PERFORMANCE QUALIFICATION PROTOCOL OF HPHV STEAM STERILIZER

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1.0 PROTOCOL APPROVAL:

Prepared By			
Name	**Designation**	**Signature**	**Date**

Reviewed By			
Name	**Designation**	**Signature**	**Date**

Approved By			
Name	**Designation**	**Signature**	**Date**

2.0 OBJECTIVE:

The objective of this protocol is to carrying out Performance qualification of **HPHV Steam Sterilizer** to establish documented evidence that the system is capable to meets the pre determine specification of quality parameter and quality attribute.

3.0 SCOPE:

This protocol covers all aspects of Performance Qualification of HPHV Steam Sterilizer installed in Media Preparation Room (Quality Control) at …….

4.0 RESPONSIBILITY:

Responsibilities of different department involved in different activities related to the Performance qualification of HPHV Steam Sterilizer**:**

DEPARTMENT	RESPONSIBILITY
QUALITY ASSURANCE	• Preparation, Review and Approval of PQ protocol. • Execution of PQ protocol along with the co-ordination of other departments. • Review of results and compilation of report. • Handling of failure (If Any).
QUALITY CONTROL	• Review of PQ protocol. • Analytical Support. • Provide the equipment / area as per validation requirement. • Handling of failure (If Any).
ENGINEERING	• Review of PQ protocol. • Execution of PQ protocol along with QA validation team. • Handling of failure (If Any).

5.0 EQUIPMENT/INSTRUMENT/UTILITY DETAILS:

Equipment Name	HPHV Steam Sterilizer
Equipment ID.	
Manufacturer's Name	
Supplier's Name	
Place of Installation	Media Preparation Room

6.0 SYSTEM DESCRIPTION:

The HPHV Steam Sterilizer used to perform below mentioned all type of Operations.

S.No.	Type of Test/Cycle	No. of Run	Description of Load/Cycle	Type of Load distribution
1.	Vacuum Leak Test	1	Before and after fitting sensor port	VLT
2.	Bowie Dick Test	1	After passing of VLT (After fitting sensor port)	B&D
3.	Standard Process-I	1	Empty Chamber	Heat distribution standard-I
		1	For Solid Load Maximum	Heat Penetration Standard-I
		1	For Solid Load Minimum	
		1	Liquid Load-I Maximum	
		1	Liquid Load-I Minimum	
4.	Standard Process-II	1	Empty Chamber	Heat distribution standard-II
		1	Liquid Load-II Maximum	Heat Penetration Standard-II
		1	Liquid Load-II Minimum	
5.	HPHV	1	Empty Chamber	Heat distribution HPHV
		1	Petri Plate Load Maximum	Heat Penetration HPHV
		1	Garment Load	
		1	Accessories Load Maximum	
		1	Accessories Load Minimum	

A) Vacuum Leak Test Cycle:

This cycle is used to check any Vacuum leakage of Sterilizer Chamber.

B) Bowie Dick Test:

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.

This cycle is generally used as test cycle for checking of successful air removal from chamber & Load.

C) Standard Process:

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.

The Standard process is made up of three phases:

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.

D) HPHV Cycle:

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:

Vacuum Steam Pulsing

Heat up

Sterilization Hold

Vacuum drying

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. 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 negative pressure in chamber is brought to atmospheric pressure by injecting sterile air through air filter.

The sterilized load is then unloaded from the chamber.

7.0 REASON FOR QUALIFICATION:

- Periodic Qualification.
- Qualification after any modification and renovation.
- This study will establish that the parameters are followed, critical variables are under control and the quality of the output is maintained, as desired.

Note: Actual reason shall be mentioned in report at the time of preparation.

8.0 SITE OF STUDY

Media Preparation Room.

9.0 FREQUENCY OF QUALIFICATION

S.No.	Test	Run		Frequency
		Initial Qualification	Periodic Qualification	
A. Pre – Qualification Test				
1.	Verification of calibration status of measuring instruments	Once	Once	Half Yearly (± 15 days)
2.	Verification of calibration of test instruments.	Once	Once	
3.	Verification of SOP status	Once	Once	
B. Qualification Test				
4.	Vacuum Leak Test	Once	Once	Half Yearly (± 15 days)
5.	Bowie Dick Test	Once	Once	
6.	Standard Process-I	Once	Once	
7.	Standard Process-II	Once	Once	
8.	HPHV	Once	Once	

10.0 PRE-QUALIFICATION REQUIREMENTS:

Prior to conducting the performance qualification protocol the following conditions must be fulfilled.

