PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

PERFORMANCE QUALIFICATION

PROTOCOL

FOR

HPHV STEAM STERILIZER

EQUIPMENT ID. No.	
LOCATION	**UNIT PREPARATION & STERILIZATION ROOM**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

PROTOCOL CONTENTS

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

1.0 PROTOCOL PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (ENGINEERING			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM 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, Approval and Compilation of the Performance Qualification. • Protocol Training. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol. • 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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

5.0 EQUIPMENT DETAILS:

Equipment Name	**HPHV Steam Sterilizer**
Equipment	**…….**
Serial No.	**…….**
Capacity	**675 L**
Size	**750 x 750 x 1200 mm**
Manufacturer's Name	**M/s Machin Fabrik**
Supplier's Name	**M/s Machin Fabrik**
Location of Installation	**Unit preparation & Sterilization Room Block (Three Piece Line)**

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

6.0 SYSTEM DESCRIPTION:

The sterilizer manufactured by M/s Machine Fabrik is designed for the best possible adaptation to the need of sterilization. The High Pressure High Vacuum Sterilizer can be efficiently used to perform two type of sterilization –

- Standard Steam sterilization
- High Pressure High Vacuum Sterilization
- The chamber of the sterilizer can be tested by the following methods:
- Chamber Leak Test
- Bowie Dick test

Standard HPHV is a Jacketed Pressure Vessel. The Standard Steam Sterilization cycle is initiated by introducing Steam into the Jacket. This essentially aids in Preheating the Chamber and Effective Utilization of Heat Energy.

When a Particular Pressure inside the Jacket is achieved, Steam is introduced into the chamber. Air being heavier than Steam is displaced by Gravity Displacement Method which ensures Uniform Steam Distribution and Penetration. The equipment is also provided with Steam Traps with Air Vent to ensure Maximum Air Removal and Steam Condensate without allowing steam to pass through it.

As the Temperature of the Chamber increases, and reaches to the Sterilization Temperature, the control system in place controls this temperature for the Sterilization Time.

After the sterilization hold period is completed, steam from the chamber is exhausted to bring the chamber pressure to atmosphere.

The High pressure High Vacuum Steam Sterilization Process consists of following phases:-

- Vacuum steam pulsing
- Heat up
- Sterilization hold
- Vacuum drying
- Sterile air in

The Standard Steam Sterilization Process consists of following phases: -

- Heat up
- Sterilization hold
- Exhaust

A double door Steam Sterilizer is an industrial steam sterilizer especially designed for:

- Steam Sterilization of Garments, Mopping pads, Gloves.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Steam Sterilization of Filtration Accessories.
- Steam Sterilization of Filling Machine Components, Manufacturing Accessories etc.
- Steam Sterilization of Pressure vessel.

HIGH PRESSURE HIGH VACUUM STEAM STERILIZATION:

- In this process, the steam is introduced into the jacket which insures preheating of chamber and effective utilization of heat energy. As the pressure inside chamber reaches a set level, almost 100% removal of air is ensured by creating vacuum and pulsing in steam in the chamber. The steam/ vacuum pulsing not only ensure absence of air pockets and cold spots but also ensure uniform temperature distribution.
- The vacuum is created with the help of water ring type vacuum pump.
- After fixed no. of pulses, the steam pressure in the chamber is increased till the sterilization temperature is reached. The control system in place then controls this chamber temperature for the sterilization time.
- After the sterilization hold period is completed, 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 charge inside the chamber .After the vacuum drying time is complete, then chamber is brought to atmospheric pressure by injection of sterile air.

  The sterile charge is then unloaded from the chamber. Thus, the high pressure high vacuum steam sterilization cycle consists of following phases:-

- Vacuum steam pulsing
- Heat up
- Sterilization Hold
- Vacuum Drying
- Sterile Air In

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

7.0 REASON FOR QUALIFICATION:

- New equipment in Unit Preparation Room.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

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.
- Yearly ± one month

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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.
- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of high pressure high vacuum steam sterilizer
- SOP for Preventive Maintenance of high pressure high vacuum steam sterilizer.

10.1 TEST EQUIPMENT:

S.No.	Test Instrument
1.	Duly Calibrated Data logger with calibrated K/T/PT-100 sensors.
2.	Biological Indicator 10^6 spores i.e. *Geobacillus stearothermophilus* must be checked for spore population.
3.	Chemical Indicator (Steam Clox).
4.	All parts of autoclave used for measurement like temperature sensors, pressure gauges, and timers must be calibrated.

10.2 TEST EQUIPMENT CALIBRATION:

Review the calibration status for the test equipment (Data Logger with K/T/PT-100 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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

10.3 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.

10.4 PRE & POST CALIBRATION OF TEMPERATURE SENSORS:

A) PREPARATION OF ICE BATH:

- Prepare a container with Crushed Ice and add enough Purified Water to ensure a proper Slush Solution.
- Allow the Temperature to Stabilize. Ensure to add sufficient crushed ice to maintain the Equilibrium State of ice and water.
- Measure the temperature by using reference digital Thermometer.

B) 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 50°C, 100°C,121°C & 150 °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.

C) 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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

REMARK: Test mentioned in clause no 10.4 shall be applicable in case if no external party is involve in autoclave validation. if external agency is involved it will provide pre & post calibration certificate or at the time of completion of validation post calibration can be done at site also .

11.0 TESTS AND CHECKS:

- The autoclave will be considered validated on successful completion of the following tests.
- Vacuum Leak test (3 cycles) in cold condition
- Vacuum Leak test (3 cycles) in Hot condition
- Warm up cycle
- Bowie-Dick Test (3 cycles)
- Empty chamber heat distribution studies (3 cycles) at 121.4°C for 30 min with temperature sensors (HPHV process -1).
- Empty chamber heat distribution studies (3 cycles) at 121.4°C for 30 min with temperature sensors (HPHV process -2).
- Empty chamber heat distribution studies (3 cycles) at 121.4°C for 30 min with temperature sensors. (Standard Process)
- Detection of cold spot.
- Detection of Hot 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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Load Pattern:

1. Vacuum Leak Test (Cold) (3 Cycles)
2. Bowie-Dick Test (3 Cycles)
3. Warm up cycle (3 Cycles)
4. Vacuum Leak Test (Hot leak) (3 Cycles)
5. Empty Chamber Heat Distribution Study in H.P.H.V (3 Cycle) HPHV-1
6. Empty Chamber Heat Distribution Study in H.P.H.V (3 Cycle) HPHV-2
7. Empty Chamber Heat Distribution Study. In Standard load (3 Cycle)
8. Heat Penetration Study in Minimum Garment Loaded Chamber (H.P.H.V process-1) (3 Cycle)
9. Heat Penetration Study in Maximum Garment Loaded Chamber (H.P.H.V process-2) (3 Cycle)
10. Heat Penetration Study. In filling Machine parts Accessories load (H.P.H.V process-1) (3 Cycle)
11. Heat Penetration Study. in Mixed Load (Standard load) (3 Cycle)
12. Heat Penetration Study in Manufacturing accessories Load (Standard load) (3 Cycle)
13. Heat Penetration Study in Filtration accessories load (Standard load) (3 Cycle).
14. Post Vacuum leak test.
15. Estimation of the F_0 Process minimum for Heat Penetration Studies.
16. Biological/ Bacteriological evaluation in at least one cycle or each cycle of Heat Penetration Studies.
17. Estimation of Desired & Actual Spore Log Reduction.

11.1 VACUUM LEAK TEST (COLD):

A) Objective

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

B) Procedure

- Operate the equipment as per SOP on operation & cleaning of HPHV Stem 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	=	-0.040 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.

C) Acceptance Criteria

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

D) 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 WARM UP CYCLE

A) Objective

To warm up the chamber prior to start the cycle.

B) Procedure

- Operate the equipment as per SOP. on operation of HPHV Steam sterilizer.
- Set the following parameters For warm up cycle

S.No.	Parameter	Purpose	Set Value
1.	Pre vacuum	To create vacuum for air removal	-0.500 bar
2.	Warm up Temp	--	121.4 °C
3.	Warm up Hold	--	10 min
4.	Temp. Control band	To control max & min level of temperature during sterilization period	0.2°C
5.	Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 bar
6.	Post vacuum	To achieve set level of vacuum	-0.400
7.	Post vacuum hold time	To dry the load.	2 min
8.	Process end pressure	To end the process & allow to unload the material	-0.040 bar

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

11.3 VACUUM LEAK TEST (HOT)

A) Objective

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

B) Procedure

- Operate the equipment as per SOP. on operation and 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
Small valve set point	--	120.0 °C
Ster. Hold temp.	Sterilization	121.4°C
Ster. Hold time	To hold the sterilization period as per the set time	10 min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2°C
Overshoot temperature	To alarm the excess temperature in the chamber during sterilization hold period.	124.0 ° C
Sterilization stop temp.	To stop sterilization hold time in case the chamber temperature falls below this value during sterilization period.	120.9°C
Sterilization reset temp.	To reset the sterilization hold time in case the chamber temperature falls below this value during sterilization period.	120.5 °C
Post vacuum start press.	To exhaust the steam from chamber & to start the vacuum pump	0.200 bar

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter	Purpose	Set value
Post vacuum	To achieve set level of vacuum	-0.500 bar
Vacuum drying hold	--	5 min
Delay before hold	--	3 min
Vacuum hold time	To dry the load.	10 min
Acceptable leakage	--	0.013 bar
Process end pressure	To end the process & allow to unload the material	-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.

