sensors inside the Chamber

Sensor No.	Location in the Chamber
01	In the drain of the autoclave chamber. T1
02	Upper left front corner of non sterile side with inbuilt sensor T2
03	Lower left sterile side with inbuilt sensor T3
04	Upper right, on sterile side of the chamber with inbuilt sensor T4
05	Lower Right Non sterile side of the chamber with inbuilt sensor T5
06	Left side centre (front) on non sterile side
07	Middle of the chamber lower side

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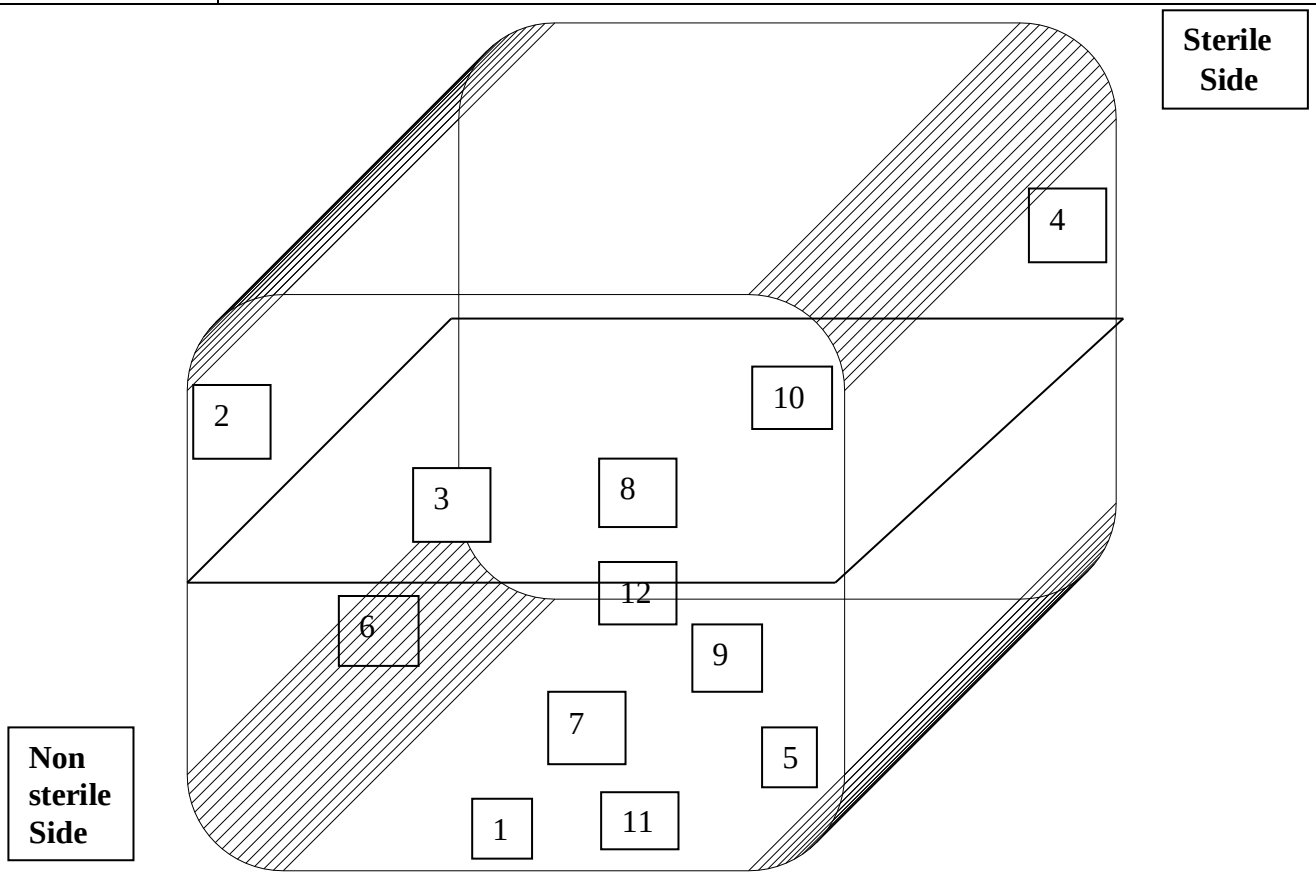
08	Middle of the chamber upper side
09	Lower right, on sterile side of the chamber
10	upper right, on sterile side of the chamber
11	Upper front, non sterile side of the chamber
12	Lower front, non sterile side of the chamber



11.4.2 ACCEPTANCE CRITERIA

- There should be uniform distribution of heat in the steam sterilizer chamber during the sterilization hold period and the temperature at each temperature mapping probe should be within the range of 121.4°C to 124°C during the Sterilization Hold Period.
- Temperature Uniformity at a given time of Temperature recording between all probes during hold period should not be more than ± 1°C.
- Equilibrium Time for Temperature Hold NMT 15 Second

11.4.3 OBSERVATION :

- Record the observations in Performance Qualification Report.

11.4.4 EVALUATION OF RESULT

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- If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface.
- After taking proper corrective measures, Heat Distribution shall be re-performed.

11.5 HEAT DISTRIBUTION STUDY FOR HPHV PROCESS (EMPTY CHAMBER):

11.5.0 Objective

- To verify Temperature Uniformity throughout the Chamber and to locate the Cold Spot in Empty Chamber.
- The sterilizer is capable of attaining a temperature of 121.4°C during the sterilization hold period with steam pressure of 1.1 to 1.2 Kg/cm².
- To verify that at any location(s) where the probes are placed, achieving Minimum Sterilization Temperature 121.4 °C throughout the Sterilization Temperature Hold will be considered as Cold Spot.

11.5.1 EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated sensors

11.5.2 Procedure

- Insert 12 Nos. of Temperature Sensors inside the Chamber through the Validation Port of the Steam Sterilizer.
- Seal the validation port with Silicon Sealant to ensure no steam leakage during operation of steam sterilizer.
- Fix the Probes at the location in Sterilizer Chamber so that probes do not touch any metallic surface. Positions of Temperature Sensors are shown in Figure.
- Connect the Sensors to Data Logger, which can scan and print the actual temperature observed at different locations with respect to time.
- Set the following parameters in PLC & operate the Steam Sterilizer as per SOP and also start the data logger to record actual temperatures within the sterilization chamber with respect to time.
- Set the following parameters in PLC.

Parameter Settings for HPHV Process:

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar

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Parameter	Purpose	Set Value
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls	120.9 ºC
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- After completion of Sterilization Cycle collect thermograph from the multipoint temperature recorder of the steam sterilizer and attach in Performance Qualification Report.
- Download the data from data logger into the computer for data-analysis & graph preparation. Take print out & attach in Performance Qualification Report.
- Record the temperatures observed at different locations in the Performance Qualification Report
- Three cycles shall be carried out as per above Parameters and Procedure.
- Compile the data generated during the qualification, for complete evaluation of the system.

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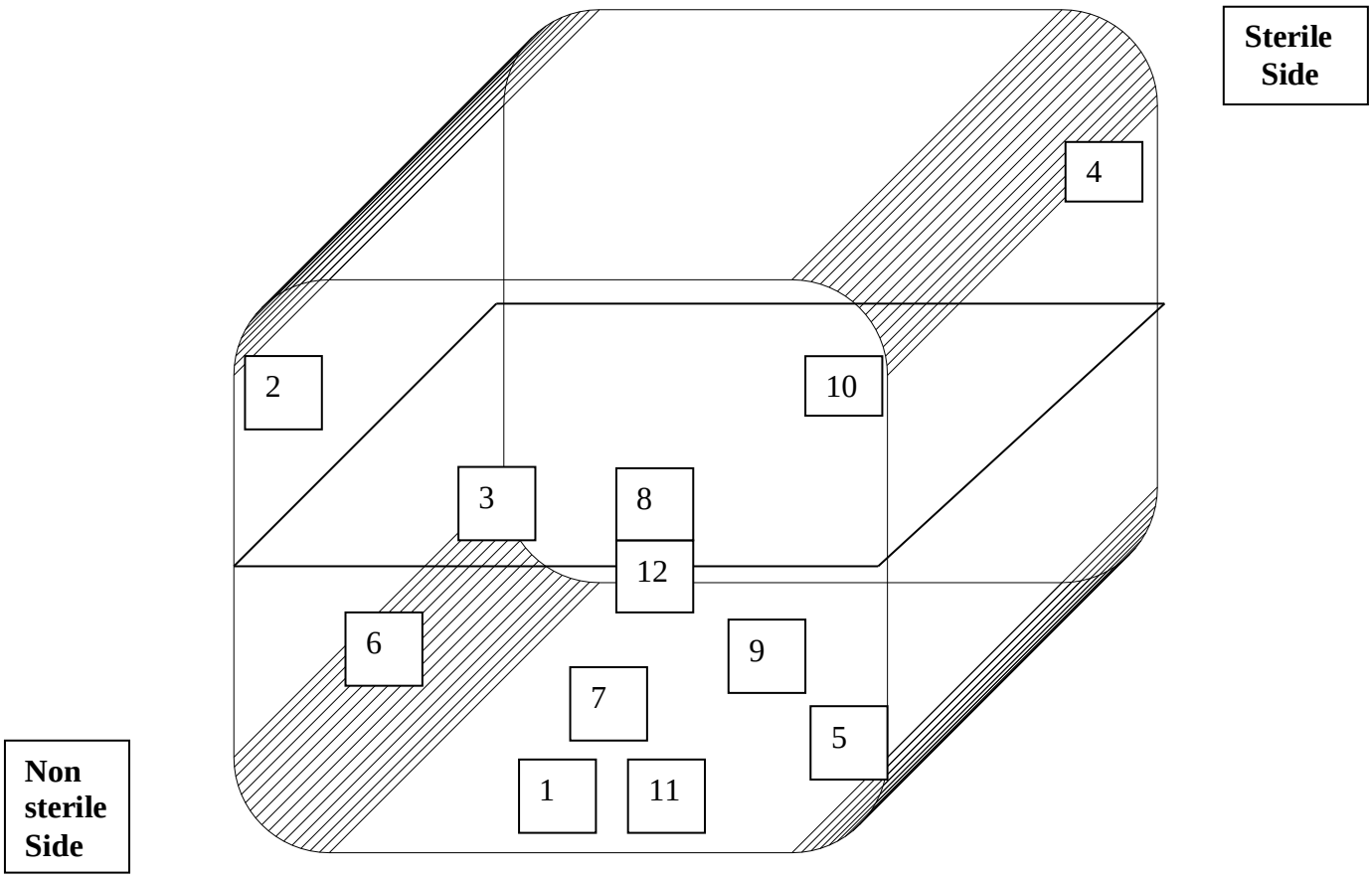
Location of Temperature Sensors inside the Chamber