10.1 Training:

Training shall be provided to all concern personnel before execution as per SOP "Training of Employees" and record in Training Attendance Sheet. Each person who involve in execution, verification and review, shall entry in the **Annexure-I** (Signature Log).

10.2 Verification of calibration status of measuring and test instruments

Objective:

To verify the calibration of measuring and test instruments to be used during the execution of the performance qualification.

Test Procedure:

Verify the calibration certificate of all the measuring and test instruments use during the execution of the performance qualification before start of activity. Record the observation in **Annexure – II**

Acceptance criteria:

Instruments shall be within calibrated status.

10.3 Verification of SOP status

Objective:

To verify that the current version of SOP shall be used during performance qualification study.

Test Procedure:

Verify that the current version of SOP shall be used during performance qualification study by reviewing SOP. Record the observations and results in the format enclosed as **Annexure- III**

Acceptance Criteria:

All SOP shall be available in current version.

11.0 TESTS AND CHECKS

11.1 VACUUM LEAK TEST:

OBJECTIVE:

To verify the rate of vacuum drop is within the acceptable limits when the Steam Sterilizer chamber is subjected to the vacuum.

TEST MATERIAL / EQUIPMENT:

- Thermocouple data loggers

PROCEDURE:

- Operate the equipment as per the respective SOP.
- Set the following parameters:

  Pre Vacuum = -0.700 bar
  Delay before hold = 03 min.
  Vacuum Hold Time = 10 Min.
  Acceptable Leakage = 0.013 bar
  Process End Pressure = -0.030 bar
- Record Vacuum hold start pressure and Vacuum hold end pressure.
- Calculate the difference of pressure per 10 min.
- One cycle shall be carried out as per above mentioned instructions.

ACCEPTANCE CRITERIA:

Actual Vacuum leakage should not be more than **0.013 bars / 10 minute.**

RESULT RECORDING:

Calculate the actual Vacuum leakage and record the results in performance qualification report.

11.2 BOWIE-DICK TEST:

OBJECTIVE:

Objective of this test is 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 holding time (11 minutes at 121.4°C).

TEST MATERIAL / EQUIPMENT:

- Thermocouple data loggers
- Bowie dick Indicator

PROCEDURE:

- Operate the equipment as per the respective SOP.
- Set the following parameters:

Pre Vacuum	-0.600 bar
Pre Pressure	0.500 bar
No. of Pre Pulses	3 nos.
Heat Up 1	110.0 °C
Heat Up Hold 1	5 min.
Heat Up 2	115.0 °C
Heat Up Hold 2	4 min.
Heat Up 3	119.0 °C
Heat Up Hold 3	3 min.
Heat Up Band	0.2 °C
Small Valve SP	120.4 °C
Sterilization Hold Temp.	121.4 °C
Sterilization Hold Time	660 sec
Control Band	0.2 °C
Overshoot Temp.	124.0°C
Sterilization Stop Temp.	120.9°C
Sterilization Reset Temp.	120.5°C
Process Band Pressure	0.030 bar

- Place one Bowie-Dick Test Pack in the center of the sterilization chamber, supported approximately 100 to 200 mm above the sterilization chamber base.
- The printout taken during the Bowie-Dick test cycle & the Bowie-Dick Test indicator should be attached.
- Compile the observations made during the qualification test for complete evaluation of the system.
- Take one cycle.

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 pattern indicates inadequate air removal from the sterilization chamber.

RESULT RECORDING:

Calculate the actual Vacuum leakage and record the results in performance qualification report.

11.3 HEAT DISTRIBUTION STUDY (EMPTY CHAMBER):

Heat Distribution study shall be carried out by the using of 10 nos. of Temperature mapping probes with Standard Process at 121.4°C and 115.5°C & HPHV cycle at 121.4°C.