C) Acceptance Criteria

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

D) 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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

11.4 BOWIE-DICK TEST:

A) 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).
- 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.

B) Procedure

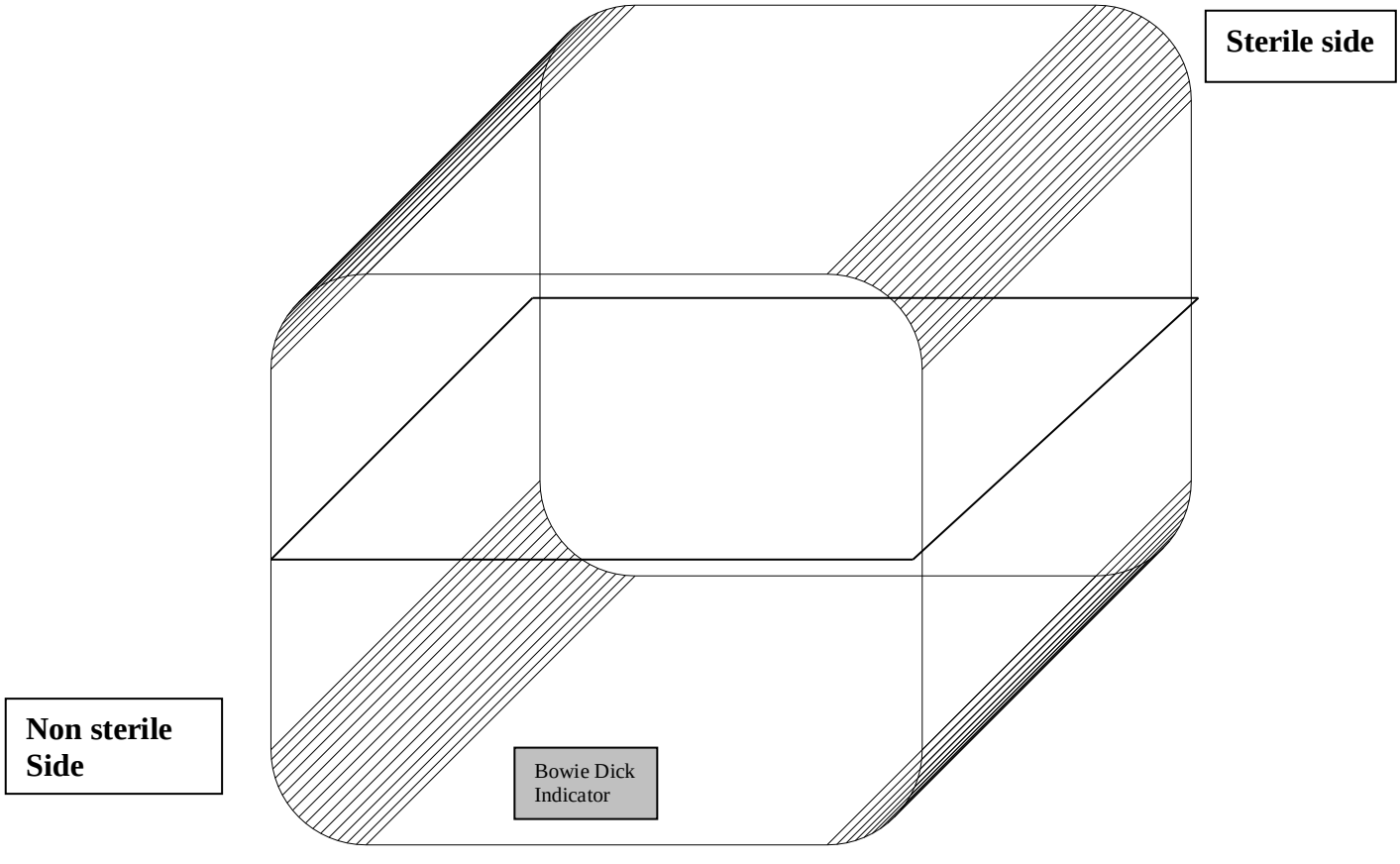
- Operate the equipment as per SOP on operation of HPHV Steam sterilizer
- Set the following parameters in PLC.

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 pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 bar
Small valve sp	--	120.0 °C
Ster. Hold temp.	Sterilization	121.4°C
Ster. Hold time	To hold the sterilization period as per the set time	660 sec.
Temperature control band	To control max. & min. level of temperature during sterilization period	0.2 ° C
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 period	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

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter	Purpose	Set Value
Process end pressure	To end the process & allow to unload the material	0.040 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.
- 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.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.



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

C) 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.

D) Observation :

Record the observations in Performance Qualification Report.

E) 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.

11.5 EMPTY CHAMBER HEAT DISTRIBUTION STUDY (HPHV PROCESS -1)

A) OBJECTIVE:

- Objective of this test is to verify Temperature Uniformity throughout the Chamber and to locate the Cold Spot in Empty Chamber.
- The profile point having the lowest temperature or slowest to heat is designated as Cold Spot

B) EQUIPMENT/INSTRUMENTS

- Duly Calibrated Data logger with calibrated PT-100 sensors

C) PROCEDURE:

- Insert 12 nos. of Temperature Sensors inside the Chamber through the Validation Port of the Steam Sterilizer.
- Seal the validation port with Silicone 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 2. 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 at every 1 Minute.
- Set the following parameters in PLC.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter settings for H.P.H.V-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
Small valve set point	--	120.0ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
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	-0.500 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.100 Bar
No. Of post pulses	To achieve effective drying	3 Nos.
Process end pressure	To end the process & allow to unload the material	-0.040 Bar

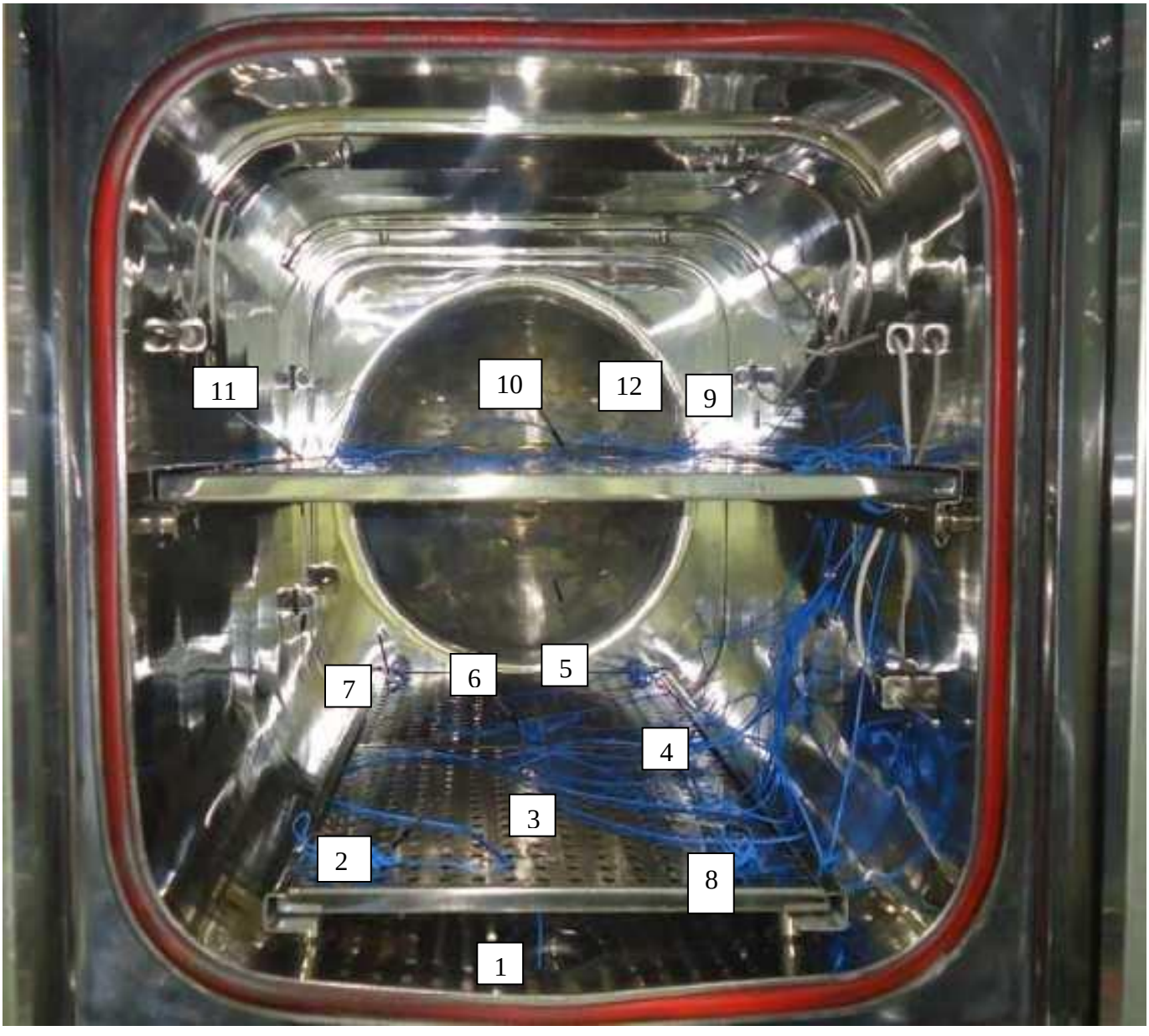
PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- 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 consecutive cycles shall be carried out as per above Parameters and Procedure.
- Location of sensor shall be changed in each cycle during performance qualification.
- Position of sensors should in upward direction.
- Position of biological indicator should be horizontal
- Compile the data generated during the qualification, for complete evaluation of the system.