Sensor No.	Location in the Chamber
01	In the drain of the autoclave chamber.
02	Upper left front corner of non sterile side with inbuilt sensor T2
03	Lower left sterile side with inbuilt sensor T3
04	Upper right, on sterile side of the chamber with inbuilt sensor T4
05	Lower Right sterile side of the chamber with inbuilt sensor T5
06	Left side centre (front) on non sterile side
07	Middle of the chamber lower side
08	Middle of the chamber upper side
09	Lower right, on sterile side of the chamber
10	upper right, on sterile side of the chamber
11	Upper front, non sterile side of the chamber
12	Lower front, non sterile side of the chamber



PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

11.5.3 ACCEPTANCE CRITERIA

- There should be uniform distribution of heat in the steam sterilizer chamber during the sterilization hold period and the temperature at each temperature mapping probe should be within the range of 121.4°C to 124°C during the Sterilization Hold Period.
- Temperature Uniformity at a given time of Temperature recording between all probes during hold period should not be more than ± 1°C.
- Equilibrium Time for Temperature Hold NMT 15 Second

11.5.4 OBSERVATION :

- Record the observations in Performance Qualification Report.

11.5.5 EVALUATION OF RESULT

- Heat Distribution Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold Period is found within ± 1°C.
- If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface.
- After taking proper corrective measures, Heat Distribution shall be re-performed.

11.6 HEAT PENETRATION STUDY:

11.6.0 Objective

- To ensure that the steam is sufficiently penetrating into the innermost portions of the load subjected for Sterilization to achieve desired Temperature of 121.4°C during the whole Sterilization Hold Period with Steam Pressure of 1.2 to 1.4 Kg/Cm^2.
- To ensure that if Sterilization Temperature (121.4°C) is not achieved throughout the cycle, load configuration or size of the load has to be reviewed and Sterilization Cycles to be repeated.
- To ensure that temperature spread within the range of 121.4°C to 124°C during Sterilization Hold Period indicate that, Uniform Heating Process which is achieved in the Empty Chamber Heat Distribution Study is not affected by load. There could be the possibility of lag period for attaining 121.4°C during heat penetration trials as the probes are placed deep into the load.
- Heat Penetration studies shall be carried out with the following different loads:

  Heat Penetration studies.
- Minimum Inner Garment Load **(HPHV Process)**
- Maximum Inner Garment Load **(HPHV Process)**

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Minimum Sterile Garment Load **(HPHV Process)**
- Maximum Sterile Garment Load **(HPHV Process)**
- Heat Penetration Study **(HPHV Process) with Pressure Vessel, Clamp & Gasket**
- Accessory load **(HPHV Process)**
- Mixed (Miscellaneous) Load **(HPHV Process)**

11.7 HEAT PENETRATION STUDY H.P.H.V-PROCESS-1 (INNER GARMENT LOADED CHAMBER) (MINIMUM LOAD):

A) Load Details:

- Inner - 08 Nos.
- Lower- 08 Nos.
- Cap- 08 Nos
- Inner Booties -8 Pair. (16Nos)

B) Load Configuration:

- One perforated box (C1) containing 4 set of garments (Inner, Lower ,Cap & Inner Booties enclosed in bag) on Upper back side of trolley (Sterile door side)
- One perforated box (C2) containing 4 set of garments, (Inner, Lower, Cap & Inner Booties enclosed in bag) placed on lower front of trolley (Non Sterile door side).

C) Equipment / Instrument Used:

- Duly Calibrated Data logger with calibrated sensors.
- Biological Indicators
- Chemical Indicators

D) Procedure

- Conduct the study with loaded chamber cycles with temperature sensors, Chemical & Biological Indicators.
- Switch ON the MAINS of the control panel and set the respective parameters according to cycles & transfer the load to sterilizer and connect the probes as per the given locations, Simultaneously keep the biological indicator & Chemical Indicator strip with each sensor.
- Close the door of sterilizer and start the cycle as per for operating Instructions.
- Ensure that tip of the probe should not touch any metal surface.
- Set the following parameters in PLC.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter settings for H.P.H.V. Process-1

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls	120.9 ºC
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Simultaneously insert new chart in chart recorder provided on the control panel of an autosclave & run the cycle as per SOP for operating instruction.
- Simultaneously start the recording with data logger for each 5 Sec. and take printout at the end of the cycle switch off.
- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators and send to microbiology for incubation.
- Finally calculate the F_0 value for Heat Penetration Study.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Three consecutive cycles shall be carried out as per above Parameters and Procedure.
- Compile the data generated during the qualification, for complete evaluation of the system.

Location of Temperature Sensors with Biological Indicator Placement in Minimum Garment Loaded Chamber

Sensor No.	Location in the Chamber
S1	In the drain of the autoclave chamber. T1
S2	Adjacent To Autoclave Inbuilt Sensor T2
S3	Adjacent To Autoclave Inbuilt Sensor T3
S4	Adjacent To Autoclave Inbuilt Sensor T4
S5	Adjacent To Autoclave Inbuilt Sensor T5
S6	Center of Garment pack located at lower surface in C1
S7	Center of Garment pack located in middle left of C1
S8	Center of Garment pack located in Upper surface of C1
S9	Outer side near C1 wall of Garment pack located at middle right in C1
S10	Center of Garment pack located in upper surface of C2
S11	Center of Garment pack located in Lower surface of C2
S12	Center of Garment pack located in middle left of C2

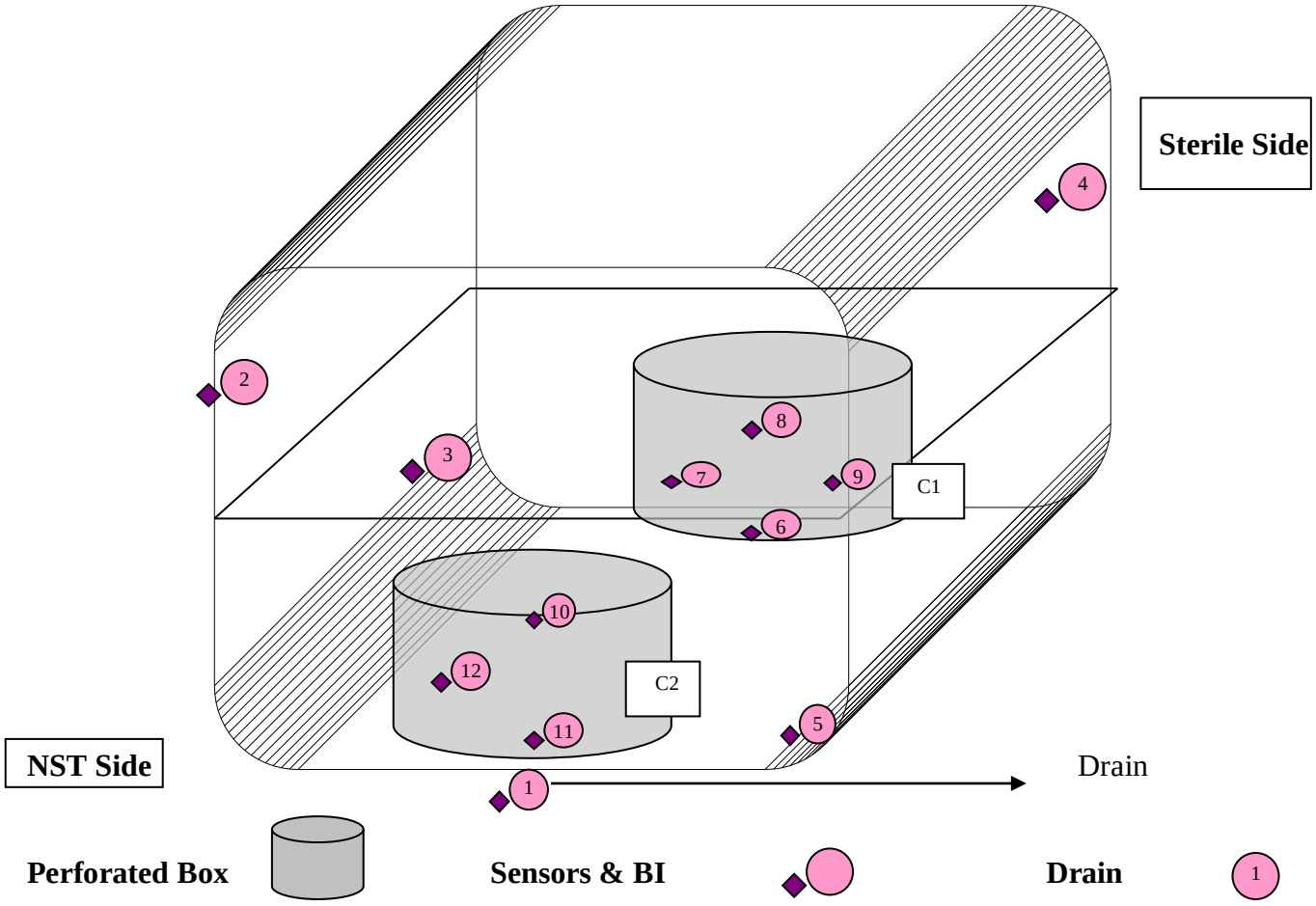


Figure: Location of Temperature Sensors & Biological Indicators inside the Chamber in Inner garment minimum load in HPHV -1 (Front View, Non Sterile Side)