OBJECTIVE:

The sterilizer is capable of attaining the sterilization temperature during the sterilization hold period. Temperature spread within the specified range of sterilization temperature during sterilization cycle will demonstrate the uniform heat distribution within the chamber.

METHOD APPLIED:

- Pass 10 nos. temperature mapping probes into chamber through the port of the sterilizer. Seal the port so that steam leakage does not take place. Suspend the probes in the chamber in different position so that probes do not touch any metallic surface.
- Connect the probes to a suitable data logger, which can scan and print the actual temperature observed at different locations with respect to time.

- Set the parameters for the cycle 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.
- When the sterilization cycle completes:

  Collect thermograph from the multipoint temperature recorder of the sterilizer and attached the same.

  Download the data from data logger into the computer for data-analysis and printing. Record the temperatures observed at different locations.
- Compile the data generated during the validation, for complete evaluation of the system.

ACCEPTANCE CRITERIA:

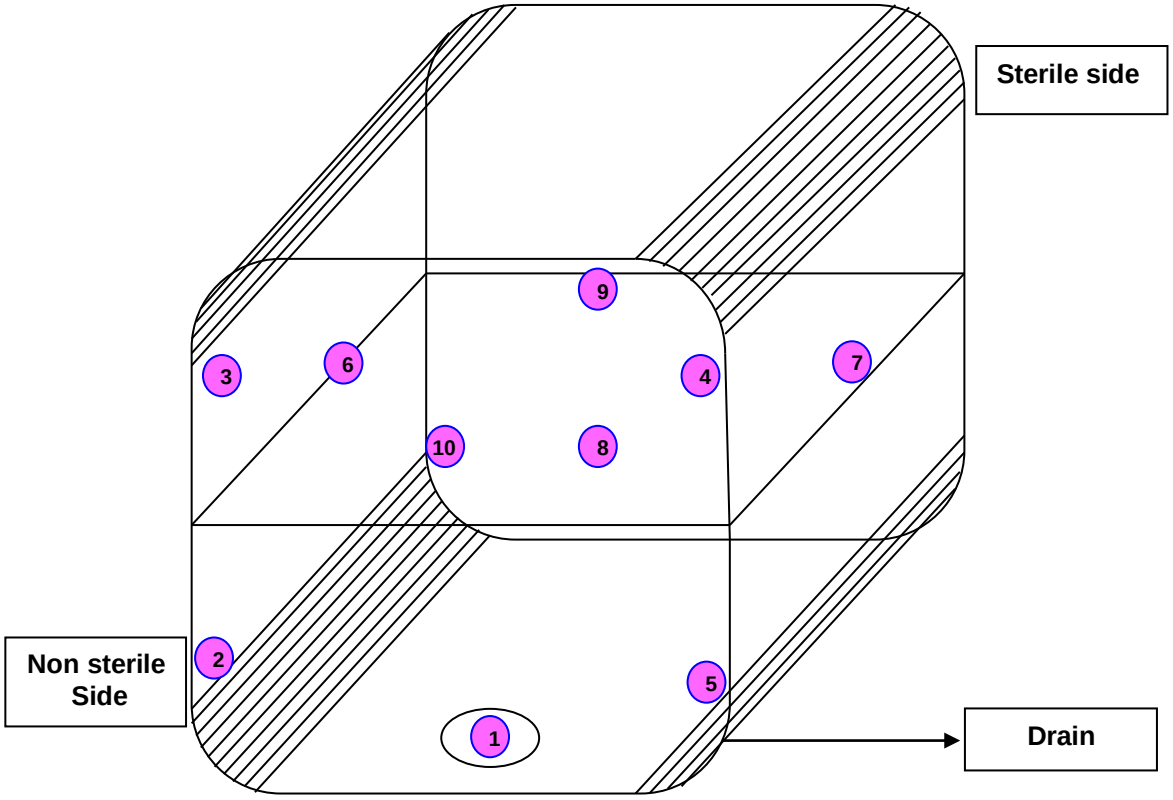
- There should be uniform distribution of temperature within the range of 121.4°C to 124°C for the Sterilization Temperature of 121.4°C & 115.5°C to 119°C for the sterilization Temperature of 115.5°C at each probe in sterilizer chamber during sterilization hold period.
- The equilibration time determined from the measured temperature should not exceed 30 sec.
- The measured temperatures on individual sensor should not fluctuate by more than 2^{o}C.
- The measured temperatures on sensors should not differ from one another by more than 2^{o}C.
- The chemical indicators should change the color from Pink to Green at least three compartments.