Location of Temperature Sensors in Empty Chamber Heat Distribution Study inside the Chamber

Sensor No.	Location of sensors in the Chamber
S1	In the drain of the autoclave chamber.
S2	Lower left front corner of non sterile side in autoclave chamber
S3	Lower middle of non sterile side in autoclave chamber
S4	Lower right front of non sterile side in autoclave chamber
S5	Lower back sterile side in autoclave chamber
S6	Lower back sterile side in autoclave chamber
S7	Lower back left corner of sterile side in autoclave chamber
S8	Front, non sterile side of the chamber
S9	Upper right corner of sterile side in autoclave chamber
S10	Upper Middle of chamber
S11	Upper left corner of sterile side in autoclave chamber
S12	Upper right back of sterile side in autoclave chamber

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER



PHOTOGRAPH SHOWING LOCATION OF TEMPERATURE SENSORS IN EMPTY CHAMBER HEAT DISTRIBUTION STUDY INSIDE THE CHAMBER

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

D) 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 124.0°C during the Sterilization Hold Period.
- Temperature Uniformity at a given time of Temperature recording between all in built probes during hold period should not be more than ± 1°C.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.

E) OBSERVATION:

Record the observations in Performance Qualification Report.

F) EVALUATION OF RESULT:

- Heat Penetration Test shall be qualified if penetration of heat in the steam sterilizer chamber during the sterilization hold period is uniform and Temperature uniformity at a given time 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 Penetration shall be re-performed.

11.6 HEAT DISTRIBUTION STUDY FOR HPHV PROCESS (EMPTY CHAMBER) HPHV-I1

A) 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 To verify that at any location(s) where the probes are placed, achieving Minimum Sterilization Temperature throughout the Sterilization Hold period will be considered as Cold Spot.

B) EQUIPMENT/INSTRUMENTS

- Duly Calibrated Data logger with calibrated PT-100 sensors

C) PROCEDURE:

- Insert 12 nos. of Temperature Sensors inside the Chamber through the Validation Port of the Steam Sterilizer.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Seal the validation port with Silicone 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 2. 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 at every 1 Minute.
- Set the following parameters in PLC.

Parameter settings for H.P.H.V-1 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	1 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
Small valve set point	--	120.0ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
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	-0.500 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.100 Bar

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

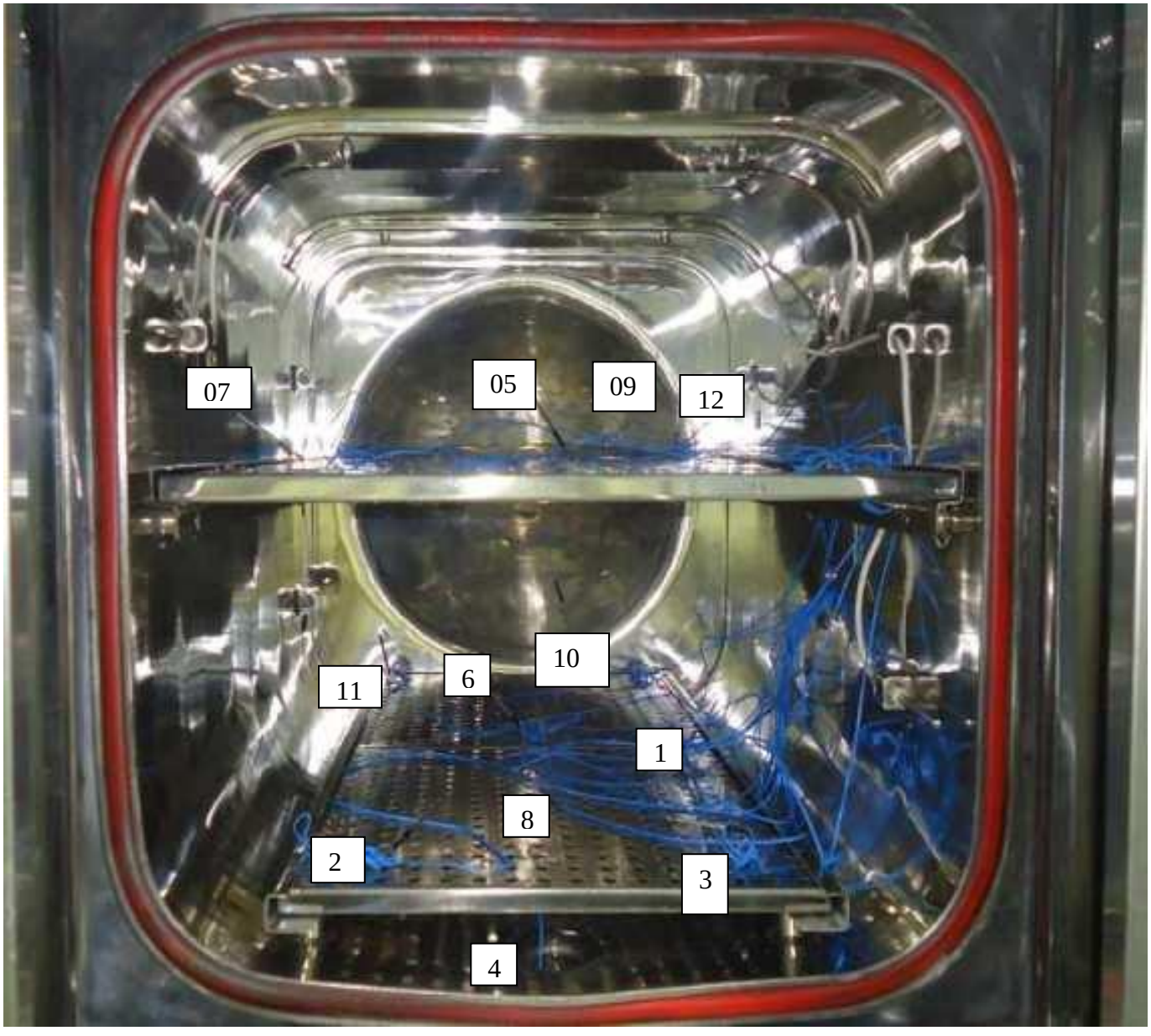
Parameter	Purpose	Set Value
No. Of post pulses	To achieve effective drying	3 Nos
Process end pressure	To end the process & allow to unload the material	-0.040 Bar

- 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 consecutive cycles shall be carried out as per above Parameters and Procedure.
- Location of sensor shall be changed in each cycle during performance qualification.
- Compile the data generated during the qualification, for complete evaluation of the system.

Location of Temperature Sensors in Empty Chamber Heat Distribution study inside the Chamber

Sensor No.	Location of sensors in the Chamber
S1	Lower right front of non sterile side in autoclave chamber
S2	Lower left front corner of non sterile side in autoclave chamber
S3	Front, non sterile side of the chamber
S4	In the drain of the autoclave chamber.
S5	Upper Middle of chamber
S6	Lower back sterile side in autoclave chamber
S7	Upper left corner of sterile side in autoclave chamber
S8	Lower middle of non sterile side in autoclave chamber in autoclave chamber
S9	Upper right back of sterile side in autoclave chamber
S10	Lower back sterile side in autoclave chamber
S11	Lower back left corner of sterile side in autoclave chamber
S12	Upper right corner of sterile side in autoclave chamber

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER



PHOTOGRAPH SHOWING LOCATION OF TEMPERATURE SENSORS IN EMPTY CHAMBER HEAT DISTRIBUTION STUDY INSIDE THE CHAMBER

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

11.7 EMPTY CHAMBER HEAT DISTRIBUTION STUDY IN STANDARD PROCESS

A) 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 throughout the Sterilization Hold period will be considered as Cold Spot.