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

E) Acceptance Criteria

- There should be uniform distribution of temperature within the range of 121.4°C to 124°C at each probe in sterilizer chamber during sterilization hold period.
- The chemical indicators should change the color from Pink to Green.
- All Biological Indicators should show no growth after incubation.
- The calculated Minimum F_0 value should be more than Biological F_0 value for the Biological indicator
- SLR Actual should be more than SLR Desired.
- Equilibrium Time for Temperature Hold NMT 15 Second.

F) Observation :

Record the observations in Performance Qualification Report.

G) Evaluation of Result

- Heat Penetration Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold is found within ± 1°C. If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface. After taking proper corrective measures, Heat Penetration shall be re-performed.

11.8 HEAT PENETRATION STUDY H.P.H.V PROCESS-1 (INNER GARMENT LOADED CHAMBER) (MAXIMUM LOAD):

Load Details:

A) Lower – 32 Nos

Inner – 32 Nos

Cap –32 Nos

Inner Booties – 32 Pair (64 Nos.)

Load configuration:

- One perforated box (C1) containing 11 set of garments (Inner, Lower, Cap & Inner Booties enclosed in a bag) Placed on Tray (T1) on Sterile Side
- One perforated box (C2) containing 11 set of garments (Inner, Lower, Cap & Inner Booties enclosed in a bag) Placed on Tray (T2) on Non Sterile Side
- One perforated box (C3) containing 10 set of Garments (Inner, Lower, Cap & Inner Booties enclosed in a bag) Placed on perforated box C1 & C2.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

B) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated sensors.
- Biological Indicators
- Chemical Indicators

C) Procedure

- Conduct the study with loaded chamber cycles with temperature sensors, Chemical & Biological Indicators.
- Switch ON the MAINS of the control panel and set the respective parameters according to cycles &.transfer the load to sterilizer and connect the probes as per the given locations. Simultaneously keep the biological indicator & Chemical Indicator strip with each sensor Close the door of sterilizer and start the cycle as per operating Instructions for autoclave.
- Ensure that tip of the probe should not touch any metal surface.
- Set the following parameters in PLC.

Parameter settings for H.P.H.V. Process-1

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls	120.9 ºC

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Simultaneously insert new chart in chart recorder provided on the control panel of an autoclave & run the cycle as per SOP for operating instruction of autoclave, simultaneously start the recording with data logger for each 5 Sec. and take printout at the end of the cycle switch off.
- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators and send to microbiology for incubation
- Each Cycle performed three times.
- Finally calculate the F_0 value for Heat Penetration Study.
- Compile the data generated during the qualification, for complete evaluation of the system.

Location of Temperature Sensors with Biological Indicator Placement in Maximum Garment Loaded Chamber

Sensor No.	Location in the Chamber
S1	In the drain of the autoclave chamber T1
S2	Adjacent To Autoclave Inbuilt Sensor T2
S3	Adjacent To Autoclave Inbuilt Sensor T3
S4	Adjacent To Autoclave Inbuilt Sensor T4
S5	Adjacent To Autoclave Inbuilt Sensor T5
S6	Center of Garment pack located at upper surface in C1
S7	Center of Garment pack located in middle of C1
S8	Center of Garment pack located at lower surface in C3
S9	Center of Garment pack located in upper surface of C3
S10	Center of Garment pack located at lower surface in C2
S11	Center of Garment pack located in middle right in box C2
S12	Center of Garment pack located at upper surface in C2

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

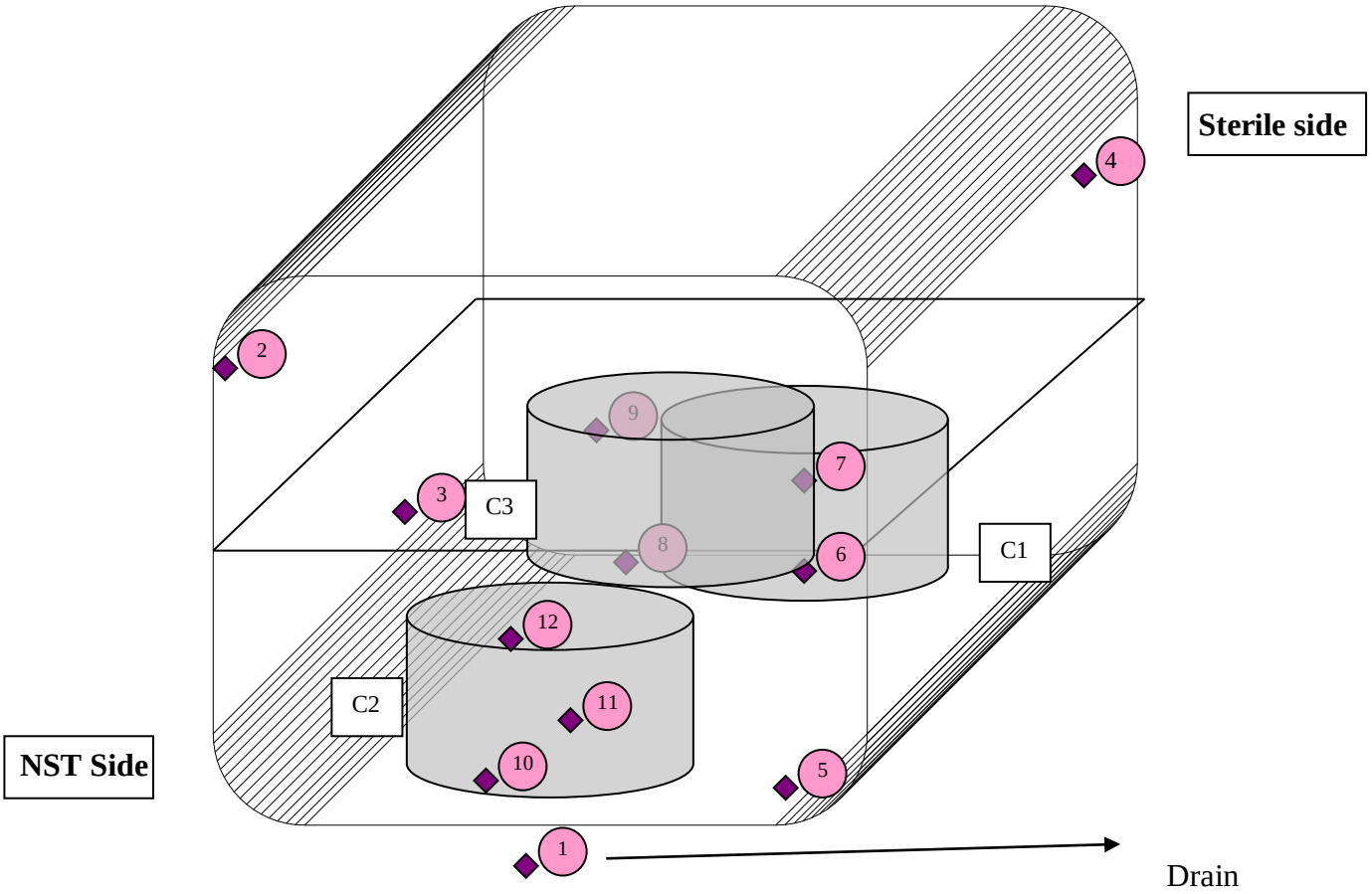


Figure: Location of Temperature Sensors, & Biological Indicators inside the Chamber in Load (HPHV Process -1) (inner Garment maximum load) (Front View, Non Sterile Side)

Perforated Box **Sensors & BI** **Drain** 1

D) Observation:

- Record the observations in Performance Qualification Report

E) Acceptance Criteria

- There should be uniform distribution of temperature within the range of 121.4°C to 124°C at each probe in sterilizer chamber during sterilization hold period
- The chemical indicators should change the color from Pink to Green.
- All Biological Indicators should show no growth after incubation.
- The calculated Minimum F_0 value should be more than Biological F_0 value for the Biological indicator strip.
- SLR Actual should be more than SLR Desired.
- Equilibrium Time for Temperature Hold NMT 15 Second

H) Evaluation of Result

- Heat Penetration Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold is found within ± 1°C. If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface. After taking proper corrective measures, Heat Penetration shall be re-performed.