RESULT RECORDING:

Record the results in the performance qualification report and attach the Print out, Thermograph of Autoclave & Data Logger.

Location of Temperature sensors inside the Chamber:

SENSOR NO.	LOCATION IN THE CHAMBER
S1	In the drain of the autoclave chamber.
S2	Lower left front corner of Non sterile side
S3	Upper left front corner of Non sterile side
S4	Upper right front corner of Non sterile side
S5	Lower right front corner of Non sterile side
S6	Middle left side of the chamber
S7	Middle right side of the chamber
S8	Middle front, Non sterile side of the chamber
S9	Middle back, sterile side of the chamber
S10	Lower left, sterile side of the chamber



Sensor

11.4 HEAT PENETRATION STUDY (WITH LOADED CHAMBER):

Heat Penetration Study shall be carried out by the using of 10 nos. of Temperature mapping probes with different loads at the sterilization temperature of 121.4°C & with RVS broth media load at the sterilization temperature of 115.5°C & HPHV cycle at 121.4°C.

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 1.1 to 1.2 Kg/cm².
- 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.

METHOD APPLIED:

- Pass 10 nos. temperature mapping probes into chamber through the port of the sterilizer. Seal the port so that steam leakage does not take place.
- Suspend or insert the probes into the load in the chamber in different position so that probes do not touch any metallic surface.
- Connect the probes to a suitable data logger, which can scan and print the actual temperature, observed at different locations with respect to time.
- Set the parameters for the cycle in PLC & operate the steam sterilizer as per SOP No. DQC/128 and also start the data logger to record actual temperatures within the sterilization chamber with respect to time.
- When the sterilization cycle completes;

  Collect thermograph from the multipoint temperature recorder of the sterilizer and attached the same.

  Download the data from data logger into the computer for data-analysis and printing. Record the temperatures observed at different locations.
- Penetration study shall include only one run with respect to each load.

- Compile the data generated during the validation, for complete evaluation of the system.

ACCEPTANCE CRITERIA:

- There should be temperature within the range of 121.4°C to 124°C for the Sterilization Temperature of 121.4°C & 115.5°C to 119°C for the sterilization Temperature of 115.5°C at each probe in sterilizer chamber during sterilization hold period.
- The equilibration time determined from the measured temperature should not exceed 30 sec.
- The measured temperatures on individual sensor should not fluctuate by more than 2°C.
- The measured temperatures on sensors should not differ from one another by more than 2°C.
- The chemical indicators should change the color from Pink to Green at least three compartments.
- 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 **$SLR_{Desired}$.**

RESULT RECORDING:

Record the results in the performance qualification report and attach the Print out, Thermograph of Autoclave & Data Logger.

F_0 CALCULATION:

1. For *Geobacillus stearothermophilus* used at the Sterilization Temperature of 121°C:

a) Numerical F_0 Value:

The actual observations obtained during the heat penetration study at different temperature sensing locations are compiled 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 of lethality factors)

Where,

dt : Time interval between successive temperature measurements (in min)

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 (10^0C or as mentioned in COA).

b) F_0 Value for Biological Indicators:

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

Fo = D_{121} (log A – log B) …… (b)

Where,

D_{121} : D value of the biological indicator at 121^0C

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

$SAL_{desired}$: 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 the biological indicator at 121^0C

2. For *Bacillus subtilis* used at the Sterilization Temperature of 115°C:

a) Numerical F_0 Value:

The actual observations obtained during the heat penetration study at different temperature sensing locations are compiled 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.