B) EQUIPMENT/INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated PT-100 sensors

C) 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 2.
- 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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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.
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
Small valve set point	--	120.0 ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2ºC
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 the 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	120.5ºC
Process end pressure	To end the process & allow to unload the material	-0.040 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

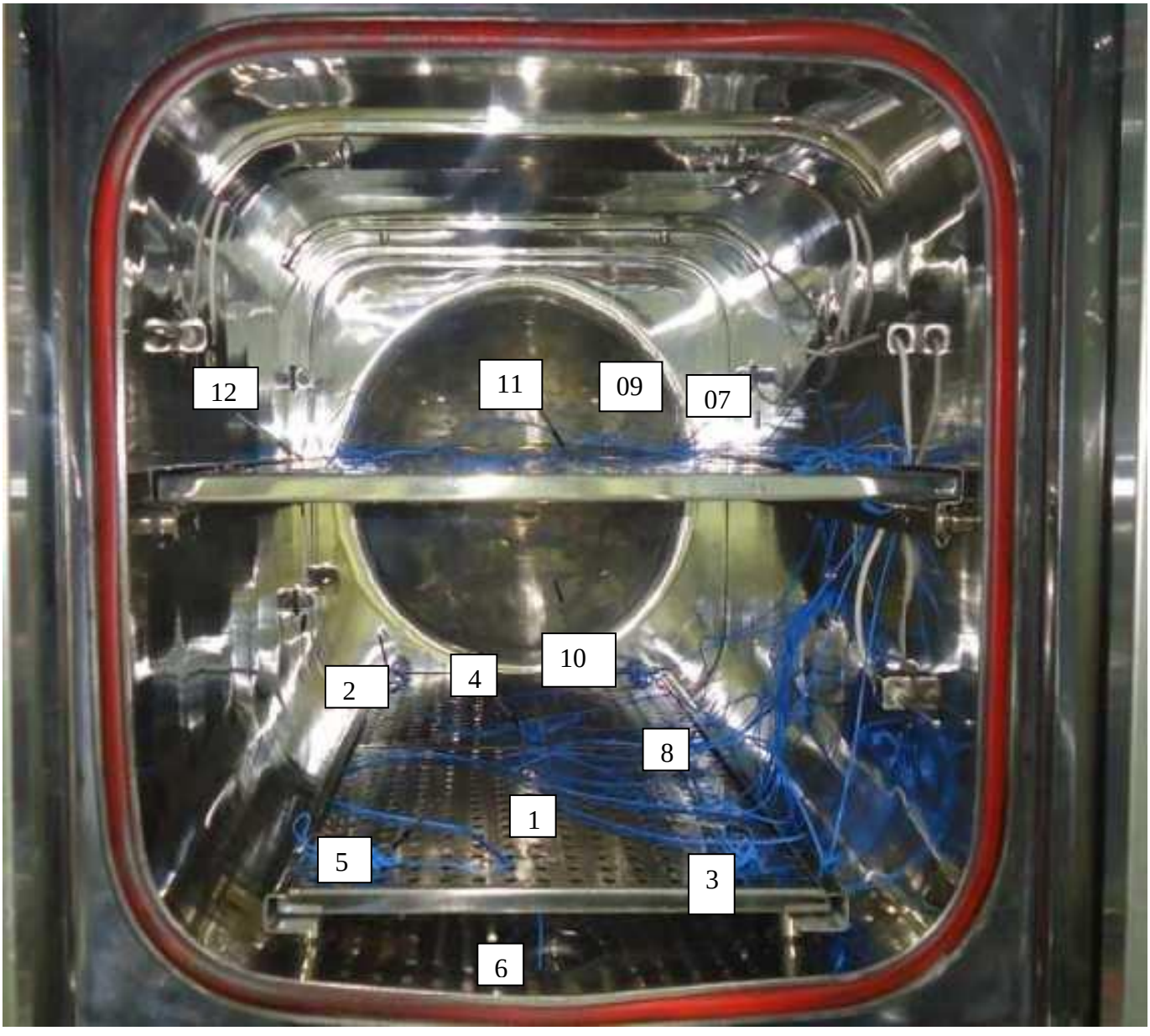
PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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

Location of Temperature Sensors in Empty Chamber Heat Distribution Study inside the Chamber

Sensor No.	Location of sensors in the Chamber
S1	Lower middle of non sterile side in autoclave chamber in autoclave chamber
S2	Lower back left corner of sterile side in autoclave chamber
S3	Front, non sterile side of the chamber
S4	Lower back sterile side in autoclave chamber
S5	Lower left front corner of non sterile side in autoclave chamber
S6	In the drain of the autoclave chamber.
S7	Upper right corner of sterile side in autoclave chamber
S8	Lower right front of non sterile side in autoclave chamber
S9	Upper right back of sterile side in autoclave chamber
S10	Lower back sterile side in autoclave chamber
S11	Upper Middle of chamber
S12	Upper left corner of sterile side in autoclave chamber

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER



PHOTOGRAPH SHOWING LOCATION OF TEMPERATURE SENSORS IN EMPTY CHAMBER HEAT DISTRIBUTION STUDY INSIDE THE CHAMBER

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

D) 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.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.

E) OBSERVATION :

- Record the observations in Performance Qualification Report.

F) 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 give time 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.

11.8 HEAT PENETRATION STUDY:

A) 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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- To ensure that any location(s) where the probes is placed, achieving Minimum Sterilization Temperature of 121.4°C during Sterilization Temperature Hold Period will be considered as Cold Spot.
- Heat Penetration studies shall be carried out with the following different loads:

Heat Penetration studies in HPHV cycle.

- Minimum Garment Load
- Maximum Garment Load
- Filling Machine Parts & Assessory Load

Heat Penetration studies in Standard cycle.

- Filtration assessory load
- Mixed Load
- Manufacturing accessories load

11.8.1 HEAT PENETRATION STUDY H.P.H.V.

(GARMENT LOADED CHAMBER) (MINIMUM):

A) Load Details:

- Antistatic Sterile area garments - 15 Nos.
- Booties - 15 Nos.
- Head Gears - 15Nos.
- Gloves (6 inches) – 15 pairs
- Mopping pads -3 Nos.

B) Load Configuration:

- One perforated box (C1) containing 5 sets of garments (Boiler Suit, Head Gear & Booties) & 05 pairs of gloves ,placed on lower front of trolley (Non sterile door side)
- One perforated box (C2) containing 5 sets of garments, (Boiler Suit, Head Gear & Booties) & 05 pairs of gloves , 03 pairs of mopping pads placed on lower backside of trolley (Sterile door side).
- One perforated box (C3) containing 5 sets of garments (Boiler Suit, Head Gear & Booties) & 05 pairs of gloves placed on lower front of trolley (Non sterile door side).

C) Equipment / Instrument Used:

- Duly Calibrated Data logger with calibrated PT-100 sensors.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Biological Indicators
- Chemical Indicators (Steam Clox)

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 & steam clox 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.
- Position of sensors should in upward direction.
- Position of biological indicator should be horizontal.
- Set the following parameters in PLC.

Parameter settings for H.P.H.V. 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
Small valve set point	--	120.0ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
Ster. Reset temp.	To reset the sterilization hold time incase the chamber	120.5ºC

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter	Purpose	Set Value
	temperature falls below this value during sterilization period.	
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	-0.500 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.100 Bar
No. Of post pulses	To achieve effective drying	3 Nos
Process end pressure	To end the process & allow to unload the material	-0.040 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.
- Simultaneously start the recording with data logger for each 30 Sec. and take printout at the end of the cycle.
- When Pressure becomes -0.040 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.
- 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 sensor shall be changed in each cycle during performance qualification.
- Location of sensors should be in upward direction
- Location of biological indicator should be horizontal.

Location of Temperature Sensors in Heat penetration Study in Garment Minimum Loaded Chamber

Sensor No.	Location of sensors in the Chamber
S1	Center of Garment pack no 1 located at top in SS perforated box C1
S2	Center of Garment pack no 3 located at middle in SS perforated box C1
S3	In the drain of the autoclave chamber.
S4	Center of Garment pack no 4 in SS perforated box C2
S5	Adjacent To Autoclave Inbuilt Sensor T2
S6	Center of Garment pack no 1 located at top in SS perforated box C3
S7	Center of Garment pack located at bottom in in SS perforated box C3
S8	Adjacent To Autoclave Inbuilt Sensor T4

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S9	Adjacent To Autoclave Inbuilt Sensor T5
S10	Center of Garment pack located at lower surface in C2
S11	Adjacent To Autoclave Inbuilt Sensor T3
S12	Center of Garment pack located at upper surface in C1