11.9 HEAT PENETRATION STUDY H.P.H.V-PROCESS-1 (STERILE GARMENT LOADED CHAMBER) (MINIMUM LOAD):

I) Load Details:

- Antistatic Sterile garments - 08 Nos.
- Head Gears - 08 Nos.
- Booties - 08 pair (16 Nos.)

J) Load Configuration:

- One perforated box (C1) containing 3 set of garments (Boiler Suit, Head Gear & Booties enclosed in bag) placed on lower back side in chamber on tray T1 (Sterile door side)
- One perforated box (C2) containing 3 set of garments, (Boiler Suit, Head Gear & Booties enclosed in bag) placed on lower front side of in chamber on tray T2 (Non Sterile door side)
- One perforated box (C3) containing 2 set of garments, (Boiler Suit, Head Gear & Booties enclosed in bag) placed above C1 & C2

K) Equipment / Instrument Used:

- Duly Calibrated Data logger with calibrated sensors
- Biological Indicators
- Chemical Indicators

L) Procedure

- Conduct the study with loaded chamber cycles with temperature sensors, Chemical & Biological Indicators.
- Switch ON the MAINS of the control panel and set the respective parameters according to cycles &.transfer the load to sterilizer and connect the probes as per the given locations. Simultaneously keep the biological indicator & Chemical Indicator strip with each sensor. Close the door of sterilizer

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- and start the cycle as per for operating Instructions. Ensure that tip of the probe should not touch any metal surface.
- Set the following parameters in PLC.

Parameter settings for H.P.H.V. Process-1

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls	120.9 ºC
Ster. Reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period.	120.5ºC
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Insert new chart in chart recorder provided on the control panel of an autoclave, & run the cycle as per SOP for operating instruction.
- Simultaneously start the recording with data logger for each 5 Sec. and take printout at the end of the cycle switch off.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators and send to microbiology for incubation.
- Finally calculate the F_0 value for Heat Penetration Study. Each Cycle Should be Performed at Three times. Compile the data generated during the qualification, for complete evaluation of the system.

Location of Temperature Sensors with Biological Indicator Placement in Minimum Garment Loaded Chamber

Sensor No.	Location in the Chamber
S1	In the drain of the autoclave chamber. T1
S2	Adjacent To Autoclave Inbuilt Sensor T2
S3	Adjacent To Autoclave Inbuilt Sensor T3
S4	Adjacent To Autoclave Inbuilt Sensor T4
S5	Adjacent To Autoclave Inbuilt Sensor T5
S6	Center of Garment pack located at lower surface in C1
S7	Center of Garment pack located at upper surface of C1
S8	Center of Garment pack located at lower surface in C3
S9	Center of Garment pack located at upper surface of C3
S10	Center of Garment pack located in lower surface of C2
S11	Center of Garment pack located in upper surface of C2
S12	Center of Garment pack located in lower surface of C2

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

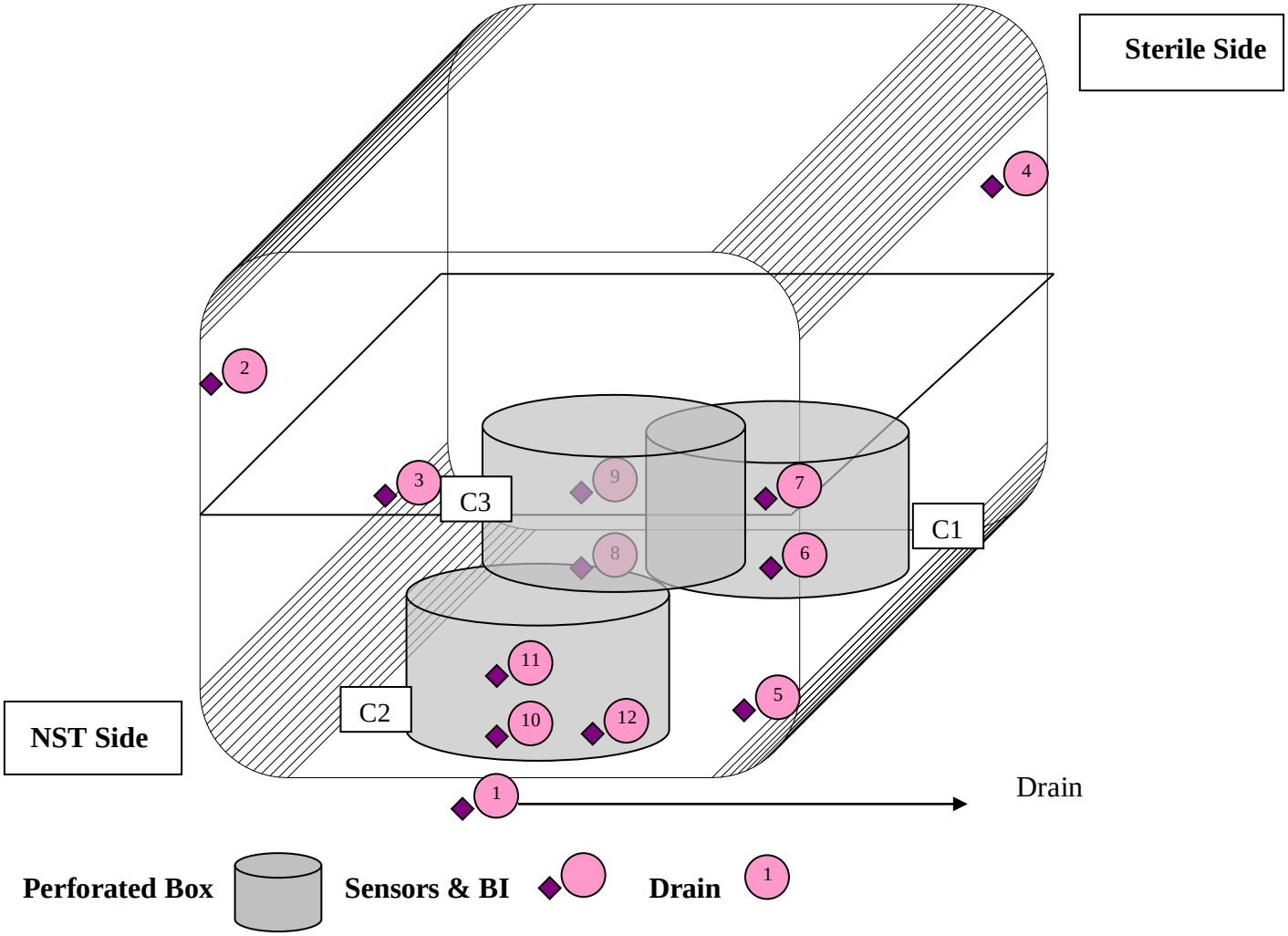


Figure: Location of Temperature Sensors,& Biological Indicators inside the Chamber in garment minimum load in HPHV -1 (Front View, Non Sterile Side)

M) Acceptance Criteria

- There should be uniform distribution of temperature within the range of 121.4°C to 124°C at each probe in sterilizer chamber during sterilization hold period
- The chemical indicators should change the color from Pink to Green.
- All Biological Indicators should show no growth after incubation.
- The calculated Minimum F_0 value should be more than Biological F_0 value for the Biological indicator strip.
- SLR Actual should be more than SLR Desired.
- Equilibrium Time for Temperature Hold NMT 15 Second

N) Observation :

Record the observations in Performance Qualification Report

O) Evaluation of Result

- Heat Penetration Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold is found within ± 1°C. If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface. After taking proper corrective measures, Heat Penetration shall be re-performed.

11.10 HEAT PENETRATION STUDY H.P.H.V PROCESS-1 (STERILE GARMENT LOADED CHAMBER) (MAXIMUM LOAD):

Load Details:

F) Antistatic Sterile garments – 28 Nos
Head Gears –28 Nos
Booties – 28 Pair (56 Nos.)

Load configuration:

- One perforated box (C1) containing 07 set of Garments (Boiler Suit, head gears, Booties enclosed in a bag) placed on Perforated Tray (T1) (Sterile side door)
- One perforated box (C2) containing 07 set of Garments (Boiler Suit, head gears, Booties enclosed in a bag) placed over perforated box (C1) (Sterile side door)
- One perforated box (C3) containing 07 set of Garments (Boiler Suit, head gears, Booties enclosed in a bag) placed on Tray (T1) & (T2) (Middle of the Chamber)
- One perforated box (C4) containing 07 set of Garments (Boiler Suit, head gears, Booties enclosed in a bag) placed over (C3) (Middle of the Chamber)

G) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated sensors.
- Biological Indicators
- Chemical Indicators

H) Procedure

- Conduct the study with loaded chamber cycles with temperature sensors, Chemical & Biological Indicators.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Switch ON the MAINS of the control panel and set the respective parameters according to cycles & transfer the load to sterilizer and connect the probes as per the given locations, simultaneously keep the biological indicator & Chemical Indicator strip with each sensor.
- Close the door of sterilizer and start the cycle as per operating Instructions for autoclave
- Ensure that tip of the probe should not touch any metal surface.

  Set the following parameters in PLC.

Parameter settings for H.P.H.V. Process-1

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls	120.9 ºC
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Insert new chart in chart recorder provided on the control panel of an autoclave& run the cycle as per SOP for operating instruction of autoclave, simultaneously start the recording with data logger for each 5 Sec. and take printout at the end of the cycle switch off.
- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators and send to microbiology for incubation
- Finally calculate the F_0 value for Heat Penetration Study.
- Each cycle Should be Performed at Three times
- Compile the data generated during the qualification, for complete evaluation of the system.