$F_0 = dt \sum 10^{(T-115)/Z}$ _____ (a)

$F_0 = dt \sum$ (Sum of lethality factors)

Where,

dt : Time interval between successive temperature measurements (in min).
T : Observed temperature at that particular time (as per the actual temperatures recorded)
Z = change in the heat resistance of *Bacillus subtilis* spores as temperature is changed (10^0C or as mentioned in COA).

b) F_0 Value for Biological Indicators:

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

$Fo = D_{115} (\log A - \log B)$ …… (b)

Where,

D_{115} : D value of the biological indicator at 115^0C
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
$SAL_{desired}$: Desired level of sterility (10^{-6})

d) Actual Spore log reduction:

Calculate actual reduction in spore population by using the formula-

$SLR_{Actual} = F_0 / D_{115}$---------- (d)

Where,

F_0 : Minimum calculated F_0 value

D_{115} : D value of the biological indicator at 115^0C

Heat penetration studies shall be carried out with the following different loads:

LOAD NO.	LOAD TYPE
1.	Solid Load Maximum
2.	Solid Load Minimum
3.	Liquid Load-I Maximum
4.	Liquid Load-I Minimum
5.	Liquid Load-II Maximum
6.	Liquid Load-II Minimum
7.	Petri plate load maximum
8.	Garment Load (Full Load)
9.	Other Accessories load maximum
10.	Other Accessories load Minimum

LOAD DETAILS

a) Temperature probe and biological indicator placement in the Garment Load (Full Load):

Load details (15 Sets of Garments)

- Garment Packet – 15 Nos.
- Mopper – 10 Nos.

Load configuration:

- 8 Sets of Garment (including Boiler Suit, Booties & Head Gears) shall be placed on the upper shelf.
- Remaining 7 Sets of Garment (including Boiler Suit, Booties & Head Gears) & 10 nos. of mopper shall be placed on the lower shelf.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Left side Garment pack located at back of upper shelf
S3 / B3	Right side Garment pack located at back of upper shelf
S4 / B4	Left side Garment pack located at front of upper shelf
S5 / B5	Right side Garment pack located at front of upper shelf
S6 / B6	Middle Garment pack located at back of lower shelf
S7 / B7	Middle Garment pack located at front of upper shelf
S8 / B8	Left side Garment pack located at front of lower shelf
S9 / B9	Right side Garment pack located at back of lower shelf
S10/ B10	Left side Garment pack located at back of lower shelf

Photographical Representation of Load & Sensors inside chamber

b) Temperature probe and biological indicator placement in the Petri Plate Load Maximum

Load details

Petri Plates– 300 Nos.

Load configuration:

- 150 plates in the pattern of 10x5x3 shall be placed on the upper shelf.
- 150 plates in the pattern of 10x5x3 shall be placed on the Lower shelf.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Left side Petri plate pack located at back of upper shelf
S3 / B3	Right side Petri plate pack located at back of upper shelf
S4 / B4	Left side Petri plate pack located at front of upper shelf
S5 / B5	Right side Petri plate pack located at front of upper shelf
S6 / B6	Middle Petri plate pack located at back of lower shelf
S7 / B7	Middle Petri plate pack located at front of upper shelf
S8 / B8	Left side Petri plate pack located at front of lower shelf
S9 / B9	Right side Petri plate pack located at back of lower shelf
S10 / B10	Left side Petri plate pack located at back of lower shelf

c) Temperature probe and biological indicator placement in the Solid Media Load Maximum:

Load details:

- Glass Bottles – 1000 ml. (Containing 750 ml. Agar Media) – 13 Nos.
- Glass Bottles – 500 ml. (Containing 400 ml. Agar Media) – 2 Nos.

Load configuration:

- Glass Bottel – 1000 ml. containing 750 ml. Agar Media (13 Nos.)
- Glass Bottles – 500 ml. Containing 400 ml. Agar Media (2 Nos.)

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the 1st glass bottle of 1000 ml at right side row
S3 / B3	Inside the 2nd glass bottle of 1000 ml at right side row
S4 / B4	Inside the 3rd glass bottle of 1000 ml at right side row
S5 / B5	Inside the 4th glass bottle of 1000 ml at right side row
S6 / B6	Inside the 1st glass bottle of 500 ml at middle row
S7 / B7	Inside the 3rd glass bottle of 1000 ml at middle row
S8 / B8	Inside the 5th glass bottle of 1000 ml at middle row
S9 / B9	Inside the 1st glass bottle of 500 ml at left side row
S10 / B10	Inside the 3rd glass bottle of 1000 ml at left side row

Photographical Representation of Load & Sensors inside chamber

d) Temperature probe and biological indicator placement in the Solid Media Load Minimum:

Load details:

- Glass Bottles – 1000 ml. (Containing 600 ml. Agar Media) – 2 Nos.
- 10 ml.Tubes – 25 x 150 mm. (Containing 10 ml. Agar Media) – 60 Nos.