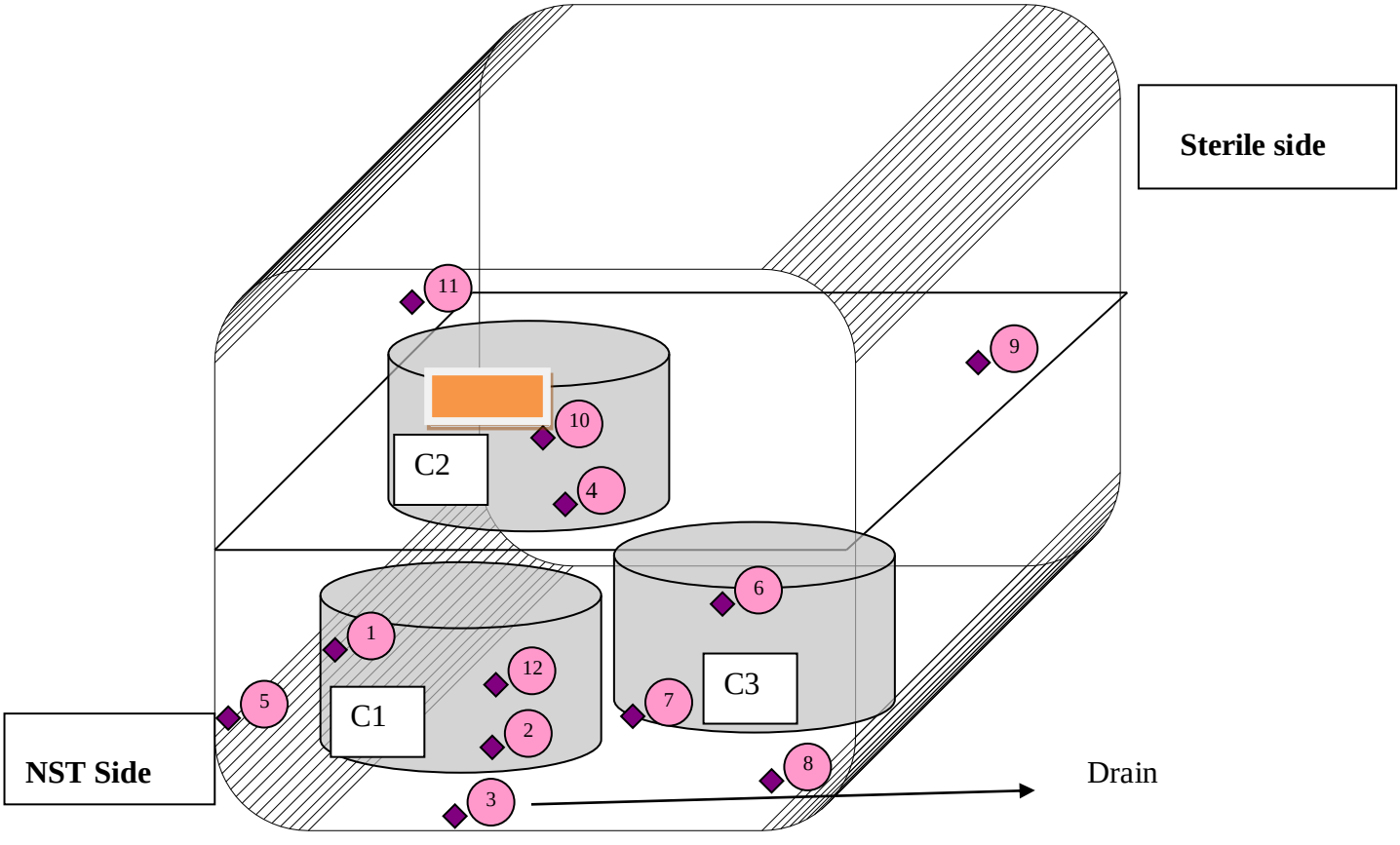


Figure 1: Location of Temperature Sensors, & Biological Indicators inside the Chamber in (HPHV -1) (Garment minimum load) (Front View, Non Sterile Side)

Perforated Box. **Sensors & BI** **mopping pad**

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Photograph Showing Location Of Temperature Sensors In Empty Chamber Heat penetration Study in garment minimum load Inside The Chamber

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT 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 124.0°C at each probe in sterilizer chamber during sterilization hold period.
- The chemical indicators should change the color from purple 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.
- Temperature Uniformity at a given time of Temperature recording between all probes during hold period should not be more than ± 1°C.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.

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 give time 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 Penetration shall be re-performed.

11.8.2 HEAT PENETRATION STUDY H.P.H.V.

(GARMENT LOADED CHAMBER) (MAXIMUM)

Load Details:

A) Clean Room Garments – 30 Nos.

Booties – 30 Nos.

Head Gears -30 Nos.

Gloves (6 inches)–30 Pairs

Mopping pads -06 Nos.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Load configuration:

- One SS perforated box containing 08 set of Garments, 08 Booties, 08 head gears, 08 pairs of gloves Placed on Tray (T1)I in SS container C1 .
- One SS perforated box containing 08 set of Garments, 08 Booties, 08 head gears, 08 pairs of gloves Placed on Tray (T1)I in SS container C2 .
- One SS perforated box containing 08 set of Garments, 08 Booties, 08 head gears, 08 pairs of gloves Placed on Tray (T1) in SS container C3 .
- One SS perforated box containing 06 set of Garments, 06 Booties, 06 head gears, 06 pairs of gloves Placed on Tray (T1)I in SS container C4.

B) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated PT-100 sensors.
- Biological Indicators
- Chemical Indicators (Steam Clox)

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 & steam clox 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.
- Position of sensors should in upward direction.
- Position of biological indicator should be horizontal.
- Set the following parameters in PLC.

Parameter settings for H.P.H.V. 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

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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
Small valve set point	--	120.0ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period.	124.0ºC
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	3 Nos
Process end pressure	To end the process & allow to unload the material	-0.040 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 30 Sec. and take printout at the end of the cycle switch off.
- When Pressure becomes -0.040 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.
- 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 sensor shall be changed in each cycle during performance qualification

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Photograph Showing Location Of Temperature Sensors In Empty Chamber Heat penetration Study in garment maximum load Inside The Chamber

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Location of Temperature Sensors in Heat penetration Study in Garment Maximum Loaded Chamber

Sensor No.	Location of sensors in the Chamber
S1	Center of Garment pack no 1at top in SS perforated container C1
S2	Center of Garment pack no 5 at bottom in SS perforated container C1
S3	In the drain of the autoclave chamber.
S4	Center of Garment pack no 5 at bottom position in SS perforated container C3
S5	Adjacent To Autoclave Inbuilt Sensor T2
S6	Center of Garment pack no 1at top in SS perforated container C2
S7	Center of Garment pack no 2 in SS perforated container C2
S8	Adjacent To Autoclave Inbuilt Sensor T4
S9	Adjacent To Autoclave Inbuilt Sensor T5
S10	Center of Garment pack no 2 at top in SS perforated container C3
S11	Adjacent To Autoclave Inbuilt Sensor T3
S12	Center of Garment pack no 4 at top in SS perforated container C1

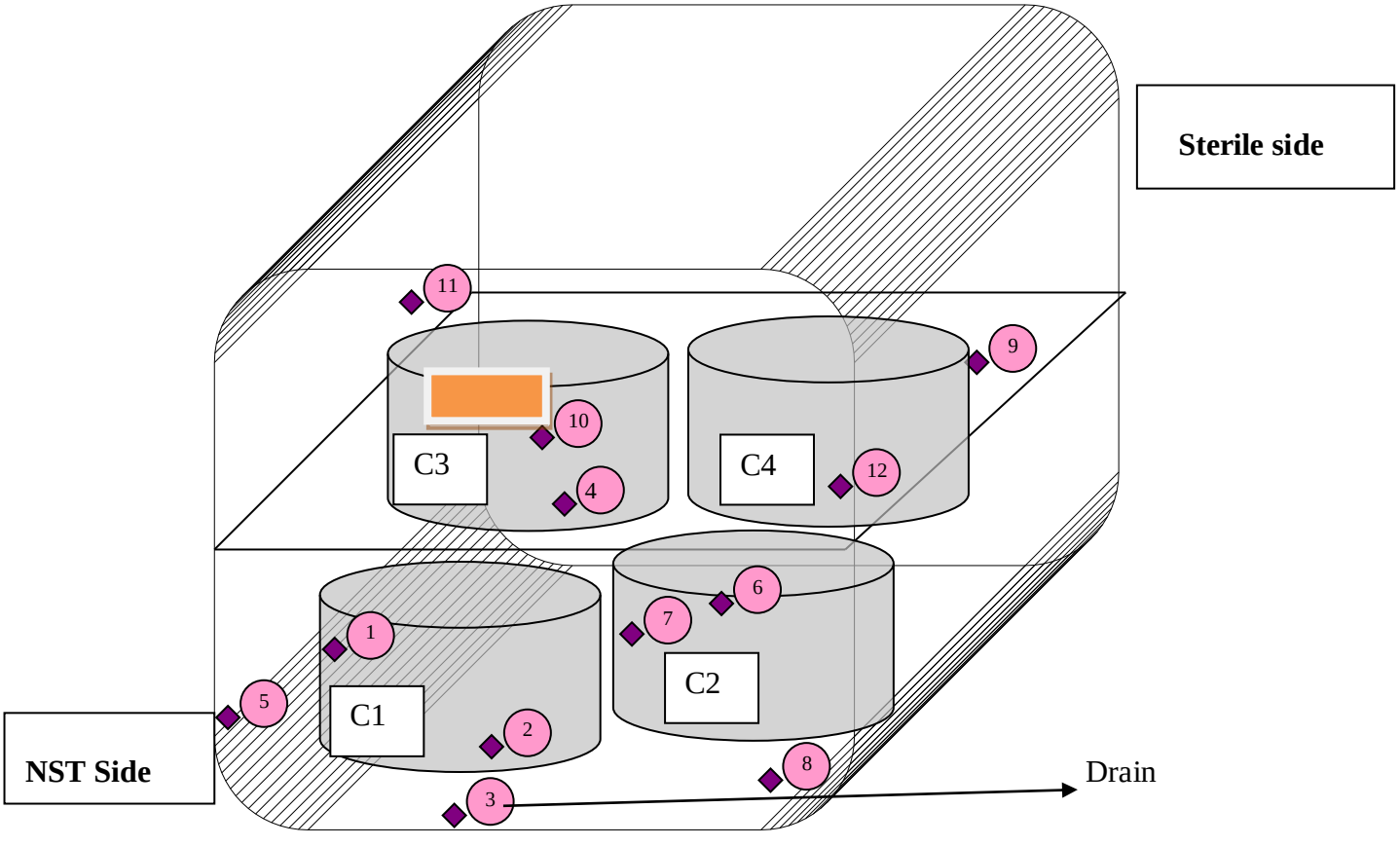


Figure 1: Location of Temperature Sensors, & Biological Indicators inside the Chamber in Load -1I (HPHV -1) (Garment maximum load) (Front View, Non Sterile Side)

Perforated Box. **Sensors & BI** **mopping pad**

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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 124.0°C at each probe in sterilizer chamber during 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.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.
- 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.