Location of Temperature Sensors with Biological Indicator Placement in Maximum Garment Loaded Chamber

Sensor No.	Location in the Chamber
S1	In the drain of the autoclave chamber T1
S2	Adjacent To Autoclave Inbuilt Sensor T2
S3	Adjacent To Autoclave Inbuilt Sensor T3
S4	Adjacent To Autoclave Inbuilt Sensor T4
S5	Adjacent To Autoclave Inbuilt Sensor T5
S6	Center of Garment pack located at lower surface in box C1 (Sterile side)
S7	Center of Garment pack located in upper surface of box C1(Sterile side)
S8	Center of Garment pack located at lower surface in C2 (Sterile side)
S9	Center of Garment pack located in lower surface of C3 (Non-Sterile side)
S10	Center of Garment pack located at upper surface in C3 (Non-Sterile side)
S11	Center of Garment pack located in lower surface of C4 (Non-Sterile side)
S12	Center of Garment pack located at upper surface in C4 (Non-Sterile side)

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

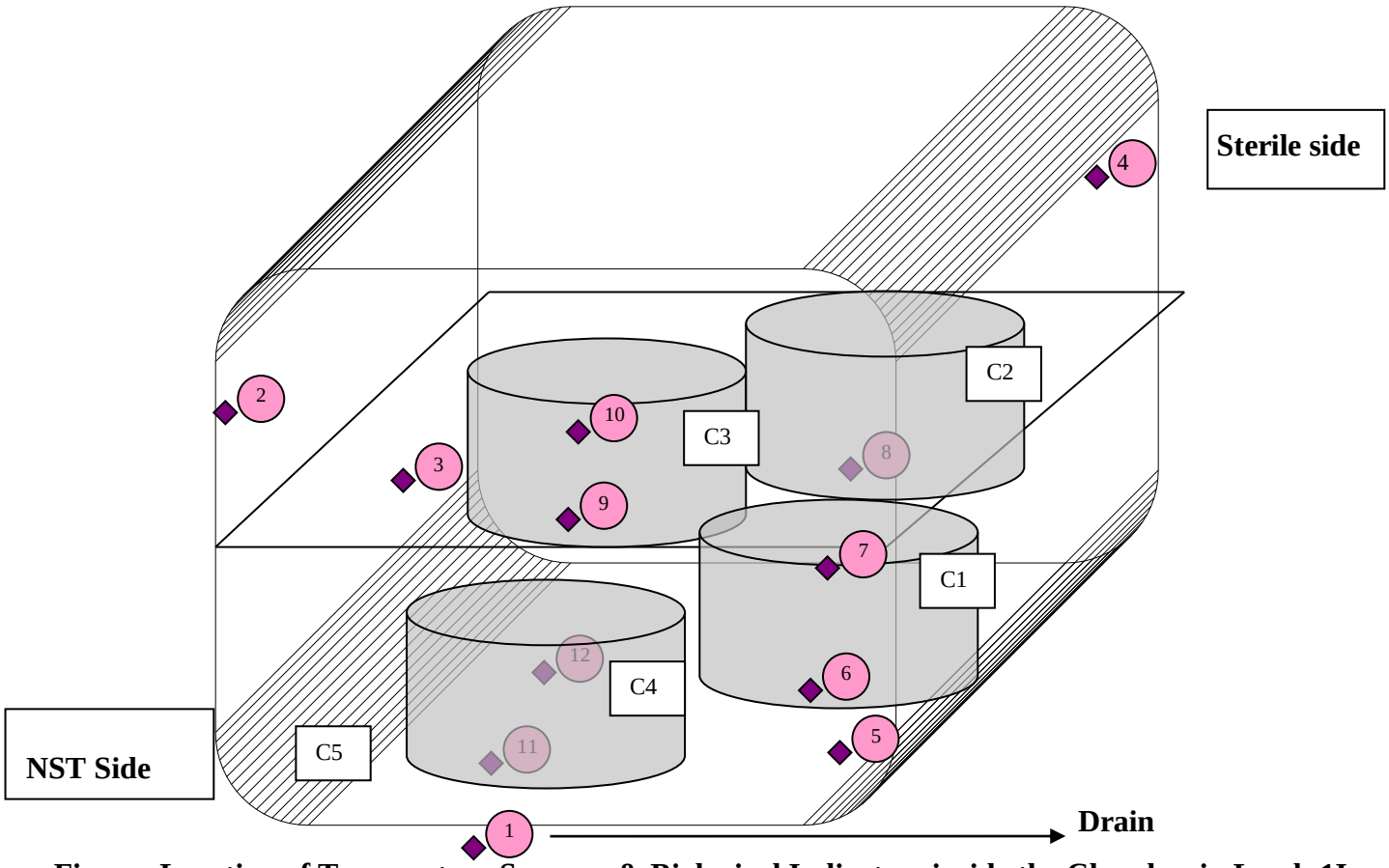


Figure: Location of Temperature Sensors, & Biological Indicators inside the Chamber in Load -1I (HPHV -1) (Garment maximum load) (Front View, Non Sterile Side)

Perforated Box **Sensors & BI** **Drain** 1

I) Observation:

- Record the observations in Performance Qualification Report

J) Acceptance Criteria

- There should be uniform distribution of temperature within the range of 121.4°C to 124°C at each probe in sterilizer chamber during sterilization hold period
- The chemical indicators should change the color from Pink to Green.
- All Biological Indicators should show no growth after incubation.
- The calculated Minimum F_0 value should be more than Biological F_0 value for the Biological indicator strip.
- SLR Actual should be more than SLR Desired.
- Equilibrium Time for Temperature Hold NMT 15 Second

P) Evaluation of Result

- Heat Penetration Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold is found within ± 1°C. If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface. After taking proper corrective measures, Heat Penetration shall be re-performed.

11.11 HEAT PENETRATION STUDY HPHV PROCESS.

A) Load details:

Pressure Vessel	: 01 Nos.
Clamp	: 10 Nos.
Gasket	: 10 Nos.

B) Load configuration:

- Pressure Vessel (1 Nos.) Placed in middle of chamber.
- Clamp (10 Nos.) Placed in the chamber in front of Non Sterile Side.
- Gasket (10 Nos.) Placed in the chamber in front of Non Sterile Side.

C) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated sensors.
- Biological Indicators
- Chemical Indicators

D) PROCEDURE:

- Conduct study with loaded chamber cycles with temperature probes, Chemical & Biological Indicators.
- Switch ON the MAINS of the control panel and set the respective parameters according to cycles &.transfer the load to sterilizer and connect the probes as per the given locations, simultaneously keep the biological indicator & Chemical Indicator strip with each sensor
- Close the door of sterilizer and start the cycle as per operating Instructions for autoclave
- Ensure that tip of the probe should not touch any metal surface.
- Set the following parameters in PLC.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter settings for HPHV Process

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls	120.9 ºC
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Simultaneously Insert new chart in chart recorder provided on the control panel of autoclave and record the chamber temperature and pressure for every minute.
- Run the cycle as per SOP for operating instructions of HPHV Steam Sterilizer, simultaneously start the recording with data logger for each 5 Sec. and take printout at the end of the cycle.
- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators & chemical indicator.
- Send the BI to microbiology laboratory for incubation.
- Finally calculate the F_0 value & Spore Log Reduction in each load.
- Compile the data generated during the qualification, for complete evaluation of the system.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Each Cycle should be performed at Three times.

Location of Temperature Sensors & Biological Indicator Placement in (Pressure Vessel)

SENSOR No.	LOCATION IN THE CHAMBER
S1	In the Chamber Drain with inbuilt sensor T1
S2	Adjacent to autoclave inbuilt sensor T2
S3	Adjacent to autoclave inbuilt sensor T3
S4	Adjacent to autoclave inbuilt sensor T4
S5	Adjacent to autoclave inbuilt sensor T5
S6	Inside the pipe of pressure vessel
S7	On the Centre pipe of pressure vessel
S8	On the Centre pipe of pressure vessel
S9	In the mid of Centre pipe of pressure vessel
S10	On the Centre pipe of pressure vessel
S11	On the Centre pipe of pressure vessel
S12	At the starting Centre pipe of pressure vessel