Load configuration:

- Glass Bottles – 1000 ml. containing 600 ml. Agar Media (2 Nos.) & 10 ml Tubes – 25x150 mm. each tube containing 10 ml. Agar Media (60 Nos.)

Location of Sensor & Biological Indicator in the chamber :

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the 1st glass bottle of 1000 ml. at right side
S3 / B3	Inside the 2nd glass bottle of 1000 ml. at left side
S4 / B4	Inside the 10ml. tube place at the middle of stand
S5 / B5	Inside the 10ml. tube place at the right front corner of stand
S6 / B6	Inside the 10ml. tube place at the right back corner of stand
S7 / B7	Inside the 10ml. tube place at the Left front corner middle of stand
S8 / B8	Inside the 10ml. tube place at the Left back corner of stand
S9 / B9	Right side of chamber
S10 / B10	Left Side of chamber

Photographical Representation of Load & Sensors inside chamber

e) Temperature probe and biological indicator placement in the Liquid Load-1 Maximum:

Load details:

- Culture Tube (38 x 200 mm containing 100 ml broth media)– 90 Nos.

Load configuration:

- 90 culture tube arrange in five tube stand (twenty culture tube in each stand) five tube stand shall be placed separately in the chamber.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the Culture tube arrange in stand no.-4
S3 / B3	Inside the Culture tube arrange in stand no.-2
S4 / B4	Inside the Culture tube arrange in stand no.-3
S5 / B5	Inside the Culture tube arrange in stand no.-5
S6 / B6	Inside the Culture tube arrange in stand no.-2
S7 / B7	Inside the Culture tube arrange in stand no.-1
S8 / B8	Inside the Culture tube arrange in stand no.-2
S9 / B9	Inside the Culture tube arrange in stand no.-4
S10 / B10	Inside the Culture tube arrange in stand no.-1

Photographical Representation of Load & Sensors inside chamber

f) Temperature probe and biological indicator placement in the Liquid Load-1 Minimum:

Load details:

- Culture Tube (38 x 200 mm containing 100 ml broth media) – 20 Nos.
- Test Tube (18 x 150 mm containing 10 ml broth media) – 120 Nos.
- Glass Bottle (500 ml containing 400 ml broth) – 02 Nos.

Load configuration:

- 20 culture tubes arrange in one stand shall be placed in the chamber.
- 120 tubes arrange in two stands (60 tubes in each stand) shall be placed separately in the chamber.
- Two glass bottles - 500 ml. containing 400 ml. broth media shall be placed in chamber.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the Culture tube place in middle of stand
S3 / B3	Inside the Culture tube arrange in right side front corner of stand
S4 / B4	Inside the Culture tube arrange in left side back corner of stand
S5 / B5	Inside the Culture tube in chamber
S6 / B6	Inside the glass bottle-1
S7 / B7	Inside the glass bottle-2
S8 / B8	Inside the tube place at the center of stand no.-1
S9 / B9	Inside the tube place at the center of stand no.-2
S10 / B10	Left Side of chamber

Photographical Representation of Load & Sensors inside chamber

g) Temperature probe and biological indicator placement in the Liquid media load-2 maximum:

Load details:

- Tube (25 x 150 mm containing 10 ml RVS broth media) – 150 Nos.
- Tube (38 x 200 mm containing 100ml RVS broth media) – 20 Nos.