F) 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 give time 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 Penetration shall be re-performed

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

11.8.3 HEAT PENETRATION STUDY H.P.H.V.

(FILLING MACHINE PARTS & ASSESSORY LOAD)

A) Load details:

Pump	: 12 Nos.
Manifold	: 03 Nos.
Bucket	: 10 lit (01 Nos.)
Needles	: 36 nos.
Silicon tube	: 15 Nos. (01 meter)
Silicon tube	: 24 nos. (1.5 meter)
T.C. Nipple	: 02 Nos.
Forceps	: 04 Nos.
Silicon tube	: 02 Nos. (02 meter)
Gloves	: 2.5 Feet
Autoclavable	: 02 Nos.

B) Load configuration:

- One Perforated box containing pumps (12Nos.)in S.S Perforated box C1
- Forceps (4 Nos.), T.C. Nipple (02 Nos.),Needles (36 Nos.) in S.S perforated box C2
- Manifold (1Nos.) Placed on base.
- Silicon tube (24 Nos.), Silicon tube 15 Nos. silicon tube 02 Nos. in .S perforated box C3
- Bucket (10 L.) 01 Nos.
- Gloves 2.5 feet
- Autoclavable bottle (02 Nos.)

C) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated PT-100 sensors.
- Biological Indicators
- Chemical Indicators (Steam Clox)

D) PROCEDURE:

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- 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 & steam clox 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.
- Position of sensors should in upward direction.
- Position of biological indicator should be horizontal.
- Set the following parameters in PLC.

Parameter settings for H.P.H.V. 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
Small valve set point	--	120.0ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2 ° C
Overshoot temp.	To indicate through the alarm when there is excess temp. In the chamber during sterilization hold period. `	124.0ºC
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

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

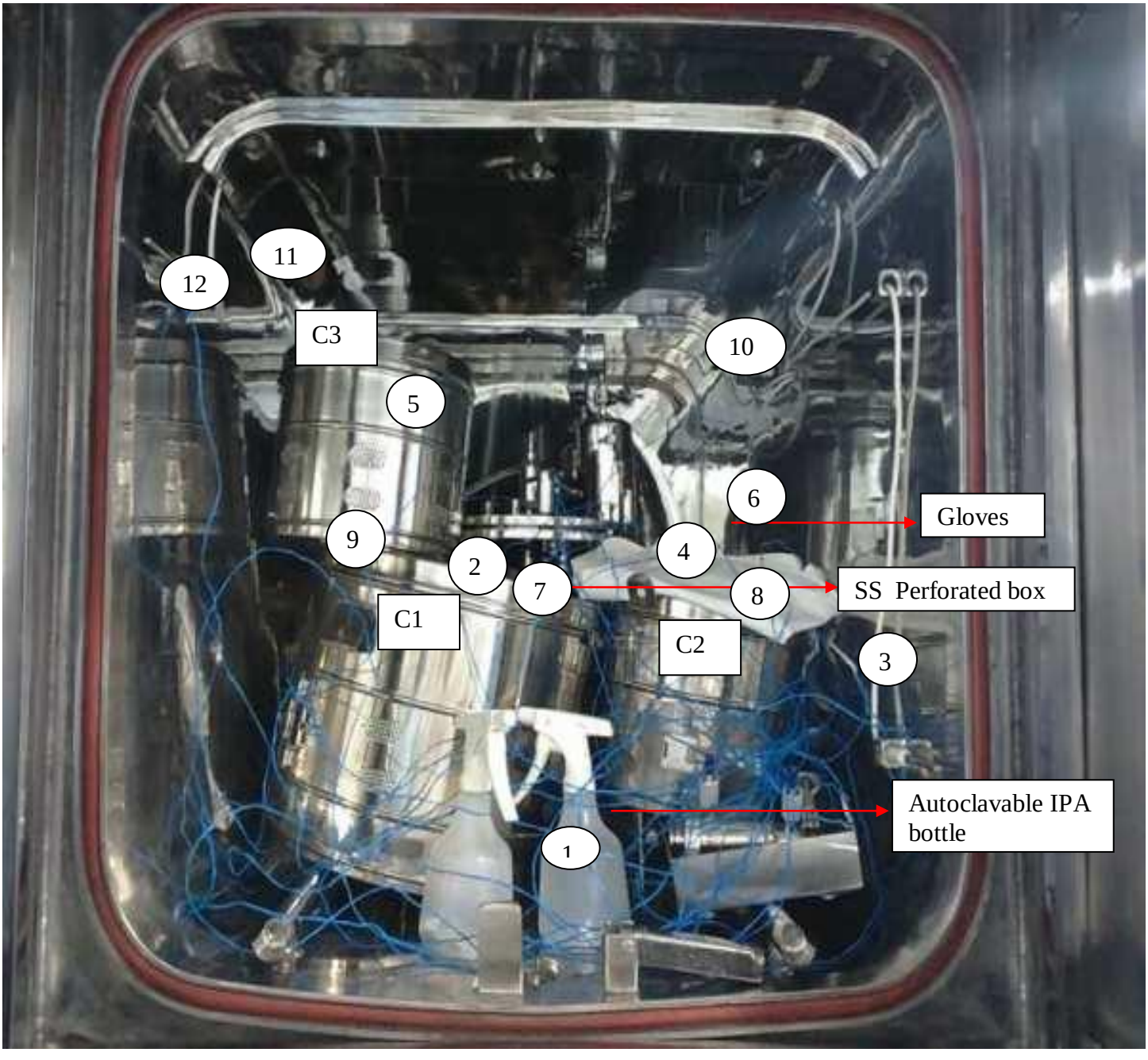
Parameter	Purpose	Set Value
Post vacuum	To achieve set level of vacuum	-0.600 Bar
Post vacuum hold time	To dry the load.	5 Min
Post pressure	To break the vacuum by filtered air	-0.200 Bar
No. Of post pulses	To achieve effective drying	2 Nos`
Process end pressure	To end the process & allow to unload the material	-0.040 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 instruction.
- Simultaneously start the recording with data logger for each 30 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 lab 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.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.
- Location of sensor shall be changed in each cycle during qualification.
  - **Location of Temperature Sensors in Heat penetration Study in Filling Machine Parts & accessory load**
  -

Sensor	Location of sensors in the Chamber
S1	Chamber Drain
S2	In SS perforated box C1
S3	Adjacent to autoclave inbuilt sensor T4
S4	In SS perforated box C2
S5	In SS perforated box C3
S6	Inside the gloves
S7	In SS perforated box C1
S8	In SS perforated box C2
S9	Inside perforated box C1
S10	Inside located at upper right side of sterile side adjacent to autoclave inbuilt sensor T5
S11	Inside located at upper left side of sterile side adjacent to autoclave inbuilt sensor T3

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S12	Inside located at left side of nonsterile side adjacent to autoclave inbuilt sensor T2



PHOTOGRAPH SHOWING LOCATION OF TEMPERATURE SENSORS IN HEAT PENETRATION STUDY IN FILLING MACHINE PART & ACCESSORY LOAD INSIDE THE CHAMBER

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT 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 124.0°C at each probe in sterilizer chamber during sterilization hold period in loaded chamber.
- Temperature Uniformity at a given time of Temperature recording between all probes during hold period should not be more than ± 1°C.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.
- 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.

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 give time 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 Penetration shall be re-performed.

11.8.4 HEAT PENETRATION STUDY IN MANUFACTURING ACCESSORIES LOAD (STANDARD LOAD.)

LOAD DETAILS:

- SS Mug 5 lit - (2 Nos.).
- SS Mug 1 lit -(1 Nos.).
- SS Mug 2 lit - (1 Nos.).
- SS Laddle (03 Nos.)
- Spatula 04 Nos.
- Pressure Vessel 50 Lit. (01 Nos)
- Pressure Vessel 30 Lit. (01 Nos)

- Mixing rod (01 Nos)
- S.S Container 01 Nos.

A) LOAD CONFIGURATION:

- 2 Nos. SS Mug 5.0 L. at front of non sterile side.
- 1 Nos. SS Mug 1.0 L. at front of non sterile side.
- 1 Nos. SS Mug 2.0 L. at front of non sterile side.
- Final filter housing (10 inch) : 03 Nos.
- Vent Filter : 02 Nos.
- Membrane housing with holder : 01 Nos. (293 mm)
- 1 Nos. pressure vessel 50 L on sterile side
- 1 Nos. pressure vessel 30 L on sterile side
- 1 Nos. SS container 10 L. at non sterile side.
- 1 SS Ladle & SS mixing rod at the base of autoclave chamber at non sterile side.

B) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated PT-100 sensors.
- Biological Indicators
- Chemical Indicators (Steam Clox)

C) 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 H.P.H.V. 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.
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

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter	Purpose	Set Value
No. of pulses	To achieve effective heat distribution	5 Nos.
Pre pressure down final	--	0.600 Bar
Small valve set point	--	120.0 ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2ºC
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 the 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	120.5ºC
Process end pressure	To end the process & allow to unload the material	-0.040 Bar

- Transfer the load to sterilizer and connect the probes as per the given locations. Simultaneously keep the biological indicator & steam clox 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.
- Position of sensors should in upward direction.
- Position of biological indicator should be horizontal
- 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 30 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.