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

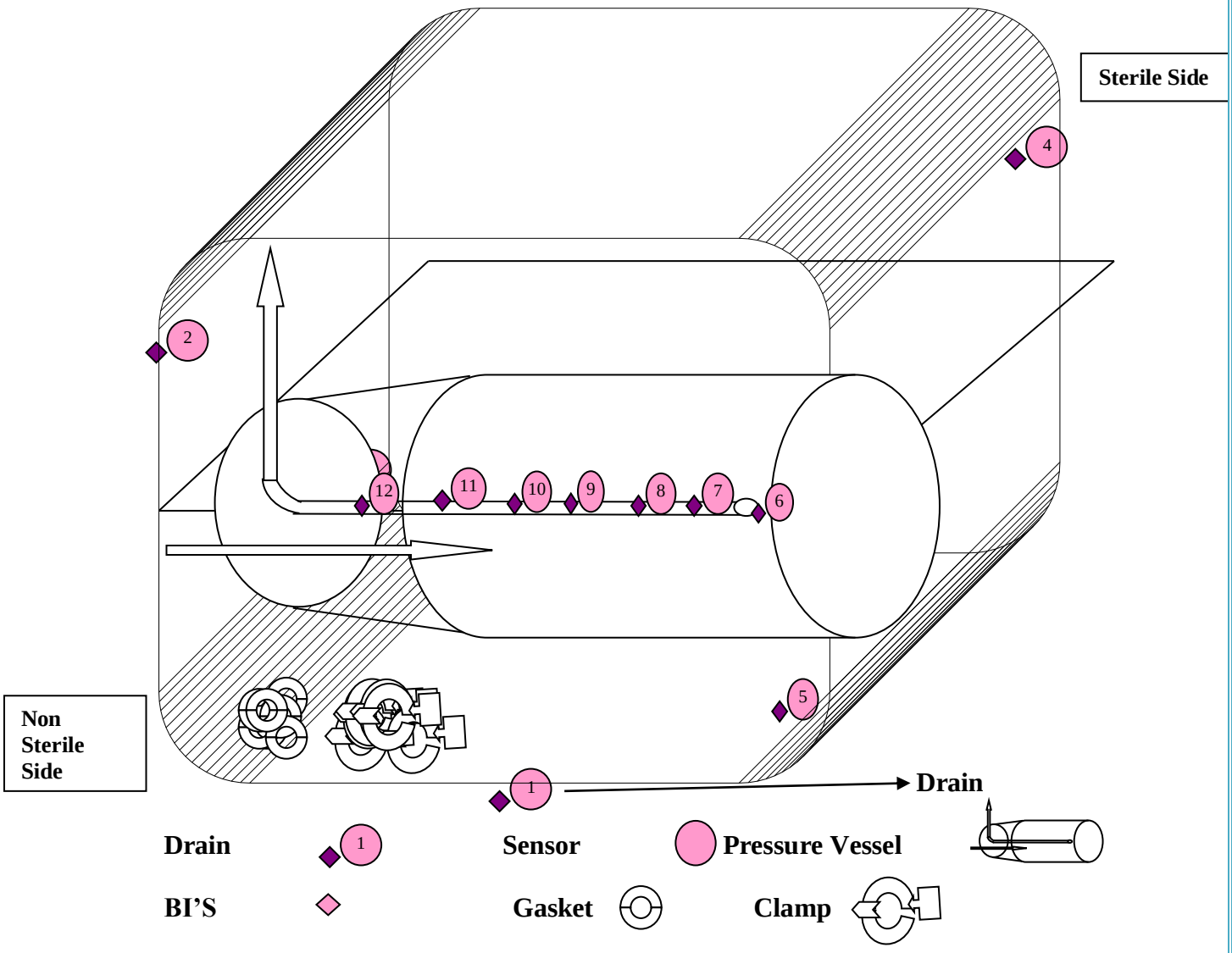


Figure: Location of temperature sensors, & Biological Indicator inside the chamber in Pressure vessel load in HPHV Process

E) ACCEPTANCE CRITERIA:

- There should be uniform distribution of temperature within the range of **121.4°C to 124°C** at each probe in sterilizer chamber during sterilization hold period in loaded chamber.
- The calculated Minimum F0 value should be more than Biological F0 value for the Biological indicator strip.
- Actual SLR should be more than SLR Desired.
- All Biological Indicators should show no growth after incubation
- The chemical indicators should change the color from Pink to Green.
- Equilibrium Time for Temperature Hold NMT 15 Second

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

F) OBSERVATION :

- Observation shall be recorded in Performance Qualification Report.

G) EVALUATION OF RESULT:

- Heat Penetration Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold is found within ± 1°C. If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface. After taking proper corrective measures, Heat Penetration shall be re-performed.

11.12 HEAT PENETRATION STUDY H.P.H.V PROCESS –II (ACCESSORY LOAD)

A) Load details:

Moping pad	: 12 Nos.
Gloves	: 10 Pair
Silicon Tube 2 meter	: 02 Nos.
Filter Housing with filter	: 01 Nos.
IPA Bottles	: 04 Nos.
Bucket of three bucket system	: 03 Nos.
SS Flexible pipe 2 meter	: 02 Nos.

B) Load configuration:

- (Moping pad(12 Nos.), Gloves (10 Pair), Silicon Tube 2 meter (02 Nos.), Filter Housing with filter (01 Nos.) , IPA Bottles (04 Nos.), Bucket of three bucket system & SS Flexible pipe 2 meter (02 Nos.).

C) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated sensors.
- Biological Indicators
- Chemical Indicators

D) PROCEDURE:

- Conduct study with loaded chamber cycles with temperature probes, Chemical & Biological Indicators.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Switch ON the MAINS of the control panel and set the respective parameters according to cycles &.transfer the load to sterilizer and connect the probes as per the given locations, simultaneously keep the biological indicator & Chemical Indicator strip with each sensor
- Close the door of sterilizer and start the cycle as per operating Instructions for autoclave
- Ensure that tip of the probe should not touch any metal surface.
- Set the following parameters in PLC.

Parameter settings for H.P.H.V. Process-II

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls	120.9 ºC
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

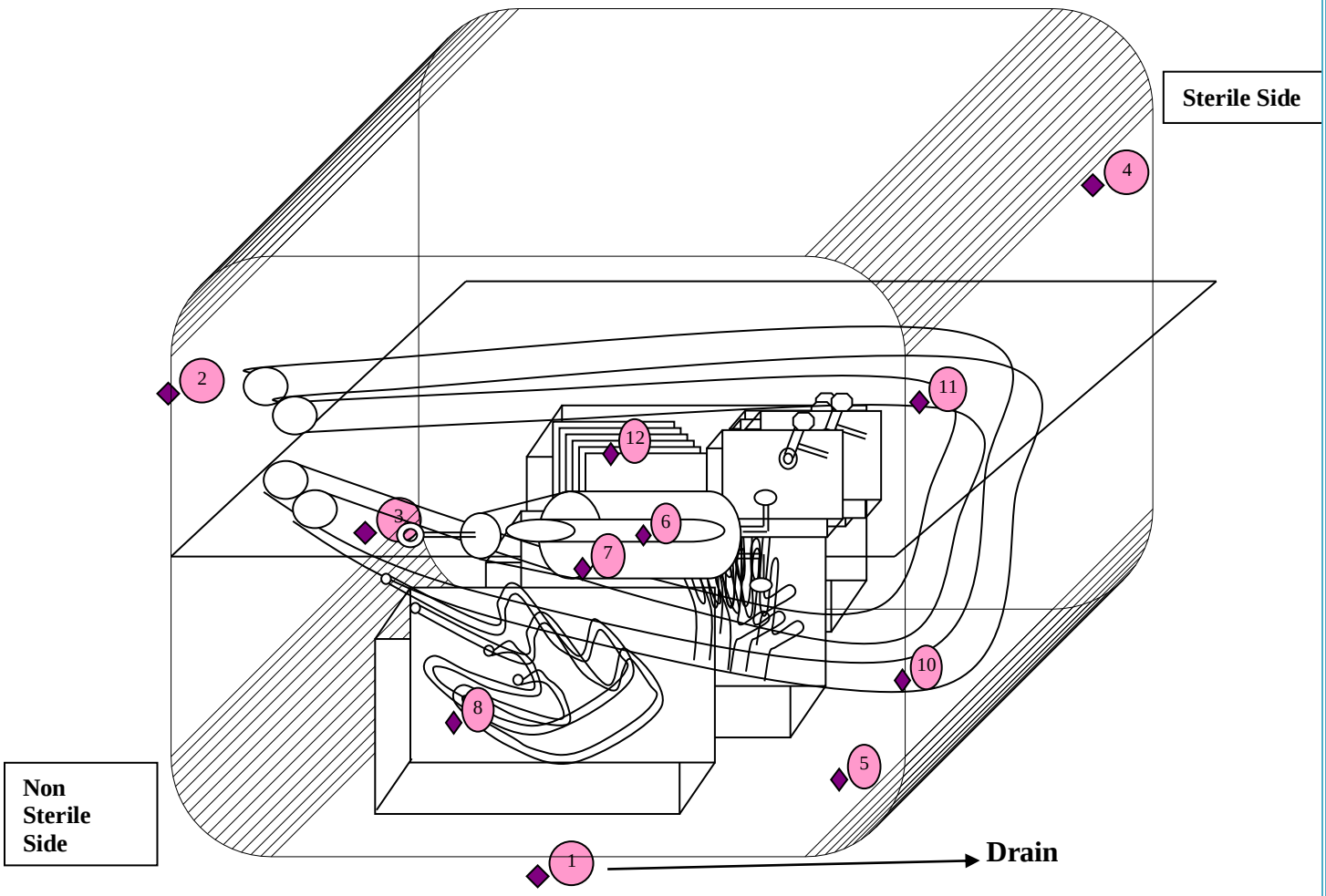
PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Simultaneously Insert new chart in chart recorder provided on the control panel of autoclave and record the chamber temperature and pressure for every minute.
- Run the cycle as per SOP for operating instructions of HPHV Steam Sterilizer, simultaneously start the recording with data logger for each 5 Sec. and take printout at the end of the cycle.
- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators & chemical indicator.
- Send the BI to microbiology laboratory for incubation.
- Finally calculate the F_0 value & Spore Log Reduction in each load.
- Compile the data generated during the qualification, for complete evaluation of the system.
- Each Cycle should be performed at Three times.