Load configuration:

- 150 tubes (25 x 150 mm) arrange in three stands (Fifty test tubes in each stand) shall be placed separately in the chamber.
- 20 tubes (38 x 200 mm) arrange in one stand shall be placed separately in chamber.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the tube (25x150 mm) arrange in stand no.-1
S3 / B3	Inside the tube (25x150 mm) arrange in stand no.-1
S4 / B4	Inside the tube (25x150 mm) arrange in stand no.-1
S5 / B5	Inside the tube(25x150 mm) arrange in stand no.-2
S6 / B6	Inside the tube (25x150 mm) arrange in stand no.-2
S7 / B7	Inside the tube (25x150 mm) arrange in stand no.-2
S8 / B8	Inside the tube (25x150 mm) arrange in stand no.-3
S9 / B9	Inside the tube (25x150 mm) arrange in stand no.-3
S10 / B10	Inside the tube (38x200 mm) arrange in stand

Photographical Representation of Load & Sensors inside chamber

h) Temperature probe and biological indicator placement in the Liquid media load-2 minimum:

Load details:

- Tube (25 x 150 mm containing 10 ml RVS broth media) – 120 Nos.
- Tube (38 x 200 mm containing 100ml RVS broth media) – 12 Nos.

Load configuration:

- 120 tubes (25x150 mm) arrange in three stands (Fifty tubes in two stands & 20 tubes in one stand) three stands shall be placed separately in the chamber.
- 12 tubes (38x200 mm) arrange in one stand shall be placed separately in chamber.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the tube (25x150 mm) arrange in stand no.-1
S3 / B3	Inside the tube (25x150 mm) arrange in stand no.-1
S4 / B4	Inside the tube (25x150 mm) arrange in stand no.-1
S5 / B5	Inside the tube(25x150 mm) arrange in stand no.-2
S6 / B6	Inside the tube (25x150 mm) arrange in stand no.-2
S7 / B7	Inside the tube (25x150 mm) arrange in stand no.-2
S8 / B8	Inside the tube (25x150 mm) arrange in stand no.-3
S9 / B9	Inside the tube (25x150 mm) arrange in stand no.-3
S10 / B10	Inside the tube (38x200 mm) arrange in stand

Photographical Representation of Load & Sensors inside chamber

i) Temperature probe and biological indicator placement in the Other Accessories Maximum:

Load details-

- Scissors - 05 Nos.
- Forceps - 10 Nos.
- Micro tips Box/Packet - 04 Nos
- Filter Flask - 01 Nos.
- Filtration Funnel - 03 Nos.
- Manifold assembly - 01 Nos.
- Air Sampler Lid -02 Nos.
- SS container - 03 Nos.
- Spreader packet - 40 Nos.
- Disinfectant Spray bottles -03 Nos.
- Swab sampling template -01 Nos.
- Compressed gas accessories -01 Nos.
- Micropipette - 01 Nos.
- SS Coupon -02 Nos.
- Spatula -05 Nos.
- Empty tubes - 12 Nos.

Load configuration:

- Scissors 05 Nos., Forceps 10 Nos., Micro tips Box/Packet 04 Nos., Filter Flask-1 Nos., Filtration Funnel-03Nos., Manifold assembly- 01 Nos., Air Sampler Lid 02 Nos. SS container-03 Nos., Spreader packet-10 x 04 Nos., Disinfectant Spray bottles-03 Nos., swab sampling template, compressed gas accessories, micropipette-01 Nos. SS Coupon-02 Nos. spatula -05 Nos.
- 12 empty tubes placed in stand shall be placed inside the chamber.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the compressed gas sampler in the chamber
S3 / B3	Inside the Air sampler in the chamber
S4 / B4	Inside the micropipette in the chamber
S5 / B5	Inside the Filter Flask in the chamber
S6 / B6	Inside the Spreader packet in the chamber
S7 / B7	Inside the empty tube in the chamber
S8 / B8	Inside the empty tube in the chamber
S9 / B9	Inside the Disinfectant Spray bottles in the chamber
S10 / B10	Inside the SS container in the chamber

j) Temperature probe and biological indicator placement in the Other Accessories Minimum:

Load details-

- Water sampling bottles -22 Nos.
- Filtration Funnel -17 Nos.
- Silicon Tube - 02 Nos.
- Scissors -03 Nos.
- Forceps -05 Nos.
- Filter Paper -02 Nos.
- Micro tips Box - 03 Nos.
- Filter Flask - 02 Nos.
- Goggles - 10 Nos.