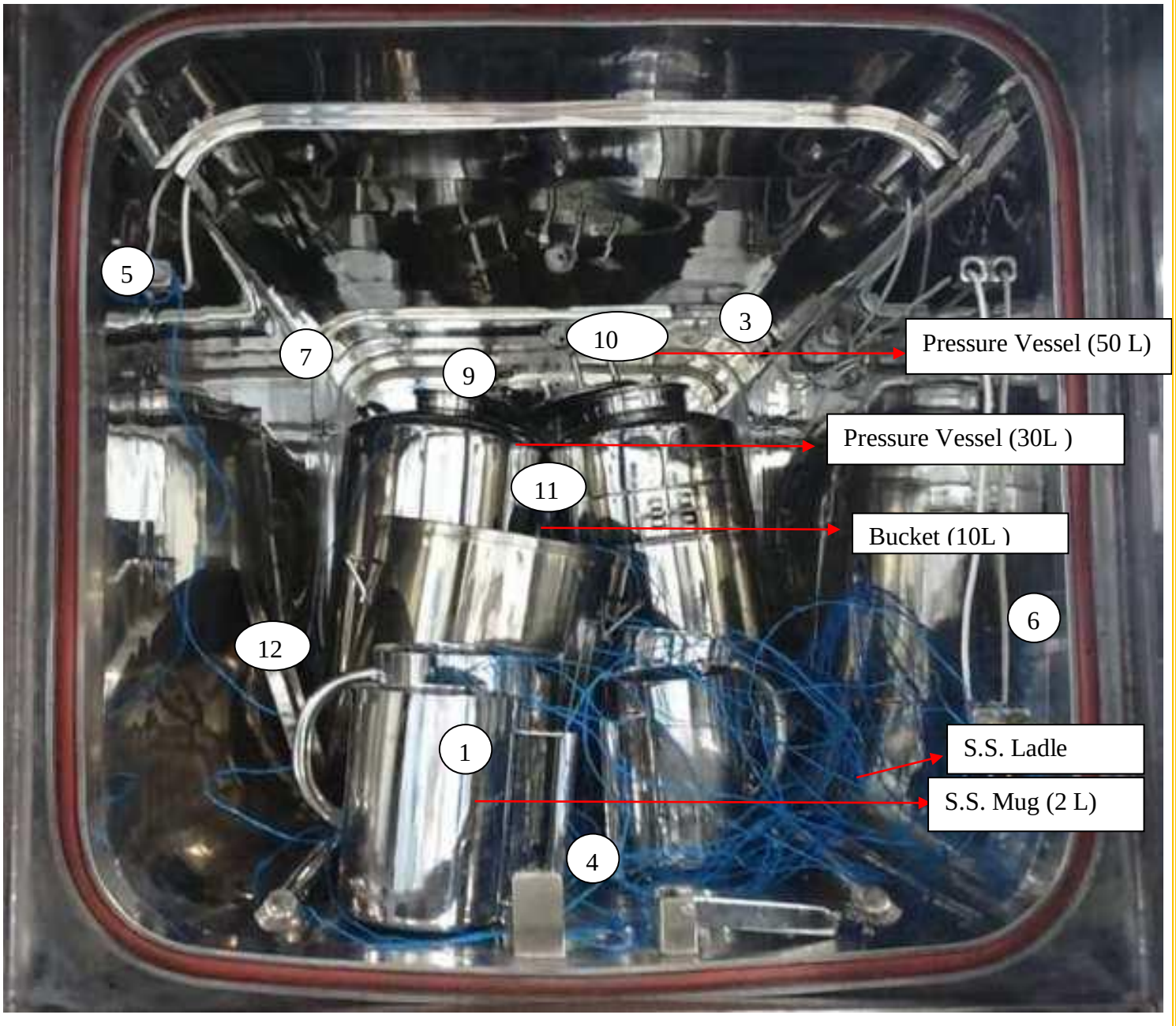
PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Three consecutive cycles shall be carried out as per above Parameters and Procedure.
- Location of sensors shall be changed in each cycle during each cycle.

Location of Temperature Sensors in Heat penetration Study in manufacturing accessories load

Sensor No.	Location of sensors in the Chamber
S1	Inside SS Mug 2 L. located at bottom left Front non sterile side.
S2	Near Filter housing
S3	Adjacent to autoclave inbuilt sensor T5
S4	Chamber Drain
S5	Adjacent to autoclave inbuilt sensor T2
S6	Adjacent to autoclave inbuilt sensor T4
S7	Adjacent to autoclave inbuilt sensor T3
S8	Near membrane holder assembly
S9	Inside Pressure vessel (30L.)
S10	Inside Pressure vessel (50L.)
S11	Inside the SS Perforated container
S12	At bottom left Front non sterile side.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER



PHOTOGRAPH SHOWING LOCATION OF TEMPERATURE SENSORS IN HEAT PENETRATION STUDY IN MANUFACTURING ACCESSORY LOAD INSIDE THE CHAMBER

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

D) ACCEPTANCE CRITERIA:

- There should be uniform distribution of temperature within the range of **121.4°C to 124.0°C** at each probe in sterilizer chamber during 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.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.
- 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.

E) OBSERVATION :

- Record the observations in Performance Qualification Report

F) 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 give time 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 Penetration shall be re-performed.

11.8.5 HEAT PENETRATION STUDY IN MIXED LOAD (STANDARD LOAD)

Load Details

Mopping bucket - 03 Nos.
Mopping head - (02 Nos.)
Forceps - (04 Nos.)
SS Mug (2.0 L) - (02 Nos.)
Silicon tube (1.5 Meter) - (02 Nos.)
SS Perforated box (01 Nos.)

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

A) Load Configuration

- Forceps 04 Nos., Silicone Tube 02 Nos., in SS perforated box
- SS Mug kept on base of chamber
- Mopping head , Mopping bucket kept on base of chamber

B) EQUIPMENT / INSTRUMENT USED:

- Duly Calibrated Data logger with calibrated PT-100 sensors.
- Biological Indicators
- Chemical Indicators (Steam Clox)

C) 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 H.P.H.V. 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.
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
Small valve set point	--	120.0 ºC

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

Parameter	Purpose	Set Value
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2ºC
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 the 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	120.5ºC
Process end pressure	To end the process & allow to unload the material	-0.040 Bar

- Transfer the load to sterilizer and connect the probes as per the given locations. Simultaneously keep the biological indicator & steam clox 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.
- Position of sensors should in upward direction.
- Position of biological indicator should be horizontal.
- 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 30 Sec. and take printout at the end of the cycle switch off.
- When Pressure becomes -0.040 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.
- Three consecutive cycles shall be carried out as per above Parameters and Procedure.

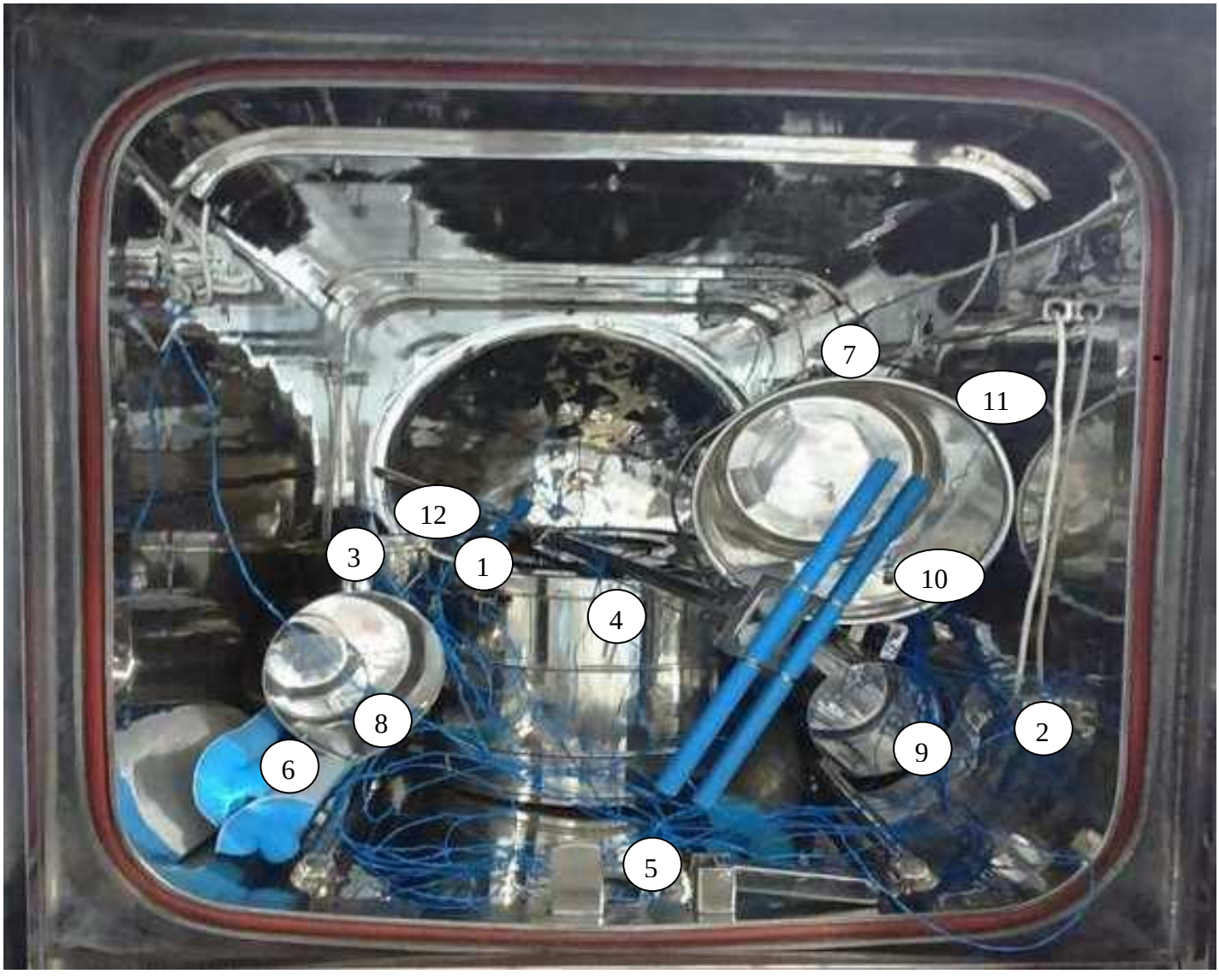
PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Location of sensors shall be changed in each cycle during each cycle.
-