Location of Temperature Sensors & Biological Indicator Placement in (Accessory Load)

SENSOR No.	LOCATION IN THE CHAMBER
S1	In the Chamber Drain with inbuilt sensor T1
S2	Adjacent to autoclave inbuilt sensor T2
S3	Adjacent to autoclave inbuilt sensor T3
S4	Adjacent to autoclave inbuilt sensor T4
S5	Adjacent to autoclave inbuilt sensor T5
S6	Innermost Side of the filter
S7	Inner Side of the filter Assembly
S8	Inner Side of the first silicon pipe
S9	Inner Side of the second silicon pipe
S10	Inner Side of the first SS Flexible pipe
S11	Inner Side of the Second SS Flexible pipe
S12	Inner Side of the Moppers

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER



Drain 1 **BI**

Moping pad **Gloves**

Silicon Tube 2 meter **Filter Housing with filter**

IPA Bottles **Bucket of three bucket system**

SS Flexible pipe 2 meter **Sensor**

Figure: Location of temperature sensors, & Biological Indicator inside the chamber in Accessory load in HPHV-1

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

E) ACCEPTANCE CRITERIA:

- There should be uniform distribution of temperature within the range of **121.4°C to 124°C** at each probe in sterilizer chamber during sterilization hold period in loaded chamber.
- The calculated Minimum F0 value should be more than Biological F0 value for the Biological indicator strip.
- Actual SLR should be more than SLR Desired.
- All Biological Indicators should show no growth after incubation
- The chemical indicators should change the color from Pink to Green.
- Equilibrium Time for Temperature Hold NMT 15 Second

F) OBSERVATION :

- Observation shall be recorded in Performance Qualification Report.

G) EVALUATION OF RESULT:

- Heat Penetration Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold is found within ± 1°C. If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface. After taking proper corrective measures, Heat Penetration shall be re-performed.

11.13 HEAT PENETRATION STUDY H.P.H.V. PROCESS-2 (Mixed Load)

A) Load Details

Silicon Tube 2 meter	: 02 Nos.
Bucket of three bucket system	: 03 Nos.
SS Mug 05 Liters	: 01 Nos.
SS Mug 02 Liters	: 01 Nos.
SS Mug 01 Liter	: 01 Nos.
IPA Bottles	: 04 Nos.
Bio Barrier Paper (1x1 meter)	: 04 Nos.
Eye Google	: 10 Nos.

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

B) Load Configuration

Silicon Tube 2 meter (02 Nos.), Bucket of three bucket system, SS Mug 05 Liters (01 Nos.), SS Mug 02 Liters (01 Nos.), SS Mug 01 Liter (01 Nos.), IPA Bottles 04 Nos., Bio barrier Paper (1x1 meter) 04 Nos. & Eye Google (10 Nos.).

C) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated sensors.
- Biological Indicators
- Chemical Indicators

D) PROCEDURE:

- Conduct study with loaded chamber cycles with temperature probes, Chemical & Biological Indicators.
- Switch ON the MAINS of the control panel and set the respective parameters according to cycles
- Set the following parameters in PLC.

Parameter settings for HPHV Process-2

Parameter	Purpose	Set Value
Pre vacuum	To create vacuum for air removal	-0.600 Bar
Pre pressure	To break the vacuum with steam	0.500 Bar
No. of Pre pulses	To repeat the vacuum pressure pulses	3 No.
Pre Pressure up	For pressure pulses to improve heat distribution	0.700 Bar
Pre Pressure down	For pressure pulses to improve heat distribution	0.300 Bar
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Sterilization Stop Tem.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period	120.9 ºC
Ster. Reset temp.	To reset the sterilization hold time incase the chamber temperature falls below this value during sterilization period.	120.5ºC

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter	Purpose	Set Value
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 Bar
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos
Process end pressure	To end the process & allow to unload the material	-0.030 Bar

- Transfer the load to sterilizer and connect the probes as per the given locations. Simultaneously keep the biological indicator & Chemical Indicator strip with each sensor Close the door of sterilizer and start the cycle as per for operating Instructions.
- Ensure that tip of the probe should not touch any metal surface.
- Simultaneously Insert new chart in chart recorder provided on the control panel of autoclave and Chart recorder record the chamber temperature and pressure for every minute.
- Run the cycle as per SOP for operating instruction.
- Simultaneously start the recording with data logger for each 5 Sec. and take printout at the end of the cycle switch off.
- When Pressure becomes -0.030 bars open the door with the help of safety gloves & remove the Biological Indicators.
- Send the BI to microbiology lab for incubation
- Compile data for each loaded cycle in corresponding Annexure with graphical representation.
- Finally calculate the F_0 value & Spore Log Reduction in each load.
- Each cycle Should be Performed at Three times

SENSOR No.	LOCATION IN THE CHAMBER
S1	In the Chamber Drain with inbuilt sensor T1
S2	Adjacent to autoclave inbuilt sensor T2
S3	Adjacent to autoclave inbuilt sensor T3
S4	Adjacent to autoclave inbuilt sensor T4
S5	Adjacent to autoclave inbuilt sensor T5
S6	Inner Side of the first silicon pipe from right side.
S7	Inner Side of the first silicon pipe from left right side.
S8	Inner Side of the second silicon pipe from right side.

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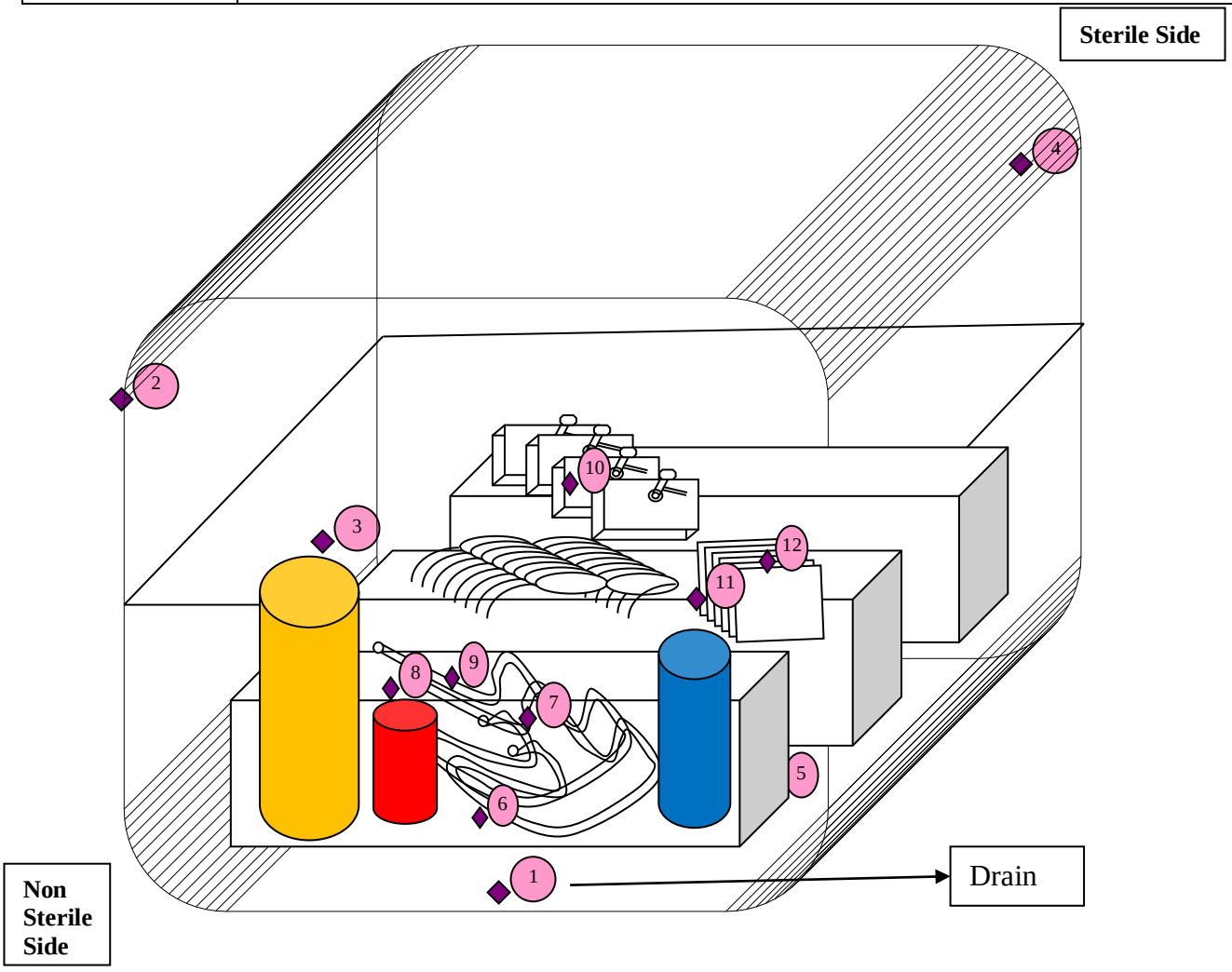
S9	Inner Side of the second silicon pipe from left right side.
S10	Inner Side of the IPA Bottle
S11	Inner Side of the **Bio Barrier Paper**
S12	Inner Side of the **Bio Barrier Paper**



Drain 1 **BI**

Sensor

Silicon Tube 2 meter

Bucket of three bucket system

SS Mug 05 Liters

SS Mug 02 Liters

SS Mug 01 Liter

IPA Bottles

Bio Barrier Paper (1x1 meter)

Eye Google

Figure: Location of temperature sensors, & Biological Indicator inside the chamber in Mix load in HPHV -1

PERFORMANCE QUALIFICATION PROTOCOL FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

E) ACCEPTANCE CRITERIA:

- There should be uniform distribution of temperature within the range of **121.4°C to 124°C** at each probe in sterilizer chamber during sterilization hold period.
- The calculated Minimum F0 value should be more than Biological F0 value for the Biological indicator strip.
- Actual SLR should be more than SLR Desired.
- All Biological Indicators should show no growth after incubation
- The chemical indicators should change the color from Pink to Green.
- Equilibrium Time for Temperature Hold NMT 15 Second.