Load configuration:

Water sampling bottles-22 Nos., Filtration Funnel-17 Nos., Silicon Tube 2 Nos. Scissors 03 Nos., Forceps 5 Nos. Filter Paper in 02 Nos. Micro tips Box 03 Nos., Filter Flask-02 Nos., Goggles-10 Nos.

Location of Sensor & Biological Indicator in the chamber

SENSOR / BI NO.	LOCATION IN THE CHAMBER
S1 / B1	In the drain of the autoclave chamber.
S2 / B2	Inside the water sampling bottle in the chamber
S3 / B3	Inside the water sampling bottle in the chamber
S4 / B4	Inside the water sampling bottle in the chamber
S5 / B5	Inside the Filtration funnel in the chamber
S6 / B6	Inside the Filtration funnel in the chamber
S7 / B7	Inside the silicon tube in the chamber
S8 / B8	Inside the filter flask in the chamber
S9 / B9	Inside the micro tip box in the chamber
S10 / B10	Inside the goggles in the chamber

12.0 REFERENCES:

Following documents are referred during preparation of the protocol.

Document Name	Document Number
Validation Master Plan	
Preparation of Validation and Qualification Protocol & Report	
ISO Guideline	ISO-14644-1,2,3
PIC/S Guide to Good Manufacturing Practices for Medicinal Products, Annex-I- Manufacture of Sterile Medicinal Products	PE-009-09 Sept 2009
WHO guideline	WHO-TRS-961
Operation & Cleaning of HPHV Steam Sterilizer.	
Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products	Schedule – M

13.0 DOCUMENTS TO BE ATTACHED:

- Raw data of Microbiological Analysis
- Biological indicator test report
- Calibration Certificates for Data Logger.
- Calibration Certificates for Thermal Sensors.
- Raw data of test & checks

14.0 NON COMPLIANCE:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in 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.

15.0 DEVIATION FROM PRE-DEFINED SPECIFICATION

Any deviation, if followed, shall be handled as per **SOP of "Handling of Deviation" or EQMS** and same shall be a part of Performance Qualification Report.

16.0 CHANGE CONTROL

Any Change Control, if followed, shall be handled as per **SOP of "Change Management" or EQMS** and same shall be a part of Performance Qualification Report.

17.0 ABBREVIATIONS

ABBREVIATIONS	FULL FORM
VMP	Validation Master Plan
S.No.	Serial Number
SOP	Standard Operating Procedure
QA	Quality Assurance
QC	Quality Control
ISO	International organization for standardization
PQ	Performance Qualification
WHO	World Health Organization
EQMS	Electronic Quality Management System
cGMP	Current Good Manufacturing Practices
SLR	Spore Log Reduction
SAL	Sterility Assurance Level
BI	Biological Indicator
COA	Certificates of Analysis
PLC	Programmable Logical Controller
mm	Milimeter
°C	Degree centigrade

18.0 ANNEXURE:

ANNEXURE NUMBER	ANNEXURE TITLE	FORMAT NUMBER
ANNEXURE- I	SIGNATURE LOG	
ANNEXURE- II	CALIBRATION VERIFICATION OF TEST INSTRUMENTS	
ANNEXURE- III	SOP STATUS VERIFICATION	

19.0 REVISION HISTORY:

REVISION NUMBER	CHANGE CONTROL NO.	DETAILS OF CHANGES	REASON FOR CHANGE	EFFECTIVE DATE	UPDATED BY
00	NA				

ANNEXURE I

SIGNATURE LOG				
S.NO.	NAME	FULL SIGNATURE	INITIALS	DATE

COMMENTS

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REVIEWED BY
SIGN/DATE

ANNEXURE II
CALIBRATION VERIFICATION OF TEST INSTRUMENTS

S.NO.	EQUIPMENT/INSTRUMENT NAME	ID OR S. NO.	CALIBRATION DONE DATE	CALIBRATION DUE DATE

COMMENTS

_____

_____

_____

DONE BY
SIGN/DATE

REVIEWED BY
SIGN/DATE

ANNEXURE III

SOP STATUS VERIFICATION

S.NO.	DOCUMENTS / SOP NAME	DOCUMENTS / SOP NO. AND REVISION

COMMENTS

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DONE BY
SIGN/DATE

REVIEWED BY
SIGN/DATE