Location of Temperature Sensors in Heat penetration Study in mixed load

Sensor No.	Location of sensors in the Chamber
S1	Inside SS container S1 located at bottom Front sterile side.
S2	Adjacent to autoclave inbuilt sensor T4
S3	Adjacent to autoclave inbuilt sensor T3
S4	Inside SS container S1 located at bottom Front sterile side.
S5	Chamber Drain
S6	Adjacent to autoclave inbuilt sensor T2
S7	Adjacent to autoclave inbuilt sensor T5
S8	Inside SS Mug
S9	Inside SS Mug
S10	Inside SS bucket
S11	At front of chamber near non sterile side
S12	Inside SS bucket

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER



Photograph Showing Location Of Temperature Sensors In Heat penetration Study in mixed load Inside The Chamber

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

D) ACCEPTANCE CRITERIA:

- There should be uniform distribution of temperature within the range of **121.4°C to 124.0°C** at each probe in sterilizer chamber during 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.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.
- 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.

E) OBSERVATION :

- Record the observations in Performance Qualification Report

F) 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 give time 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 Penetration shall be re-performed.

11.8.6 HEAT PENETRATION STUDY IN STANDARD CYCLE:

FILTRATION ACCESSORY LOAD-1

A) Load Details:

- Pressure Vessel 50 L. (01 Nos.)
- Pressure Vessel 30 L. (01 Nos.)
- Filter Housing 10 inch (01 Nos.)
- Autoclavable IPA Bottle (08 Nos.)
- SS Bucket (02 Nos.)
- SS mug 5.0 L (02 Nos.)

- SS mug 2.0 L (02 Nos.)
- SS mug 1.0 L (01 Nos.)
- Mopping pads (04 Nos.)
- Mixing rod (01 Nos.)
- Glass Measuring cylinder 1000 ml (01 Nos.)
- Glass Measuring cylinder 100 ml (01 Nos.)
- Silicon tube (2 feet) - (2 nos.)
- Eye Goggles (5 nos.)

B) Load Configuration:

- 1 Nos. Pressure vessels (50 liters) placed inside the chamber towards sterile side (P1).
- 1 Nos. of filter housing (10 inch liters) placed inside the chamber.
- 4 Nos. of autoclavable IPA Bottle placed inside the chamber.
- SS Mug 1 LTR (01 Nos.)
- SS Perforated box (01 Nos.) containing mopping pads (04 nos.)
- Glass Measuring cylinder 1000 ml (01 Nos.) 100 ml (01 Nos).at the base of chamber at non sterile side.
- Eye Goggles (5 nos.) at the base of chamber at non sterile side.

C) Equipment / Instrument Used:

- Duly Calibrated Data logger with calibrated PT-100 sensors.
- Biological Indicators
- Chemical Indicators (Steam Clox)

D) Procedure:

- Conduct the study with loaded chamber cycles with temperature sensors, Chemical & Biological Indicators.
- Transfer the load to sterilizer and connect the 13 Nos. of Temperature Sensors, chemical indicators (only in 1st Cycle) & biological indicators as per the locations defined in Figure 15.
- Connect the outputs of all the probes to the temperature data logger and close the door of sterilizer.
- Set the following parameters in PLC.

Parameter Settings For Standard Process

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

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.
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
Small valve set point	--	120.0 ºC
Ster. Hold temp.	Sterilization	121.4ºC
Ster. Hold time	To hold the sterilization period as per the set time	30 Min
Temp. Control band	To control max & min level of temperature during sterilization period	0.2ºC
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 the 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	120.5ºC
Process end pressure	To end the process & allow to unload the material	-0.040 Bar

- Simultaneously insert new chart in chart recorder provided on the control panel of Steam Sterilizer and adjust the start time and temperature of the instrument.
- Position of sensors should in upward direction.
- Position of biological indicator should be horizontal.
- Run the cycle as per SOP for operating instruction.
- After attaining temperature 121.4°C, record the chamber temperature and pressure for every minute.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

- Simultaneously start the recording with data logger for each 30 Sec. and take printout at the end of the cycle switch off.
- When Pressure becomes - 0.050 bar 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.
- 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 in Heat penetration Study in Filtration accessories load

Sensor No.	Location of sensors in the Chamber
S1	Middle lower side of the chamber
S2	In the drain of the autoclave chamber.
S3	In side SS Perforated container
S4	In back side of chamber towards sterile side
S5	Near neck of pressure vessel
S6	Back left upper side of the chamber adjacent to autoclave sensor T3
S7	Adjacent to autoclave sensor T2
S8	Near neck of Filter housing
S9	Adjacent to autoclave sensor T4
S10	Back side of the chamber near sterile side
S11	Adjacent to autoclave sensor T5
S12	In back side of chamber near sterile side

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

PHOTOGRAPH SHOWING LOCATION OF TEMPERATURE SENSORS IN FILTRATION ACCESSORY LOAD

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT 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.
- Temperature Uniformity at a given time of Temperature recording between in built probes during hold period should not be more than ± 2°C.
- Temperature Uniformity at a given time of Temperature recording between in built probes & external data logger probes during hold period should not be more than ± 3°C.
- The chemical indicators should change the color from Pink to Green.
- All Biological Indicators should show no growth after incubation.
- The calculated Minimum F0 value should be more than Biological F0 value for the Biological indicator strip.
- SLR Actual should be more than SLR Desired.

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 give time 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 Penetration shall be re-performed.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

11.8.7 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.

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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

12.0 HECKLIST 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.	Vacuum Leak Test (Cold)	NMT 0.013 BAR
2.	Bowie-Dick Test	Uniform color changes of Bowie Dick test Indicator shows the absence of Entrapped air or non condensable gases inside the chamber
3.	Vacuum Leak Test (Hot)	NMT 0.013 BAR
4.	Heat Distribution Study in Empty Chamber H.P.H.V process	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
5.	Heat Distribution Study in Empty Chamber standard process	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
6.	Heat Penetration Study in Garment Minimum Loaded	• 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

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S. No.	Name of Test or Check	Acceptance Criteria
		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.
7.	Heat Penetration Study in Garment Maximum Load	• 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 in Filling Machine parts & Accessories load	• There should be uniform distribution of temperature within the range of 121.4°C to 124°C at each probe in

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S. No.	Name of Test or Check	Acceptance Criteria
		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.
9.	Heat Penetration Study in Mixed Loaded	• 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

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S. No.	Name of Test or Check	Acceptance Criteria
		SLR Desired.
10.	Heat Penetration Study in Manufacturing accessories load	• 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.
11.	Heat Penetration Study in Filtration accessories load.	• 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

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

S. No.	Name of Test or Check	Acceptance Criteria
		should be more than Biological F_0 value for the Biological indicator strip. • SLR Actual should be more than SLR Desired.
13.	Post vacuum	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).
- PDA technical report 01 (Sterilization by Moist Heat).

14.0 DOCUMENTS TO BE ATTACHED:

- Copy of SOPs.
- Biological Indicator Incubation Report.
- Calibration Certificates for Data Logger.
- Calibration Certificates of Sensors.
- Raw data of process

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.

PERFORMANCE QUALIFICATION PROTOCOL CUM REPORT FOR HIGH PRESSURE HIGH VACUUM STEAM STERILIZER

18.0 ABBREVIATIONS:

QC	:	Quality Control
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PPQ	:	Protocol Performance Qualification
SOP	:	Standard Operating Procedure
Sec.	:	Seconds
ID.	:	Identification
ID	:	Inner Diameter
PPQ	:	Protocol Performance qualification
°C	:	Degree Centigrade
HPHV	:	High pressure high vacuum
NMT	:	Not more than
Min.	:	Minute
SS	:	Stainless steel
SLR	:	Spore log reduction
SAL	:	Sterility assurance level