F) OBSERVATION :

- Record the observations in Performance Qualification Report

G) EVALUATION OF RESULT:

- Heat Penetration Test shall be qualified if distribution of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time of Temperature recording between all probes during hold is found within ± 1°C. If Temperature Uniformity is not achieved, check whether sensor is touching any metal surface. After taking proper corrective measures, Heat Penetration shall be re-performed.

11.14 VACUUM LEAK TEST :

11.14.0 Objective

To verify the Leakage in Sterilization Chamber during Vacuum Hold when the Sterilization Chamber is empty.

11.14.1 Procedure

- Operate the equipment as per SOP on operation of HPHV Steam sterilizer

Set the following parameters

Pre Vacuum	=	- 0.700 Bar
Delay before Hold	=	3 Minute
Vacuum Hold Time	=	10 Minute
Acceptable Leakage	=	NMT 0.013 Bar
Process End Pressure	=	-0.030 Bar

- Check the pressure of the chamber initially.
- Record the pressure of the chamber after three min. of getting start the autoclave.
- Record the pressure of the chamber after ten min. of getting start the autoclave.
- Measure the difference between the pressures.
- Calculate the difference of pressure per min.
- Take Three Consecutive Cycles of VLT.

11.14.2 Acceptance Criteria

Actual vacuum leakage should be not more than **0.013 Bar.**

11.14.3 Evaluation of Result

If Actual vacuum leakage is not within the specified limit, check the Gasket & other joints of the chamber. If the Minimum vacuum leakage is not achievable, Gasket shall be changed or any other appropriate measures be taken to achieve the acceptance criteria.

11.15 BIOLOGICAL CHALLENGE TEST

A) OBJECTIVE:

- To demonstrate the degree of process lethality provided by the Sterilization cycle.

B) EQUIPMENT / INSTRUMENT USED:

- Biological Indicator (spores of ***Geobacillus stearothermophilus***).

C) PROCEDURE

- After determining the worst case items and worst locations i.e. cold spots, challenge these items/locations with biological indicator (spores of *Geobacillus stearothermophilus).*
- Carry out the microbial challenge study concurrently with loaded chamber Heat Penetration studies.
- Place, previously population validated biological indicator ampoules of specified 10^6 Spores per unit along with the probes at the same location, within each load type of the specified load pattern, as in the loaded chamber heat penetration studies. Retain two biological indicators as positive control.
- Operate the autoclave as per SOP on operation of HPHV Steam sterilizer.
- Record the chamber temperature and pressure for every minute.

- Simultaneously start the recording with data logger and take printouts.
- At the end of the cycle Switch OFF the autoclave.
- Remove the biological indicator with the help of safety gloves and incubate all exposed & unexposed BI.
- After incubation observe the indicator for growth. (+ve when purple color change to yellow color, -ve when purple color remain as such.)
- If indicator shows positive results increase holding time and validate the cycle for this period to get minimum Sterility Assurance Level (SAL) 10^{-6}.Run three consecutive cycles.
- Biological Indicator Detail & testing Result are Mention in performance Qualification Report by Manually.

D) ACCEPTANCE CRITERIA:

- Visually observe the ampoules, test +ve when purple color change to yellow color, test -ve when purple color remain as such.
- If no evidence of growth observed in any of the inoculated tube and growth observed in positive control tube, the test meets the criteria to achieve the desired level of sterility.

11.15.0 ESTIMATION OF F_0 VALUE:

A) Numerical F_0 Value:

The actual observations obtained during the heat penetration studies at different temperature sensing locations are complied in the table and the observed temperature shell be subjected for calculation of F_0 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.

$F_0 = dt \sum 10^{(T-121)/Z}$ …… (a)

$F_0 = dt \sum$ (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).

B) F_0 Value for Biological Indicators:

The biological F_0 value for biological indicator strip exposed during the sterilization can be calculated as follows.

$F_0 = D_{121}$ (log A – log B)…….. (b)

Where,

D_{121}	D value of the biological indicator at 121°C.
A	Experimental Biological indicator concentration or spore population.
B	Desired level of sterility (SAL- 10^{-6}).

C) Desired Spore Log Reduction:

Calculate the desired reduction in spore population by using the formula-

$SLR_{desired} = \log A - \log SAL_{desired}$ ……..(c)

Where,

A = Experimental population of Biological Indicator at 121 °C.

$SAL_{desired}$ = Desired level of sterility (10^{-6}).

D) Actual Spore Log Reduction:

Calculate actual reduction in spore population by using the formula-

$SLR_{Actual} = F_0 / D_{121}$……. (d)

Where,

F_0 = Minimum calculated F_0 value.

D_{121}= D value of Biological Indicator.

E) Sterility Assurance Level :

= SLR_{Actual} - Initial population of BI

12.0 CHECKLIST OF ALL TESTS & CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

S. No.	NAME OF TEST OR CHECK	ACCEPTANCE CRITERIA
1.	Steam Quality Test	Should be Compiles
2.	Vacuum Leak Test (Cold) **(3 Trial)**	NMT 0.013 BAR
3.	Vacuum Leak Test (Hot) **(3 Trial)**	
4.	Bowie-Dick Test **(3 Trial)**	Uniform color changes of Bowie Dick test Indicator sho the absence of Entrapped air or non condensable gases inside the chamber
5.	Heat Distribution Study. Standard Process (Empty Chamber) **(3 Trial)**	There should be uniform distribution of heat in the

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S. No.	NAME OF TEST OR CHECK	ACCEPTANCE CRITERIA
6.	Heat Distribution Study. HPHV Process -01(Empty Chamber) **(3 Trial)**	steam sterilizer chamber during the sterilization hold period and the temperature at each temperature mapping probe should be within the range of 121.4°C to 124°C during the Sterilization Hold Period
7.	Heat Penetration Study H.P.H.V.- (Inner Garment Loaded Chamber) (Minimum) **(3 Trial)**	• There should be uniform distribution of temperature within the range of 121.4°C to 124°C at each probe in sterilizer chamber during sterilization hold period • The chemical indicators should change the color from Pink to Green. • All Biological Indicators should show no growth after incubation. • The calculated Minimum F_0 value should be more than Biological F_0 value for the Biological indicator strip. • SLR Actual should be more than SLR Desired.
8.	Heat Penetration Study H.P.H.V.- (Inner Garment Loaded Chamber) (Maximum) **(3 Trial)**	
9.	Heat Penetration Study H.P.H.V.- (Garment Loaded Chamber) (Minimum) **(3 Trial)**	
10.	Heat Penetration Study H.P.H.V. (Garment Loaded Chamber) (Maximum) **(3 Trial)**	
11.	Heat Penetration Study HPHV Cycle (Pressure Vessel , Clamp & Gasket) **(3 Trial)**	
12.	Heat Penetration Study H.P.H.V. (Accessories Loaded Chamber) **(3 Trial)**	
13.	Heat Penetration Study H.P.H.V. (Mixed Loaded Chamber) **(3 Trial)**	
14.	Post Vacuum **(3 Trial)**	NMT 0.013 BAR

13.0 REFERENCES:

The Principle References are as following:

- Validation Master Plan.
- Schedule - M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2. Good Manufacturing Practices and Inspection.
- HTM 2010 Part-3 (Validation & Verification).
- EN285
- PDA Technical Report 01 (Sterilization by Moist Heat).

14.0 DOCUMENTS TO BE ATTACHED:

- Biological Indicator Incubation Report.
- Calibration Certificates for Data Logger.
- Calibration Certificates of Sensors.
- Printouts of Thermograph of all the cycles from high pressure high vacuum steam sterilizer for time, temperature and pressure profile.

15.0 NON COMPLIANCE:

All the Non-compliances of procedure, specifications, and sampling, analysis and documentation activities shall be monitored & recorded.

16.0 DEVIATION FROM PRE-DEFINED SPECIFICATION, IF ANY:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA will study the impact of deviation. If deviation is acceptable and it does not have an Impact on operation as well as on performance of the machine & prepare final conclusion.

17.0 CHANGE CONTROL, IF ANY:

- If any change control is required during PQ, inform to Head QA for necessary action.
- Document the details observed.
- The Head QA will study the impact of change. If change is acceptable and it does not have an impact on operation as well as on performance of the machine & prepare final conclusion.

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18.0 ABBREVIATIONS:

℃	:	Degree Centigrade
BI	:	Biological Indicator
CI	:	Chemical Indicator
HPHV	:	High pressure high vacuum
ID.	:	Identification
LTD.	:	Limited
Min.	:	Minute
NMT	:	Not more than
No.	:	Number
PPQ	:	Protocol Performance Qualification
QC	:	Quality Control
Sec.	:	Seconds
SOP	:	Standard Operating Procedure
SS	:	Stainless steel
PPQ	:	Performance Qualification Protocol
SLR	:	Spore Log Reduction